



Final Regulatory Determination 5 Support Document

Disclaimer

This document is designed to provide technical background information for the U.S. Environmental Protection Agency's (EPA's) fifth Regulatory Determination (RD 5) for drinking water contaminants under Safe Drinking Water Act (SDWA) provisions, based on the EPA's fifth Contaminant Candidate List (CCL 5).

This document is not a regulation itself, and it does not substitute for SDWA or the EPA's regulations. Mention of trade names or commercial products does not constitute endorsement or recommendations for use.

Executive Summary

This document provides background information to support the U.S. Environmental Protection Agency's (EPA) fifth Regulatory Determination (RD 5) for drinking water contaminants under the Safe Drinking Water Act (SDWA) provisions, based on the fifth Contaminant Candidate List (CCL 5). The regulatory determination decisions are presented in the *Federal Register*. This report, which accompanies the EPA's final regulatory determination, does not itself constitute a regulation or a formal determination.

This regulatory determination support document consists of an introductory chapter on the CCL 5 and RD 5 process (Chapter 1), a chapter on data sources and data evaluation (Chapter 2), and chapters (Chapters 3 - 11) devoted to contaminants receiving a final regulatory determination under RD 5: 2-aminotoluene (*o*-toluidine), cylindrospermopsin, ethoprop, microcystins, molybdenum, permethrin, profenofos, tebuconazole, and tribufos. It also includes two appendices. Appendix A provides summary information on the nine RD 5 contaminants that are receiving final regulatory determinations, and Appendix B is the protocol that the EPA followed in RD 5 decision-making.

The EPA evaluates contaminants for regulatory determination based on three statutory criteria. Regulation with a national primary drinking water regulation (NPDWR) is warranted if:

- (a) the contaminant may have an adverse effect on the health of persons;
- (b) the contaminant is known to occur or there is substantial likelihood that the contaminant will occur in public water systems (PWSs) with a frequency and at levels of public health concern; and
- (c) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

The EPA may determine that a contaminant satisfies all three criteria and warrants a NPDWR (a positive determination), or that it does not satisfy all three criteria and does not warrant regulation at this time (a negative determination). Another possible outcome for a contaminant is a decision to make no regulatory determination. SDWA requires the EPA to make a minimum of five regulatory determinations per cycle.

Following a standard protocol to evaluate contaminants against the statutory criteria, the EPA gathered data and information on health effects and occurrence in PWSs, as well as physical and chemical properties; source, use, and release; environmental fate and transport; and occurrence in ambient water. The EPA also evaluated the availability of analytical methods and treatment technologies.

The EPA has made final determinations that 2-aminotoluene, cylindrospermopsin, ethoprop, microcystins, molybdenum, permethrin, profenofos, tebuconazole, and tribufos do not satisfy all three criteria and do not warrant regulation with NPDWRs at this time. The final determinations are presented formally in the *Federal Register*.

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Chapter 1: Introduction

A chapter from:

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Abbreviations

AM	Assessment Monitoring
ATSDR	Agency for Toxic Substances and Disease Registry
BCAA	Bromochloroacetic Acid
BCIM	Bromochloroiodomethane
BDCAA	Bromodichloroacetic Acid
BDCNM	Bromodichloronitromethane
BDIM	Bromodiiodomethane
CASRN	Chemical Abstracts Service Registry Number
CCL	Contaminant Candidate List
CCL 1	First Contaminant Candidate List
CCL 2	Second Contaminant Candidate List
CCL 3	Third Contaminant Candidate List
CCL 4	Fourth Contaminant Candidate List
CCL 5	Fifth Contaminant Candidate List
CCLCP	Contaminant Candidate List Classification Process
CDIM	Chlorodiiodomethane
DBAN	Dibromoacetoneitrile
DBCAA	Dibromochloroacetic Acid
DBCNM	Dibromochloronitromethane
DBIM	Dibromoiodomethane
DBP	Disinfection Byproduct
DCAN	Dichloroacetoneitrile
DCIM	Dichloroiodomethane
DDE	1,1-Dichloro-2,2-bis(<i>p</i> -chlorophenyl)ethylene
EPA	U.S. Environmental Protection Agency
EPTC	<i>S</i> -ethyl dipropylthiocarbamate
FW	Finished Water
HA	Health Advisory
HC	Health Canada
HFPO-DA	Perfluoro-2-methyl-3-oxahexanoic Acid
HRL	Health Reference Level
IRIS	Integrated Risk Information System
MBC	Carbendazim
MCL	Maximum Contaminant Level
MDBP	Microbial/Disinfection By-Product
MTBE	Methyl tert-butyl ether
NA	Not Applicable
NCOD	National Contaminant Occurrence Database
NDBA	N-nitrosodibutylamine
NDEA	N-nitrosodiethylamine
NDMA	N-nitrosodimethylamine
NDPA	N-nitrosodipropylamine
NDPhA	N-Nitrosodiphenylamine
NDWAC	National Drinking Water Advisory Council
NIRS	National Inorganics and Radionuclides Survey
NMEA	N-nitrosomethylethylamine

NPDWR	National Primary Drinking Water Regulation
NPYR	N-pyrrolidine
NRC	National Research Council
OGWDW	Office of Ground Water and Drinking Water
OPP	Office of Pesticide Programs
OPPT	Office of Pollution Prevention and Toxics
OW	Office of Water
PCCL	Preliminary Contaminant Candidate List
PCCL 3	Third Preliminary Contaminant Candidate List
PFAS	Per-and Polyfluoroalkyl Substances
PFBS	Perfluorobutane Sulfonic Acid
PFHxS	Pefluorohexanesulfonic Acid
PFNA	Perfluorononanoic Acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctanesulfonic Acid
PPRTV	Provisional Peer-Reviewed Toxicity Value
PWS	Public Water System
RD 1	First Regulatory Determination
RD 2	Second Regulatory Determination
RD 3	Third Regulatory Determination
RD 4	Fourth Regulatory Determination
RD 5	Fifth Regulatory Determination
RDX	Royal Demolition eXplosive
SAB	Science Advisory Board
SDWA	Safe Drinking Water Act
SS	Screening Survey
TBAA	Tribromoacetic Acid
TCEP	Tris(2-chloroethyl) Phosphate
TCNM	Chloropicrin (Trichloronitromethane)
TIM	Iodoform (Triiodomethane)
UCM	Unregulated Contaminant Monitoring
UCMR 1	First Unregulated Contaminant Monitoring Rule
UCMR 2	Second Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 4	Fourth Unregulated Contaminant Monitoring Rule
UCMR 5	Fifth Unregulated Contaminant Monitoring Rule
WHO	World Health Organization

Chapter 1: Introduction

1.1 Purpose and Scope

The 1996 Safe Drinking Water Act (SDWA) Amendments (Section 1412(b)(1)) direct the U.S. Environmental Protection Agency (EPA) to publish every five years a list of currently unregulated contaminants (i.e., contaminants that are not currently regulated under SDWA) that may pose risks for drinking water (referred to as the Contaminant Candidate List, or CCL) and to make determinations every five years of whether to regulate or not regulate with a national primary drinking water regulation (NPDWR) at least five contaminants from the CCL.

This document supports the EPA's fifth Regulatory Determination (RD 5), which is based on an evaluation of contaminants on the fifth Contaminant Candidate List (CCL 5). This regulatory determination support document provides:

- A summary of the statutory requirements, previous activities related to the CCL and regulatory determinations, and the approach used to select and evaluate CCL 5 contaminants for RD 5;
- Background information on the data sources used to evaluate CCL 5 contaminants, including data sources on physical and chemical properties, use and environmental release, environmental fate, health effects, and occurrence and exposure; and
- A description of the information evaluated by the Agency for each contaminant, including information and data on physical and chemical properties, use and environmental release, environmental fate, health effects, and occurrence and exposure.

The nine regulatory determination candidates discussed in this document are: 2-aminotoluene (*o*-toluidine), cylindrospermopsin, ethoprop, microcystins, molybdenum, permethrin, profenofos, tebuconazole, and tribufos.

This document also includes two appendices. Appendix A presents summary information on the nine contaminants that are receiving final regulatory determinations. Appendix B presents the protocol that the EPA used for RD 5 decision-making.

1.2 Background on the CCL and Regulatory Determinations

1.2.1 Statutory Requirements for CCL and Regulatory Determinations

The statutory requirements for the CCL and regulatory determinations are presented in SDWA Section 1412(b)(1). The 1996 SDWA Amendments require the EPA to publish the CCL every five years. The CCL is a list of contaminants that are not subject to any proposed or promulgated NPDWRs but are known or anticipated to occur in public water systems (PWSs) and may require regulation under SDWA to protect public health. SDWA requires consultation with the scientific community, including the EPA's Science Advisory Board (SAB); opportunity for public comments; and consideration of the National Contaminant Occurrence Database (NCOD), established under Section 1445(g) of the Act. The 1996 SDWA Amendments also direct the EPA to determine whether to regulate or not regulate at least five contaminants from the CCL every five years. There are three criteria to be considered in making a regulatory determination. A decision to regulate is warranted if:

- (a) the contaminant may have an adverse effect on the health of persons;
- (b) the contaminant is known to occur or there is substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern; and
- (c) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

If, after considering public comment on a preliminary determination, the Agency makes a final determination to regulate a contaminant, the EPA will initiate the process to propose and promulgate an NPDWR. In that case, the statutory time frame provides for Agency proposal of a regulation within 24 months and action on a final regulation within 18 months of proposal. A final decision to not regulate is considered a final Agency action and is subject to judicial review. Since SDWA does not require the EPA to make a regulatory determination for all contaminants on the CCL, another possible outcome for some contaminants is no regulatory determination. In the case of a negative determination or no determination, the Agency may choose to publish a Health Advisory (HA), which is a non-regulatory action, or issue other guidance.

Additional information about the statutory requirements, the procedures the EPA uses to comply with them, and the inter-relationships between the Regulatory Determinations and other SDWA-mandated programs is provided in the Protocol in Appendix B.

1.2.2 The First Contaminant Candidate List (CCL 1)

The 1996 SDWA Amendments required the EPA to publish the first CCL (CCL 1) 18 months after the date of enactment. Following the 1996 SDWA Amendments, the EPA sought input from the National Drinking Water Advisory Council (NDWAC) on the process that should be used to identify contaminants for inclusion on CCL 1. For chemical contaminants, the Agency developed screening and evaluation criteria based on recommendations from the NDWAC. For microbiological contaminants, the NDWAC recommended that the Agency seek external expertise to identify and select potential waterborne pathogens. As a result, the Agency convened an international panel of microbiologists and public health experts who developed criteria for screening and evaluation and subsequently developed an initial list of potential microbiological contaminants.

With the short time frame required, the first CCL was largely based on expert knowledge and the evaluation of readily available information. The EPA obtained beneficial input from the NDWAC, the scientific community, and the public through stakeholder meetings and the public comments received on the draft CCL 1 published on October 6, 1997 (62 FR 52193; USEPA, 1997). The EPA published the final CCL 1, which contained 50 chemical and 10 microbiological contaminants, on March 2, 1998 (63 FR 10274; USEPA, 1998). A more detailed discussion of how the EPA developed CCL 1 can be found in those *Federal Register* notices.

1.2.3 The First Regulatory Determination (RD 1)

The EPA published its preliminary regulatory determinations for a subset of contaminants listed on CCL 1 on June 3, 2002 (67 FR 38222; USEPA, 2002). The Agency published its final regulatory determinations on July 18, 2003 (68 FR 42898; USEPA, 2003). The EPA identified nine contaminants from the 60 contaminants listed on CCL 1 that had sufficient data and information available to make regulatory determinations. The nine contaminants were *Acanthamoeba*, aldrin, dieldrin, hexachlorobutadiene, manganese, metribuzin, naphthalene, sodium, and sulfate. The Agency determined that a NPDWR was not

necessary for any of these nine contaminants. The Agency did, however, issue guidance on *Acanthamoeba* and health advisories for manganese, sodium, and sulfate.

The decision-making process that the EPA used to make its regulatory determinations for CCL 1 was based on substantial expert input and recommendations from different groups including stakeholders, the National Research Council (NRC), and the NDWAC. In March 2000, the EPA convened a Working Group under the NDWAC to help develop an approach for making regulatory determinations. The Working Group developed a protocol for analyzing and presenting the available scientific data and recommended methods to identify and document the rationale supporting a regulatory determination decision. The Working Group developed separate but similar protocols for microorganisms and chemicals. The approach for chemicals was based on an assessment of the impact of acute, chronic, and lifetime exposures, as well as a risk assessment that includes evaluation of occurrence, fate, and dose-response. The NDWAC protocol for chemicals provided a semi-quantitative, systematic approach for addressing each of the three Regulatory Determination criteria. The NDWAC Working Group report was presented to and accepted by the entire NDWAC in July 2000. In June 2002, the EPA consulted with the SAB Drinking Water Committee and requested its review and comment on whether the protocol the EPA developed, based on the NDWAC recommendations, was consistently applied and appropriately documented. SAB provided verbal feedback regarding the use of the NRC and NDWAC recommendations in the EPA's decision criteria for making its regulatory determinations. SAB recommended that the Agency provide a transparent and clear explanation of the process for making regulatory determinations. The Agency took SAB's recommendation into consideration and further explained the regulatory determination evaluation process in the 2003 *Federal Register* notice (68 FR 42898; USEPA, 2003) and in the supporting documentation.

1.2.4 The Second Contaminant Candidate List (CCL 2)

The process used to identify contaminants for inclusion on CCL was improved after CCL 1. To develop an enhanced, more robust approach to evaluating the risk of potential drinking water contaminants for future CCLs, the Agency requested assistance from the NRC. The NRC's evaluation, and other parallel assessments, overlapped with the deadline requirements to produce the second CCL (CCL 2). Hence, while the EPA was developing the more rigorous process, CCL 2 was based on the process used for CCL 1, and reflected the changes related to the first Regulatory Determination (RD 1). The CCL 2 carried forward the 51 chemical and microbial contaminants remaining on CCL 1 after RD 1. The Agency published its draft CCL 2 *Federal Register* notice on April 2, 2004 (69 FR 17406; USEPA, 2004) and the final CCL 2 *Federal Register* notice on February 24, 2005 (70 FR 9071; USEPA, 2005).

1.2.5 The Second Regulatory Determination (RD 2)

Continuing to follow the process established under RD 1, the Agency published its preliminary regulatory determinations for contaminants listed on CCL 2 on May 1, 2007 (72 FR 24016; USEPA, 2007). In the May 1, 2007 notice, the EPA made preliminary determinations for 11 of the 51 contaminants listed on CCL 2. These contaminants were: boron, the dacthal mono- and di-acid degradates, 1,1-dichloro-2,2-bis(*p*-chlorophenyl)ethylene (DDE), 1,3-dichloropropene, 2,4-dinitrotoluene, 2,6-dinitrotoluene, *S*-ethyl dipropylthiocarbamate (EPTC), fonofos, terbacil, and 1,1,2,2-tetrachloroethane. The Agency determined that an NPDWR was not necessary for any of these 11 contaminants. The EPA finalized those regulatory determinations on CCL 2 on July 30, 2008 (73 FR 44251; USEPA, 2008a). The

Agency issued new or updated health advisories for boron, the dacthal degradates, 2,4-dinitrotoluene, 2,6-dinitrotoluene, and 1,1,2,2-tetrachloroethane.

1.2.6 The Third Contaminant Candidate List (CCL 3)

As noted above, after CCL 1, the Agency realized the need to develop an enhanced approach to evaluate the risk of potential drinking water contaminants based on occurrence in drinking water and adverse health effects—both demonstrated and potential—for future CCLs. The Agency requested assistance from the NRC for guidance on methods and processes to identify and narrow a universe of potential contaminants into a smaller, more focused list of contaminants in drinking water for the future CCLs. The NRC recommended a multi-step process including using prototype classification algorithms that evaluate attributes in conjunction with expert judgment to identify contaminants for future CCLs. The approach would be based on predictive features or attributes that characterize the occurrence in drinking water and health effects of each contaminant. The NRC described two health effects attributes, severity and potency, and three occurrence attributes: prevalence, magnitude, and persistence/mobility.

The details of the NRC recommendation are available in the report entitled *Classifying Drinking Water Contaminants for Regulatory Considerations* (NRC, 2001). It is important to emphasize that the NRC report only gives a broad framework for the EPA to develop its own prototype classification scheme and then to calibrate the scheme using diagnostic contaminants.

Following up on the NRC recommendations, the EPA requested that the NDWAC provide advice on whether to pursue the stepped approach recommended in the NRC report and on how it could be implemented. The NDWAC formed a subcommittee, the Work Group on the Contaminant Candidate List Classification Process (CCLCP Work Group), to provide advice to the NDWAC.

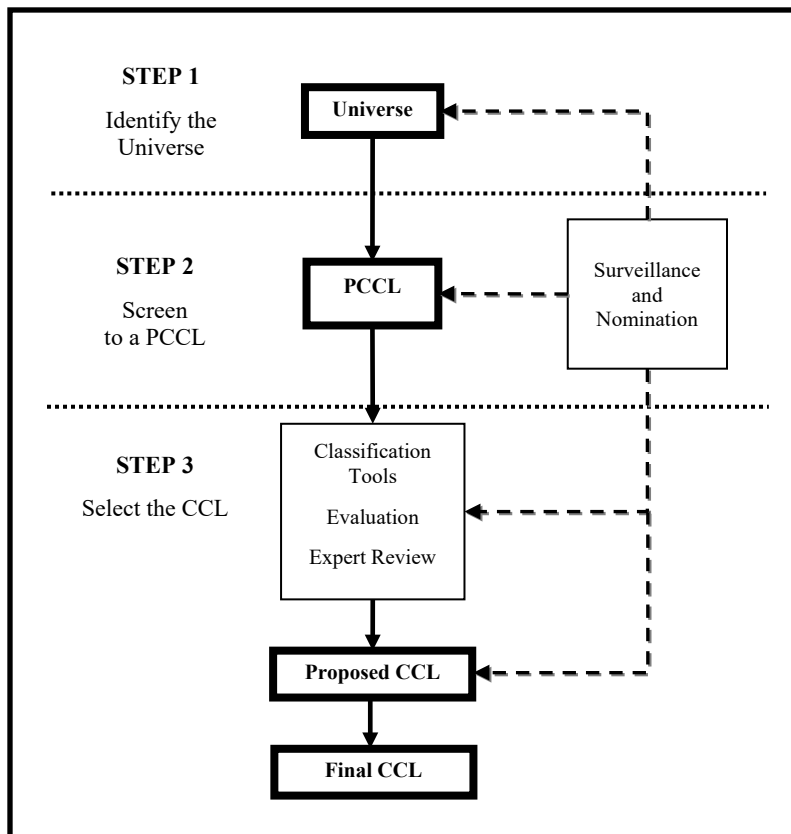
Based on the deliberations of the CCLCP Work Group, the NDWAC released a report in June 2004 that found merit in the NRC recommendations, but noted that the EPA may need several CCL cycles to fully develop and implement the NRC recommended approach. While the NDWAC agreed with the overall approach, the group noted that not all the data and information needed to fully develop the NRC-envisioned CCL were available at the time. The NDWAC also recognized that the Agency would be developing a new and powerful tool that could be refined and improved in successive efforts. Therefore, the NDWAC recommended that the Agency take advantage of the knowledge gained in implementing the approach and improve upon it in subsequent CCLs using an adaptive management process.

Based on these consultations with expert groups and stakeholders, the EPA developed a systematic approach to select contaminants for the third CCL (CCL 3) that includes the following key steps:

- (1) The identification of a broad universe of potential drinking water contaminants (CCL 3 Universe);
- (2) A screening process that uses readily available information on health effects and occurrence in water to narrow that universe of contaminants to a Preliminary CCL (PCCL); and
- (3) A structured classification process that “scores” and ranks contaminants, to develop a CCL from the PCCL, involving prototype classification models as tools, coupled with expert review and assessment.

New and emerging contaminants can enter the process at multiple points based on surveillance and nomination. Exhibit 1-1 illustrates the process used to evaluate contaminants for CCL 3.

Exhibit 1-1: General Overview of the Approach Used to Establish CCL 3



Chemical and microbial contaminants were evaluated separately. To populate the CCL 3 Universe of chemicals, an extensive preliminary list of substances was compiled from a wide variety of data sources that met specific criteria. The preliminary list was refined by removing chemicals with an existing NPDWR, substances that are considered mixtures of chemicals, and “non-chemically defined” entries. The resultant CCL 3 Universe included approximately 6,000 chemicals (see USEPA, 2009a for further details on the CCL 3 Universe process).

The CCL 3 Universe of chemicals was then screened using a framework that took into account both health effects and occurrence data. In the case of health effects, the EPA evaluated both quantitative and qualitative information on the hazard and dose-response properties of the contaminants. For occurrence, the EPA evaluated both quantitative and qualitative information on occurrence in water, releases to the environment, and amounts produced. The result of this screening process was that 561 chemical contaminants were selected for the Preliminary CCL 3 (PCCL 3) from the approximately 6,000 chemicals in the CCL 3 Universe (see USEPA, 2009b for details on the screening process).

To select contaminants for CCL 3 from among the 561 PCCL 3 contaminants, the EPA used classification models as a support tool to handle larger, more complex assortments of data in a consistent and reproducible manner. The classification models were trained based on past

expert decisions for a sample of chemicals. To enable numerical scoring of the contaminants, using complex data, a scaling system was developed for four attributes: severity, potency, magnitude, and prevalence (see USEPA, 2009c for details). Contaminants were scored for each of these attributes, and the scores were run through three calibrated models. The EPA Evaluation Team made several post-model refinements to compile the draft list of CCL 3 chemical contaminants.

The protocol the EPA used to select the microbial contaminants for the CCL 3, as described in detail in the draft CCL 3 notice (73 FR 9628; USEPA, 2008b), followed the same general outline. The first step was to identify a universe of potential microbial drinking water contaminants. The second step was to screen that universe of microbiological contaminants to develop a Preliminary Contaminant Candidate List (PCCL). Lastly, the EPA selected the draft CCL 3 microbial list by ranking the PCCL contaminants based on occurrence in drinking water (including consideration of waterborne disease outbreaks) and human health effects.

The EPA also put out a special call for nominations to CCL 3 (USEPA, 2009d), held expert panel consultations, consulted with the SAB, and accepted public comments (USEPA, 2009e). The draft CCL 3 was published on February 21, 2008 (73 FR 9628; USEPA, 2008b), and the final CCL 3 was published on October 8, 2009 (74 FR 51850; USEPA, 2009f). The final CCL 3 consisted of 104 chemicals or chemical groups, and 12 microbiological contaminants.

1.2.7 The Third Regulatory Determination (RD 3)

The Agency published its preliminary regulatory determinations for contaminants listed on CCL 3 on October 20, 2014 (79 FR 62716; USEPA, 2014a). In that *Federal Register* notice, the EPA made preliminary determinations for 5 of the 116 contaminants listed on CCL 3. A preliminary positive determination was made for strontium. Preliminary negative determinations were made for dimethoate, 1,3-dinitrobenzene, terbufos, and terbufos sulfone. The EPA also announced in that notice that decisions about whether or not to regulate the contaminants chlorate, N-nitrosodibutylamine (NDBA), N-nitrosodimethylamine (NDMA), N-nitrosodipropylamine (NDPA), N-nitrosodiethylamine (NDEA), N-nitrosomethylethylamine (NMEA), and N-pyrrolidine (NPYR) would not be made under Regulatory Determinations 3 but rather as part of the Six-Year Review of existing Microbial / Disinfection Byproduct (MDBP) regulations. On January 4, 2016 (81 FR 13; USEPA, 2016a), the EPA finalized the negative determinations for dimethoate, 1,3-dinitrobenzene, terbufos, and terbufos sulfone. The EPA announced a delay in issuing a final regulatory determination on strontium in order to consider additional data.

The third Regulatory Determination (RD 3) process was formalized in a protocol document that was reviewed by an expert panel in October 2011, and revised in response to reviewer suggestions (USEPA, 2014b). The RD 3 Protocol captures the process that had been used for RD 1, RD 2 and RD 3 in accordance with NDWAC recommendations discussed in Section 1.2.3.

In the *Federal Register* notice for the second Regulatory Determination (RD 2) preliminary determinations (72 FR 24016; USEPA, 2007), the EPA presented an update on the Agency's evaluation of perchlorate and solicited public comment on the information and options for perchlorate. The EPA published an off-cycle determination to regulate perchlorate on February 11, 2011 (76 FR 7762; USEPA, 2011); this final regulatory determination for perchlorate was considered part of the third Regulatory Determination cycle. Subsequently, after evaluating additional information, the EPA withdrew the determination to regulate perchlorate

(85 FR 43990; USEPA, 2020a). More recently, in response to a federal court decision, the EPA has committed to issue an NPDWR for perchlorate. The Agency issued a proposed NPDWR for perchlorate on January 6, 2026 (91 FR 398; USEPA, 2026). Additional information about the perchlorate regulatory determination and the proposed NPDWR can be found on the EPA's website: <https://www.epa.gov/dwstandardsregulations/perchlorate-drinking-water>.

1.2.8 The Fourth Contaminant Candidate List (CCL 4)

The draft fourth CCL (CCL 4) was published on February 4, 2015 (80 FR 6076; USEPA, 2015) and the final CCL 4 was published on November 17, 2016 (81 FR 81099; USEPA, 2016b). The final CCL 4 consists of 97 chemicals or chemical groups and 12 microbiological contaminants. Most CCL 4 contaminants were carried over from CCL 3 (which, as described above, was developed according to a rigorous process with input from multiple stakeholders over the course of multiple years). The EPA added two contaminants (manganese and nonylphenol) to the CCL 4 list based on nominations. The EPA struck from the list those CCL 3 contaminants that had been subject to recent preliminary or final regulatory determinations (perchlorate, dimethoate, 1,3-dinitrobenzene, terbufos, terbufos sulfone, strontium) and three pesticides with cancelled registrations (disulfoton, fenamiphos, molinate).

1.2.9 The Fourth Regulatory Determination (RD 4)

The Agency published its preliminary regulatory determinations for contaminants listed on CCL 4 on March 10, 2020 (85 FR 14098; USEPA, 2020b). In that *Federal Register* notice, the EPA made preliminary determinations for 8 of the 109 contaminants listed on CCL 4. Preliminary positive determinations were made for perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA). Preliminary negative determinations were made for 1,1-dichloroethane, acetochlor, methyl bromide (bromomethane), metolachlor, nitrobenzene, and RDX, also known as Royal Demolition eXplosive. The EPA also presented an update on three other CCL 4 contaminants: strontium, 1,4-dioxane, and 1,2,3-trichloropropane. On March 3, 2021 (86 FR 12272; USEPA, 2021a), the EPA finalized the positive determinations for PFOS and PFOA and the negative determinations for 1,1-dichloroethane, acetochlor, methyl bromide, metolachlor, nitrobenzene, and RDX. For the fourth Regulatory Determination (RD 4), the EPA followed a written protocol similar to that prepared under RD 3.

Subsequent to the positive determinations for PFOS and PFOA, an NPDWR for these and several other per- and polyfluoroalkyl substances (PFAS) was proposed by the EPA on March 29, 2023 (88 FR 18638; USEPA, 2023) and finalized on April 26, 2024 (89 FR 32532; USEPA, 2024). The final rule established NPDWRs for PFOS, PFOA, perfluorohexanesulfonic acid (PFHxS), perfluorononanoic acid (PFNA), perfluoro-2-methyl-3-oxahexanoic acid (HFPO-DA, also known as "GenX"), and mixtures containing two or more of PFHxS, PFNA, HFPO-DA, and perfluorobutanesulfonic acid (PFBS). Concurrent with the proposed PFAS rule, the EPA also announced preliminary regulatory determinations for PFHxS, PFNA, HFPO-DA, and PFBS. Concurrent with the final PFAS rule, the EPA also announced final regulatory determinations for PFHxS, PFNA, and HFPO-DA, and mixtures containing two or more of PFHxS, PFNA, HFPO-DA, and PFBS. On May 14, 2025, the EPA announced an intention to retain the NPDWRs for the PFOS and PFOA, to rescind the NPDWRs for PFHxS, PFNA, HFPO-DA and mixtures containing two or more of PFHxS, PFNA, HFPO-DA, and PFBS, and to reconsider the regulatory determinations for PFHxS, PFNA, HFPO-DA and mixtures containing two or more of PFHxS, PFNA, HFPO-DA, and PFBS (USEPA, 2025a).

1.3 The Fifth Contaminant Candidate List (CCL 5)

The draft CCL 5 was published on July 19, 2021 (86 FR 37948; USEPA, 2021b) and the final CCL 5 was published on November 14, 2022 (87 FR 68060; USEPA, 2022). The final CCL 5 consists of 66 chemicals, 3 chemical groups (cyanotoxins, disinfection byproducts or DBPs, and PFAS), and 12 microbial contaminants.

To produce CCL 5, the EPA used a three-step process similar to that described above for CCL 3. During step 2 (developing the PCCL), the EPA added publicly nominated contaminants, excluded contaminants that had received recent regulatory determinations (strontium, PFOS, PFOA, 1,1-dichloroethane, acetochlor, methyl bromide, metolachlor, nitrobenzene, and RDX), and excluded cancelled pesticides that were determined not to be persistent.

1.4 Overview of the Fifth Regulatory Determination (RD 5)

The Regulatory Determinations 5 process is very similar to that used in earlier rounds of regulatory determinations. Throughout the RD 5 process, the EPA conducted its evaluations in a manner consistent with the Agency's *Implementation of Gold Standard Science* (USEPA, 2025b), including through utilizing a standardized process for evaluating RD 5 contaminants, as described in Appendix B. The three-phase process used for those evaluations is described in detail in the RD 5 protocol presented in Appendix B. The procedure is briefly described below, along with outcomes.

1.4.1 RD 5 Phase 1: Data Availability

In the first phase, the EPA evaluated data availability, including: (a) the availability of a suitable health assessment, from which a critical health effect could be identified and a health reference level (HRL) calculated,¹ (b) the availability of nationally representative finished water occurrence data, and (c) the existence of a widely available analytical method for detecting the contaminant in drinking water.

The list of contaminants evaluated included all of the individual chemical and microbial contaminants listed in CCL 5, plus members of the three groups listed in CCL 5 (cyanotoxins, DBPs, and PFAS), and strontium. Three cyanotoxins were included in the Phase 1 screening, along with several dozen DBPs and PFAS. Three members of the PFAS group with available data, namely perfluorononanoic acid (PFNA), perfluorohexanesulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid and its ammonium salt (HFPO-DA, also known as GenX or GenX chemicals), were removed from consideration because they had already received final positive regulatory determinations in conjunction with the development of the PFAS NPDWR. Strontium was included in RD 5 because it remains a priority unregulated contaminant even though it was not listed on CCL 5. The EPA refrained from issuing a final regulatory determination on strontium during RD 3 in order to consider additional data, and is continuing to evaluate this contaminant as a candidate for regulation.

As indicated in Exhibit 1-2, the EPA found that 35 of the evaluated contaminants met the data availability criteria. These contaminants proceeded to the second phase of the RD 5 process and are referred to as the “short list.”

¹ An HRL is a health-based concentration against which the Agency evaluates occurrence data when making decisions about regulatory determinations.

Exhibit 1-2: Contaminants Proceeding from Phase 1 to Phase 2

CASRN	Common Name	Best Health Effects Data Source	Best Occurrence Data Source	Occurrence Data Type
96-18-4	1,2,3-Trichloropropane	IRIS 2009	UCMR 3 (AM)	National FW
95-63-6	1,2,4-Trimethylbenzene	IRIS 2016	UCM Rounds 1 and 2	National FW
123-91-1	1,4-Dioxane	OPPT 2020	UCMR 3 (AM)	National FW
95-53-4	2-Aminotoluene	PPRTV 2012	UCMR 4 (AM)	National FW
319-84-6	alpha-Hexachlorocyclohexane	IRIS 1987	UCMR 4 (AM)	National FW
7440-42-8	Boron	OW 2008	NIRS	National FW
63-25-2	Carbaryl	OPP 2017	UCM Round 2	National FW
14866-68-3	Chlorate	OPP 2021	UCMR 3 (AM)	National FW
7440-48-4	Cobalt	PPRTV 2008	UCMR 3 (AM)	National FW
143545-90-8	Cylindrospermopsin	OW 2015	UCMR 4 (AM)	National FW
60-57-1	Dieldrin	OW 2003	UCM Round 2	National FW
60-51-5	Dimethoate	OPP 2015	UCMR 2 (AM)	National FW
330-54-1	Diuron	OPP 2020	UCMR 1 (SS)	Non-National FW
13194-48-4	Ethoprop	OPP 2015	UCMR 2 (AM)	National FW
NA	<i>Legionella pneumophila</i>	OW Human Health Criteria Document 1999	Miscellaneous literature	Non-National FW
7439-93-2	Lithium	PPRTV 2008	NIRS	National FW
7439-96-5	Manganese	WHO 2021	UCMR 4 (AM)	National FW
16752-77-5	Methomyl	OPP 2018	UCM Round 2	National FW
NA	Microcystins	OW 2015	UCMR 4 (AM)	National FW
7439-98-7	Molybdenum	ATSDR 2020	UCMR 3 (AM)	National FW
924-16-3	N-Nitrosodi-n-butylamine (NDBA)	OW Six Year Review 3 Technical Support Document 2016	UCMR 2 (SS)	National FW
55-18-5	N-Nitrosodiethylamine (NDEA)	OW Six Year Review 3 Technical Support Document 2016	UCMR 2 (SS)	National FW
62-75-9	N-Nitrosodimethylamine (NDMA)	OW Six Year Review 3 Technical Support Document 2016	UCMR 2 (SS)	National FW
621-64-7	N-Nitrosodi-n-propylamine (NDPA)	OW Six Year Review 3 Technical Support Document 2016	UCMR 2 (SS)	National FW
930-55-2	N-Nitrosopyrrolidine (NPYR)	OW Six Year Review 3 Technical Support Document 2016	UCMR 2 (SS)	National FW
375-22-4	Perfluorobutanoic acid (PFBA)	IRIS 2022	PFAS state data	Non-National FW
52645-53-1	Permethrin	OPP 2020	UCMR 4 (AM)	National FW
41198-08-7	Profenofos	OPP 2015	UCMR 4 (AM)	National FW
1918-16-7	Propachlor	OPP 1998	UCM Round 2	National FW
91-22-5	Quinoline	IRIS 2001	UCMR 4 (AM)	National FW
7440-24-6	Strontium	HC 2019	UCMR 3 (AM)	National FW
107534-96-3	Tebuconazole	OPP 2021	UCMR 4 (AM)	National FW
13071-79-9	Terbufos	OPP 2015	UCMR 1 (SS)	Non-National FW

CASRN	Common Name	Best Health Effects Data Source	Best Occurrence Data Source	Occurrence Data Type
78-48-8	Tribufos	OPP 2015	UCMR 4 (AM)	National FW
7440-62-2	Vanadium	PPRTV 2009	UCMR 3 (AM)	National FW

Note: Chapter 2 provides a general overview of the sources of data that the EPA used to evaluate drinking water contaminants, including sources of health effects and occurrence data.

AM = Assessment Monitoring

ATSDR = Agency for Toxic Substances and Disease Registry

CASRN = Chemical Abstracts Service Registry Number

FW = Finished Water

HC = Health Canada

IRIS = Integrated Risk Information System

NA = Not Applicable

NIRS = National Inorganics and Radionuclides Survey

OPP = Office of Pesticide Programs

OPPT = Office of Pollution Prevention and Toxics

OW = Office of Water

PFAS = Per- and Polyfluoroalkyl Substances

PPRTV = Provisional Peer-Reviewed Toxicity Value

SS = Screening Survey

UCM = Unregulated Contaminant Monitoring

UCMR 1 = First Unregulated Contaminant Monitoring Rule

UCMR 2 = Second Unregulated Contaminant Monitoring Rule

UCMR 3 = Third Unregulated Contaminant Monitoring Rule

UCMR 4 = Fourth Unregulated Contaminant Monitoring Rule

WHO = World Health Organization

For the remaining contaminants evaluated, Exhibit 1-3 summarizes why each did not proceed to the second phase of the RD 5 process.

Exhibit 1-3: Contaminants Not Proceeding from Phase 1 to Phase 2

(i) Has nationally representative finished water data but no health assessment	
17-alpha ethynyl estradiol	Chlorpyrifos
Anatoxin-a	Methyl tert-butyl ether (MTBE)
(ii) Has health assessment and other finished drinking water data but no occurrence at levels > ½ HRL	
2-Hydroxyatrazine*	Malathion
2,4-Dinitrophenol	Methylmercury*
6-Chloro-1,3,5-triazine-2,4-diamine	N-Nitrosodiphenylamine (NDPhA)*
Acrolein*	Norfluzon
Anthraquinone*	Perfluorobutane sulfonic acid (PFBS) ¹
Bisphenol A*	Phorate
Bromoxynil*	Phosmet*
Carbendazim (MBC)	Propanil
Desethylatrazine	Propazine
Desisopropyl atrazine	Propargite*
Diazinon	Propoxur
Dichrotophos	Saxitoxin
Ethalfuralin*	Tebupirimfos*
Fipronil*	Thiamethoxam*

Flufenacet (Thiaflumide)*	Tri-allate*
Fluometuron	Tributyl phosphate*
Formaldehyde	Tris(2-chloroethyl) phosphate (TCEP)*
Iprodione*	Tungsten*
(iii). Has other finished drinking water data but no health assessment	
4-Nonylphenol (all isomers)*	Dibromiodomethane (DBIM)
Bromochloroacetic acid (BCAA)	Dichloroacetonitrile (DCAN)
Bromochloriodomethane (BCIM)	Dichloriodomethane (DCIM)
Bromodichloroacetic acid (BDCAA)	Fluconazole*
Bromodichloronitromethane (BDCNM)*	Iodoform (triiodomethane, TIM)
Bromodiodomethane (BDIM)	Select Fifth Unregulated Contaminant Monitoring Rule (UCMR 5) PFAS
Chlorodiodomethane (CDIM)	Tribromoacetic acid (TBAA)
Chloropicrin (trichloronitromethane, TCNM)	Enteroviruses
Desvenlafaxine*	<i>Naegleria fowleri</i>
Dibromoacetonitrile (DBAN)	<i>Pseudomonas aeruginosa</i>
Dibromochloroacetic acid (DBCAA)	<i>Shigella sonnei</i> *
Dibromochloronitromethane (DBCNM)*	
(iv) Does not have nationally representative or other finished water data	
Acephate	Chlordecone (Kepone)
Bensulide	
(v) Lacks a widely available analytical method, occurrence not evaluated	
Adenoviruses*	<i>Helicobacter pylori</i> *
Caliciviruses*	<i>Mycobacterium abscessus</i> *
<i>Campylobacter jejuni</i> *	<i>Mycobacterium avium</i> *
<i>Escherichia coli</i> (O157)*	
Other situations	
Oxyfluorfen* ²	

*Does not have a widely available analytical method for occurrence monitoring

Notes:

1. Note also that PFBS is a member of a group of four PFAS that, as a mixture, has received an off-cycle regulatory determination and is regulated with a maximum contaminant level (MCL) (89 FR 32532; USEPA, 2024).

2. Oxyfluorfen has a health assessment and nationally representative data (from UCMR 4), but matrix interference was discovered during UCMR 4 that could make the analytical method unsuitable for use in regulatory monitoring. (Despite the high bias produced by the matrix interference, the UCMR 4 results show low occurrence, so the matrix interference issue does not necessarily invalidate the oxyfluorfen UCMR 4 findings for use in regulatory determinations.)

1.4.2 RD 5 Phase 2: Data Evaluation

In the second phase, the EPA gathered and evaluated the full range of relevant data available for “short list” contaminants. Occurrence data (both finished water and ambient water data) were analyzed against the HRL threshold. Outcomes of the data evaluation included:

- (1) Identifying contaminants occurring or likely to occur at levels and frequencies of public health concern.
- (2) Identifying contaminants that have no or low potential for public health concern and no data gaps.

Those in the first group were evaluated as candidates for a positive determination in Phase 3. Those in the second group were evaluated as candidates for a negative determination in Phase 3. Exhibit 1-4 lists the contaminants that proceeded from Phase 2 to Phase 3.

Exhibit 1-4: Contaminants Proceeding from Phase 2 to Phase 3

1,2,3-Trichloropropane	Molybdenum
1,4-Dioxane	Permethrin
2-Aminotoluene	Profenofos
Cylindrospermopsin	Quinoline
Ethoprop	Strontium
Manganese	Tebuconazole
Microcystins	Tribufos

1.4.3 RD 5 Phase 3: Regulatory Determination Assessment

In the third and final phase, the Agency assessed contaminants that had reached this point against the three statutory criteria listed in Section 1.2.1 above. Additional detail on how the statutory criteria are interpreted and applied is found in the RD 5 protocol in Appendix B.

Outcomes of the regulatory determination assessment could include a determination to regulate, a determination not to regulate, or a decision to make no determination (for example: if additional data-gathering is warranted, or if a contaminant will be evaluated as a candidate for regulation as part of a different program or on a different schedule).

As the outcome of Phase 3, the EPA is making a final determination to not regulate nine contaminants: 2-aminotoluene, cylindrospermopsin, ethoprop, microcystins, molybdenum, permethrin, profenofos, tebuconazole, and tribufos. These nine contaminants are the subject of Chapters 3-11 of this support document. The EPA is making no determination about the remaining five contaminants, 1,2,3-trichloropropane, 1,4 dioxane, manganese, quinoline, and strontium. Final RD 5 Phase 3 outcomes are presented formally in the *Federal Register*.

The final determinations were made following publication of preliminary determinations (90 FR 3830; USEPA, 2025c) and consideration of public comments.

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Chapter 2: Data Sources and Data Evaluation

A chapter from:

Final Regulatory Determination 5 Support Document

EPA Report 815-R-26-002

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Abbreviations

ADI	Acceptable Daily Intake
ATSDR	Agency for Toxic Substances and Disease Registry
AwwaRF	American Water Works Association Research Foundation
BMD	Benchmark Dose
CalEPA	California Environmental Protection Agency
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CCL	Contaminant Candidate List
CCL 5	Fifth Contaminant Candidate List
CCR	Consumer Confidence Reports
CDC	Centers for Disease Control and Prevention
CDR	Chemical Data Reporting
CDW	Committee on Drinking Water
CWS	Community Water System
CWSS	Community Water System Survey
DBP	Disinfection Byproduct
D/DBPR	Disinfectants and Disinfection Byproduct Rule
DTXSID	Distributed Structure Searchable Toxicity Substance Identifier
DWSHA	Drinking Water Standards and Health Advisory Document
DWTP	Drinking Water Treatment Plant
DWW	Drinking Water Watch
EFSA	European Food Safety Authority
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	Food Quality Protection Act
GDWQ	Guidelines for Drinking-Water Quality
GWUDI	Groundwater Under Direct Influence of Surface Water
HAA	Haloacetic Acid
HED	Health Effects Division
HESD	Health Effects Support Document
HHRA	Human Health Risk Assessment
HRL	Health Reference Level
HSDB	Hazardous Substances Data Bank
IOC	Inorganic Compound
IREL	Interim Reregistration Eligibility Decision
IRIS	Integrated Risk Information System
IUR	Inventory Update Reporting
K _H	Henry's Law Constant
K _{oc}	Organic Carbon Partitioning Coefficient
K _{ow}	Octanol-Water Partitioning Coefficient
LCMRL	Lowest Concentration Minimum Reporting Level
LOAEL	Lowest-Observed-Adverse-Effect Level
LT-MDL	Long-Term Method Detection Level
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal

MDL	Method Detection Limit
MRL	Minimum Reporting Level
MTBE	Methyl Tertiary Butyl Ether
NAWQA	National Water-Quality Assessment
NCBI	National Center for Biotechnology Information
NCFAP	National Center for Food and Agricultural Policy
NCOD	National Drinking Water Contaminant Occurrence Database
NDWAC	National Drinking Water Advisory Council
NHANES	National Health and Nutrition Examination Survey
NIRS	National Inorganics and Radionuclides Survey
NOAEL	No-Observed-Adverse-Effect Level
NPDWR	National Primary Drinking Water Regulation
NPL	National Priorities List
NPS	National Pesticide Survey
NTNCWS	Non-Transient Non-Community Water System
NWIS	National Water Information System
OEHHA	Office of Environmental Health Hazard Assessment
OGWDW	Office of Ground Water and Drinking Water
OPP	Office of Pesticide Programs
OPPT	Office of Pollution Prevention and Toxics
ORD	Office of Research and Development
OW	Office of Water
PAH	Polycyclic Aromatic Hydrocarbon
PDP	Pesticide Data Program
PFAS	Per- and Polyfluoroalkyl Substances
PHG	Public Health Goal
PMP	Pilot Monitoring Program
POD	Point of Departure
PPRTV	Provisional Peer Reviewed Toxicity Value
PWS	Public Water System
QA	Quality Assurance
RD 5	Fifth Regulatory Determination
RED	Reregistration Eligibility Decision
RfC	Reference Concentration
RfD	Reference Dose
SDWA	Safe Drinking Water Act
SDWIS/Fed	Safe Drinking Water Information System / Federal Version
SOC	Synthetic Organic Compound
STORET	Storage and Retrieval Data System
SVOC	Semivolatile Organic Chemicals
SYR2	Second Six-Year Review
SYR3	Third Six-Year Review
SYR4	Fourth Six-Year Review
TDI	Tolerable Daily Intake
TNCWS	Transient Non-Community Water System
TRED	Tolerance Reassessment Progress and Risk Management Decision
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act

TT	Treatment Technique
UCM	Unregulated Contaminant Monitoring
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 1	First Unregulated Contaminant Monitoring Rule
UCMR 2	Second Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 4	Fourth Unregulated Contaminant Monitoring Rule
USDA	United States Department of Agriculture
USGS	United States Geological Survey
USNLM	United States National Library of Medicine
UV	Ultraviolet
VOC	Volatile Organic Compound
WHO	World Health Organization
WQP	Water Quality Portal
WRF	Water Research Foundation

Chapter 2: Data Sources and Data Evaluation

This chapter provides a general overview of the sources of data that the U.S. Environmental Protection Agency (EPA) used to evaluate drinking water contaminants under the fifth Regulatory Determination (RD 5), based on the fifth Contaminant Candidate List (CCL 5), in accordance with the requirements of the Safe Drinking Water Act (SDWA). The chapter includes information about the quality of the data and about how the EPA used the data. For more information about the RD 5 process, see Chapter 1 of this report and the RD 5 protocol in Appendix B. For an overview of RD 5 outcomes, see Chapter 1. For detailed findings on individual contaminants receiving a final regulatory determination under RD 5, see Chapters 3–11. Appendix A provides a concise summary of the data gathered for those nine contaminants.

The outline of this chapter mirrors the organization of the contaminant-specific chapters that follow. Section 2.1 identifies the sources used to gather contaminant background information and chemical and physical properties. Section 2.2 describes information sources used to characterize contaminant production, use, and release. Section 2.3 describes how environmental fate and transport were evaluated and what information sources were used. Section 2.4 describes the sources of information used for health effects evaluations. (For information about the process of evaluating health effects information, and the use of carcinogenic and non-carcinogenic health effects data for the derivation of a health reference level (HRL), see the RD 5 protocol in Appendix B.) Section 2.5 describes the primary and supplemental sources of ambient and drinking water occurrence information used to evaluate contaminant occurrence and exposure and provides information about occurrence data handling (involving detection and reporting thresholds and rounding). Section 2.6 presents information on evaluation of analytical methods, and Section 2.7 describes the processes used to evaluate the availability of treatment technologies. Note that this chapter describes data sources used to evaluate all CCL 5 contaminants in all phases of the RD 5 process (see Appendix B), not just the nine contaminants discussed in the following chapters as having proceeded to Phase 3.

2.1 Contaminant Background, Chemical, and Physical Properties

The EPA consulted a number of standard sources to gather information on contaminant background and properties. The most important source was the National Center for Biotechnology Information (NCBI) PubChem database, which houses and displays information from a variety of formerly stand-alone sources such as the U.S. National Library of Medicine's (USNLM) Hazardous Substances Data Bank (HSDB) and USNLM's ChemIDPlus database. Additional sources included Toxicity Profiles published by the Agency for Toxic Substances and Disease Registry (ATSDR), reports on pesticide reregistration or registration review prepared by the EPA's Office of Pesticide Programs (OPP), and standard chemistry reference books. To fill some information gaps, primary literature was consulted as well, with preference given to peer-reviewed sources.

2.2 Contaminant Production, Use, and Release

Quantitative data on natural and anthropogenic sources of contaminants in the environment, including data on production, use, and industrial releases, were obtained from specific primary sources and data compilations. The most important of these are profiled below.

Inventory Update Reporting (IUR) and Chemical Data Reporting (CDR) Programs

The Toxic Substances Control Act (TSCA) requires the EPA to compile, keep current, and publish a Chemical Substance Inventory, a list of chemical substances that are manufactured

or processed in the United States. Following the promulgation of the 1986 Inventory Update Reporting (IUR) rule, chemical manufacturers (including importers) were required to report to the EPA every four years the identity of and basic manufacturing information for organic chemical substances manufactured (including imported) in quantities of 10,000 pounds or more annually at individual sites. Modifications of the IUR rule in 2003 and 2005 expanded the range of chemicals and plant sites reporting, expanded the type of data reported, raised the production volume threshold that triggers reporting from 10,000 pounds to 25,000 pounds, and made certain further adjustments. Additional information on domestic processing and use was required to be reported for chemicals produced or imported in amounts of 300,000 pounds or more at a single site. In 2011 the Agency issued the Chemical Data Reporting (CDR) Rule, which replaced the IUR Rule and established a somewhat modified program, including annual data gathering and periodic reporting. CDR makes use of a two-tiered system of reporting thresholds, with 25,000 pounds the threshold for some contaminants and 2,500 pounds the threshold for others (USEPA, 2020; USEPA 2022a).

The EPA makes certain non-confidential information gathered under IUR and CDR available to the public. This includes aggregated national total annual production volumes for chemicals based on reports filed. As a result of the changes in reporting thresholds and other program modifications, results from different cycles might not be directly comparable. At the time of report preparation, data from the 2006 IUR cycle (representing production in calendar year 2005) and the 2012, 2016, and 2020 cycles of CDR (representing production in calendar years 2011 through 2019) were publicly available, and these were the data analyzed for RD 5 and presented in tables in the chapters that follow.

In many cases, results are reported as falling in specified ranges (e.g., <25,000 pounds, 100 million to <500 million pounds, 1 billion pounds or greater). The set of ranges used has not always been consistent from cycle to cycle. Sometimes results are reported as exact values. A result of “0” indicates that the EPA received one or more reports indicating no production. A result of “no data for chemical” indicates that the EPA received no reports about production of this chemical in the given year. A result of “CBI” (Confidential Business Information) indicates that production quantities were withheld as confidential business information.

When interpreting IUR and CDR data, it should be borne in mind that only production that exceeded the reporting thresholds is included, and that reporting thresholds have changed over time.

Toxics Release Inventory (TRI)

The EPA established the Toxics Release Inventory (TRI) in 1987 in response to Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). EPCRA Section 313 requires facilities to report to the EPA, and also to states, annual information on toxic chemical releases from facilities that meet reporting criteria. EPCRA Section 313 also requires the EPA to make this information available to the public. In 1990 Congress passed the Pollution Prevention Act, which required that additional data on waste management and source reduction activities be reported under TRI. TRI tracks not only the types and quantities of toxic chemicals released to the air, water, and land by facilities, but also the quantities of chemicals sent to other facilities for further management (USEPA, 2003a; USEPA, 2019a; USEPA, 2022b).

Facilities are required to report releases and other waste management activities related to TRI chemicals if they manufacture, process, or otherwise use more than established threshold quantities of these chemicals. Currently, for most chemicals, reporting of releases is required if

25,000 pounds or more of the chemical are manufactured or processed at a facility, or if 10,000 pounds or more are otherwise used at the facility. Lower thresholds are in place for persistent bioaccumulative toxic chemicals such as dioxin and dioxin-like compounds, and for per- and polyfluoroalkyl compounds or PFAS (USEPA, 2022b).

The EPA makes TRI data available to the public in several different ways. For the purpose of RD 5 analysis and reporting, the data were accessed via the EPA’s TRI Explorer.

Although TRI can provide a general idea of release trends, these trends should be interpreted with caution since reporting requirements have changed over time. For example, the reporting threshold for the manufacturing and processing of TRI chemicals changed between 1987 and 1989, dropping from 75,000 pounds per year in 1987 to 50,000 in 1988 to the current 25,000 in 1989; this creates the potential for uncertainty in data trends over time (USEPA, 1999a). In addition, only those facilities that meet specific criteria are required to report to the TRI program. For example, small facilities (those with fewer than 10 full-time employees and those that do not exceed certain manufacturing and use thresholds) are not required to report releases. Finally, TRI data on releases cannot be used as a direct measure of general public exposure to a chemical (USEPA, 2019a).

EPA Pesticide Industry Sales and Usage Report

The EPA’s OPP and Office of Chemical Safety and Pollution Prevention periodically issue Pesticides Industry Sales and Usage reports. The reports provide contemporary and historical information on production, importation, exportation, usage, and sales of pesticide active ingredients. The focus is on classes of pesticides, with some limited information on the “most commonly used” individual pesticide chemicals. The most recent report presents data on usage rates for individual chemicals from 2012, along with historical data from as far back as 2005 (USEPA, 2017).

The data presented in the EPA’s Pesticide Industry Sales and Usage reports represent the best information available to the EPA from public and proprietary databases and market research reports determined to meet the Agency’s data quality standards. Publicly available data come from OPP’s Pesticide Data Center, and from a variety of other sources, including national data from the United States Department of Agriculture (USDA). Proprietary data sources include widely used commercial data compilations (USEPA, 2017).

Certain considerations apply when using or interpreting data presented in the Pesticide Industry Sales and Usage reports. OPP cautions that “the numbers in the report represent approximate values rather than precise values with known statistical properties” (USEPA, 2017). In addition, OPP notes: “We caution the reader not to infer too much from changes in the amount of pesticides used from year to year. Changes in the amount of pesticides used are not necessarily correlated to changes in the level of pest control or changes in the human health or environmental risks associated with pesticide use” (USEPA, 2017).

National Center for Food and Agricultural Policy (NCFAP) Pesticide Use Database

The National Center for Food and Agricultural Policy (NCFAP), a private non-profit institution, has assembled a national Pesticide Use Database. NCFAP annual pesticide use estimates for circa 1992 and circa 1997 are based on state-level commercial agriculture usage patterns for the periods 1990-1993 and 1995-1998, and state-level crop acreage for 1992 and 1997. The database contains estimates of pounds applied and acres treated in each state for 220

active ingredients and 87 crops. The majority of the chemicals monitored are herbicides, but the database also includes significant numbers of fungicides and insecticides (NCFAP, 2000).

The NCFAP data are estimates and have several limitations. First, the database only includes applications of pesticides to cropland (foliar, soil, and in furrow applications). Non-cropland applications, such as uses for homes, greenhouses, livestock, ornamentals, or golf courses, are not included. The database does not include non-bearing orchards or vineyards, or governmental Area-wide Eradication programs. Second, in interpreting the NCFAP database, it should be noted that records are compiled from a wide variety of sources. NCFAP states that there is no way to determine the accuracy of any of the estimates in the database, adding that some are based on surveys of farmers, while others are expert opinions from knowledgeable extension service specialists. When data for particular states and crops are unavailable, as they are in many cases, values are assigned on the basis of data from a nearby state (NCFAP, 2000).

United States Geological Survey (USGS) Pesticide Use Maps

The United States Geological Survey (USGS, 2023a) produces maps of annual usage for several hundred pesticide active ingredients used in United States crop production. The pesticide use maps show the average annual pesticide use intensity expressed as average weight (in pounds) of a pesticide applied to each square mile of agricultural land in a county. The USGS maps are created using data from proprietary surveys of farm operations, USDA Census of Agriculture, and other sources.

USGS used two methods to estimate pesticide usage, since pesticide usage information was not available in some districts. “EPest-High” estimates were generated by projecting usage estimates for such districts based on usage in neighboring districts. “EPest-Low” estimates were generated by assuming no usage in such districts.

USGS notes that the maps are suitable for making national, regional, and watershed assessments of annual pesticide use, but that reliability of estimates generally decreases with scale (USGS, 2023a).

2.3 Environmental Fate and Transport

The Environmental Fate section includes information about contaminant persistence and mobility found in the literature, and sometimes also presents inferences about likely persistence and mobility based on physical and chemical properties, including the organic carbon partitioning coefficient (K_{oc}), the octanol-water partitioning coefficient (expressed as $\log K_{ow}$), the Henry’s Law constant (K_H), water solubility, and vapor pressure. Coverage typically includes fate and transport in air, soil, and water. Information on bioconcentration may also be included. Sources consulted when researching fate and transport include NCBI’s PubChem database, ATSDR Toxicological Profiles, EPA pesticide registration documents, and journal articles.

2.4 Adverse Health Effects

To support a regulatory determination, the EPA evaluates whether a health assessment is available. The Agency relies on EPA health assessments and externally peer-reviewed health assessments from other authoritative sources to determine if, how, and at what level a contaminant “may have an adverse effect on the health of persons.” Literature searches are conducted in a manner consistent with the EPA’s Scientific Integrity Policy (USEPA, 2012a) and with the Agency’s *Implementation of Gold Standard Science* (USEPA, 2025). When conducting the literature searches for health effects assessments, the EPA prioritized assessments that are reproducible, transparent, communicative of error and uncertainty, subject to unbiased peer

review, and without conflicts of interest. The EPA leveraged the CCL 5 health assessment database to identify qualifying health assessments and searched the following list of qualifying health assessment sources to identify assessments published since the CCL 5 cutoff date for RD 5 contaminants. If a new qualifying health assessment was identified, it was added to the health assessment database and considered in the assessment selection process. See Section B.5.1 of the RD 5 protocol (Appendix B) for more information about qualifying health assessments and the hierarchy used to select the best available assessment for RD 5. The most recent health assessment from each source was considered in the assessment selection process for RD 5.

For currently registered pesticide chemicals, one source of assessments was used:

- EPA Office of Pesticide Programs (OPP) Reregistration Eligibility Decisions (REDs), Health Effects Division (HED) Human Health Risk Assessments (HHRAs) (available at: <https://ordspub.epa.gov/ords/pesticides/f?p=chemicalsearch:1>)

For all other chemicals, sources of qualifying assessments included the following EPA program offices and other authoritative national, international and state programs:

- EPA Office of Pesticide Programs (OPP) Reregistration Eligibility Decisions (REDs), Health Effects Division (HED) Human Health Risk Assessments (HHRAs) (available at: <https://ordspub.epa.gov/ords/pesticides/f?p=chemicalsearch:1>)
- EPA Office of Pollution Prevention and Toxics (OPPT) Toxic Substance Control Act (TSCA) Risk Evaluations (available at: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under>)
- EPA Office of Research and Development (ORD) Integrated Risk Information System (IRIS) Assessments (available at: <http://www.epa.gov/iris/>)
- EPA ORD Provisional Peer-Reviewed Toxicity Values (PPRTVs) (available at: <https://www.epa.gov/pprtv/provisional-peer-reviewed-toxicity-values-pprtvs-assessments>)
- EPA Office of Water (OW) Health Assessments: Drinking Water Standards and Health Advisory Documents (DWSHAs), Health Effects Support Documents (HESDs) (available at: <https://www.epa.gov/sdwa/drinking-water-contaminant-human-health-effects-information#hhl>)
- Centers for Disease Control and Prevention's (CDC) Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles (available at: <https://www.atsdr.cdc.gov/toxprofiledocs/index.html>)
- World Health Organization (WHO) Guidelines for Drinking Water Quality (GDWQ) (available at: <https://www.who.int/teams/environment-climate-change-and-health/water-sanitation-and-health/chemical-hazards-in-drinking-water>)
- Health Canada Guidelines for Canadian Drinking Water Quality (available at: https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/water-quality.html#tech_doc)
- European Food Safety Authority (EFSA) publications peer-reviewed by a scientific panel (available at: https://www.efsa.europa.eu/en/publications?sort=computed_sort_date&order=desc)
- California Environmental Protection Agency (CalEPA) Public Health Goals (PHGs) (available at: <https://oehha.ca.gov/water/public-health-goals-phgs>)

The EPA health assessment and non-EPA health assessment sources are summarized below.

2.4.1 EPA Health Assessments:

Office of Pesticide Program's (OPP) REDs, IREDs, TREDs, HHRAs ***(<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>)***

For currently registered pesticide chemicals, toxicity information from Health Effects Division Human Health Risk Assessments (HED HHRAs) were used as the basis of HRL derivation. These HED HHRAs are a component of EPA OPP risk assessments, which are used to make safety determinations for pesticides. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires all pesticides sold or distributed in the United States (including imported pesticides) to be registered by the EPA (for more information about EPA pesticide registration see USEPA, 2023). Pesticide registrations, reregistration decisions, and registration review decisions are based on final OPP risk assessments, which evaluate the most current and best available scientific data and assess the current risks (USEPA, 2023). As a component of the OPP risk assessment, an HED HHRA may be a stand-alone document or part of a larger, more encompassing risk management decision document known as a Reregistration Eligibility Decision (RED), Interim Reregistration Eligibility Decision (IRED) or Tolerance Reassessment Progress and Risk Management Decision (TRED). In either case, HED HHRAs undergo peer review by scientific experts prior to publication in the Federal Register (USEPA, 2023). It is important to note that although some HED HHRAs are labeled “draft,” these assessments are considered final at the time of publication in the Federal Register. HED HHRAs can be updated at any time based on the availability of new scientific information. For RD 5, OW coordinated with OPP to ensure the most recent HED HHRA that is the basis of the current pesticide registration decision was selected.

Reregistration Eligibility Decisions (REDs)

When the EPA completes the review and risk management decision for a pesticide that is subject to reregistration (that is, one initially registered before November 1984), the Agency generally issues a Reregistration Eligibility Decision or RED document. The RED summarizes the risk assessment conclusions and outlines any risk reduction measures necessary for the pesticide to continue to be registered in the United States.

Interim Reregistration Eligibility Decisions (IREDs)

The EPA issues an IRED for a pesticide that is undergoing reregistration, requires a reregistration eligibility decision, and also needs a cumulative assessment as a result of the Food Quality Protection Act (FQPA) because it is part of a group of pesticides that share a common mechanism of toxicity. The IRED, issued after the EPA completes the individual pesticide's aggregate risk assessment, may initiate risk reduction measures—for example, reducing risks to workers or eliminating uses that the registrant no longer wishes to maintain—to gain the benefits of these changes before the final RED can be issued, following the Agency's consideration of cumulative risks.

Reports on FQPA Tolerance Reassessment Progress and Risk Management Decisions (TREDs)

The EPA issues a TRED for a pesticide that requires tolerance reassessment decisions but does not require a reregistration eligibility decision at present, because: (a) the pesticide was initially registered after November 1, 1984, and by law is not included within the scope of the reregistration program; (b) the EPA completed a RED for the pesticide before FQPA was

enacted on August 3, 1996; or (c) the pesticide is not registered for use in the United States but tolerances are established that allow crops treated with the pesticide to be imported from other countries.

A TRED may be issued as a stand-alone report if no changes in the tolerances for a pesticide are required as a result of the EPA's review. If tolerance revisions are required, then the TRED may be issued as a *Federal Register* Notice. Like IREDs, some TREDs will not become final until the EPA considers the cumulative risks of all the pesticides in the cumulative group.

Human Health Risk Assessments (HHRAs)

(https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/overview-risk-assessment-pesticide-program#human_health)

The EPA issues an HHRA for a pesticide when a pesticide is undergoing registration or registration review, or when a tolerance is being reviewed or established for a new use of an already registered pesticide (for more information on the tolerance reassessment process see: <https://www.epa.gov/sites/production/files/2015-08/documents/paper44.pdf>). The HHRA estimates the nature and probability of adverse health effects in humans who may be exposed to chemicals in contaminated environmental media, now or in the future. HHRAs use the National Research Council's four-step process for risk assessment: (a) hazard identification, (b) dose response assessment, (c) exposure assessment, and (d) risk characterization.

The EPA searched OPP's Chemical Search database (<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>) by name and Chemical Abstracts Services Registry Number (CASRN) for each RD 5 chemical. If the status of the chemical's "Latest Registration Process" indicated that there is an active registration, the EPA coordinated with OPP HED to identify the OPP health assessment supporting the most recent registration decision. The identified health assessment was automatically selected as the best available qualifying assessment for that chemical. If the search returned no results, or the chemical's "Latest Registration Process" status was "None" (indicative of no active registrations), the EPA searched for and identified qualifying health assessments for these chemicals from all remaining databases listed in this section.

Office of Pollution Prevention and Toxics (OPPT) Final Risk Evaluations for Chemicals under TSCA (<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under>)

Under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the EPA evaluates potential risks from new and existing chemicals and acts to address any unreasonable risks chemicals may have on human health and the environment. The TSCA Chemical Substance Inventory contains all existing chemical substances manufactured, processed, or imported in the United States that do not qualify for an exemption or exclusion under TSCA. For high-priority chemicals, the EPA conducts a Risk Evaluation that includes hazard and exposure assessments and a risk characterization to inform risk determination.

The EPA searched TSCA's Risk Evaluation database for each RD 5 chemical by the chemical's name and CASRN. If the contaminant is an industrial chemical regulated under TSCA and its final EPA OPPT Risk Evaluation is relevant to the drinking water pathway and is based on the best available science, then the most current OPPT TSCA Risk Evaluation was selected as the health assessment source for HRL derivation.

Office of Research and Development (ORD) Assessments:**Integrated Risk Information System (IRIS)**

https://cfpub.epa.gov/ncea/iris_drafts/atoz.cfm?list_type=alpha

The EPA's Integrated Risk Information System (IRIS) is a human health assessment program that compiles and evaluates information on health effects that may result from exposure to environmental contaminants. Through the IRIS Program, the EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information on human health effects that may result from exposure to various substances in the environment; coverage includes more than 550 chemical substances.

The heart of the IRIS database is its collection of searchable documents that describe the health effects of individual substances and that contain descriptive and quantitative information in the following categories:

- Non-cancer effects: Oral reference doses and inhalation reference concentrations (RfDs and RfCs, respectively) for effects known or assumed to be produced through a nonlinear (possibly threshold) mode of action. In most instances, RfDs and RfCs are developed for the noncarcinogenic effects of substances.
- Cancer effects: Descriptors that characterize the weight of evidence for human carcinogenicity, oral slope factors, and oral and inhalation unit risks for carcinogenic effects. Where a nonlinear mode of action is established, RfD and RfC values may be used.

The EPA searched the IRIS database for each RD 5 chemical by the chemical's name and CASRN (with and without the dashes).

Provisional Peer Reviewed Toxicity Value (PPRTV)

https://hhpprtv.ornl.gov/quickview/pprtv_papers.php

A PPRTV is a toxicity value derived for use in the Superfund Program when a toxicity value is not available in IRIS. (IRIS is the first tier in the Superfund hierarchy of human health toxicity values.) PPRTVs are derived after a review of the relevant scientific literature, incorporating the methods, sources of data, and guidance for value derivation used by the EPA IRIS Program. All PPRTVs receive internal review by EPA scientists and external peer review by independent scientific experts. PPRTVs differ from IRIS toxicity values in that PPRTVs do not receive the multi-program consensus review provided for IRIS values. This is because IRIS values are generally intended to be used in all EPA programs, while PPRTVs are developed specifically for the Superfund Program.

PPRTV assessments are eligible to be updated on a 5-year cycle to incorporate new data or methodologies that might impact the toxicity values or characterization of potential for adverse human health effects. In general, the need for a PPRTV is eliminated once an analogous IRIS value becomes available. Once IRIS values become available, PPRTVs are removed from the PPRTV electronic library. It should also be noted that sometimes available information is not sufficient to derive a PPRTV. Some PPRTV Derivation Support Documents conclude that a PPRTV cannot be derived based upon the available information.

The EPA searched the PPRTV database for each RD 5 chemical by the chemical's name and CASRN (with and without the dashes).

Office of Water (OW) Assessments:

(<http://water.epa.gov/drink/standards/hascience.cfm>; <https://www.epa.gov/sdwa/drinking-water-health-advisories-has>)

OW's health effects support documents (HESDs) and toxicity assessments address exposure from drinking water and other media, summarize toxicokinetics, and conduct hazard identification and dose-response assessment for chemicals known or anticipated to be found in drinking water. HESDs address the first two steps of the risk assessment process: hazard identification and dose response assessment. To prepare an HESD, the Agency performs a literature search for studies published after the most recent available health assessment (identified from among the various EPA and non-EPA sources listed in this section). The Agency collects and evaluates any peer-reviewed publications identified through the literature search for their impact on the prior assessment's RfD or cancer assessment. The HESDs are independently and externally peer-reviewed and undergo public comment.

OW's drinking water health advisories (HAs) address the third and fourth steps of the risk assessment process: exposure assessment and risk characterization. The EPA develops HAs to provide information on the chemical and physical properties, occurrence and exposure, health effects, quantification of toxicological effects, other regulatory standards, analytical methods, and treatment technologies for drinking water contaminants. HAs describe concentrations of drinking water contaminants at which adverse health effects are not anticipated to occur over specific exposure durations (e.g., one-day, ten-days, and a lifetime). The EPA's health advisories are non-enforceable and non-regulatory and provide technical information to states agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination.

The EPA searched the OW website to identify new health assessments for each RD 5 chemical. No OW health assessments have been published for these chemicals since the CCL 5 cutoff date.

2.4.2 Non-EPA Health Assessments:

The sources of non-EPA health assessments discussed below were recognized by the Agency as qualifying for RD 5 purposes because of their standardized methods for characterizing health effects data and their relevancy to drinking water exposures. Although the methods applied in these assessments to account for uncertainties may vary, they are considered comparable to EPA methods for deriving toxicity values (USEPA, 2002a; USEPA, 2005a). The EPA may choose to apply additional uncertainty factors to toxicity values from non-EPA health assessments in accordance with EPA guidance. Refer to the websites linked below each assessment source for more information about the methods used to derive oral reference values and oral cancer slope factors.

Agency for Toxic Substances & Disease Registry (ATSDR)

(<http://www.atsdr.cdc.gov/az/a.html>)

By Congressional mandate, ATSDR produces "toxicological profiles" for hazardous substances found at National Priorities List (NPL) sites. These hazardous substances are ranked based on frequency of occurrence at NPL sites, toxicity, and potential for human exposure. Toxicological profiles are developed from a priority list of 275 substances. ATSDR toxicological

profiles succinctly characterize the toxicological and adverse health effects information for these hazardous substances. Each peer-reviewed profile identifies and reviews the key literature that describes a hazardous substance's toxicological properties. Other pertinent literature is also presented, but is described in less detail than the key studies.

ATSDR establishes oral minimal risk levels for non-neoplastic endpoints for acute (14 days or less), intermediate (15-364 days), and chronic (365 days or more) exposure durations. Minimal risk levels for oral chronic exposure are derived using approaches similar to the EPA's RfDs. However, ATSDR and the EPA use different approaches when the database is limited to subchronic studies and no adequate chronic study is available. In such cases, the EPA derives a chronic RfD from a subchronic study, incorporating an additional uncertainty factor to account for use of a subchronic study. ATSDR derives an intermediate duration minimal risk level but generally does not derive a chronic oral minimal risk level by incorporating an additional uncertainty factor to account for using a less-than-lifetime study. Also, ATSDR does not derive minimal risk levels for cancer. Therefore, ATSDR does not perform quantitative cancer assessments or assign formal cancer classifications or descriptors.

The EPA searched the ATSDR A-Z index to identify health assessments for each RD 5 chemical by name. The Agency also searched each tab in the "Tox Profiles in Progress" section of the ATSDR website to determine the status of health assessments in progress. If the chemical name was not found in the A-Z index, the EPA also searched by synonymous names and segments of the chemical name (e.g., by "estradiol" and "alpha" when searching for 17-alpha ethynyl estradiol) to ensure a health assessment was not missed due to the formatting of a name in the A-Z index. The EPA also searched for the chemical by its group name, if applicable (e.g., cyanotoxins or polycyclic aromatic hydrocarbons (PAHs)). Synonyms for each chemical were curated by searching the CompTox Chemicals Dashboard (<https://comptox.epa.gov/dashboard>) by the chemical's DTXSID. If a health assessment was identified by searching a synonym, the EPA made note of this for future searches.

World Health Organization (WHO)

(https://www.who.int/water_sanitation_health/publications/drinking-water-quality-guidelines-4-including-1st-addendum/en/)

The WHO Guidelines for Drinking-Water Quality (GDWQ) include facts sheets and comprehensive review documents for many individual chemicals. WHO derives guideline values for many of these chemicals to be used as a basis for the development of national standards that, if properly implemented, will ensure the safety of drinking water supplies through the elimination, or reduction to a minimum concentration, of constituents of water that are known to be hazardous to health. For each chemical contaminant or substance considered, a lead institution prepares a background document evaluating the risks to human health from exposure to the chemical in drinking water. Under the responsibility of the coordinators for a group of chemicals considered in the guidelines, the draft health criteria documents are submitted to a number of scientific institutions and selected experts for peer review. There may also be an opportunity for public comment. Comments are taken into consideration by the coordinators and authors and then the documents are submitted for final evaluation to a "final task force" meeting that reviews the health risk assessment and public and peer review comments and, where appropriate, decides upon guideline values.

Guideline values established by WHO are health-based drinking water concentrations (similar to EPA HAs) that are derived from tolerable daily intakes (TDIs) (similar to EPA RfDs).

In addition to the 10-fold default uncertainty factors applied for interspecies and intraspecies variation, other uncertainty factors may also be used to account for database deficiencies, the use of shorter-duration studies to measure long-term effects of exposure, and the use of a lowest-observed-adverse-effect level (LOAEL) rather than a no-observed-adverse-effect level (NOAEL) for the point of departure (POD). These additional uncertainty factors, determined by subject matter experts, are generally between 2- and 10-fold if applicable. WHO develops a single guideline value that is based on either a cancer or non-cancer endpoint.

The EPA searched the WHO A-Z index to identify health assessments for each RD 5 chemical by name. If an assessment was not found after searching by chemical name, the EPA searched by synonymous names and segments of the chemical name (e.g., by “estradiol” and “alpha” for 17-alpha ethynyl estradiol) to ensure a health assessment was not missed due to the formatting of a name in the A-Z index. The EPA also searched for the chemical by its group name, if applicable (e.g., cyanotoxins or PAHs). Synonyms for each chemical were curated by searching the CompTox Chemicals Dashboard (<https://comptox.epa.gov/dashboard>) by the chemical’s DTXSID. If a health assessment was identified by searching a synonym, the EPA made note of this for future searches.

Health Canada Guidelines for Canadian Drinking Water Quality Technical Documents
(https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/water-quality.html#tech_doc)

The Guidelines for Canadian Drinking Water Quality are established by Health Canada in collaboration with the Federal-Provincial-Territorial Committee on Drinking Water (CDW) and other federal government departments. Each guideline is established based on current, published scientific research related to health effects, aesthetic effects, and operational considerations. Health-based guidelines are established on the basis of a comprehensive review of the known health effects associated with each contaminant, plus exposure levels and the availability of treatment and analytical technologies. Aesthetic effects (e.g., taste, odor) are taken into account when these play a role in determining whether consumers will consider the water drinkable. Operational considerations are factored in when the presence of a substance may interfere with or impair a treatment process or technology (e.g., turbidity interfering with chlorination or ultraviolet (UV) disinfection) or adversely affect drinking water infrastructure (e.g., corrosion of pipes).

Guidelines for Canadian Drinking Water Quality are developed specifically for contaminants that meet all of the following criteria:

- Exposure to the contaminant could lead to adverse health effects in humans;
- The contaminant is frequently detected or could be expected to be found in a large number of drinking water supplies throughout Canada; and
- The contaminant is detected, or could be expected to be detected, in drinking water at a level that is of possible human health significance.

If a contaminant or issue of interest does not meet all these criteria, Health Canada and CDW may choose not to establish a numerical guideline or develop a guideline technical document. In that case, advice may be provided through a guidance document in order to convey operational or management information related to a contaminant or issue of concern. Guidelines are periodically reviewed to assess whether they need to be updated. When a guideline is

reaffirmed, both the year of the original publication and the year of reaffirmation are shown after the name of the parameter.

For substances with no threshold (e.g., mutagens and genotoxic carcinogens), Health Canada assumes that there is some probability of harm to human health at any level of exposure. Health-based values for carcinogens are generally established on the basis of an estimation of lifetime cancer risk that would be sufficiently small so as to be “essentially negligible,” which Health Canada has defined in the context of drinking water guidelines as a range from one new cancer above background per 100,000 people to one new cancer above background per 1,000,000 people (i.e., 10^{-5} to 10^{-6}) over a lifetime of 70 years. For non-carcinogens, an approach similar to the EPA’s RfD methodology is used.

The EPA searched the chemicals listed in the “Chemical/Physical Parameters” section of Health Canada’s list of Guidelines to identify health assessments for each RD 5 chemical by name. (Assessments in the “Screening Values” section of the list were ignored because these are not peer-reviewed and therefore do not qualify for assessment selection.) If an assessment was not found after searching by chemical name, the EPA searched by synonymous names and segments of the chemical name (e.g., by “estradiol” and “alpha” for 17-alpha ethynyl estradiol) to ensure a health assessment was not missed due to the formatting of a name in the A-Z index. The EPA also searched for the chemical by its group name, if applicable (e.g., cyanotoxins or PAHs). Synonyms for each chemical were curated by searching the CompTox Chemicals Dashboard (<https://comptox.epa.gov/dashboard>) by the chemical’s DTXSID. If a health assessment was identified by searching a synonym, the EPA made note of this for future searches.

European Food Safety Authority (EFSA) peer-reviewed publications
(<https://www.efsa.europa.eu/en/publications>)

The European Food Safety Authority (EFSA) forms a common basis for governing food and feed in the European Member States by adopting measures to keep unsafe food off the market and ensuring that systems exist to identify and respond to food safety problems in order to ensure the proper functioning of the internal market and to protect human health. These measures are generally based on a comprehensive and independent risk analysis and enable Community institutions and Member States to make informed risk management decisions to ensure food and feed safety.

The Authority publishes scientific outputs in their open access, online scientific journal, titled *EFSA Journal*. Scientific Opinions are outputs that can include risk assessments for individual chemicals, which are based on available data and serve as the scientific basis for food law. EFSA can issue Scientific Opinions on its own or at the request of the European Commission, European Parliament, Member States, or as foreseen in relevant sectoral legislation, under Articles 28 through 40 in Chapter 3 of the founding regulation (EC No. 178/2002). Scientific Opinions are prepared and adopted by the Scientific Committee or a Scientific Panel, who applies external peer review to scientific research deliverables intended for official publication by the Agency as final products. After acceptance of a mandate, an expert Working Group is established to produce a draft opinion which is then subject to scrutiny and review by the relevant Scientific Panel before its eventual adoption. EFSA opens a range of its scientific meetings to observers and key outputs are subject to public consultation and published as Technical Reports in EFSA Supporting Publications. Existing procedures for the allocation of scientific tasks to the Member States should be re-evaluated within a year, with evaluation procedures remaining at least as stringent as before.

EFSA derives health-based guidance values in their risk assessments that are used as the basis for the development of tolerable daily intakes (TDIs). A TDI is established in EFSA health assessments to ensure that lifetime exposure, up to the TDI concentration, does not lead to appreciable adverse health effects in the general population.

The EPA searched the EFSA database for published health assessments that have been prepared or reviewed by a scientific committee or panel (i.e., peer-reviewed) for each RD 5 chemical by its CASRN (with and without the dashes) and name. The EPA also searched by synonymous names and segments of the chemical name (e.g., by “estradiol” and “alpha” for 17-alpha ethynyl estradiol) to ensure a health assessment was not missed due to the formatting of a name in the A-Z index. The EPA also searched for the chemical by its group name, if applicable (e.g., cyanotoxins or PAHs). Synonyms for each chemical were curated by searching the CompTox Chemicals Dashboard (<https://comptox.epa.gov/dashboard>) by the chemical’s DTXSID. If a health assessment was identified by searching a synonym, the EPA made note of this for future searches.

Publicly available and externally peer-reviewed state assessments (e.g., CalEPA OEHHA Public Health Goals)
(<https://oehha.ca.gov/water/public-health-goals-phgs>)

The CalEPA Office of Environmental Health Hazard Assessment (OEHHA) establishes a Public Health Goal (PHG), which is a water concentration that is the state’s equivalent to the Maximum Contaminant Level Goal (MCLG). The PHG can be based on either cancer or noncancer endpoints. When the PHG is based on cancer endpoints, CalEPA estimates a cancer potency factor and then uses the potency factor to estimate the daily water intake that is equivalent to a 10^{-6} cancer risk, utilizing lifestage adjusted drinking water intake and drinking water equivalent exposures that include exposures from inhalation and dermal routes from bathing and showering. When the PHG is based on noncancer endpoints, the reference value, called the Acceptable Daily Intake (ADI), may utilize a point of departure (POD) derived using the EPA’s benchmark dose (BMD) modeling. A total (maximum) uncertainty factor of 3,000 may be utilized, with intrahuman variability of up to 30-fold compared to 10-fold by the EPA.

The EPA searched the OEHHA database for each RD 5 chemical by CASRN (with and without the dashes) and chemical name. If the chemical was not found, the EPA also searched by synonymous names and segments of the chemical name (e.g., by “estradiol” and “alpha” for 17-alpha ethynyl estradiol) to ensure a health assessment was not missed due to the formatting of a name in the A-Z index. The EPA also searched for the chemical by its group name, if applicable (e.g., cyanotoxins or PAHs). Synonyms for each chemical were curated by searching the CompTox Chemicals Dashboard (<https://comptox.epa.gov/dashboard>) by the chemical’s Distributed Structure Searchable Toxicity Substance Identifier (DTXSID). If a health assessment was identified by searching a synonym, the EPA made note of this for future searches.

2.5 Contaminant Occurrence and Exposure

2.5.1 General Considerations

Detection and Reporting Thresholds

Several types of concentration thresholds are important in the characterization of chemical contaminant occurrence in drinking water. This section clarifies some of the terminology used in this report.

Typically, an analytical method allows for low-level detection of a contaminant in water at concentrations that cannot be reliably quantified. Thus, there is a distinction between the *detection limit* (the threshold at or above which the presence or absence of an identified compound can be distinguished with a specified degree of confidence) and a *quantitation limit* or *reporting level* (a somewhat higher threshold, at or above which the concentration of a contaminant can be measured with a specified degree of precision and accuracy). Such thresholds can vary from method to method, from contaminant to contaminant, from laboratory to laboratory, and even from technician to technician, based on method limitations, chemical properties, technician skill, and the quality of analytical instrumentation. Published analytical methods specify the standards of precision and accuracy that define acceptable laboratory performance, and often estimate “normal” or expected detection limits. In practice, the limits vary.

The *reporting level* is the threshold at or above which a contaminant’s presence or concentration is officially quantitated. Reporting levels may be established by the laboratory or by those who design and carry out a study. The requirements for precision and accuracy that are included in a published analytical method help to dictate where laboratories establish a reporting level for a particular analyte.

In the absence of an otherwise established reporting level, laboratories generally report results as low as can be reliably measured based on precision and accuracy acceptance criteria and the lowest calibration standard used in the development of their instrument calibration curve, i.e., at the quantitation level. Sometimes the terms “quantitation level” and “reporting level” are used interchangeably in the laboratory context.

In a well-designed occurrence study, the investigator will establish a reporting level for each contaminant in advance of data collection, based on analytical method(s) chosen, laboratory capabilities, and other considerations. Setting a reporting level is a balancing act. A reporting level set too high will result in the under-reporting of contaminants that are present, while a reporting level set too low may lead to data quality problems: e.g., some of the participating laboratories may be unable to reliably quantify results at the low threshold. In the case of many of the EPA’s nationwide drinking water studies, the selected reporting level is known officially as the Minimum Reporting Level (MRL). The MRL for each contaminant in each study is set at a level that the EPA believes can be achieved with specified confidence by a broad spectrum of capable laboratories across the nation.

In some cases, an investigator may establish a “common reporting level,” a high, uniform reporting threshold for multiple contaminants that facilitates inter-contaminant comparison. A common reporting level can be applied retrospectively. Some studies report results at low contaminant-specific thresholds and also at a high common reporting level. Longitudinal studies and data compilations sometimes select a high retrospective reporting level to facilitate comparison of results from older data collection efforts with results from newer efforts that employed more advanced analytical techniques with lower quantitation limits.

Knowing the reporting level(s) associated with a study or data set can help with interpretation of the results. For instance, knowing that the reporting level is lower than a health-based threshold provides assurance that all exceedances of that threshold were captured in the study results. Also, knowledge of reporting levels can help a reader to determine whether data from two studies are directly comparable. Compilations of data from multiple sources must be interpreted with caution if reporting levels are not documented, as they may have varied widely.

To facilitate interpretation of occurrence results in the contaminant-specific chapters that follow, reporting levels are provided whenever they are available. In many cases reporting levels are not known, and this too is documented. In some cases, the lowest reported concentration values can give a rough idea of what the reporting threshold(s) might have been. (Generally, the reporting level could not have been higher than the lowest reported concentration. If a sufficiently large number of detections are reported, the lowest reported concentration is likely a good approximation of the reporting level.)

Frequently the word *detection* is used in discussions of contaminant occurrence as shorthand for a sampling result that is equal to or exceeds a given reporting level, and *non-detection* for a result that does not equal or exceed the reporting level. Thus, even a sample that exhibits a result that exceeds the laboratory detection limit could, in the context of a particular study or data compilation, be considered a non-detection. That convention is followed in this report, unless otherwise noted. For ambient water samples, laboratories will often report estimated values that are equal to or greater than the detection limit but less than the reporting level. In EPA drinking water programs, this practice is not used.

For more on detection levels, reporting levels, and MRLs in the context of analytical method evaluation, see Section 2.6.

Rounding

In reporting quantitative occurrence findings, the EPA is sensitive to the issue of presenting numbers with the proper number of significant digits, if it can be determined, and the challenge of presenting findings in a uniform format. The EPA draws data from a wide variety of sources, some of which are better-documented than others, and calculates other values from available data. The EPA uses the following guidelines in this support document.

When presenting results obtained from published studies or other sources, the EPA reports the numbers exactly as given in the source or retains the number of significant figures given in the source. (All water concentration values are converted to micrograms per liter.)

When calculating new values, the EPA follows the following guidelines: With limited exceptions, calculated percentages are presented to two decimal places. With limited exceptions, calculated concentration values (e.g., median and 99th percentile concentrations) are rounded, if necessary, to have no more than three significant figures, and extrapolated population estimates are also rounded, if necessary, to have no more than three significant figures. Beyond these guidelines, ordinary best practices for rounding are applied.

2.5.2 Occurrence in Ambient Water

This section describes sources the EPA consulted to evaluate the occurrence in U.S. ambient water (e.g., aquifers, rivers, lakes) of RD 5 contaminants receiving a regulatory determination.

USGS National Water-Quality Assessment (NAWQA) – Ambient Water Analysis

The USGS instituted the National Water-Quality Assessment (NAWQA) program in 1991 to examine ambient water quality status and trends in the United States. The NAWQA program generates high quality contaminant occurrence and other water quality parameter data for significant watersheds and aquifers across the nation. The program collects data on surface and groundwater chemistry, hydrology, land use, stream habitat, and aquatic life in parts or all of nearly all 50 states. The program is designed to apply nationally consistent methods to provide a

uniform basis for contaminant occurrence comparisons and assessments among study basins across the country and over time. The occurrence assessments can also serve to facilitate interpretation of natural and anthropogenic factors affecting national water quality. The Water Quality Portal (WQP) houses a collection of chemical, biological, and physical water quality data used in the NAWQA Program. For more detailed information on NAWQA program design and implementation, refer to Leahy and Thompson (1994) and Hamilton et al. (2004).

The process of sampling, analysis, and data synthesis is divided into cycles of approximately ten years: Cycle 1 covered 1991–2001, Cycle 2 covered 2002–2012, and Cycle 3 covered 2013–2023. Study units are sampled and analyzed on a staggered schedule within each cycle. Each NAWQA cycle begins with a two-year startup phase for planning and retroactive analysis, followed by a three-year intensive data collection phase, and finally a five-year phase for analyzing the data, developing reports, and continuing a low level of monitoring (NRC, 2012).

In Cycle 1 (1991–2001), 51 study units were sampled. Data were gathered from 6,307 wells from 272 groundwater networks or clusters and from 505 surface water monitoring sites, primarily rivers and streams but also some lakes and reservoirs (NRC, 2012).

In Cycle 2 (2002–2012), the number of study units was reduced from 51 to 42 (NRC, 2012). Long-term stream monitoring was established at 113 streams representing 8 major river basins. Long-term groundwater monitoring was established at sites representing 20 principal aquifers with more than 10 to 15 years of consistent monitoring data available (Rowe et al., 2013).

In Cycle 3 (2013–2023), surface water monitoring was scheduled to be conducted at 313 sites, up from 113 sites in Cycle 2. Groundwater assessments in Cycle 3 were designed to evaluate status and trends at the principal aquifer and national scales. Assessments were planned in 24 principal aquifers that account for the majority of current and future national groundwater use for drinking water (Rowe et al., 2010; Rowe et al., 2013). In 2019, USGS announced that the third cycle of NAWQA would be the last, and that some NAWQA activities would be wound down before the end of the cycle, but that “long-term surface-water and groundwater-quality monitoring operated by the NAWQA Project will continue,” with some exceptions (USGS, 2019).

The EPA downloaded NAWQA data from the WQP in September 2023 using USGS’s dataRetrieval package (WQP, 2023; DeCicco et al., 2023). The EPA’s analysis of the NAWQA data is a simple, non-parametric analysis that provides summary statistics to characterize contaminant occurrence. The EPA included in the analysis all samples that could be classified as groundwater and surface water, and also the limited number of samples labelled as finished water. Other types of samples (e.g., from soil, sediment, and wastewater) were excluded. EPA cleaned the data set to eliminate duplicate records and to include only quantified detections and unambiguous non-detections, which meant (among other tests) checking for mismatches between concentration values and data detection flags, removing records for reported detections with negative concentration values or values equal to 0, and removing records for reported detections without units or with units that could not be converted.

The EPA calculated detection frequencies as the percentage of samples and the percentage of sites with at least one detection. No weighting was applied. The EPA determined the minimum and maximum detection concentrations and calculated other descriptive statistics

including the median, 90th percentile, and 99th percentile concentrations (based only on samples with detections). Reporting levels varied over time during the NAWQA program.

USGS has issued many special reports based on NAWQA data. There may be some overlap between the general NAWQA data assessment and data found in individual NAWQA studies and projects and compilations (described below).

USGS Analysis: National Synthesis Assessments

Through a series of National Synthesis efforts, the USGS NAWQA program prepares comprehensive analyses of data on topics of particular concern. These National Synthesis assessments aggregate NAWQA contaminant occurrence and water quality parameter data from individual study units and other sources to provide a national perspective on those topics.

Pesticide National Synthesis Project: Pesticides in the Nation's Streams and Ground Water

The NAWQA Pesticide National Synthesis Project is a national-scale assessment of the occurrence and behavior of pesticides in streams and groundwater of the United States and the potential for pesticides to adversely affect drinking-water supplies or aquatic ecosystems.

Results from the Pesticide National Synthesis analysis, based on complete Cycle 1 (1992-2001) data from NAWQA study units, are posted on the NAWQA Pesticide National Synthesis website (Gilliom et al., 2007). Data for surface water and groundwater are presented separately, and results in each category are subdivided by land use category. Land use categories include agricultural, urban, mixed (deeper aquifers of regional extent in the case of groundwater), and undeveloped. The Pesticide National Synthesis analysis is a first step toward the USGS goals of describing the occurrence of pesticides in relation to different land use and land management patterns and developing a deeper understanding of the relationship between spatial occurrence of contaminants and their fate, transport, persistence, and mobility characteristics.

The surface water summary data presented in the Pesticide National Synthesis (Gilliom et al., 2007) only includes stream data. Sampling data from a single one-year period, generally the year with the most complete data, were used to represent each stream site. Sites with few data or significant gaps were excluded from the analysis. NAWQA stream sites were sampled repeatedly throughout the year to capture and characterize seasonal and hydrologic variability.

Groundwater data reported in the Pesticide National Synthesis only include samples from wells; data from springs and agricultural tile drains were not included. In the National Synthesis analysis (Gilliom et al., 2007), USGS uses a single sample to represent each well, generally the earliest sample with complete data for the full suite of analytes.

Over the course of Cycle 1, some NAWQA analytical methods were improved or changed. Hence, detection thresholds varied over time for some compounds. USGS used the maximum Long-Term Method Detection Level (LT-MDL) for each analyte as a uniform reporting threshold (Gilliom et al., 2007).

Volatile Organic Compounds (VOC) National Synthesis: Volatile Organic Compounds in the Nation's Ground Water and Drinking-Water Supply Wells

Zogorski et al. (2006) discuss the major findings and conclusions of a national assessment of 55 volatile organic compounds (VOCs) in groundwater from 1985-2002. VOC data from 2,401 domestic wells and 1,096 public wells were available from aquifer studies,

shallow groundwater studies, and a national source-water survey to characterize the occurrence of VOCs. One VOC analysis per well was included in the assessment.

VOC National Synthesis: Random and Focused VOC Surveys

The VOC National Synthesis began in 1994. The most comprehensive VOC National Synthesis reports to date are one random survey and one focused survey carried out by USGS in collaboration with the Metropolitan Water District of Southern California and the Oregon Health & Science University, with funding provided by the Water Research Foundation (WRF) (formerly known as AwwaRF). The random survey (Grady, 2003) targeted surface and groundwaters used as source water by community water systems (CWSs). Samples were taken from the source waters of 954 CWSs in 1999 and 2000. The random survey was designed to be nationally representative of CWS source water. In the focused survey (Delzer and Ivahnenko, 2003), 451 samples were taken from source waters serving 134 CWSs between 1999 and 2001. These surface and groundwaters were chosen because they were suspected or known to contain methyl tertiary butyl ether (MTBE). The focused survey was designed to provide insight into temporal variability and anthropogenic factors associated with VOC occurrence. Details of the monitoring plan for these two studies, including detection limits, are provided by Ivahnenko et al. (2001). Separately, AwwaRF also published the results of this monitoring effort (AwwaRF, 2003).

VOC National Synthesis: Compilation of Historical VOC Monitoring Data

Additional products of the VOC National Synthesis include a compilation of historical VOC monitoring data from multiple studies (Squillace et al., 1999). The data were collected from 2,948 wells between 1985 and 1995 by local, state, and federal agencies. Data were reviewed by USGS to ensure they met data quality criteria. Most of the data were from early study unit monitoring. The samples represent both urban and rural areas, and both drinking water and non-drinking water wells.

Trace Elements National Synthesis Project: Trace Elements and Radon in Groundwater, 1992-2003

Ayotte et al. (2011) conducted an assessment as part of the NAWQA program, collecting water samples in ambient groundwater and drinking water aquifers to evaluate the occurrence of trace-element concentrations. A total of 1,309 samples were collected between 1992 and 2003 across the United States from more than 40 principal and other aquifers.

Non-NAWQA National Water Information System (NWIS) Data

The National Water Information System (NWIS) is the nation's principal repository of water resources data collected by USGS from more than 1.9 million sites in all U.S. states and territories (USGS, 2023b). All USGS water quality and flow data are stored in NWIS, including site characteristics, streamflow, groundwater level, precipitation, and chemical analyses of water, sediment, and biological media, though not all parameters are available for every site. NWIS houses the NAWQA data and includes other USGS data from a range of unspecified projects. NWIS encompasses many more samples at many more sites than are involved in the NAWQA Program. Although NWIS is comprised of primarily ambient water data, some finished drinking water data are included as well. The non-NAWQA data housed in NWIS generally involve fewer constituents per sample than the NAWQA data. Unlike the NAWQA data, the non-NAWQA data are a miscellaneous collection, so they are not as well-suited for making temporal and geographic comparisons.

The EPA evaluated contaminant monitoring results from the non-NAWQA data in NWIS separately from NAWQA data. NWIS data were downloaded from the WQP in September 2023 using USGS's dataRetrieval package (WQP, 2023; DeCicco et al., 2023). The EPA's analysis of the non-NAWQA NWIS data is a simple, non-parametric analysis that provides summary statistics to characterize contaminant occurrence. The EPA included in the analysis all samples that could be classified as groundwater and surface water, and also the limited number of samples labelled as finished water. Other types of samples (e.g., from soil, sediment, and wastewater) were excluded. EPA cleaned the data set to eliminate duplicate records and to include only quantified detections and unambiguous non-detections, which meant (among other tests) checking for mismatches between concentration values and data detection flags, removing records for reported detections with negative concentration values or values equal to 0, and removing records for reported detections without units or with units that could not be converted.

Storage and Retrieval (STORET) Data

From its launch in 1999 until it was decommissioned in June 2018, the EPA's Storage and Retrieval (STORET) Data Warehouse was collaboratively populated with raw biological, chemical, and physical data from surface water and groundwater sampling by federal, state and local agencies, Native American Tribes, volunteer groups, academics, and others. Legacy STORET data, as well as more current STORET data, are accessible through the WQP.

STORET data are from monitoring locations in all 50 states as well as multiple territories and jurisdictions of the United States. The WQP STORET data presented in the contaminant-specific chapters were downloaded from the WQP in September 2023, using USGS's dataRetrieval package (WQP, 2023; DeCicco et al., 2023). The EPA reviewed STORET groundwater data from wells and springs and surface water data from lakes, rivers/streams, and reservoirs. The STORET data set also included limited data from public water systems (PWSs). The database does not specify whether PWS sampling was conducted before or after treatment.

EPA cleaned the data set to eliminate duplicate records and to include only quantified detections and unambiguous non-detections, which meant (among other tests) checking for mismatches between concentration values and data detection flags, removing records for reported detections with negative concentration values or values equal to 0, and removing records for reported detections without units or with units that could not be converted.

Limitations of WQP STORET data quality include variations in the extent of national coverage and data completeness from parameter to parameter. Data may have been collected as part of targeted, rather than randomized, monitoring. Furthermore, there are no restrictions on submission of data based on analytical methods or quality assurance (QA) practices.

Since reporting levels vary and are not always provided in the WQP STORET data, it is generally not possible to present a single reporting level or even a range of reporting levels. Instead, the chapters that follow point out the minimum detected concentration. The minimum detected concentration is probably in or near the range of reporting levels (see Section 2.5.1).

2.5.3 Occurrence in Drinking Water – Primary Data Sources

The primary sources of the drinking water occurrence data used to support the RD 5 process, including selection and evaluation of RD 5 contaminants receiving a regulatory determination, were the following:

- the First Unregulated Contaminant Monitoring Rule (UCMR 1)

- the Second Unregulated Contaminant Monitoring Rule (UCMR 2)
- the Third Unregulated Contaminant Monitoring Rule (UCMR 3)
- the Fourth Unregulated Contaminant Monitoring Rule (UCMR 4)
- Rounds 1 and 2 of the Unregulated Contaminant Monitoring (UCM) program
- the National Inorganics and Radionuclides Survey (NIRS)

All six of these sources are national assessments that were administered or overseen by the EPA. UCMR 1, UCMR 2, UCMR 3, UCMR 4 and NIRS are designed to be statistically representative of national contaminant occurrence in public drinking water systems. (NIRS, which does not include surface water systems, is designed to be statistically representative of national contaminant occurrence in groundwater systems.) The UCM program was a predecessor to the Unregulated Contaminant Monitoring Rule (UCMR) program. Although UCM was not designed to be statistically representative of national contaminant occurrence, the Agency subsequently developed a peer-reviewed cross-section-based approach to elicit national estimates from UCM data (see further discussion below).

Summary occurrence values calculated for contaminants from primary data sources as part of the RD 5 process include counts of the number and percent of systems, and population served by systems, with at least one analytical detection above a given concentration threshold (i.e., the HRL). The EPA considered this to be a straightforward and accurate way to present these data for the regulatory determination process. More specifically, the EPA used the data sources to generate the following occurrence and potential-for-exposure summary statistics for RD 5 contaminants receiving regulatory determinations:

- The total number of systems and the total population served by systems;
- The number and percentage of samples with detections, the 90th and 99th percentile concentrations from samples with detections, and the minimum, median, and maximum concentration from samples with detections;
- The number and percentage of systems with at least one detected concentration greater than or equal to the MRL, greater than the $\frac{1}{2}$ HRL,¹ and greater than the HRL; and
- The number of people and percentage of the population served by systems with at least one detected concentration greater than or equal to the MRL, greater than the $\frac{1}{2}$ HRL, and greater than the HRL.

The final published UCMR 2, UCMR 3, and UCMR 4 data sets provide source water type (e.g., groundwater, surface water) for the specific PWS *facility* at which the sample was taken. The UCMR figures for “population served” are based on the PWS as a whole. For the purpose of the analysis presented in this document, the EPA used the PWS-level source water designations from the Safe Drinking Water Information System / Federal version (SDWIS/Fed) and population served information from each UCMR round (based on the SDWIS/Fed population data as of the UCMR applicability date: June 30, 2005, for UCMR 2, December 31,

¹ The use of the $\frac{1}{2}$ HRL threshold is based on a recommendation from the National Drinking Water Advisory Council (NDWAC) working group that provided recommendations on the first regulatory determinations effort (USEPA, 2000).

2010, for UCMR 3, and December 31, 2015, for UCMR 4) (USEPA, 2009a; USEPA, 2014; USEPA, 2022c). Note that some systems' source waters include both groundwater and surface water. To establish a single PWS-level source water type, SDWIS/Fed categorized any system that includes both groundwater and surface water sources as a "surface water" system. In this analysis, therefore, some results attributable to a surface water system may be associated with a groundwater source at a mixed source water system.

Where the data from the primary sources permit, national extrapolations are made to estimate the number of systems and the population in various size and source categories potentially exposed to a given level of contamination. The extrapolations are made primarily using national inventory information from the SDWIS/Fed. Other sources of data used to support national extrapolations include the Community Water System Survey (CWSS) and the UCMR program. When SDWIS/Fed data are used for national extrapolation of findings from a survey, the SDWIS/Fed data freeze is selected to coincide most closely with the timing of the survey design. For example, 2015 SDWIS/Fed inventory information was used for all extrapolations of UCMR 4 results.

The analytical approach that is used to evaluate the contaminant monitoring data was previously developed for other EPA Office of Ground Water and Drinking Water (OGWDW) national occurrence studies, including the first Six-Year Review of National Primary Drinking Water Regulations (USEPA, 2003b), UCMR 1 (USEPA, 2008a), and previous rounds of the regulatory determination process (USEPA, 2002b; USEPA, 2008b; 73 FR 44251). In each case, the data analysis process and presentation were peer-reviewed and subject to public and stakeholder review and comment.

Robust data from the UCMR program can support a more involved statistical analysis (Stage 2 analysis) to assess and estimate the annual mean concentrations at systems, for comparisons with HRLs. The Stage 2 approach, also peer-reviewed, is presented in the reports *Occurrence Estimation Methodology and Occurrence Findings for Six-Year Review of National Primary Drinking Water Regulations* (USEPA, 2003b) and *The Analysis of Regulated Contaminant Occurrence Data from Public Water Systems in Support of the Second Six-Year Review of National Primary Drinking Water Regulations* (USEPA, 2009b).

The following sections provide a brief summary of primary drinking water data sources and the approach used to estimate contaminant occurrence in each case. The ongoing UCMR program is discussed first (covering the first four cycles, in order), followed by the older UCM and NIRS programs. For some data sources, readers are referred to support documents from earlier Contaminant Candidate List (CCL) and Regulatory Determination efforts for additional study details.

First Unregulated Contaminant Monitoring Rule (UCMR 1)

In 1999, the EPA developed the UCMR program in coordination with the CCL and the National Drinking Water Contaminant Occurrence Database (NCOD) to provide national occurrence information on unregulated contaminants (USEPA, 1999b; 64 FR 50556). The UCMR is currently the EPA's primary authority for collecting monitoring data on the occurrence of unregulated contaminants in PWSs.

The EPA designed UCMR 1 data collection with three parts (or tiers) for monitoring, primarily based on the availability of analytical methods and related analytical laboratory capability. Contaminants for which well established laboratory methods were available were scheduled to undergo full UCMR 1 List 1 Assessment Monitoring. Contaminants whose

laboratory methods were less well established, such that laboratory capacity or cost could be a concern, were placed on List 2; these were scheduled for a “Screening Survey” at a smaller group of systems. The purpose of the Screening Survey was to develop a preliminary assessment of national occurrence for contaminants of concern that may be difficult to monitor at the larger scale of Assessment Monitoring. List 3 monitoring (“Pre-Screen Testing”) was intended to address contaminants with analytical methods that are in an early stage of development; the analyses would be limited to a few special laboratories. The expectation was that Pre-Screen Testing would only involve a limited number of systems determined to be most vulnerable to the targeted contaminants. The EPA did not implement Pre-Screen Testing under UCMR 1 due to the lack of suitable candidate methods.

The EPA required all large (serving more than 10,000 people) community water systems (CWSs) and non-transient non-community water systems (NTNCWSs), plus a statistically representative national sample of 800 small (serving 10,000 people or fewer) CWSs and NTNCWSs, to conduct Assessment Monitoring of List 1 contaminants.² Approximately one-third of the participating small systems were scheduled to monitor for the List 1 contaminants during each calendar year from 2001 through 2003. Large systems could conduct one year of monitoring anytime during the 2001-2003 UCMR 1 period. The EPA specified a quarterly monitoring schedule for surface water systems and a twice per year, six-month-interval monitoring schedule for groundwater systems. Monitoring was scheduled so that one sampling event occurred during the most vulnerable season for the water system.³ The objective of the peer-reviewed UCMR 1 sampling approach for small systems was to collect contaminant occurrence data from a statistically selected, nationally representative sample of small systems. The small system sample was stratified and population-weighted, and it included some other sampling adjustments such as ensuring the selection of at least two systems from each state. With contaminant monitoring data from all large CWSs and NTNCWSs and a nationally representative sample of small CWSs and NTNCWSs, the UCMR 1 List 1 Assessment Monitoring program provides a contaminant occurrence data set suitable for national drinking water estimates.

In total, 372,086 sample results were collected under the UCMR 1 List 1 Assessment Monitoring program at 3,090 large systems and 797 small systems. Approximately 33,800 samples were collected for each contaminant. The UCMR 1 List 1 Monitoring program included systems from all 50 states, the District of Columbia, four U.S. territories, and Tribal lands in five EPA Regions.

Under UCMR 1, the Screening Survey for List 2 contaminants was designed to be conducted by a total of 300 systems (120 large systems and 180 small systems). PWSs for List 2 monitoring were randomly selected from among the systems required to conduct Assessment Monitoring. In total, 34,813 sample results were collected under the UCMR 1 List 2 Screening Survey Monitoring program. Each Screening Survey contaminant had data from up to 118 large

² Large and small systems that purchase 100 percent of their water supply were not required to participate in the UCMR 1 Assessment Monitoring or Screening Survey.

³ Under UCMR1, the most vulnerable season was considered to be the season of greatest likelihood of contaminant occurrence, generally in the months of late spring and early summer, which are characterized by high volumes of surface water runoff and groundwater recharge.

systems and 178 small systems. The UCMR 1 Screening Survey data are too sparse to be nationally representative, but the EPA considered them under RD 5 as supplemental data.

See USEPA (2001a) and USEPA (2008a) for more information on UCMR 1 study design and data analysis.

Second Unregulated Contaminant Monitoring Rule (UCMR 2)

UCMR 2 monitoring was conducted from 2008 through 2010 and was designed to provide nationally representative contaminant occurrence data. Similar in design to UCMR 1, UCMR 2 required surface water systems to monitor quarterly and groundwater systems to monitor semi-annually to capture seasonal variability. As with UCMR 1, there were multiple tiers of monitoring: Assessment Monitoring for contaminants with commonly used analytical method technologies, and Screening Survey monitoring for contaminants that require specialized analytical method technologies not in wide or common use at the time of study. (Again, there was no Pre-Screen Testing.)

One difference between the UCMR 1 and UCMR 2 is that the UCMR 2 Screening Survey consists of a larger sample of PWSs, as described in following paragraphs, and therefore provides monitoring data statistically robust enough to support national contaminant occurrence estimates. See USEPA (2005b; 70 FR 49093), USEPA (2007; 72 FR 367), and USEPA (2015) for more information on the UCMR 2 program, including study design and data analysis.

For UCMR 2, all large (serving 10,001 - 100,000 people) and very large (serving more than 100,000 people) CWSs and NTNCWSs, plus a statistically representative national sample of 800 small (serving 10,000 people or fewer) CWSs and NTNCWSs, were required to conduct Assessment Monitoring. Each participating system was required to monitor during a 12-month period between January 2008 and December 2010. In total, 321,481 sample results were collected under the UCMR 2 List 1 Assessment Monitoring program at 3,340 large systems and 800 small systems.

For the UCMR 2 Screening Survey, monitoring was required by all very large CWSs and NTNCWSs (approximately 400 systems that collectively serve a large proportion of the national population), 320 representative large CWSs and NTNCWSs, and 480 representative small CWSs and NTNCWSs. Each participating system was required to monitor during a 12-month period between January 2008 and December 2010. With approximately 1,200 systems participating in the Screening Survey, sufficient data were generated to provide a confident national estimate of contaminant occurrence and population exposure. In UCMR 2, between 11,000 and 18,000 sampling results were collected for each analyte (depending on the sampling design). In total, 209,123 sample results were collected under the UCMR 2 List 2 Screening Survey Monitoring program at 398 very large systems, 320 large systems and 480 small systems. Analysis of UCMR 2 results is found in *Occurrence Data from the Second Unregulated Contaminant Monitoring Regulation (UCMR 2)* (USEPA, 2015).

Third Unregulated Contaminant Monitoring Rule (UCMR 3)

UCMR 3 monitoring was conducted primarily from 2013 through 2015. Similar in design to UCMR 1 and UCMR 2, UCMR 3 required surface water systems to monitor quarterly and groundwater systems to monitor semi-annually to capture seasonal variability. As with UCMR 1 and UCMR 2, there were multiple tiers of monitoring: Assessment Monitoring for contaminants with commonly used analytical method technologies, Screening Survey monitoring for contaminants that require specialized analytical method technologies not in wide or common use,

and pre-screen testing for contaminants that require newer analytical method technologies not in wide or common use. See USEPA (2012b; 77 FR 26072) and USEPA (2019b) for more information on the UCMR 3 study design and data analysis, including a complete list of analytes.

For UCMR 3, all large (serving between 10,001 and 100,000 people) and very large (serving more than 100,000 people) CWSs and NTNCWSs, plus a statistically representative national sample of 800 small (serving 10,000 people or fewer) CWSs and NTNCWSs, were required to conduct Assessment Monitoring. Each participating system was required to monitor during a 12-month period between January 2013 and December 2015. In total, 957,047 sample results were collected under the UCMR 3 List 1 Assessment Monitoring program at 408 very large systems, 3,716 large systems and 799 small systems.

For the UCMR 3 Screening Survey, monitoring was required by all very large CWSs and NTNCWSs (collectively serving a large proportion of the national population), 320 representative large CWSs and NTNCWSs, and 480 representative small CWSs and NTNCWSs. Participating systems were required to monitor during a 12-month period between January 2013 and December 2015. With approximately 1,200 systems participating in the Screening Survey, sufficient data were generated to provide a confident national estimate of contaminant occurrence and population exposure. In total, 82,570 sample results were collected under the UCMR 3 List 2 Screening Survey Monitoring program at 408 very large systems, 315 large systems and 478 small systems.

For the UCMR 3 Pre-Screen Testing, the EPA selected 800 representative groundwater PWSs that serve 1,000 or fewer people, do not disinfect, and have wells located in areas of karst or fractured bedrock. The pool of systems eligible for Pre-Screen Testing included transient non-community water systems (TNCWSs) as well as CWSs and NTNCWSs. The selected PWSs were to monitor for two viruses, and related pathogen indicators, during a 12-month period between January 2013 and December 2015. In total, 11,459 sample results were collected under the UCMR 3 List 3 Pre-Screen Testing Monitoring program at 799 small systems.

Analysis of UCMR 3 results is found in the chapters that follow and in *Occurrence Data from the Third Unregulated Contaminant Monitoring Regulation (UCMR 3)* (USEPA, 2019b).

Fourth Unregulated Contaminant Monitoring Rule (UCMR 4)

UCMR 4 monitoring was conducted primarily from 2018 through 2020. Under UCMR 4, data were collected for 30 List 1 contaminants. No List 2 or List 3 contaminants were included in UCMR 4. The List 1 analytes included 10 cyanotoxins (nine individual cyanotoxins and one cyanotoxin group), plus 20 “additional contaminants,” consisting of two metals, eight pesticides and one pesticide manufacturing byproduct, three brominated haloacetic acid (HAA) disinfection byproducts groups, three alcohols, and three semivolatile organic chemicals (SVOCs). In addition, data were gathered for two HAA indicators. See USEPA (2016a; 81 FR 92666) and USEPA (2024a) for more information on the UCMR 4 study design and data analysis, including a complete list of analytes.

Monitoring of the 10 cyanotoxins was required only at systems served by surface water or groundwater under the direct influence of surface water (GWUDI). The UCMR 4 program required cyanotoxin monitoring at all large (serving more than 10,000 people) CWSs and NTNCWSs served by surface water or GWUDI, plus a statistically representative national sample of 800 small (serving 10,000 or fewer people) CWSs and NTNCWSs served by surface water or GWUDI. Monitoring of the 20 additional contaminants and the two HAA indicators was not restricted by source water type. The UCMR 4 program specified that all large CWSs and

NTNCWSs, plus a statistically representative national sample of 800 small CWSs and NTNCWSs (a different set of 800 than the set of 800 required to monitor for the cyanotoxins), were required to monitor for the 20 additional contaminants and the two HAA indicators. Participating systems that are not subject to HAA compliance monitoring under the Disinfectants and Disinfection Byproduct Rules (D/DBPRs) were excused from monitoring the HAAs (and associated indicators) under UCMR 4. In total, 982,308 sample results were collected under UCMR 4 List 1 Assessment Monitoring at 4,237 large systems and 1,596 small systems.

Monitoring for cyanotoxins was conducted twice per month over a period of four consecutive months between March and November, since the warmer months are when harmful algal bloom events are most likely to occur in the Northern Hemisphere. Monitoring for other UCMR 4 contaminants was conducted on a more conventional UCMR schedule, with four quarterly samples from surface water and GWUDI systems and two semiannual samples from groundwater systems.

Analysis of UCMR 4 results is found in the chapters that follow and in *Occurrence Data from the Fourth Unregulated Contaminant Monitoring Rule (UCMR 4)* (USEPA, 2024a).

Unregulated Contaminant Monitoring (UCM) Program Rounds 1 and 2

In 1987, the EPA initiated the UCM program to fulfill a 1986 SDWA Amendment requirement to monitor for specified unregulated contaminants. The UCM required PWSs serving more than 500 people to conduct monitoring. The intent of the monitoring was to gather information on the occurrence of select contaminants in drinking water for future regulatory decision-making purposes.

The EPA implemented the UCM program in two phases or rounds. The first round of UCM monitoring generally extended from 1988 to 1992 and is referred to as UCM Round 1 monitoring. The second round of UCM monitoring generally extended from 1993 to 1997 and is referred to as UCM Round 2 monitoring.

UCM Round 1 monitoring initially involved 34 required VOCs, 14 VOCs to be monitored at states' discretion, and two synthetic organic compounds (SOCs). Monitoring for these unregulated compounds was to be conducted alongside monitoring for regulated compounds (USEPA, 1987; 52 FR 25720). The final database for this round of monitoring included 62 regulated and unregulated contaminants (USEPA, 2001b). UCM Round 2 involved monitoring for 20 VOCs from the Round 1 required list and 14 VOCs from the Round 1 discretionary list, plus 13 SOCs and sulfate. The final database for this round of monitoring included 48 unregulated contaminants (USEPA, 2001b). There was no requirement that the monitoring data be reported to the EPA, so individual states maintained the data in different forms and formats. In response to various initiatives and information collection requests, many states voluntarily submitted the UCM data to the EPA. The EPA worked to assemble the state data into a composite data set that would support national occurrence estimates.

The UCM Round 1 and Round 2 data sets do not contain detailed reporting level information. Reporting levels varied and were not explicitly labeled as MRLs, method detection limits (MDLs), etc.

The UCM Round 1 database contains contaminant occurrence data from 38 states, Washington, D.C., and the U.S. Virgin Islands. The UCM Round 2 database contains data from 35 states and several Tribes. However, some state data sets were incomplete; hence national occurrence estimates based on raw UCM Round 1 or Round 2 data could be skewed to low-

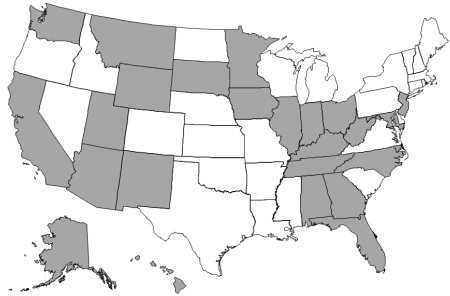
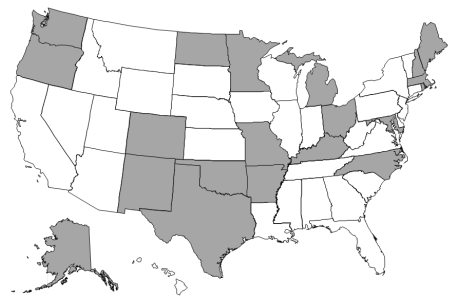
occurrence or high-occurrence settings (e.g., some states only reported detections). In addition, certain types of land use and geologic/hydrologic settings could be over- or under-represented. To address potential biases in the data (including those due to incompleteness and lack of representativeness), the EPA developed national cross-sections from the UCM Round 1 and Round 2 state data using an approach similar to that used for the EPA's 1999 Chemical Monitoring Reform (USEPA, 1999c), the first Six-Year Review (USEPA, 2003b), and the first round of Regulatory Determinations (USEPA, 2002b). This national cross-section approach for occurrence analyses was supported by scientific peer reviewers and stakeholders. Using this approach, the EPA constructed national cross-sections using 24 of the 38 states from the UCM Round 1 database and 20 of the 34 states from the UCM Round 2 database. The support document *The Analysis of Occurrence Data from the Unregulated Contaminant Monitoring (UCM) Program and National Inorganics and Radionuclides Survey (NIRS) in Support of Regulatory Determinations for the Second Drinking Water Contaminant Candidate List* (USEPA, 2008c) provides a description of how the national cross-sections for the Round 1 and Round 2 data sets were developed and utilized for making regulatory determinations.

Since UCM Round 1 and Round 2 data represent different time periods and include occurrence data from different states, the EPA developed separate national cross-sections for each data set. The UCM Round 1 national cross-section, consisting of data from 24 states, includes approximately 3.3 million records from approximately 22,000 unique PWSs. The UCM Round 2 national cross-section, consisting of data from 20 states, includes approximately 3.7 million records from slightly more than 27,000 unique PWSs. The UCM Round 1 and 2 national cross-sections represent significantly large samples of national occurrence data. Within each cross-section, the actual number of systems and analytical records for each contaminant varies.

The EPA constructed the national cross-sections in a way that provides a balance and range of states with varying pollution potential indicators, a wide range of geologic and hydrologic conditions, and a very large sample of monitoring data points. While the EPA recognizes that some limitations exist, the Agency believes that the national cross-sections do provide a reasonable estimate of the overall distribution and the central tendency of contaminant occurrence across the United States. For more information on the development of national cross-sections, refer to USEPA (1999c), USEPA (2002b), and USEPA (2003b). See Exhibit 2-1 for a listing of states in each national cross-section.

Exhibit 2-1: Cross-Section States for UCM Round 1 and Round 2

UCM Round 1 – 24-State Cross-Section		UCM Round 2 – 20-State Cross-Section	
Alabama	Minnesota*	Alaska*	New Hampshire
Alaska*	Montana	Arkansas	New Mexico*
Arizona	New Jersey	Colorado	North Carolina*
California	New Mexico*	Kentucky*	North Dakota
Florida	North Carolina*	Maine	Ohio*
Georgia	Ohio*	Maryland*	Oklahoma
Hawaii	South Dakota	Massachusetts	Oregon
Illinois	Tennessee	Michigan	Rhode Island
Indiana	Utah	Minnesota*	Texas
Iowa	Washington*	Missouri	Washington*
Kentucky*	West Virginia		
Maryland*	Wyoming		

Source: USEPA, 2008c

* States in both Round 1 and Round 2 cross-sections

National Inorganics and Radionuclides Survey (NIRS)

In the mid-1980's, the EPA implemented NIRS to provide a statistically representative sample of the national occurrence of select inorganic and radionuclide contaminants in CWSs served by groundwater. The survey is stratified based on system size (population served by the system). Most of the NIRS data are from smaller systems (92 percent from systems serving 3,300 persons or fewer).

The NIRS database includes findings for 42 radionuclides and inorganic compounds (IOCs). NIRS provides contaminant occurrence data from 989 groundwater CWSs in 49 states (all except Hawaii) as well as Puerto Rico. Surface water systems were not included in the study, in part because IOCs tend to occur more frequently and at higher concentrations in groundwater than in surface water. Each of the 989 randomly selected CWSs was sampled once between 1984 and 1986.

Because the NIRS data were collected in a randomly designed sample survey, the summary statistics are representative of national occurrence in groundwater CWSs. Information about NIRS monitoring and data analysis is available in Longtin (1988) and USEPA (2008c).

One limitation of NIRS is a lack of occurrence data for surface water systems. To provide perspective on the occurrence of the inorganic compounds in surface water systems relative to groundwater systems, the EPA also reviews various supplemental data sources.

2.5.4 Occurrence in Drinking Water – Supplemental Data Sources

The Agency evaluated many additional sources of drinking water occurrence information (including information on occurrence in “source” or “untreated” water, e.g., at the wellhead in groundwater systems) to augment the primary drinking water occurrence data, to evaluate the likelihood of contaminant occurrence, and to more fully characterize the presence of contaminants in the environment. These data sources are generally narrower in geographic scope than the primary drinking water data sources.

This section provides brief descriptions of many of the supplemental drinking water information/data sources cited in contaminant data discussions in this document. In addition, the EPA considered selected studies published in the technical literature. Preference was given to peer-reviewed studies and formal published reports over grey literature.

Fifth Unregulated Contaminant Monitoring Rule (UCMR 5)

At the time of report preparation, UCMR 5 monitoring is underway. Sample collection is scheduled to occur from 2023 through 2025. UCMR 5 provides for monitoring on 29 PFAS and lithium, all as List 1 contaminants. No List 2 or List 3 contaminants were included in UCMR 5. The UCMR 5 program requires monitoring for List 1 contaminants at all CWSs and NTNCWSs serving more than 10,000 people, all CWSs and NTNCWSs serving 3,300 to 10,000 people subject to availability of appropriations and sufficient laboratory capacity, plus a statistically representative sample of 800 CWSs and NTNCWSs serving fewer than 3,300 people (USEPA, 2021; 86 FR 73131). When UCMR 5 monitoring is complete, the data will constitute a nationally representative source of occurrence information. The limited UCMR 5 sampling data available from preliminary reporting, although not nationally representative, were taken into account under RD 5.

Information Collection Rule

The Monitoring Requirements for Public Drinking Water Supplies: *Cryptosporidium*, *Giardia*, Viruses, Disinfection Byproducts, Water Treatment Plant Data and Other Information Requirements (USEPA, 1996; 61 FR 24353), also known as the “Information Collection Rule,” required all PWSs serving at least 100,000 people to monitor and collect data on disinfection byproducts (DBPs) over an 18-month period from July 1997 to December 1998. The DBP data were collected from 296 very large water systems (that is, systems serving a population of more than 100,000), including both surface water systems and groundwater systems. These very large systems provided extensive information on the occurrence of DBPs and on water treatment operations. The Information Collection Rule data were collected as part of a national research project to support development of national drinking water standards. The EPA used the data to identify national and regional patterns. The data were not intended to support conclusions about individual systems or treatment plants.

Information Collection Rule monitoring was conducted on a “per plant” basis; some participating systems had more than one water treatment plant. For each plant, samples were collected at source water, treatment plant, and distribution system locations. Each sampling point generally represented either a point of entry into the distribution system, a point of maximum residence time, or a point of average residence time. Samples were collected monthly for some parameters such as pH, alkalinity, total organic carbon, etc. Quarterly samples were collected for other parameters such as trihalomethanes and haloacetic acids (USEPA, 1996; 61 FR 24353).

While the Information Collection Rule only covered 296 systems, it was a census of the largest systems in the nation, serving over half of the nation's population served by PWSs. Additional details on the data collection process for the Information Collection Rule, along with an independent analysis of the data, can be found in a report sponsored by the Microbial/Disinfection Products Council (McGuire et al., 2002).

State Monitoring Data

Because there is no national database that automatically receives and stores all relevant data from states regarding the occurrence of contaminants in public drinking water systems, the EPA gathers data from state drinking water monitoring websites in support of national occurrence assessments. For RD5, data were gathered from 28 states. For 24 of the 28 states, data were available through the Drinking Water Watch (DWW) portal on the state's website. Available data from 1990 through 2022 were downloaded. Available data for other states/entities that had been submitted to the EPA through the second, third, and fourth Six-Year Review efforts (SYR2, SYR3, and SYR4) were also evaluated. As part of the Six-Year Reviews, some states submitted PWS occurrence data for unregulated contaminants along with requested data on regulated contaminants. Data representing 1998-2005 monitoring were collected for SYR2, data from 2006-2011 for SYR3, and data from 2012-2019 for SYR4. For all rounds of the Six-Year Review, these unregulated data provide varying degrees of completeness in their coverage of the states/entities and are not necessarily representative of occurrence in those states/entities. For more details on data compiled under SYR2, SYR3, and SYR4, refer to USEPA (2009b), USEPA (2016b), and USEPA (2024b), respectively.

2000 Community Water System Survey (2000 CWSS)

The 2000 CWSS (USEPA, 2002c; USEPA, 2002d) gathered data on the financial and operating characteristics of a random sample of CWSs nationwide. In addition, the Survey asked all CWSs serving more than 500,000 people (a total of 83 systems) to provide monitoring results for five regulated compounds (arsenic, atrazine, 2,4-D, simazine, and glyphosate) and four unregulated compounds (radon, MTBE, metolachlor, and boron), including results from raw water (i.e., before treatment) at each intake and from finished water (i.e., following treatment) at each treatment plant. The EPA received completed questionnaires from 58 of the 83 systems. Not all systems answered every question. Note that because reported results are incomplete, they are only illustrative, not statistically representative, and are only used as supplemental information.

2006 Community Water System Survey (2006 CWSS)

The 2006 CWSS (USEPA, 2009c; USEPA, 2009d) gathered data on the financial and operating characteristics of a random sample of CWSs nationwide. All systems serving more than 500,000 people (94 systems in 2006) were included in the sample, and systems in that size category were asked questions about concentrations of unregulated contaminants in their raw and finished water. Not all eligible systems responded to the survey and, of the systems that responded to the survey, not all systems answered every question. The CWSS report states that the EPA supplemented the data set on unregulated contaminant occurrence at systems serving more than 500,000 people by gathering additional information from publicly available sources (e.g., consumer confidence reports) (USEPA, 2009d). Note that because reported results are incomplete, they are only illustrative, not statistically representative, and are only used as supplemental information.

Water Systems' Consumer Confidence Reports (CCRs)

Consumer Confidence Reports (CCRs) are annual water quality reports that CWSs are required to provide to their customers. These reports summarize information on water sources, detected contaminants, and system compliance with EPA drinking water standards; they may also include general educational material. Under the CCR Rule (40 CFR Subpart O), CWSs with 15 or more connections or serving at least 25 year-round residents must prepare and distribute a CCR to all billing units or service connections every year. Systems serving 100,000 or more residents are also required to post their current CCRs on a publicly accessible Internet site. For RD 5, the EPA reviewed CCRs published by the 25 systems that serve over one million customers (as identified in SDWIS/Fed from the fourth quarter 2021 data) for unregulated contaminant occurrence information for the years 2018 through 2021. Since reporting of monitoring results for unregulated contaminants in CCRs is not systematic, the results of this review are merely illustrative and are only used as supplemental information.

United States Department of Agriculture (USDA) Pesticide Data Program (PDP)

The USDA Pesticide Data Program (PDP) maintains a national pesticide residue database. PDP was initiated in 1991 to collect data on pesticide residues in the U.S. food supply, following a rigorous statistical design. Sampling and testing have been conducted on fruits and vegetables, select grains, milk, and (between 2001 and 2013) drinking water (USDA, 2022).

The PDP drinking water program was initiated at CWSs in New York and California in 2001. Since then, the drinking water sampling program has expanded, with a somewhat changing mix of states sampled each year. At one time or another, CWSs in 29 states and Washington, D.C., contributed raw or finished water data or both to the program (USDA, 2023). The CWSs selected for sampling tend to be small- and medium-sized systems (primarily CWSs serving fewer than 50,000 persons), systems served by surface water, and systems located in agricultural regions. Sampling of raw (“untreated”) water in addition to finished water began in 2004. Sampling of both raw and finished drinking water was discontinued after 2013 (USDA, 2023). Note that temporal trends cannot be evaluated based on these data since the list of CWSs included in the project varied from year to year (USDA, 2022; USDA, 2023).

USGS-EPA Pilot Monitoring Program (PMP)

In 1999, the Pilot Monitoring Program (PMP) was initiated by the USGS and the EPA to provide information on pesticide concentrations in drinking water. The program focused on small drinking-water supply reservoirs in areas with high pesticide use to test the sampling approach in areas where pesticides are probably present (Blomquist et al., 2001). Sampling sites represented a variety of geographic regions as well as different cropping patterns. The ideal site candidates were mostly small reservoirs located in high pesticide-use areas with a high runoff potential. Twelve water-supply reservoirs considered vulnerable to pesticide contamination were selected from the list of candidates. These 12 sites were located in California, Indiana, Ohio, Oklahoma, Louisiana, Missouri, South Carolina, South Dakota, New York, North Carolina, Pennsylvania and Texas. Sampling began in 1999. Because of drought conditions in the Eastern United States and California in 1999, the program was extended through 2000 at nine of the twelve monitoring sites.

Samples were collected quarterly throughout the year and at weekly or biweekly intervals following the primary pesticide-application periods. Water samples were collected from the raw-water intake and from finished drinking water taps prior to entering the distribution system. At some sites, samples were also collected at the reservoir outflow.

EPA / United States Geological Survey (USGS) Nationwide Reconnaissance of Contaminants of Emerging Concern

As part of a joint study by the EPA and the USGS to assess human exposure to contaminants of emerging concern, water samples were collected from 25 drinking water treatment plants (DWTPs) in 24 states (Glassmeyer et al., 2017). Participation in the study was voluntary. Participants were selected based on nomination by EPA and USGS regional personnel and DWTP self-nomination as well as consideration of high wastewater contribution and the availability of pharmaceutical concentration data. Final sample locations were chosen to represent a wide range of geography, diversity in disinfectant type used, and a range of production volumes. Phase I of the study (2007) analyzed a subset of contaminants and sites to test experimental design. During Phase II of the study (2010-2012), samples were collected from groundwater and surface water sources and treated drinking water from 25 DWTPs.

National Pesticide Survey (NPS)

In 1990, the EPA completed a national survey of pesticides in the source water of drinking water wells. The purpose of the National Pesticide Survey (NPS) was to determine the national occurrence frequencies and concentrations of select pesticides in the nation's drinking water wells and to improve the EPA's understanding of how pesticide occurrence in groundwater correlates with patterns of pesticide usage and groundwater vulnerability. The survey included 566 CWS wells and 783 rural domestic wells. Sampling was conducted between 1988 and 1990. The survey targeted areas representing a variety of pesticide usage levels and groundwater vulnerability. The survey was designed to provide a statistically reliable estimate of pesticide occurrence in the nation's drinking water wells. It was not designed to provide statistically valid results at the state or local level. Wells were sampled for 101 pesticides, 25 pesticide degradates, and nitrate (USEPA, 1990).

Miscellaneous Source Water and Drinking Water Studies

Note that there may be some overlap between the NAWQA data assessment presented earlier in the ambient water occurrence section and the summaries of NAWQA studies presented below.

Selected Trace Elements in Ground Water in the Glacial Aquifer System of the Northern United States (Groschen et al., 2009), 1991-2003

Using NAWQA data, Groschen et al. (2009) assessed the occurrence and distribution of several contaminants in groundwater of the glacial aquifer system in the Northern United States, which underlies portions of New England, the Midwest, the Pacific Northwest, and Alaska. The study analyzed data collected from 1,590 monitoring wells and water supply wells sampled between 1991 and 2003.

Organic Compounds in Source Water of Selected Community Water Systems (Hopple et al., 2009 and Kingsbury et al., 2008)

As part of the NAWQA program, Hopple et al. (2009) and Kingsbury et al. (2008) conducted studies to characterize anthropogenic organic compounds in PWS source waters in the United States. Hopple et al. (2009) focused on groundwater and Kingsbury et al. (2008) focused on surface water. In Phase 1 of the studies, geographically diverse source water samples were collected between October 2002 and July 2005 from surface water intakes at 9 CWSs and from wells in 12 aquifers that serve as CWS sources. In Phase 2, source and finished water samples were collected at a subset of sites between June 2004 and September 2005.

Volatile Organic Compounds in Drinking Water of Selected Community Water Systems (Grady and Casey, 2001), 1993-1998

USGS compiled and analyzed occurrence data for VOCs in finished drinking water in 12 Northeast and Mid-Atlantic states (Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, and Virginia). State agencies supplied USGS with VOC data collected during 1993 through 1998 for 20 percent of the CWSs in the 12-state area, which were chosen to be representative in terms of geography, water source, and system size. Grady and Casey (2001) summarize information on the quality of drinking water from 2,110 randomly selected CWSs in the study area.

Water Quality in Public-Supply Wells (Toccalino et al., 2010)

To assess risks posed by contaminants in public-supply wells, water samples were collected from source (untreated) groundwater from 932 public-supply wells located in parts of 40 NAWQA Study Units in 41 states (Toccalino et al., 2010). Each well was sampled once between 1993 and 2007. Six water-quality properties and 215 chemical contaminants (58 regulated and 157 unregulated in drinking water) were analyzed. The public wells sampled in this study belonged to 629 unique PWSs, representing about 0.5 percent of the approximately 140,000 groundwater-supplied PWSs in the United States but nearly 25 percent of the national population served by groundwater PWSs.

Water Quality in Domestic Wells (DeSimone, 2009)

Between 1991 and 2004, USGS assessed water quality from domestic wells across the United States using NAWQA data (DeSimone, 2009). The program included analysis of major ions, trace elements, nutrients, radon, and organic compounds (pesticides and VOCs) at approximately 2,100 domestic wells (private drinking water wells) across 48 states, covering 30 regional aquifers. In addition, USGS summarized data from wells sampled for NAWQA agricultural land-use assessment studies to provide an indication of the potential effects of agricultural land-use practices on the groundwater in the aquifers studied.

Water Quality in Carbonate Aquifers (Lindsey et al., 2008)

As part of the NAWQA program, Lindsey et al. (2008) assessed the water quality in carbonate aquifers, which account for 22 percent of the groundwater pumped by the nation's PWSs. From 1993 to 2005, the study analyzed 1,042 wells and springs across 12 aquifer systems and 20 states for major ions, radon, nutrients, pesticides, and VOCs. The 12 aquifer systems selected for this study represent a wide range of climate, land-use types, and degrees of confinement. The water use associated with the sampling sites used in this study fell into four categories: domestic water use, public water use, "unused" (e.g., monitoring well or an abandoned domestic well), and other (e.g., aquaculture, commercial, dewatering, industrial cooling, etc.). The study authors evaluated occurrence of most VOCs at a uniform assessment level of 0.2 µg/L.

Contaminant Occurrence in Source and Finished Water in the Sioux Falls Area, South Dakota (Hoogstraal, 2012), 2009-2010

In 2009-2010, the city of Sioux Falls and the USGS assessed the occurrence of anthropogenic organic compounds in the source waters (groundwater and surface water) and finished water in the Sioux Falls area. Samples were taken at monthly or bimonthly intervals. Eight samples were gathered at one surface water site, seven samples were gathered from one groundwater site, and 11 finished water samples were taken.

Volatile Organic Compounds (VOCs) in Domestic Wells (Moran et al., 2002; Rowe et al., 2007), 1986-1999 and 1996-2002

As part of the NAWQA program, USGS studied the occurrence of VOCs in groundwater from untreated rural self-supplied domestic wells between 1986 and 1999 (Moran et al., 2002). Private wells are not subject to EPA drinking water regulations. Water samples were collected at the wellhead prior to treatment or storage. In most samples, 55 target VOCs were analyzed. Reporting levels varied; results for most VOCs were reported at an assessment level of 0.2 µg/L.

USGS also published the findings of a subsequent national assessment of VOCs in domestic wells (Rowe et al., 2007). In this study, sampling results for 55 VOCs from 2,401 domestic wells, gathered between 1985 and 2002, were compared against health benchmarks. Samples were collected at the wellhead before treatment. A subset of 1,208 samples gathered between 1996 and 2002 were examined in greater detail for detection frequencies, concentrations, and spatial distribution.

2.5.5 Other Occurrence

The Centers for Disease Control and Prevention (CDC) National Report on Human Exposure to Environmental Chemicals

To assess the U.S. population's exposure to environmental chemicals, CDC monitors concentrations of select chemicals in human blood, serum and urine. Since 1999, the National Health and Nutrition Examination Survey (NHANES) has examined the U.S. population annually and released the data in 2-year cycles. The survey is based on a representative sample of the U.S. population based on age, gender, and race/ethnicity (CDC, 2022). The EPA consulted the biomonitoring data tables posted on the program's website, specifically the tables for "Analysis of Whole Blood, Serum, and Urine Samples, NHANES 1999-2018." The types of data available and the range of dates available vary from contaminant to contaminant.

2.6 Analytical Methods

The EPA has evaluated the availability of drinking water analytical methods for the contaminants currently prioritized for regulatory determination. In the case of a positive regulatory determination, the EPA needs to ensure that laboratories have a standardized and validated analytical method that can measure the newly regulated contaminant with confidence at the Maximum Contaminant Level (MCL) by the time a National Primary Drinking Water Regulation (NPDWR) using an MCL goes into effect. Note that SDWA provides for the promulgation of a NPDWR that requires the use of a Treatment Technique (TT) rather than an MCL in the event that it is not economically or technologically feasible to ascertain the level of the contaminant in water (SDWA 1412(b)(7)(A)).

The following analytical method performance metrics are useful and are typically available for assessing method sensitivity. The Lowest Concentration Minimum Reporting Level (LCMRL) is generally representative of the single EPA laboratory that developed the method, while the Minimum Reporting Level (MRL) is designed to be applied nationally in the context of UCMR monitoring during a specific UCMR cycle for which that MRL was developed:

- **LCMRL** – The LCMRL is a single-laboratory reporting level for selected EPA analytical methods. It is determined via a statistical model of future analyte recovery using the

method, where the future recovery is predicted to fall between 50% and 150% with 99% confidence.

- **MRL** – The MRL is a reporting level used for national application in the EPA’s UCMR program. For UCMR 1 analytes, the MRL was established by the EPA in light of anticipated laboratory capability. For UCMR 2, UCMR 3, UCMR 4, and UCMR 5 analytes, MRLs have been determined via a statistical model from raw LCMRL study data from multiple laboratories (typically three).

2.7 Treatment Technologies

The EPA evaluates whether suitable treatment technologies are available prior to promulgating a final NPDWR.

The EPA preliminarily reviewed information on treatment technologies for priority contaminants and summarized that information in the chapters that follow. Where available, the EPA relied on information in the Agency’s Drinking Water Treatability Database (<https://tdb.epa.gov/tdb/home/>). In cases where Database did not provide coverage for a contaminant, the EPA relied on searches of the primary and secondary literature.

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Chapter 3: 2-Aminotoluene

A chapter from:

Final Regulatory Determination 5 Support Document

EPA Report 815-R-26-002

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Abbreviations

ADD	Acceptable Daily Dose
ATSDR	Agency for Toxic Substances and Disease Registry
BMD	Benchmark Dose
BMD ₁₀	Benchmark Dose at 10 Percent Extra Risk*
BMDL ₁₀	Lower Bound of 95 Percent Confidence Interval on BMD ₁₀ *
BRL	Below Reporting Level
BW	Body Weight
CASRN	Chemical Abstracts Service Registry Number
CCL 5	Fifth Contaminant Candidate List
CCR	Consumer Confidence Report
CDC	Centers for Disease Control and Prevention
CDR	Chemical Data Reporting
CRL	Cancer Risk Level
CSF	Cancer Slope Factor
CWS	Community Water System
DL	Detection Limit
DWI	Drinking Water Intake
DWI-BW	Drinking Water Intake Adjusted for Body Weight
EF	Exposure Factor
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning And Community Right-to-Know Act
GWUDI	Groundwater Under the Direct Influence of Surface Water
HCl	Hydrochloric Acid
HED	Human Equivalent Dose
HRL	Health Reference Level
IUR	Inventory Update Reporting
K _H	Henry's Law Constant
K _{oc}	Organic Carbon Partitioning Coefficient
K _{ow}	Octanol/Water Partitioning Coefficient
LADWP	Los Angeles Department of Water and Power
LCMRL	Lowest Concentration Minimum Reporting Level
LOD	Limit of Detection
MAC	Maximum Acceptable Concentration
MRL	Minimum Reporting Level
MWRA	Massachusetts Water Resource Authority
NAWQA	National Water-Quality Assessment
NCBI	National Center for Biotechnology Information
ND	No Detection
NIRS	National Inorganics and Radionuclides Survey
NPDWR	National Primary Drinking Water Regulation
NTNCWS	Non-Transient Non-Community Water System
NWIS	National Water Information System
OGWDW	Office of Ground Water and Drinking Water
PAD	Population-Adjusted Dose
pK _a	Acid Dissociation Constant
POD	Point of Departure

POD/UF	Point of Departure / Uncertainty Factor
PPRTV	Provisional Peer-Reviewed Toxicity Value
PWD	Philadelphia Water Department
PWS	Public Water System
RD	Regulatory Determination
RD 5	Fifth Regulatory Determination
RfD	Reference Dose
RSD	Relative Standard Deviation
SDWA	Safe Drinking Water Act
SDWIS/Fed	Safe Drinking Water Information System / Federal Version
SIM	Selected Ion Monitoring
STORET	Storage and Retrieval Data System
TDI	Tolerable Daily Intake
TOC	Total Organic Carbon
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
UCM	Unregulated Contaminant Monitoring
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 1	First Unregulated Contaminant Monitoring Rule
UCMR 2	Second Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 4	Fourth Unregulated Contaminant Monitoring Rule
USGS	United States Geological Survey
WQP	Water Quality Portal

*These definitions apply only within this chapter.

Chapter 3: 2-Aminotoluene

The U.S. Environmental Protection Agency (EPA) is evaluating 2-aminotoluene, a contaminant on the fifth Contaminant Candidate List (CCL 5), as a candidate for regulation under the fifth Regulatory Determination process (RD 5). Information on the CCL 5 process is found in Chapter 1. Background on data sources used to evaluate CCL 5 chemicals is found in Chapter 2.

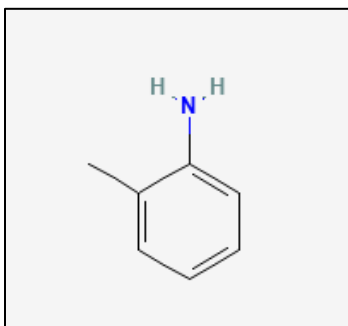
This chapter presents information and analysis specific to 2-aminotoluene, including background information on the contaminant, information on contaminant sources and environmental fate, an analysis of health effects, an analysis of occurrence in ambient and drinking water, and information about the availability of analytical methods and treatment technologies.

3.1 Contaminant Background and Chemical and Physical Properties

2-Aminotoluene is a synthetic aromatic amine used in the manufacture of dyes, rubber vulcanization accelerators, pharmaceuticals, and pesticides. Synonyms for 2-aminotoluene include o-toluidine, ortho-toluidine, 2-methylaniline, and 2-methylbenzenamine (NCBI, 2024).

Exhibit 3-1 presents the structural formula for 2-aminotoluene. Physical and chemical properties and other reference information are listed in Exhibit 3-2.

Exhibit 3-1: Chemical Structure of 2-Aminotoluene



Source: NCBI, 2024

Exhibit 3-2: Physical and Chemical Properties of 2-Aminotoluene

Property	Data
Chemical Abstracts Service Registry Number (CASRN)	95-53-4 (NCBI, 2024)
Chemical Formula	C ₇ H ₉ N (NCBI, 2024)
Molecular Weight	107.15 g/mol (NCBI, 2024)
Color/Physical State	Colorless to pale yellow liquid (NCBI, 2024)
Boiling Point	200 °C (NCBI, 2024)
Melting Point	-16.3 °C (NCBI, 2024)
Density	0.998 at 68 °F (NCBI, 2024)
Freundlich Adsorption Coefficient	--
Acid Dissociation Constant (pK _a)	--

Property	Data
Vapor Pressure	0.1 mm Hg at 68 °F; 0.3 mm Hg at 86 °F (NCBI, 2024);
Henry's Law Constant (K_H)	--
Octanol/Water Partitioning Coefficient (log K_{ow})	1.32 (USEPA, 2012)
Organic Carbon Partitioning Coefficient (K_{oc})	--
Solubility in Water	16.2 g/L at 20 °C (NCBI, 2024)
Other Solvents	--

Note: Many of these properties are temperature-dependent. Values are given for properties at 20-25°C unless otherwise noted. Due to varying experimental conditions, and due to the variabilities associated with modeling, standard information sources may provide a range of values. Where more than one value was available from these sources, one value was selected for this table based on best professional judgment.

3.2 Sources and Environmental Fate

3.2.1 Production, Use, and Release

Production data for 2-aminotoluene are available from the EPA's Inventory Update Reporting (IUR) and Chemical Data Reporting (CDR) programs, and industrial release data are available from the EPA's Toxics Release Inventory (TRI), as described below. Additional information about these sources is provided in Chapter 2.

Inventory Update Reporting (IUR) and Chemical Data Reporting (CDR) Programs

Under the authority of the Toxic Substances Control Act (TSCA), the EPA gathers information on production (including both manufacture and importation) of industrial chemicals. Under IUR, producers provided information once every four years from 1986 to 2006. Since 2012, producers have continued to provide information in accordance with the CDR Rule, which superseded the IUR in 2011. Under CDR, producers collect annual production data and report it once every four years. Results are generally presented to the public in terms of production ranges. Sometimes (e.g., to protect confidential business information) the production ranges are withheld.

Until 2006, the IUR regulation required manufacturers and importers of organic chemical substances included on the TSCA Chemical Substance Inventory to report on chemicals produced (i.e., manufactured or imported) in amounts of 10,000 pounds or more at a single site. In 2006, the minimum threshold for reporting was increased to 25,000 pounds and reporting began for inorganic chemicals (USEPA, 2008). Among changes made under CDR, a two-tier system of reporting thresholds was implemented, with 25,000 pounds as the threshold for some contaminants and 2,500 pounds as the threshold for others (USEPA, 2020). As a result of program modifications, the results from 2006 and later might not be directly comparable to results from earlier years. Under CDR, every four years manufacturers and importers are required to report annual data from each of the previous four years, provided that the thresholds of 2,500 or 25,000 pounds are met during at least one of the four years (USEPA, 2020).

Exhibit 3-3 presents the publicly available information on production of 2-aminotoluene in the United States as reported under IUR. Currently, only data from the 2006 reports (representing calendar year 2005 production) are available for download; data from earlier years are not publicly available. Reported production of 2-aminotoluene in 2005 was in the range of 10 million to under 50 million pounds.

Exhibit 3-4 presents the publicly available production data for 2-aminotoluene in the United States from 2011 to 2019 as reported under CDR. Except in 2011 when production was about 23.4 million pounds, annual production during this period ranged from 50 million to under 100 million pounds.

Exhibit 3-3: IUR Reported Annual Production (Manufacture and Importation) of 2-Aminotoluene in the United States, 2005 (pounds)

Production Year	2005
Range of Production Volume	10 million - <50 million

Source: USEPA, 2023a

Exhibit 3-4: CDR Reported Annual Production (Manufacture and Importation) of 2-Aminotoluene in the United States, 2011-2019 (pounds)

	Chemical Inventory Update Reporting Cycle								
	2011	2012	2013	2014	2015	2016	2017	2018	2019
Range of Production Volume	>23,419,290	50M - <100M	50M - <100M	50M - <100M	50M - <100M	50M - <100M	50M - <100M	50M - <100M	50M - <100M

Source: USEPA, 2023a

M = million

Toxics Release Inventory (TRI)

The EPA established TRI in 1987 in response to Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). EPCRA Section 313 requires the reporting of annual information on toxic chemical releases from facilities that meet specific criteria. This reported information is maintained in a database accessible through TRI Explorer (USEPA, 2023b).

Although TRI can provide a general idea of release trends, it has limitations. Not all facilities are required to report all releases. Facilities are generally required to report releases if they manufacture or process more than 25,000 pounds of a chemical or use more than 10,000 pounds per year. Reporting requirements have changed over time (e.g., reporting thresholds have increased or decreased), so conclusions about temporal trends should be drawn with caution. TRI data are meant to reflect releases and should not be used to estimate general public exposure to a chemical (USEPA, 2022a).

TRI data for 2-aminotoluene from the years 1988-2022 are summarized in Exhibit 3-5 (USEPA, 2023b). On-site air emissions have consistently ranged in the thousands and tens of thousands of pounds. On-site underground injections and releases to land have generally declined over the years (from early highs of around 32,000 pounds and 8,000 pounds, respectively), while reported off-site releases have increased in recent years. On-site surface water discharges have ranged from 2 to approximately 1,900 pounds; in recent years they have held steady at just under 200 pounds per year.

Exhibit 3-5: Environmental Releases of 2-Aminotoluene in the United States, 1988-2022 (pounds)

Year	On-Site Air Emissions	On-Site Surface Water Discharges	On-Site Underground Injection	On-site Releases to Land	Off-site Disposal or Other Releases	Total On- and Off-site Disposal or Other Releases
1988	46,922	1,902	250	5,024	670	54,768
1989	25,849	1,252	250	3,563	750	31,664
1990	7,443	250	11,250	8,486	1,055	28,484
1991	12,078	260	21,100	8,111	85	41,634
1992	8,787	310	31,800	6,823	188	47,908
1993	19,653	1,266	24,600	7	56	45,582
1994	13,586	534	30,300	6	302	44,728
1995	13,498	256	22,140	12	55	35,961
1996	17,842	74	17,450	10	1,401	36,777
1997	40,751	273	7,440	5	3,151	51,620
1998	7,750	5	17,020	5	11	24,791
1999	7,736	2	10,010	0	635	18,383
2000	11,069	25	7,040	0	400	18,534
2001	9,784	26	12,020	10	633	22,473
2002	10,837	6	134	250	330	11,557
2003	11,569	5	82	0	13	11,669
2004	10,397	5	360	1	11	10,774
2005	15,123	5	1,100	1	250	16,479
2006	18,032	5	760	0	50	18,847
2007	15,625	5	780	18	108	16,536
2008	12,069	5	1,500	20	72	13,666
2009	5,478	198	1,200	0	0.8	6,876
2010	5,137	198	1,300	0	0	6,635
2011	5,598	195	60	1	5	5,859
2012	6,453	195	200	0	28	6,876
2013	5,388	195	230	5	1,000	6,818
2014	3,876	198	65	5	255	4,399
2015	3,170	198	270	251	484	4,373
2016	5,625	195	3	250	765	6,838
2017	3,072	195	0	5	13,157	16,428
2018	5,541	195	0	5	4,839	10,580
2019	5,717	195	170	5	2,556	8,644
2020	5,512	194	46	1	1,635	7,387
2021	5,546	198	0	5	5,941	11,690
2022	5,624	198	0	5	3,228	9,055

Source: USEPA, 2023b

Exhibit 3-6 presents an expanded summary of total releases and total surface water discharges that includes the count of states reporting releases (USEPA, 2023b). Note that for the purposes of TRI, “state” counts include the District of Columbia and U.S. territories in addition to the 50 states. Surface water discharges of 2-aminotoluene were reported from no more than six states in any given year. The number of states reporting releases of any kind ranged from 4 to 12 in any given year.

Exhibit 3-6: Summary of Total Releases and Total Surface Water Discharges of 2-Aminotoluene, 1988-2022

Year	On-Site Surface Water Discharges (in pounds)	Count of States with Surface Water Discharges	Total Releases (in pounds)	Count of States with Releases
1988	1,902	4	54,768	11
1989	1,252	4	31,664	11
1990	250	1	28,484	9
1991	260	3	41,634	9
1992	310	4	47,908	10
1993	1,266	4	45,582	11
1994	534	6	44,728	12
1995	256	3	35,961	12
1996	74	2	36,777	12
1997	273	3	51,620	12
1998	5	1	24,791	11
1999	2	2	18,383	11
2000	25	3	18,534	11
2001	26	3	22,473	12
2002	6	2	11,557	10
2003	5	1	11,669	9
2004	5	1	10,774	9
2005	5	1	16,479	10
2006	5	1	18,847	10
2007	5	1	16,536	10
2008	5	1	13,666	10
2009	198	2	6,876	9
2010	198	2	6,635	6
2011	195	2	5,859	7
2012	195	2	6,876	7
2013	195	2	6,818	7
2014	198	2	4,399	7
2015	198	3	4,373	10
2016	195	2	6,838	10
2017	195	2	16,428	9
2018	195	2	10,580	6

Year	On-Site Surface Water Discharges (in pounds)	Count of States with Surface Water Discharges	Total Releases (in pounds)	Count of States with Releases
2019	195	2	8,644	6
2020	194	2	7,387	7
2021	198	2	11,690	5
2022	198	2	9,055	4

Source: USEPA, 2023b

3.2.2 Environmental Fate

As discussed in Chapter 2, the measures used by the EPA to assess mobility include (where available) the organic carbon partitioning coefficient (K_{oc}), log octanol-water partitioning coefficient ($\log K_{ow}$), Henry's Law Constant (K_H), water solubility, and vapor pressure. Commonly used environmental fate data sources (e.g., the National Center for Biotechnology Information (NCBI) PubChem database and Agency for Toxic Substances and Disease Registry (ATSDR) toxicological profiles) do not include discussion of the environmental fate of 2-aminotoluene. However, Gad (2024) reports the following: In soil, 2-aminotoluene will be subject to biodegradation, oxidation, and binding to soil components; in water, 2-aminotoluene will be subject to biodegradation, oxidation, and photooxidation as well as some adsorption to sediment; and in the atmosphere, 2-aminotoluene will photodegrade with a half-life of about 3 hours.

An equilibrium model estimates that 83.3% of 2-aminotoluene in the environment will partition to water and much smaller amounts will partition to air, soil, sediment, biota, and suspended sediments. An overall removal half-life for 2-aminotoluene in Rhine River water was estimated to be approximately 1 day (IPCS, 1998).

3.3 Health Effects

3.3.1 Health Assessment Identification

In order to identify qualifying health assessments for 2-aminotoluene (also referred to as *o*-toluidine), the EPA conducted a systematic web-based search of the EPA and other authoritative sources, as described in Section B.5.1.1 of the RD 5 Protocol, found in Appendix B of this document.

Exhibit 3-7 provides a summary overview of qualifying health assessments for 2-aminotoluene (i.e., health assessments from qualifying sources that provide a toxicity value relevant to chronic oral toxicity) that were published prior to the search cut-off date of January 2023. An assessment can present a noncancer oral toxicity value, a cancer oral toxicity value, or both. Information about the health assessment selected for 2-aminotoluene under RD 5 is bolded and italicized in Exhibit 3-7.

Exhibit 3-7: Qualifying Health Assessments Identified for 2-Aminotoluene

Health Assessment ^a	Oral Reference Value ^b	POD Type	Noncancer Critical Study	Oral Cancer Slope Factor ^c	Cancer Critical Study	Cancer Descriptor
<i>EPA Provisional Peer-Reviewed Toxicity Value (PPRTV) (USEPA, 2012)</i>	— ^d	—	—	<i>0.016</i>	<i>Weisburger et al. (1978)</i>	<i>L^e</i>

Notes: POD = point of departure; dash (—) = not applicable.

^a Selected health assessment and chronic toxicity value and supporting information are bolded and italicized.

^b Oral reference values are expressed in mg/kg/day unless otherwise specified; “oral reference value” can refer to the acceptable daily dose (ADD), maximum acceptable concentration (MAC), minimal risk level, point of departure / uncertainty factor (POD/UF), population-adjusted dose (PAD), reference dose (RfD), or tolerable daily intake (TDI).

^c Cancer slope factors (CSFs) are expressed in (mg/kg/day)⁻¹ unless otherwise specified.

^d The EPA PPRTV reports that there were no chronic-duration studies available to derive a chronic provisional RfD (USEPA, 2012).

^e This “Likely to be carcinogenic to humans” cancer descriptor was determined by following the process described in the EPA’s 2005 *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005).

3.3.2 Health Assessment Selection

The health assessment selected for 2-aminotoluene under RD 5 is the 2012 EPA Provisional Peer-Reviewed Toxicity Value (PPRTV) (USEPA, 2012). This is the only qualifying health assessment identified for 2-aminotoluene; it derives an oral cancer slope factor (CSF) based on the best available science. In this health assessment, the EPA determined that 2-aminotoluene is “likely to be carcinogenic to humans” by following the process described in the EPA’s 2005 *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005; USEPA, 2012). See Section B.5.1.2 of the RD 5 Protocol, in Appendix B of this document, for the decision logic that was applied to health assessment selection for RD 5 chemicals.

3.3.3 Health Reference Level (HRL) Development

Health reference levels (HRLs) are non-regulatory health-based toxicity values, expressed as concentrations in drinking water, that are used by the Agency to evaluate occurrence data for a contaminant when making decisions about regulatory determinations. See Section B.6.1.1 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA’s approach for deriving HRLs for chemicals. The input values used to derive the HRL for 2-aminotoluene are described below.

3.3.3.1 Oral Cancer Slope Factor

In the 2012 EPA PPRTV Assessment (USEPA, 2012), the EPA selected a chronic carcinogenicity study in mice and rats (Weisburger et al., 1978) as the critical study to derive an oral CSF for 2-aminotoluene. In this study, groups of male weanling Charles River CD rats (25 per dose group) and male and female albino CD-1 mice (25 per sex per dose group) were fed *o*-toluidine hydrochloric acid (HCl) in their diets for 18 months in two stages: at concentrations of 8,000 or 16,000 ppm for three months, followed by 4,000 or 8,000 ppm for 15 months. The animals were then placed on control diets for six months. To assess carcinogenicity, necropsies were performed on rats and mice that died or that were sacrificed after 6 months of exposure. Non-neoplastic degenerative or inflammatory lesions were recorded by the study authors. Significantly increasing tumor incidences occurred in both the rats and mice at both doses, including subcutaneous fibromas and fibrosarcomas in rats and vascular tumors in mice, compared to the controls ($p < 0.025$) (Weisburger et al., 1978).

An increase in subcutaneous fibromas and fibrosarcomas in male rats was the critical effect selected for derivation of an oral CSF, because this provided the most sensitive cancer endpoint with adequate fit after performing benchmark dose (BMD) modeling for individual and combined tumor types (USEPA, 2012). Time-weighted adjustments were made to reflect the decrease in dose concentrations administered after the first three months of the experiment and the six months on the control diet. The adjustments resulted in the time-weighted average human equivalent dose (HED) of 72.1 mg/kg/day for the low-dose group and 144.1 mg/kg/day for the high-dose group. The BMD modeling results for subcutaneous fibroma and fibrosarcoma yielded a benchmark dose associated with 10 percent extra risk (BMD₁₀) of 6.08 mg/kg/day and a lower bound of the 95 percent confidence interval on this benchmark dose (BMDL₁₀) of 4.50 mg/kg/day (USEPA, 2012). Because the Weisburger et al. (1978) study exposed experimental animals to *o*-toluidine HCl, the EPA converted the oral slope factor of 0.02 (mg/kg-day)⁻¹ *o*-toluidine HCl to account for the molecular weight difference of *o*-toluidine, resulting in a computed oral CSF of 0.016 (mg/kg-day)⁻¹ for 2-aminotoluene (USEPA, 2012). This oral CSF was used to derive an HRL for 2-aminotoluene under RD 5.

3.3.3.2 Exposure Factor Selection

In prioritizing the contaminants of greatest public health concern for regulatory determination, Section 1412(b)(1)(C) of the Safe Drinking Water Act (SDWA) requires the Agency to consider “among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water compared to the general population.” One way that the EPA considers potentially sensitive populations or life stages (i.e., populations or life stages that may be more susceptible or sensitive to a chemical exposure) is during the selection of exposure factors (EFs) for the development of HRLs.

Drinking water intake rate adjusted for body weight (DWI-BW) is the EF used to derive HRLs for RD 5 (USEPA, 2019). EFs are input values intended to protect the general population, including sensitive populations or life stages, from adverse effects resulting from exposure to a contaminant. The Agency selects an appropriate DWI-BW for each chemical by reviewing the critical effect and study used for HRL derivation and identifying the interval of exposure (for example, see USEPA, 2022b; USEPA, 2022c). Since the critical effect represents the most sensitive adverse effect observed in the best available studies for a given chemical, then it is reasonable to assume that the interval of exposure in the critical study could inform the selection of a DWI-BW protective of sensitive populations. When multiple potentially sensitive populations or life stages are identified based on the interval of exposure in the study used for HRL derivation, the EPA selects the population or life stage with the highest DWI-BW because it is the most health protective. See Section B.6.1.2 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA’s EF selection process.

In the critical study (Weisburger et al., 1978) selected in the 2012 EPA PPRTV Assessment (USEPA, 2012), rats and mice were exposed to 2-aminotoluene in their diets for 18 months, with exposure starting at six to eight weeks of age. Following the decision logic described in Section B.6.1.2 of the RD 5 Protocol, the EPA selected a corresponding human life stage. Six to eight week old rats are in the developmental stage approximately corresponding to a human life stage between juvenile or later childhood and adolescence (Ghasemi et al., 2021; Wang et al., 2020). For the purpose of evaluating environmental exposures, the EPA defines

childhood in humans as the period from conception through adolescence, until 21 years of age (USEPA, 2021). Therefore, the EPA used the DWI-BW representing the 90th percentile consumers-only, two-day average, direct and indirect community water consumption for children (birth to <21 years), which equals 0.0343 L/kg/day (USEPA, 2019), to derive the HRL for 2-aminotoluene.

3.3.3.3 HRL Calculation

Exhibit 3-8 summarizes the critical study and toxicity information from the qualifying health assessment and the EF (DWI-BW) that the EPA used to derive the HRL for 2-aminotoluene.

Exhibit 3-8: Basis of HRL for 2-Aminotoluene

Selected Health Assessment	Critical Study	Interval of Exposure	Critical Effect	Oral Cancer Slope Factor	Target Population	Exposure Factor
EPA Provisional Peer-Reviewed Toxicity Value (PPRTV) (USEPA, 2012)	Weisburger et al. (1978)	18 months; beginning at 6-8 weeks of age	Subcutaneous fibroma and fibrosarcoma in male rats	0.016 (mg/kg-day) ⁻¹	Children (birth to <21 years)	0.0343 L/kg/day

The EPA calculates HRLs for contaminants with a linear dose-response (typically carcinogens), including 2-aminotoluene, as follows:

$$HRL = \frac{CRL}{CSF * DWI-BW}$$

where:

CRL = Cancer risk level, one excess cancer case in a population of one million (1×10^{-6}).

CSF = Cancer slope factor (mg/kg/day)⁻¹, an upper-bound estimate of risk per increment of dose that can be used to estimate cancer risk probabilities for different exposure levels (USEPA, 2005).

DWI-BW = Drinking water intake (DWI), adjusted for body weight (BW), in units of liter per kilogram body weight per day (L/kg/day)

Using a one-in-a-million (10^{-6}) CRL, an oral CSF of 0.016 (mg/kg/day)⁻¹ (USEPA, 2012), and a DWI-BW of 0.0343 L/kg/day (USEPA, 2019), the HRL for 2-aminotoluene is calculated as follows:

$$HRL = \frac{1 \times 10^{-6}}{0.016 \text{ (mg/kg/day)}^{-1} * 0.0343 \text{ L/kg/day}}$$

$$HRL = 0.0018 \text{ mg/L}$$

or

$$HRL = 1.8 \text{ } \mu\text{g/L}$$

Following HRL derivation practices, the HRL for 2-aminotoluene is 2 µg/L after rounding to one significant figure.

3.4 Occurrence

This section presents data on the occurrence of 2-aminotoluene in ambient water and drinking water in the United States. As described in Section 3.3, an HRL of 2 µg/L was calculated for 2-aminotoluene based on carcinogenic effects. HRLs are risk-derived concentrations against which the EPA evaluates the occurrence data to determine if contaminants occur at levels of potential public health concern. Occurrence data from various sources presented below are analyzed with respect to the HRL and one-half the HRL. When possible, estimates of the population exposed at concentrations above the HRL and one-half the HRL are presented.

For additional background information about data sources used to evaluate occurrence, please refer to Chapter 2.

3.4.1 Occurrence in Ambient Water

Lakes, rivers, and aquifers are the ambient sources of most drinking water. Contaminant occurrence in ambient water provides information on the potential for contaminants to adversely affect drinking water supplies. Occurrence data for 2-aminotoluene in ambient water are available from the United States Geological Survey (USGS) National Water Information System (NWIS) database and the EPA's legacy Storage and Retrieval Data System (STORET). No data are available for this contaminant from the USGS National Water-Quality Assessment (NAWQA) program. When sources of information on ambient occurrence also include limited finished water data, those finished water data are summarized here as well.

3.4.1.1 National Water Information System (NWIS) Data

NWIS is the nation's principal repository of water resources data collected by USGS from more than 1.9 million sites in all U.S. states and territories (USGS, 2022). All USGS water quality and flow data are stored in NWIS, including site characteristics, streamflow, groundwater level, precipitation, and chemical analyses of water, sediment, and biological media, though not all parameters are available for every site. NWIS houses the NAWQA data and includes other USGS data from a range of unspecified projects. NWIS encompasses many more samples at many more sites than are involved in the NAWQA Program. Although NWIS is comprised of primarily ambient water data, some finished drinking water data are included as well. This section presents analyses of non-NAWQA data in NWIS, downloaded from the Water Quality Portal (WQP) in September 2023 (WQP, 2023).

The results of the non-NAWQA NWIS 2-aminotoluene analysis are presented in Exhibit 3-9. 2-Aminotoluene was not detected in any of the 145 samples collected at 67 sites.

Exhibit 3-9: 2-Aminotoluene NWIS Data, 1991-2023

Sample Media Type	Detection Frequency (detections are results $\geq$ reporting level)				Concentration Values (of detections, in $\mu\text{g/L}$)				
	No. of Samples	No. of Samples with Detections	No. of Sites	No. of Sites with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
Groundwater	116	0	46	0	--	--	--	--	--
Surface Water	29	0	21	0	--	--	--	--	--
Total	145	0	67	0	--	--	--	--	--

Source: WQP, 2023

"--" = No data or detections in this category

Note that some NWIS sites are associated with multiple sample media types, so site counts might not add up to totals.

3.4.1.2 Storage and Retrieval (STORET) Data

From its launch in 1999 until it was decommissioned in June 2018, the EPA's STORET Data Warehouse was collaboratively populated with raw biological, chemical, and physical data from surface water and groundwater sampling by federal, state and local agencies, Native American Tribes, volunteer groups, academics, and others. Legacy STORET data, as well as more current STORET data, are accessible through the WQP.

STORET data are from monitoring locations in all 50 states as well as multiple territories and jurisdictions of the United States. STORET's data quality limitations include variations in the extent of national coverage and data completeness from parameter to parameter. Data may have been collected as part of targeted, rather than randomized, monitoring. This section presents analyses of STORET data, downloaded from the WQP in September 2023 (WQP, 2023). The EPA reviewed STORET groundwater data from wells and springs and surface water data from lakes, rivers/streams, and reservoirs. The STORET data set also included limited data from public water systems (PWSs). The database does not specify whether PWS sampling was conducted before or after treatment.

The results of the STORET analysis for 2-aminotoluene are presented in Exhibit 3-10 through Exhibit 3-12. Samples were collected in 2021-2022. A total of 3 groundwater samples from 3 sites were tested for 2-aminotoluene. None had detections.

Exhibit 3-10: 2-Aminotoluene STORET Data – Summary of Detected Concentrations

Source Water Type	Concentration Value of Detections ($\mu\text{g/L}$)			
	Minimum	Median	90 th Percentile	Maximum
Groundwater	--	--	--	--
Surface water	--	--	--	--
Total	--	--	--	--

Source: WQP, 2023

"--" = No data or detections in this category

Exhibit 3-11: 2-Aminotoluene STORET Data – Summary of Samples and Sites

Source Water Type	Total Number of Samples	Samples with Detections		Total Number of Sites	Sites with Detections	
		Number	Percent		Number	Percent
Groundwater	3	0	0.00%	3	0	0.00%
Surface water	0	0	n/a	0	0	n/a
Total	3	0	0.00%	3	0	0.00%

Source: WQP, 2023

Exhibit 3-12: 2-Aminotoluene STORET Data – Summary of States

Source Water Type	Total Number of States	States with Detections	
		Number	Percent
Groundwater	1	0	0%
Surface water	0	0	n/a
Total¹	1	0	0%

Source: WQP, 2023

¹ The number of states with groundwater data plus the number of states with surface water data may not equal the “Total” number of states providing data because some states provided both groundwater and surface water data.

3.4.2 Occurrence in Drinking Water

Data sources reviewed by the EPA for information on contaminant occurrence in drinking water included: the EPA’s first, second, third, and fourth Unregulated Contaminant Monitoring Rules (UCMR 1, UCMR 2, UCMR 3, UCMR 4); Rounds 1 and 2 of the EPA’s Unregulated Contaminant Monitoring (UCM) program that preceded the Unregulated Contaminant Monitoring Rule (UCMR); the EPA’s National Inorganics and Radionuclides Survey (NIRS); and a range of others as discussed in Chapter 2. Among the sources reviewed, the following sources had data and information on 2-aminotoluene occurrence in drinking water and are discussed in this section:

- The EPA’s Fourth Unregulated Contaminant Monitoring Rule (UCMR 4).
- Consumer Confidence Reports (CCRs) from PWSs.

Note that there may be some overlap as sources with different purposes and audiences may have reported the same underlying data. UCMR 4 is a nationally representative data source. Other data sources profiled in this section are considered “supplemental” sources.

3.4.2.1 Primary Data Sources**3.4.2.1.1 The EPA’s Fourth Unregulated Contaminant Monitoring Rule (UCMR 4), 2018-2020**

The UCMR program was designed to provide a national assessment of the occurrence of select unregulated contaminants in PWSs. UCMR 4 was published on December 20, 2016

(USEPA, 2016) and required monitoring for 30 chemical contaminants between 2018 and 2020. Data reporting continued into 2021.

UCMR 4 Assessment Monitoring occurrence data are available for 2-aminotoluene. For UCMR 4, all large and very large community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) (serving between 10,001 and 100,000 people and serving more than 100,000 people, respectively), plus a statistically representative national sample of 800 small CWSs and NTNCWSs (serving 10,000 people or fewer), were required to conduct Assessment Monitoring during a 12-month period between January 2018 and December 2020.¹ Surface water and groundwater under the direct influence of surface water (GWUDI) sampling points were monitored four times during the applicable year of monitoring. Groundwater sampling points were monitored twice during the applicable year of monitoring. See USEPA (2016) and USEPA (2024) for more information on the UCMR 4 study design and data analysis.

The design of UCMR 4 permits estimation of national occurrence by multiplying the total number of systems (or population served) in the nation in a system size category by the percent of systems (or population served) found to exceed a specified threshold in the sample. This extrapolation methodology is applied to small systems. Because all large and very large systems were required to participate in the UCMR 4 Assessment Monitoring, national occurrence estimates in these size categories can be developed using survey census figures rather than extrapolation. Total national occurrence is estimated by summing the extrapolated figures for small systems and the census figures for the large and very large systems.

Exhibit 3-13 through Exhibit 3-17 provide an overview of 2-aminotoluene occurrence results from UCMR 4 Assessment Monitoring. The minimum reporting level (MRL) used for 2-aminotoluene in the UCMR 4 survey was 0.007 µg/L. Exhibit 3-13 shows a statistical summary of 2-aminotoluene concentrations by system size and source water type (including the minimum, median, 90th percentile, 99th percentile, and maximum). Exhibit 3-14 presents a sample-level summary of the results. Exhibit 3-15 through Exhibit 3-17 show system-level results, including national extrapolations, at three thresholds: detections, ½ the HRL, and the HRL. Detections are evaluated on a “greater than or equal to” basis ($\geq$ the MRL), while health-based thresholds are evaluated in terms of exceedances ($> \frac{1}{2}$ HRL and $>$ HRL).

As a reminder that the figures from large and very large systems represent a census of systems in those categories, results in those categories are labeled “CENSUS” in the exhibits below. No extrapolation was necessary in these categories, as it was for the small systems, to derive national estimates of occurrence. National estimates of occurrence are reported separately in each system size and source water category, and also in the aggregate.

A total of 37,517 UCMR 4 samples for 2-aminotoluene were collected from 5,030 systems. 2-Aminotoluene was detected in 117 samples (0.31 percent), with concentrations ranging from 0.007 µg/L to 0.38 µg/L. The detections were found at 86 systems, representing 1.71 percent of systems participating in the monitoring program. Extrapolating these findings suggests that an estimated 292 PWSs serving 11,500,000 people nationally have detectable levels of 2-aminotoluene. There were no exceedances of the HRL or ½ the HRL.

¹ Only 798 small systems submitted results for 2-aminotoluene.

Exhibit 3-13: 2-Aminotoluene Occurrence Data from UCMR 4 Assessment Monitoring – Summary of Reported Concentrations

Source Water Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90th Percentile	99th Percentile	Maximum
Small Systems (serving ≤ 10,000 people)					
Groundwater	0.0074	0.0102	0.0124	0.0129	0.013
Surface Water	--	--	--	--	--
All Small Systems	0.0074	0.0102	0.0124	0.0129	0.013
Large Systems (serving 10,001 - 100,000 people) -- CENSUS					
Groundwater	0.0072	0.0149	0.0655	0.127	0.13
Surface Water	0.007	0.0140	0.0388	0.123	0.15
All Large Systems	0.007	0.0140	0.0586	0.133	0.15
Very Large Systems (serving > 100,000 people) -- CENSUS					
Groundwater	0.0173	0.0310	0.0512	0.056	0.0562
Surface Water	0.007	0.0090	0.0260	0.294	0.38
All Very Large Systems	0.007	0.0093	0.0310	0.285	0.38
All Systems					
All Water Systems	0.007	0.0111	0.0459	0.147	0.38

Source: USEPA, 2024

Exhibit 3-14: 2-Aminotoluene National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of Samples

Source Water Type	Total # of Samples	Samples with Detections ≥ MRL (0.007 µg/L)		Samples with Detections > ½ HRL (1 µg/L)		Samples with Detections > HRL (2 µg/L)	
		Number	Percent	Number	Percent	Number	Percent
Small Systems (serving ≤ 10,000 people)							
Groundwater	1,908	2	0.10%	0	0.00%	0	0.00%
Surface Water	1,354	0	0.00%	0	0.00%	0	0.00%
All Small Systems	3,262	2	0.06%	0	0.00%	0	0.00%
Large Systems (serving 10,001 - 100,000 people) -- CENSUS							
Groundwater	11,028	32	0.29%	0	0.00%	0	0.00%
Surface Water	15,802	52	0.33%	0	0.00%	0	0.00%
All Large Systems	26,830	84	0.31%	0	0.00%	0	0.00%
Very Large Systems (serving > 100,000 people) -- CENSUS							
Groundwater	2,062	3	0.15%	0	0.00%	0	0.00%
Surface Water	5,363	28	0.52%	0	0.00%	0	0.00%
All Very Large Systems	7,425	31	0.42%	0	0.00%	0	0.00%
All Systems							
All Water Systems	37,517	117	0.31%	0	0.00%	0	0.00%

Source: USEPA, 2024

Exhibit 3-15: 2-Aminotoluene National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population – All Reported Detections

Source Water Type	UCMR 4 Sample		Number With At Least One Detection $\geq$ MRL (0.007 $\mu\text{g/L}$)		Percent With At Least One Detection $\geq$ MRL (0.007 $\mu\text{g/L}$)		National Inventory ¹		National Estimate of Number With At Least One Detection $\geq$ MRL (0.007 $\mu\text{g/L}$) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving $\leq 10,000$ people)										
Groundwater	519	1,540,915	2	2,460	0.39%	0.16%	53,877	38,056,639	208	60,800
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	798	2,851,285	2	2,460	0.25%	0.09%	63,501	60,915,707	208	60,800
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,469	37,632,837	23	745,054	1.57%	1.98%	1,469	37,632,837	23	745,000
Surface Water	2,340	71,511,793	48	1,394,353	2.05%	1.95%	2,340	71,511,793	48	1,390,000
All Large Systems	3,809	109,144,630	71	2,139,407	1.86%	1.96%	3,809	109,144,630	71	2,140,000
Very Large Systems (serving $> 100,000$ people) -- CENSUS										
Groundwater	69	16,759,675	2	825,686	2.90%	4.93%	69	16,759,675	2	826,000
Surface Water	354	120,303,825	11	8,512,284	3.11%	7.08%	354	120,303,825	11	8,510,000
All Very Large Systems	423	137,063,500	13	9,337,970	3.07%	6.81%	423	137,063,500	13	9,340,000
All Systems										
All Water Systems	5,030	249,059,415	86	11,479,837	1.71%	4.61%	67,733	307,123,837	292	11,500,000

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

**Exhibit 3-16: 2-Aminotoluene National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data
– Summary of System and Population Served Data – Detections > ½ the HRL (1 µg/L)**

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > ½ HRL (1 µg/L)		Percent With At Least One Detection > ½ HRL (1 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > ½ HRL (1 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	519	1,540,915	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	798	2,851,285	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,469	37,632,837	0	0	0.00%	0.00%	1,469	37,632,837	0	0
Surface Water	2,340	71,511,793	0	0	0.00%	0.00%	2,340	71,511,793	0	0
All Large Systems	3,809	109,144,630	0	0	0.00%	0.00%	3,809	109,144,630	0	0
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,030	249,059,415	0	0	0.00%	0.00%	67,733	307,123,837	0	0

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

**Exhibit 3-17: 2-Aminotoluene National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data
– Summary of System and Population Served Data – Detections > HRL (2 µg/L)**

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > HRL (2 µg/L)		Percent With At Least One Detection > HRL (2 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > HRL (2 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	519	1,540,915	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	798	2,851,285	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,469	37,632,837	0	0	0.00%	0.00%	1,469	37,632,837	0	0
Surface Water	2,340	71,511,793	0	0	0.00%	0.00%	2,340	71,511,793	0	0
All Large Systems	3,809	109,144,630	0	0	0.00%	0.00%	3,809	109,144,630	0	0
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,030	249,059,415	0	0	0.00%	0.00%	67,733	307,123,837	0	0

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

3.4.2.2 Supplemental Data Sources

3.4.2.2.1 *Water Systems' Consumer Confidence Reports (CCRs), 2018-2021*

CCRs are annual water quality reports that CWSs are required to provide to their customers. These reports summarize information on water sources, detected contaminants, and system compliance with the EPA drinking water standards; they may also include general educational material. Under the CCR Rule (40 CFR Subpart O), CWSs with 15 or more connections or serving at least 25 year-round residents must prepare and distribute a CCR to all billing units or service connections every year. Systems serving 100,000 or more residents are also required to post their current CCRs on a publicly accessible Internet site.

The EPA reviewed CCRs published by the 25 systems that serve over one million customers (as identified in Safe Drinking Water Information System / Federal version, or SDWIS/Fed, from the fourth quarter 2021 data) for unregulated contaminant occurrence information for the years 2018 through 2021. Data on 2-aminotoluene were available from CCRs prepared by eight CWSs: one system in California (Los Angeles), one system in Colorado (Denver), one system in Massachusetts (Massachusetts Water Resources Authority), two systems in New York (Suffolk County and New York City), one system in Pennsylvania (Philadelphia), one system in Ohio (Columbus), and one system in Texas (Houston). Monitoring results from three of eight systems showed detections of 2-aminotoluene.

Los Angeles Department of Water & Power (LADWP) included data on 2-aminotoluene monitoring for UCMR 4 in its 2020 and 2021 CCRs. LADWP is served by multiple surface water and groundwater sources. The sampling was conducted in 2018-2019. 2-aminotoluene was not detected.

Denver Water included data on 2-aminotoluene monitoring for UCMR 4 in its 2019 and 2020 CCRs. Denver Water is served by the South Platte River and other surface water sources. In 2019, an average 2-aminotoluene concentration of “0 µg/L” was reported for treatment plant effluent. The 2020 CCR reported an average concentration of “BRL ppb” (i.e., below reporting level).

The Town of Wellesley, Massachusetts, a community served by the Massachusetts Water Resource Authority (MWRA), included data for 2-aminotoluene in its 2020 CCR. The MWRA is a regional utility that uses surface water supplies in central Massachusetts at the Quabbin and Wachusett Reservoirs and the Ware River. In 2020, 2-aminotoluene was found in an unspecified number of samples from ND (no detection) to 0.02 ppb, with an average level detected of 0.02 ppb.

Suffolk County, New York included data on 2-aminotoluene in its 2018-2021 CCRs. Suffolk County is served by groundwater from four major aquifers beneath Long Island. In all 4 years, 2-aminotoluene was monitored for but was not detected.

New York City included data on 2-aminotoluene in its 2018 and 2019 CCRs. New York City is served by a large system of surface water networks in New York state. In both years, 2-aminotoluene was monitored for but was not detected.

The Philadelphia Water Department (PWD) included data on 2-aminotoluene in three CCRs covering 2019 through 2021. PWD is served by surface water from the Schuylkill and Delaware rivers. In all 3 years, 2-aminotoluene was monitored for but was not detected.

The City of Columbus, Ohio included data on 2-aminotoluene in its 2020 CCR. The City of Columbus water system uses surface water from the Scioto River and Big Walnut Creek, as well as groundwater sources. In 2020, data was reported from source water; the number of samples was not reported. Concentrations of 2-aminotoluene ranged from 0.0028 ppb to 0.0092 ppb.

Houston Water included data on 2-aminotoluene in CCRs covering 2019 through 2021. The CCRs from all three years reported data relative to the secondary drinking water standard. In addition, the CCRs reported data from monitoring conducted as part of the UCMR 4 program. Houston Water is served by two groundwater sources, the Evangeline and Chicot Aquifers, and two surface water sources, the San Jacinto River (with Lake Conroe & Lake Houston), and the Trinity River (with Lake Livingston). The 2019 and 2020 CCRs reported a range of 2-aminotoluene concentrations of ND to 0.011 ppb. The 2021 CCR reported a range of 2-aminotoluene concentrations of ND to 0.01 ppb.

3.4.3 Other Data

The Centers for Disease Control and Prevention (CDC) National Report on Human Exposure to Environmental Chemicals

The Centers for Disease Control and Prevention's (CDC) *National Report on Human Exposure to Environmental Chemicals* (CDC, 2022) includes data on urine concentrations (pg/mL) in smokers and non-smokers for 2-aminotoluene for the years 2013-2014. Results are presented in Exhibit 3-18. The 95th percentiles for the total of all age groups (not creatinine-corrected) were 1,960 pg/mL and 1,560 pg/mL for 2013-2014 smokers and 2013-2014 non-smokers, respectively. The 95th percentiles for the total of all age groups (creatinine-corrected) were 1,330 ng/g_{creatinine} and 1,240 ng/g_{creatinine} for 2013-2014 smokers and 2013-2014 non-smokers respectively. The limit of detection (LOD) for 2-aminotoluene (not creatinine-corrected) was 111 pg/mL for 2011-2012. (The LOD does not apply to creatinine-corrected values.) These 95th percentile values cannot be compared to the HRL because the values represent urine concentrations, not water concentrations.

Exhibit 3-18: 95th Percentile of Urine 2-Aminotoluene Concentrations, 2013-2014

Year Range	Medium Analyzed	95 th Percentile of All Samples (not creatinine-corrected), in units of pg/mL	Sample Size (not creatinine-corrected)	95 th Percentile of All Samples (creatinine-corrected), in units of ng/g _{creatinine}	Sample Size (creatinine-corrected)
2013-2014	Urine in Smokers	1,960	359	1,330	359
2013-2014	Urine in Non-Smokers	1,560	1,794	1,240	1,794

Source: CDC, 2022

3.5 Analytical Methods

The EPA has published one analytical method that is available for the analysis of 2-aminotoluene in drinking water.

- EPA Method 530, Version 1.0, *Determination of Semivolatile Organic Chemicals in Drinking Water by Solid Phase Extraction and Gas Chromatography/Mass Spectrometry (GC/MS)* has a Detection Limit (DL) of 0.007 µg/L in Full Scan mode and a DL of 0.001 µg/L in Selected Ion Monitoring (SIM) mode. The Lowest Concentration Minimum Reporting Level (LCMRL) generated by the laboratories that helped to develop the method is 0.011 µg/L in Full Scan mode and 0.003 µg/L in SIM mode. Mean recoveries in reagent water, finished water from groundwater with a hardness of 376 mg/L (as calcium carbonate) and finished drinking water from surface water with total organic carbon (TOC) of 2.0 mg/L range from 71.3 to 101.0 percent, with relative standard deviations (RSDs) of 1.3 to 24.0 percent for Full Scan mode. Mean recoveries in reagent water, finished water from groundwater with a hardness of 359 mg/L (as calcium carbonate) and finished drinking water from surface water with TOC of 5.7 mg/L range from 71.8 to 101.0 percent, with RSDs of 2.1 to 22.0 percent for SIM mode (USEPA, 2015).

Laboratories participating in UCMR 4 were required to use EPA Method 530 and were required to report 2-aminotoluene values at or above the EPA-defined MRL of 0.007 µg/L (81 FR 92666; USEPA, 2016). The MRL was set based on the capability of multiple laboratories at the time.

3.6 Treatment Technologies

The EPA evaluates whether suitable treatment technologies are available prior to promulgating a final National Primary Drinking Water Regulation (NPDWR). The preliminary summary of treatment technology availability presented here represents the results of a January 2024 literature search.

Oaikhena et al. (2023) found custom-fabricated ceramic filters to be effective as point-of-use devices for removing organic pollutants and pathogens from water. The authors consider the ceramic filters an affordable technology that could be used to provide safe drinking water in low-income countries. The filters achieved removal rates of 79.95-92.71 percent for 2-aminotoluene.

No other studies were found on treatment of 2-aminotoluene in drinking water. Several studies were found on technologies for removing 2-aminotoluene from industrial water or other aqueous media. Shokri and Mahanpoor (2017) found titanium-dioxide-catalyzed ozonation effective at degrading 2-aminotoluene in petrochemical wastewater. Wu et al. (2019) found that micellar enhanced ultrafiltration was effective for removing 2-aminotoluene from aqueous media. Garcia-Segura et al. (2017) found that electro-assisted photo-Fenton technology was effective at mineralizing recalcitrant and non-biodegradable solutions of 2-aminotoluene or preparing them for biological treatment.

3.7 References

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Chapter 4: Cyindrospermopsin

A chapter from:

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Abbreviations

ADD	Acceptable Daily Dose
AWWA	American Water Works Association
BW	Body Weight
CASRN	Chemical Abstracts Service Registry Number
CCL 5	Fifth Contaminant Candidate List
CCR	Consumer Confidence Report
CDC	Centers for Disease Control and Prevention
CDR	Chemical Data Reporting
CWS	Community Water System
DMSO	Dimethylsulfoxide
DWI	Drinking Water Intake
DWI-BW	Drinking Water Intake Adjusted for Body Weight
EF	Exposure Factor
EPA	U.S. Environmental Protection Agency
GWUDI	Groundwater Under the Influence of Surface Water
HAB	Harmful Algal Bloom
HABISS	Harmful Algal Bloom-Related Illness Surveillance System
HRL	Health Reference Level
IUR	Inventory Update Reporting
K _H	Henry's Law Constant
K _{oc}	Organic Carbon Partitioning Coefficient
K _{ow}	Octanol/Water Partitioning Coefficient
LCMRL	Lowest Concentration Minimum Reporting Level
LOAEL	Lowest-Observed-Adverse-Effect Level
MAC	Maximum Acceptable Concentration
MRL	Minimum Reporting Level
NAWQA	National Water-Quality Assessment
NIRS	National Inorganics and Radionuclides Survey
NOAEL	No-Observed-Adverse-Effect Level
NORS	National Outbreak Reporting System
NPDWR	National Primary Drinking Water Rule
NTNCWS	Non-Transient Non-Community Water System
NWIS	National Water Information System
OGWDW	Office of Ground Water and Drinking Water
OHA	Oregon Health Authority
OHHABS	One Health Harmful Algal Bloom System
OW	Office of Water
PAC	Powder Activated Carbon
PAD	Population-Adjusted Dose
pK _a	Acid Dissociation Constant
POD	Point of Departure
POD/UF	Point of Departure / Uncertainty Factor
PWS	Public Water System
RD 5	Fifth Regulatory Determination
RfD	Reference Dose
RSC	Relative Source Contribution

SDWA	Safe Drinking Water Act
SDWIS/Fed	Safe Drinking Water Information System / Federal Version
STORET	Storage and Retrieval Data System
TDI	Tolerable Daily Intake
TOC	Total Organic Carbon
TRI	Toxics Release Inventory
UCM	Unregulated Contaminant Monitoring
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 1	First Unregulated Contaminant Monitoring Rule
UCMR 2	Second Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 4	Fourth Unregulated Contaminant Monitoring Rule
UF	Uncertainty Factor
UF _A	Interspecies Uncertainty Factor
UF _D	Database Uncertainty Factor
UF _H	Intraspecies Uncertainty Factor
USGS	United States Geological Survey
UV	Ultraviolet
WBDOS	Waterborne Disease and Outbreak Surveillance System
WHO	World Health Organization
WQP	Water Quality Portal

Chapter 4: Cylindrospermopsin

The U.S. Environmental Protection Agency (EPA) is evaluating cylindrospermopsin, a contaminant on the fifth Contaminant Candidate List (CCL 5), as a candidate for regulation under the fifth Regulatory Determination process (RD 5). Information on the CCL 5 process is found in Chapter 1. Background on data sources used to evaluate CCL 5 chemicals is found in Chapter 2.

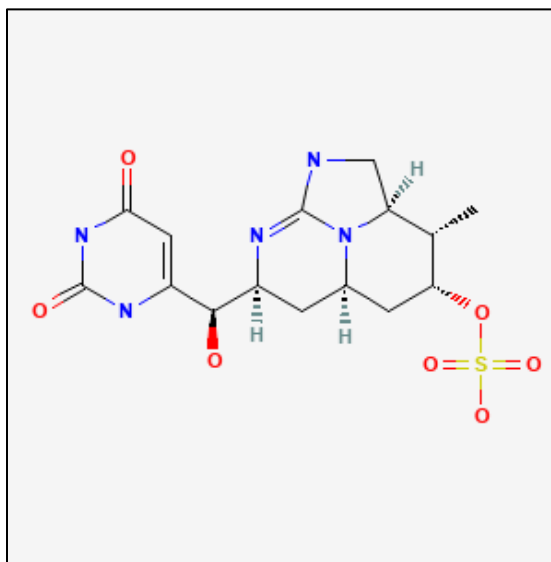
This chapter presents information and analysis specific to cylindrospermopsin, including background information on the contaminant, information on contaminant sources and environmental fate, an analysis of health effects, an analysis of occurrence in ambient and drinking water, and information about the availability of analytical methods and treatment technologies.

4.1 Contaminant Background and Chemical and Physical Properties

Cylindrospermopsin is a toxin naturally produced and released by cyanobacteria. Cyanobacteria, sometimes referred to as blue-green algae, are photosynthetic bacteria that are nearly ubiquitous in freshwater and marine environments. Harmful algal blooms (HABs) of cyanobacteria in freshwater environments can release quantities of cyanotoxins, including cylindrospermopsin.

Cylindrospermopsin is a tricyclic alkaloid (USEPA, 2015a). Exhibit 4-1 shows the chemical structure of cylindrospermopsin.

Exhibit 4-1: Chemical Structure of Cylindrospermopsin



Source: NCBI, 2022

Physical and chemical properties and other reference information for cylindrospermopsin are reported in Exhibit 4-2.

Exhibit 4-2: Chemical and Physical Properties of *Cylindrospermopsin*

Property	Data
Chemical Abstracts Service Registry Number (CASRN)	143545-90-8
Chemical Formula	C ₁₅ H ₂₁ N ₅ O ₇ S
Molecular Weight	415.43 g/mole (Chemical Book, 2012; Toxline, 2012; both as cited in USEPA, 2015a)
Color/Physical State	White powder (WHO, 2020)
Boiling Point	--
Melting Point	--
Density	2.03 g/cm ³ (Chemical Book, 2012; Toxline, 2012; both as cited in USEPA, 2015a)
Freundlich Absorption Coefficient	--
Vapor Pressure at 25°C	--
Henry's Law Constant (K _H)	--
Octanol/Water Partitioning Coefficient (log K _{ow})	-2.6 ¹ (est) (WHO, 2020)
Organic Carbon Partitioning Coefficient (K _{oc})	--
Acid Dissociation Constant (pK _a)	--
Solubility in Water	High (WHO, 2020)
Other Solvents	Dimethylsulfoxide (DMSO) and methanol (Chemical Book, 2012; Toxline, 2012; both as cited in USEPA, 2015a)

¹ K_{ow} predicted based upon XLOGP3 (Cheng et al., 2007 as cited in WHO, 2020).

Note: "--" indicates that no information was found.

Note: Many of these properties are temperature-dependent. Values are given for properties at 20-25°C unless otherwise noted. Due to varying experimental conditions, and due to the variabilities associated with modeling, standard information sources may provide a range of values. Where more than one value was available from these sources, one value was selected for this table based on best professional judgment.

4.2 Sources and Environmental Fate

Because cylindrospermopsin is naturally produced in the environment and not industrially produced, no data are available on production of cylindrospermopsin from the EPA's Inventory Update Reporting (IUR) and Chemical Data Reporting (CDR) programs, and no data are available on industrial releases of cylindrospermopsin from the EPA's Toxics Release Inventory (TRI).

4.2.1 Natural Sources

The following cyanobacteria genera are known to include cylindrospermopsin-producing species: *Aphanizomenon*, *Dolichospermum* (previously *Anabaena*), *Lyngbya*, *Raphidiopsis* (previously *Cylindrosperopsis*), and *Umezakia* (USEPA, 2022a). Cylindrospermopsin-producing cyanobacteria tend to thrive beneath the water surface and do not necessarily form visible surface scums (Falconer, 2005 as cited in USEPA, 2015a; WHO, 2020).

In contrast to other cyanotoxins such as anatoxin-a and microcystins, cylindrospermopsin may readily leach or be released from intact cyanobacterial cells into surrounding water. Field studies have found that between 24 percent and 99 percent or even up to 100 percent of cylindrospermopsin can be extracellular (Chorus and Welker, 2021).

Cyanotoxin production is influenced by environmental conditions that favor the growth of particular cyanobacterial species and strains. Factors that affect cyanobacterial growth, cyanobacteria population dynamics, and the development of blooms include nutrient concentrations, light intensity, water turbidity, temperature, competing bacteria and phytoplankton, pH, and turbulence (mixing). The concentrations of cyanotoxins released from a bloom will depend on the composition of the bloom and environmental and ecosystem influences on bloom dynamics (USEPA, 2015b).

4.2.2 Environmental Fate

As noted above, cylindrospermopsin is highly soluble in water (WHO, 2020). Its ability to partition from water to sediments is affected by the type of sediment, with some adsorption to organic carbon sediments and little adsorption to sandy and silt sediments. Cylindrospermopsin is less susceptible to sorption than anatoxin-a (Klitzke et al., 2011).

In the presence of certain algal cell pigments, photochemical degradation of cylindrospermopsin can occur rapidly. Chiswell et al. (1999) reports half-lives as short as 1.5 hours using direct sunlight and algal extract solutions in the laboratory. Without the algal cell pigments, cylindrospermopsin tends to be relatively stable in sunlight. Chiswell et al. (1999) report half-lives of 11 to 15 days for cylindrospermopsin exposed to natural sunlight in natural water samples not fortified with algal extract, and practically no degradation over 120 hours in sterile water with no algal extract. Cylindrospermopsin is also relatively stable in the dark on timescales of weeks at a wide range of temperatures and pH values, and boiling for 15 minutes does not substantially degrade cylindrospermopsin (Chiswell et al 1999).

Cylindrospermopsin is also subject to biodegradation in environmental waters. Tests using *Bacillus* bacteria isolated from cyanobacterial blooms indicate that biodegradation of cylindrospermopsin is fastest at temperatures in the range of 25 and 30 degrees C and at pH in the range of 7 and 8 (Mohamed and Alamri, 2012). Klitzke and Fastner (2012) confirm that temperature is an important factor, finding that when temperature was reduced from 20 degrees C to 10 degrees C (a temperature typical of aquifers), the biodegradation rate slowed down by a factor of ten. Klitzke and Fastner (2012) also found that biodegradation slowed significantly under anoxic conditions. The initial concentration of cylindrospermopsin is also a factor in the biodegradation rate, with faster degradation at higher initial toxin concentrations and almost no degradation at initial concentrations below 1 µg/L (Chorus and Welker, 2021). Cylindrospermopsin biodegradation often has an initial lag phase, during which time there is little loss of cylindrospermopsin, that can last from 1 to 3 weeks (Chorus and Welker, 2021).

Bioaccumulation of cylindrospermopsin in freshwater organisms has been documented. There is considerable variability in accumulation rates between and within species, but in general lower-level organisms appear to accumulate greater concentrations of cylindrospermopsin than do animals at higher trophic levels (Kinnear, 2010).

4.3 Health Effects

4.3.1 Health Assessment Identification

In order to identify qualifying health assessments for cylindrospermopsin, the EPA conducted a systematic web-based search of the EPA and other authoritative sources, as described in Section B.5.1.1 of the RD 5 Protocol, found in Appendix B of this document.

Exhibit 4-3 provides a summary overview of qualifying health assessments for cylindrospermopsin (i.e., health assessments from qualifying sources that provide a toxicity value relevant to chronic oral toxicity) that were published prior to the search cutoff date of January 2023. An assessment can present a noncancer oral toxicity value, a cancer oral toxicity value, or both. Information about the health assessment selected for cylindrospermopsin under RD 5 is bolded and italicized in Exhibit 4-3.

Exhibit 4-3: Qualifying Health Assessments Identified for Cylindrospermopsin

Health Assessment ^a	Oral Reference Value ^b	POD Type	Noncancer Critical Study	Oral Cancer Slope Factor ^c	Cancer Critical Study	Cancer Descriptor
<i>EPA Office of Water (OW) Health Effects Support Document (USEPA, 2015b)</i>	<i>0.0001^d</i>	<i>NOAEL</i>	<i>Humpage and Falconer (2002; 2003)</i>	–	–	<i>1^e</i>
World Health Organization (WHO) Provisional Guidelines for Drinking Water Quality (WHO, 2020)	0.00003	NOAEL	Humpage and Falconer (2002; 2003)	–	–	–

Notes: POD = point of departure; NOAEL = no-observed-adverse-effect level; dash (–) = not applicable.

^a Selected health assessment and chronic toxicity value and supporting information are bolded and italicized.

^b Oral reference values are expressed in mg/kg/day unless otherwise specified; “oral reference value” can refer to the acceptable daily dose (ADD), maximum acceptable concentration (MAC), minimal risk level, point of departure / uncertainty factor (POD/UF), population-adjusted dose (PAD), reference dose (RfD), or tolerable daily intake (TDI).

^c Cancer slope factors are expressed in (mg/kg/day)⁻¹ unless otherwise specified.

^d This oral reference dose is an RfD based on increased relative kidney weight in mice (USEPA, 2015b).

^e This “Inadequate information to assess carcinogenic potential” classification was determined by following the process described in the EPA’s 2005 *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005).

4.3.2 Health Assessment Selection

The health assessment selected for cylindrospermopsin under RD 5 is the 2015 EPA Office of Water (OW) Health Effects Support Document (USEPA, 2015b). This is an EPA health assessment that derives an oral toxicity value and uses the best available science in its evaluation of noncancer risk for cylindrospermopsin. Although the World Health Organization (WHO) Provisional Guidelines for Drinking Water Quality (WHO, 2020) is a more recent health assessment, it derived a toxicity value based on the same critical study as the EPA health assessment, namely Humpage and Falconer (2002; 2003). See Section B.5.1.2 of the RD 5 Protocol, in Appendix B of this document, for the decision logic that was applied to health assessment selection for RD 5 chemicals.

4.3.3 Health Reference Level (HRL) Development

Health reference levels (HRLs) are non-regulatory health-based toxicity values, expressed as concentrations in drinking water, that are used by the Agency to evaluate occurrence data for a contaminant when making decisions about regulatory determinations. See Section B.6.1.1 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA’s approach for deriving HRLs for chemicals. The input values used to derive the HRL for cylindrospermopsin are described below.

4.3.3.1 Oral Reference Value

In the 2015 EPA OW Health Effects Support Document, the EPA selected a subchronic oral toxicity study in mice (Humpage and Falconer, 2002; 2003) as the critical study to derive a point of departure (POD) for the oral reference value. In this study, doses of 0, 30, 60, 120, and 240 µg/kg/day of purified cylindrospermopsin in water were administered by gavage to groups of male Swiss albino mice (10 mice per dose for all but the highest dose group, which included 6 mice) for 11 weeks (Humpage and Falconer, 2002, 2003). The study does not report how old the mice were at the onset of exposure; however, it does report that mice weighed 20 to 25 grams at the beginning of the experiment (Humpage and Falconer, 2002; 2003). Clinical examinations of physiological and behavioral signs of toxicity were conducted at or near the end of the treatment period, including hematology evaluations (4 to 5 per dose group, except the high dose), serum chemistry evaluations (4 to 6 per dose group), urinalysis (6 or 10 per dose group) and histological evaluations. Liver, spleen, kidneys, adrenal glands, heart, testis, epididymis, and brain organ weights were also recorded postmortem (Humpage and Falconer, 2002; 2003).

Water intake was significantly reduced in all dose groups relative to control. The most sensitive effects observed by Humpage and Falconer (2002, 2003) were dose-related decreases in urinary protein/creatinine ratios (g/mmol creatinine), which at 120 and 240 µg/kg/day were significantly lower than the ratio in control group (51 percent and 37 percent of controls, respectively; both $p < 0.001$), and increased relative kidney weight at doses ≥ 60 µg/kg/day (12-23% greater than controls). Postmortem tissue examinations showed histopathological damage to the liver at doses ≥ 120 µg/kg/day, based on scores assigned for necrosis, inflammatory foci, and bile duct changes. The percentage of animals with liver lesions in the 120 and 240 µg/kg/day dose groups was 60% and 90%, compared to 10%, 10%, and 20% of animals in the 0, 30 and 60 µg/kg/day dose groups, respectively. Proximal renal tubular damage in kidney sections from two mice were found in the 240 µg/kg/day dose group. Based on the dose-related and statistically significant increase in relative kidney weight, a no-observed-adverse-effect level (NOAEL) and lowest-observed-adverse-effect level (LOAEL) of 30 and 60 µg/kg/day, respectively, were identified.

The NOAEL of 30 µg/kg/day for increased relative kidney weight in mice orally exposed to cylindrospermopsin (Humpage and Falconer, 2002; 2003) was the critical effect selected to derive an oral reference value in the 2015 EPA OW Health Effects Support Document because this was the most sensitive endpoint assessed in the critical study (USEPA, 2015b). A total uncertainty factor (UF) of 300 was applied to the POD: an intraspecies UF (UF_H) of 10, an interspecies UF (UF_A) of 10, and a database UF (UF_D) of 3. After applying the total UF, the oral reference value (a reference dose, or RfD) was calculated to be 0.0001 mg/kg/day (USEPA, 2015b). The EPA selected this oral reference value (0.0001 mg/kg/day) from the EPA OW Health Effects Support Document (USEPA, 2015b) to derive an HRL for cylindrospermopsin under RD 5.

4.3.3.2 Exposure Factor Selection

In prioritizing the contaminants of greatest public health concern for regulatory determination, Section 1412(b)(1)(C) of the Safe Drinking Water Act (SDWA) requires the Agency to consider “among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to

exposure to contaminants in drinking water compared to the general population.” One way that the EPA considers potentially sensitive populations or life stages (i.e., populations or life stages that may be more susceptible or sensitive to a chemical exposure) is during the selection of exposure factors (EFs) for the development of HRLs.

Drinking water intake rate adjusted for body weight (DWI-BW) is the EF used to derive HRLs for RD 5 (USEPA, 2019). EFs are input values intended to protect the general population, including sensitive populations or life stages, from adverse effects resulting from exposure to a contaminant. The Agency selects an appropriate DWI-BW for each chemical by reviewing the critical effect and study used for HRL derivation and identifying the interval of exposure (for example, see USEPA, 2022b; USEPA, 2022c). Since the critical effect represents the most sensitive adverse effect observed in the best available studies for a given chemical, it is reasonable to assume that the interval of exposure in the critical study could inform the selection of a DWI-BW protective of sensitive populations. When multiple potentially sensitive populations or life stages are identified based on the interval of exposure in the study used for HRL derivation, the EPA selects the population or life stage with the highest DWI-BW because it is the most health protective. See Section B.6.1.2 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA’s EF selection process.

The critical study (Humpage and Falconer, 2002; 2003) selected in the 2015 EPA OW Health Effects Support Document for cylindrospermopsin (USEPA, 2015b) measured toxicity in mice orally exposed to cylindrospermopsin in drinking water for 11 weeks. The study does not report how old the mice were at the onset of exposure; however, it does report that mice weighed 20 to 25 grams at the beginning of the experiment (Humpage and Falconer, 2002; 2003). Following the decision logic described in Section B.6.1.2 of the RD 5 Protocol, the EPA extrapolated weight to age based on conversion charts published for mice and selected the appropriate EF based on the estimated age when exposure began. The weight range reported by Humpage and Falconer (2002; 2003) at the beginning of the experiment is approximately equivalent to six to eight weeks of age in mice (Jackson Labs, 2023). Rodents at six to eight weeks of age are in the developmental stage between childhood and adolescence (Ghasemi et al., 2021; Wang et al., 2020). The EPA defines childhood in humans as the period from conception through adolescence, until 21 years of age (USEPA, 2021). Therefore, the EPA used the DWI-BW representing the 90th percentile consumers-only, two-day average, direct and indirect community water consumption for children (birth to < 21 years), which equals 0.0343 L/kg/day (USEPA, 2019), to derive the HRL for cylindrospermopsin.

4.3.3.3 Relative Source Contribution

Relative source contribution (RSC) is used to account for exposure via non-drinking water routes when deriving health-based drinking water concentrations for contaminants with threshold effects (noncarcinogens and nonlinear carcinogens). RSC is defined as the portion (percentage) of an individual’s exposure attributed to drinking water rather than other sources (e.g., food, ambient air). A 20 percent RSC is used for all RD 5 contaminants, consistent with past practice for regulatory determinations, to derive the HRL because (1) HRLs are developed prior to completing the exposure assessment; and (2) a 20 percent RSC is the lowest RSC that can be applied for deriving health-based drinking water concentrations according to EPA guidance (USEPA, 2000), and it therefore produces the most health protective HRL. Should a contaminant proceed to a National Primary Drinking Water Regulation (NPDWR), a full exposure analysis is conducted, and an RSC is derived following the Exposure Decision Tree

approach described in the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000).

4.3.3.4 HRL Calculation

Exhibit 4-4 summarizes the critical study and toxicity information from the qualifying health assessment and the EF (DWI-BW) and RSC that the EPA used to derive the HRL for cylindrospermopsin.

Exhibit 4-4: Basis of HRL for Cylindrospermopsin

Selected Health Assessment	Critical Study	Interval of Exposure	Critical Effect	Oral Toxicity Value	RSC	Target Population	Exposure Factor
EPA OW Health Effects Support Document (USEPA, 2015b)	Humpage and Falconer, (2002; 2003)	11 weeks; beginning at approx. 6-8 weeks of age	Increased relative kidney weight in mice	0.0001 mg/kg/day	0.2 (20%)	Children (birth to < 21 years)	0.0343 L/kg/day

The EPA calculates HRLs for contaminants with a threshold dose-response, including cylindrospermopsin, as follows:

$$HRL = \frac{RfD}{DWI-BW} * RSC$$

where:

RfD = Reference dose (mg/kg/day), an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. It is derived in the selected qualifying health assessment and is based on the critical effect and study identified in that assessment. Other values that can be used in place of an RfD in this equation can include a maximum acceptable concentration (MAC), minimal risk level, point of departure / uncertainty factor (POD/UF), population-adjusted dose (PAD), or tolerable daily intake (TDI).

DWI-BW = Drinking water intake (DWI), adjusted for body weight (BW), in units of liter per kilogram body weight per day (L/kg/day).

RSC = Relative source contribution, the percentage of the total exposure attributed to drinking water sources (USEPA, 2000), where the remainder of the exposure is allocated to other routes or sources. For HRL derivation in RD 5, an RSC of 20 percent is used for all contaminants.

Using an oral RfD of 0.0001 mg/kg/day (USEPA, 2015b), a DWI-BW of 0.0343 L/kg/day (USEPA, 2019) and a 20 percent RSC to account for non-drinking-water sources of exposure (USEPA, 2000), the HRL for cylindrospermopsin is calculated as follows:

$$HRL = \frac{0.0001 \text{ mg/kg/day}}{0.0343 \text{ L/kg/day}} * 0.2$$

$$HRL = 0.000583 \text{ mg/L}$$

or

$$HRL = 0.583 \text{ }\mu\text{g/L}$$

Following HRL derivation practices, the HRL for cylindrospermopsin is 0.6 $\mu\text{g/L}$ after rounding to one significant figure.

4.4 Occurrence

This section presents data on the occurrence of cylindrospermopsin in ambient water and drinking water in the United States. As described in Section 4.3, an HRL of 0.6 $\mu\text{g/L}$ was calculated for cylindrospermopsin based on non-carcinogenic effects. HRLs are risk-derived concentrations against which the EPA evaluates the occurrence data to determine if contaminants occur at levels of potential public health concern. Occurrence data from various sources presented below are analyzed with respect to the HRL and one-half the HRL. When possible, estimates of the population exposed at concentrations above the HRL and one-half the HRL are presented.

For additional background information about data sources used to evaluate occurrence, please refer to Chapter 2.

4.4.1 Occurrence in Ambient Water

Lakes, rivers, and aquifers are the ambient sources of most drinking water. Contaminant occurrence in ambient water provides information on the potential for contaminants to adversely affect drinking water supplies. Occurrence data for cylindrospermopsin in ambient water are available from the United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) program, the USGS National Water Information System (NWIS) database, the EPA's legacy Storage and Retrieval Data System (STORET), and several published studies. When sources of information on ambient occurrence also include limited finished water data, those finished water data are summarized here as well.

4.4.1.1 United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) Ambient Water Analyses

USGS instituted the NAWQA program in 1991 to examine ambient water quality status and trends in the United States. The NAWQA program generates high quality contaminant occurrence and other water quality parameter data for significant watersheds and aquifers across the nation. The program collects data on surface water and groundwater chemistry, hydrology, land use, stream habitat, and aquatic life in parts of nearly all 50 states. The program is designed to apply nationally consistent methods to provide a uniform basis for contaminant occurrence comparisons and assessments among study basins across the country and over time. The occurrence assessments can also serve to facilitate interpretation of natural and anthropogenic factors affecting national water quality. For more detailed information on NAWQA program design and implementation, refer to Leahy and Thompson (1994) and Hamilton et al. (2004).

The process of sampling, analysis, and data synthesis is divided into cycles of approximately ten years: Cycle 1 covered 1991-2001, Cycle 2 covered 2002-2012, and Cycle 3 covered 2013-2023. Study units are sampled and analyzed on a staggered schedule within each cycle. Each NAWQA cycle begins with a two-year startup phase for planning and retroactive analysis, followed by a three-year intensive data collection phase, and finally a five-year phase for analyzing the data, developing reports, and continuing a low level of monitoring (NRC, 2012).

The EPA downloaded NAWQA data from the Water Quality Portal (WQP) in September 2023 (WQP, 2023). The EPA's analysis of the NAWQA data is a simple, non-parametric occurrence analysis that provides summary statistics to characterize contaminant occurrence. The EPA included in the analysis all samples that could be classified as groundwater and surface water, and also the limited number of samples labeled as finished water. Other types of samples (e.g., from soil, sediment, and wastewater) were excluded. The EPA calculated detection frequencies as the percentage of samples and the percentage of sites with at least one detection. (A detection is an analytical result equal to or greater than the reporting level.) No weighting was applied. The EPA determined the minimum and maximum detected concentrations and calculated other descriptive statistics including the median, 90th percentile, and 99th percentile concentrations (based only on samples with detections). Reporting levels varied over time during the NAWQA program.

No sampling for cylindrospermopsin was conducted during Cycle 1 or Cycle 2. Four samples from four sites were included in Cycle 3 monitoring. All four samples were non-detections (WQP, 2023).

4.4.1.2 National Water Information System (NWIS) Data

NWIS is the nation's principal repository of water resources data collected by USGS from more than 1.9 million sites in all U.S. states and territories (USGS, 2022). All USGS water quality and flow data are stored in NWIS, including site characteristics, streamflow, groundwater level, precipitation, and chemical analyses of water, sediment, and biological media, though not all parameters are available for every site. NWIS houses the NAWQA data and includes other USGS data from a range of unspecified projects. NWIS encompasses many more samples at many more sites than are involved in the NAWQA Program. Although NWIS is comprised of primarily ambient water data, some finished drinking water data are included as well. This section presents analyses of non-NAWQA data in NWIS, downloaded from the WQP in September 2023 (WQP, 2023). These data do not overlap with the NAWQA results presented above.

The results of the non-NAWQA NWIS cylindrospermopsin analysis are presented in Exhibit 4-5. Cylindrospermopsin data are available from surface water only. Cylindrospermopsin were detected in approximately 9 percent of surface water samples (18 out of 201 samples) and at approximately 5.4 percent of sites (4 out of 74). The median detected concentration was 0.895 µg/L, and the highest detected concentration was 6.1 µg/L. Note that the NWIS data are presented as downloaded; potential outliers were not evaluated or excluded from the analysis.

Exhibit 4-5: Cylindrospermopsin NWIS Data, 1991-2023

Sample Media Type	Detection Frequency (detections are results $\geq$ reporting level)				Concentration Values (of detections, in $\mu\text{g/L}$)				
	No. of Samples	No. of Samples with Detections	No. of Sites	No. of Sites with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
Groundwater	0	0	0	0	--	--	--	--	--
Surface Water	201	18	74	4	0.18	0.895	3.64	5.76	6.1
Total	201	18	74	4	0.18	0.895	3.64	5.76	6.1

Source: WQP, 2023

"--" = No data or detections in this category

Note that some NWIS sites are associated with multiple sample media types, so site counts might not add up to totals.

4.4.1.3 Storage and Retrieval (STORET) Data

From its launch in 1999 until it was decommissioned in June 2018, the EPA's STORET Data Warehouse was collaboratively populated with raw biological, chemical, and physical data from surface water and groundwater sampling by federal, state and local agencies, Native American Tribes, volunteer groups, academics, and others. Legacy STORET data, as well as more current STORET data, are accessible through the WQP.

STORET data are from monitoring locations in all 50 states as well as multiple territories and jurisdictions of the United States. STORET's data quality limitations include variations in the extent of national coverage and data completeness from parameter to parameter. Data may have been collected as part of targeted, rather than randomized, monitoring. This section presents analyses of STORET data, downloaded from the WQP in September 2023 (WQP, 2023). The EPA reviewed STORET groundwater data from wells and springs and surface water data from lakes, rivers/streams, and reservoirs. The STORET data set also included limited data from public water systems (PWSs). The database does not specify whether PWS sampling was conducted before or after treatment.

The results of the STORET analysis for cylindrospermopsin are presented in Exhibit 4-6 through Exhibit 4-8. Cylindrospermopsin data are available from surface water only. These cylindrospermopsin samples were collected between 2015 and 2022. Cylindrospermopsin was detected in 1 (2 percent) of 50 samples at 1 (4 percent) of 25 sites. The single detection had a concentration value of 0.5 $\mu\text{g/L}$.

Exhibit 4-6: Cylindrospermopsin STORET Data – Summary of Detected Concentrations

Source Water Type	Concentration Value of Detections (µg/L)			
	Minimum	Median	90 th Percentile	Maximum
Groundwater	--	--	--	--
Surface Water	0.5	0.5	0.5	0.5
Total	0.5	0.5	0.5	0.5

Source: WQP, 2023

"--" = No data or detections in this category

Exhibit 4-7: Cylindrospermopsin STORET Data – Summary of Samples and Sites

Source Water Type	Total Number of Samples	Samples with Detections		Total Number of Sites	Sites with Detections	
		Number	Percent		Number	Percent
Groundwater	0	0	n/a	0	0	n/a
Surface Water	50	1	2.00%	25	1	4.00%
Total	50	1	2.00%	25	1	4.00%

Source: WQP, 2023

Exhibit 4-8: Cylindrospermopsin STORET Data – Summary of States

Source Water Type	Total Number of States	States with Detections	
		Number	Percent
Groundwater	0	0	n/a
Surface Water	2	1	50%
Total¹	2	1	50%

Source: WQP, 2023

¹ The number of states with groundwater data plus the number of states with surface water data may not equal the "Total" number of states providing data because some states provided both groundwater and surface water data.

4.4.1.4 Additional Ambient Water Studies

A total of 18 states voluntarily adopted use of the One Health Harmful Algal Bloom System (OHHABS) and entered 421 reports during 2016–2018 (Roberts et al., 2020). The majority of HAB events occurred during May–October (98 percent) and in freshwater bodies (90 percent). Cylindrospermopsin was reported as present in 4 (1 percent) of the 421 HAB events.

Graham et al. (2020) conducted a study of 11 large river sites located throughout the United States that were sampled during June to September 2017 to determine the occurrence of cyanobacteria with known cyanotoxin producing strains, cyanotoxin synthetase genes, and cyanotoxins. Cyanobacteria were present in the algal communities of all rivers and many of the cyanobacteria genera identified have known cyanotoxin-producing strains. Eutrophic rivers located in the midcontinent region of the United States had the highest algal biomass, abundance

of cyanotoxin synthetase genes, and cyanotoxin occurrence. Higher occurrence in these midcontinent rivers may be a result of eutrophication-related shifts in algal community composition, either within the rivers or upstream reservoirs. Of the cyanobacteria identified in the river samples, cylindrospermopsin producing strains were detected in 48 percent of samples from 63 percent of the rivers, though cylindrospermopsin itself was not detected.

Eleven freshwater HAB-associated outbreaks that occurred in 2009 or 2010 were reported to the Centers for Disease Control and Prevention (CDC) by New York, Ohio, and Washington (Hilborn et al., 2014). The reporting was voluntary and conducted through CDC's Waterborne Disease and Outbreak Surveillance System (WBDOSS) via the National Outbreak Reporting System (NORS) and the Harmful Algal Bloom-Related Illness Surveillance System (HABISS). Eight outbreak investigations included evaluation of cyanotoxins. Cylindrospermopsin was detected in two of five investigations where it was tested, in concentrations ranging from 0.3 to 9.0 µg/L.

4.4.2 Occurrence in Drinking Water

Data sources reviewed by the EPA for information on contaminant occurrence in drinking water included: the EPA's first, second, third, and fourth Unregulated Contaminant Monitoring Rules (UCMR 1, UCMR 2, UCMR 3, UCMR 4); Rounds 1 and 2 of the EPA's Unregulated Contaminant Monitoring (UCM) program that preceded the Unregulated Contaminant Monitoring Rule (UCMR); the EPA's National Inorganics and Radionuclides Survey (NIRS); and a range of others as discussed in Chapter 2. Among the sources reviewed, the following had data and information on cylindrospermopsin occurrence in drinking water and are discussed in this section:

- The EPA's Fourth Unregulated Contaminant Monitoring Rule (UCMR 4).
- State drinking water monitoring programs.
- Consumer Confidence Reports (CCRs) from PWSs.
- Additional source water and drinking water studies.

Note that there may be some overlap, as sources with different purposes and audiences may have reported the same underlying data. UCMR 4 is a national data source. Other data sources profiled in this section are considered "supplemental" sources. Also note that the presentation of STORET results in the ambient water section, above, includes some miscellaneous data from PWSs.

4.4.2.1 Primary Data Sources

4.4.2.1.1 *The USEPA's Fourth Unregulated Contaminant Monitoring Rule (UCMR 4)*

The UCMR program was designed to provide a national assessment of the occurrence of select unregulated contaminants in PWSs. UCMR 4 was published on December 20, 2016 (81 FR 92666; USEPA, 2016a) and required monitoring for 30 chemical contaminants between 2018 and 2020. Data reporting continued into 2021.

Monitoring consisted of sampling finished drinking water in PWSs that use surface water or groundwater under the influence of surface water (GWUDI). Groundwater systems were excluded from cyanotoxin monitoring. The sampling was conducted at two groups of PWSs: (a) all large systems serving more than 10,000 people (a census of large PWSs) including all

community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) and (b) a nationally representative, randomly selected group of approximately 800 small CWSs and NTNCWSs (small systems serve 10,000 or fewer people).¹ Monitoring occurred twice a month for four consecutive months from March through November (for a total of eight sampling events).² Sampling was conducted at entry points to the distribution system.

In addition to analytical sample results, UCMR 4 reporting required systems to provide information related to source water conditions and cyanobacteria / cyanotoxin occurrence and treatment, including: bloom occurrence, possible bloom treatment, and details on changes in source water quality conditions. Those additional data are not summarized in this report. See USEPA (2016a) and USEPA (2024) for more information on the UCMR 4 study design and data analysis.

The design of UCMR 4 permits estimation of national occurrence by multiplying the total number of systems (or population served) in the nation in a system size category by the percent of systems (or population served) found to exceed a specified threshold in the sample. This extrapolation methodology is applied to small systems. Because all large and very large systems were required to participate in the UCMR 4 Assessment Monitoring, national occurrence estimates in these size categories can be developed using survey census figures rather than extrapolation. Total national occurrence is estimated by summing the extrapolated figures for small systems and the census figures for the large and very large systems.

Exhibit 4-9 through Exhibit 4-13 provide an overview of cylindrospermopsin occurrence results from UCMR 4 Assessment Monitoring. The minimum reporting level (MRL) used for cylindrospermopsin in the UCMR 4 survey was 0.09 µg/L. Exhibit 4-9 shows a statistical summary of cylindrospermopsin concentrations by system size and source water type (including the minimum, median, 90th percentile, 99th percentile, and maximum). Exhibit 4-10 presents a sample-level summary of the results. Exhibit 4-11 through Exhibit 4-13 show system-level results, including national extrapolations, at three thresholds: detections, ½ the HRL, and the HRL. Detections are evaluated on a “greater than or equal to” basis ($\geq$ the MRL), while health-based thresholds are evaluated in terms of exceedances ($> \frac{1}{2}$ HRL, and $>$ HRL).

As a reminder that the figures from large and very large systems represent a census of systems in those categories, results in those categories are labeled “CENSUS” in the exhibits below. No extrapolation was necessary in these categories, as it was for the small systems, to derive national estimates of occurrence. National estimates of occurrence are reported separately in each system size and source water category, and also in the aggregate.

Cylindrospermopsin was detected in 0.04 percent of UCMR 4 samples. Reported cylindrospermopsin concentrations ranged from 0.09 µg/L (the MRL) to 0.877 µg/L. A total of 35,425 samples for cylindrospermopsin were collected from 3,484 systems. Of these systems, 12 (0.34 percent of systems, serving 0.23 percent of the PWS-served population) reported at least one detection of cylindrospermopsin. Three systems serving nearly 31,000 people reported at least one detection of cylindrospermopsin greater than ½ the HRL of 0.3 µg/L and 1 system serving 10,174 people reported at least one detection of cylindrospermopsin greater than the HRL of 0.6 µg/L. Extrapolating these findings suggests that an estimated 34 PWSs serving around 488,000 people nationally have at least one detection of cylindrospermopsin while an

¹ Only 798 small systems submitted results for cylindrospermopsin.

² This was an increased sampling frequency and a more narrow monitoring timeframe than for the 20 additional chemical contaminants monitored under UCMR 4.

estimated 14 PWSs serving 40,900 people nationally have at least one detection of cylindrospermopsin greater than ½ the HRL and 1 PWS serving 10,200 people has at least one detection greater than the HRL.

Exhibit 4-9: Cylindrospermopsin Occurrence Data from UCMR 4 Assessment Monitoring - Summary of Detected Concentrations

Source Water Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90th Percentile	99th Percentile	Maximum
Small Systems (serving ≤ 10,000 people)					
Groundwater	--	--	--	--	--
Surface Water	0.11	0.224	0.317	0.338	0.34
All Small Systems	0.11	0.224	0.317	0.338	0.34
Large Systems (serving 10,001 - 100,000 people) -- CENSUS					
Groundwater	--	--	--	--	--
Surface Water	0.09	0.203	0.550	0.844	0.877
All Large Systems	0.09	0.203	0.550	0.844	0.877
Very Large Systems (serving > 100,000 people) -- CENSUS					
Groundwater	--	--	--	--	--
Surface Water	0.09	0.100	0.108	0.110	0.11
All Very Large Systems	0.09	0.100	0.108	0.110	0.11
All Systems					
All Water Systems	0.09	0.175	0.396	0.821	0.877

Source: USEPA, 2024

-- = No data or detections in this category

Exhibit 4-10: Cylindrospermopsin National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of Samples

Source Water Type	Total # of Samples	Samples with Detections ≥ MRL (0.09 µg/L)		Samples with Detections > ½ HRL (0.3 µg/L)		Samples with Detections > HRL (0.6 µg/L)	
		Number	Percent	Number	Percent	Number	Percent
Small Systems (serving ≤ 10,000 people)							
Groundwater	0	0	0.00%	0	0.00%	0	0.00%
Surface Water	6,697	3	0.04%	1	0.01%	0	0.00%
All Small Systems	6,697	3	0.04%	1	0.01%	0	0.00%
Large Systems (serving 10,001 - 100,000 people) -- CENSUS							
Groundwater	0	0	0.00%	0	0.00%	0	0.00%
Surface Water	23,055	8	0.03%	2	0.01%	1	0.00%
All Large Systems	23,055	8	0.03%	2	0.01%	1	0.00%
Very Large Systems (serving > 100,000 people) -- CENSUS							
Groundwater	0	0	0.00%	0	0.00%	0	0.00%
Surface Water	5,673	2	0.04%	0	0.00%	0	0.00%
All Very Large Systems	5,673	2	0.04%	0	0.00%	0	0.00%

Source Water Type	Total # of Samples	Samples with Detections ≥ MRL (0.09 µg/L)		Samples with Detections > ½ HRL (0.3 µg/L)		Samples with Detections > HRL (0.6 µg/L)	
		Number	Percent	Number	Percent	Number	Percent
All Systems							
All Water Systems	35,425	13	0.04%	3	0.01%	1	0.00%

Source: USEPA, 2024

Exhibit 4-11: Cylindrospermopsin National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population – Detections

Source Water Type	UCMR 4 Sample		Number With At Least One Detection $\geq$ MRL (0.09 $\mu\text{g/L}$)		Percent With At Least One Detection $\geq$ MRL (0.09 $\mu\text{g/L}$)		National Inventory ¹		National Estimate of Number With At Least One Detection $\geq$ MRL (0.09 $\mu\text{g/L}$) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving $\leq 10,000$ people)										
Groundwater	0	0	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	798	3,602,504	2	8,478	0.25%	0.24%	9,624	22,859,068	24	53,800
All Small Systems	798	3,602,504	2	8,478	0.25%	0.24%	63,501	60,915,707	24	53,800
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	0	0	0	0	0.00%	0.00%	0	0	0	0
Surface Water	2,332	71,274,320	8	204,692	0.34%	0.29%	2,332	71,274,320	8	205,000
All Large Systems	2,332	71,274,320	8	204,692	0.34%	0.29%	2,332	71,274,320	8	205,000
Very Large Systems (serving $> 100,000$ people) -- CENSUS										
Groundwater	0	0	0	0	0.00%	0.00%	0	0	0	0
Surface Water	354	120,303,825	2	229,445	0.56%	0.19%	354	120,303,825	2	229,000
All Very Large Systems	354	120,303,825	2	229,445	0.56%	0.19%	354	120,303,825	2	229,400
All Systems										
All Water Systems	3,484	195,180,649	12	442,615	0.34%	0.23%	66,187	252,493,852	34	488,000

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

Exhibit 4-12: Cylindrospermopsin National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population Served Data – Detections > ½ the HRL (0.3 µg/L)

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > ½ HRL (0.3 µg/L)		Percent With At Least One Detection > ½ HRL (0.3 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > ½ HRL (0.3 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	0	0	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	798	3,602,504	1	1,878	0.13%	0.05%	9,624	22,859,068	12	11,900
All Small Systems	798	3,602,504	1	1,878	0.13%	0.05%	63,501	60,915,707	12	11,900
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	0	0	0	0	0.00%	0.00%	0	0	0	0
Surface Water	2,332	71,274,320	2	28,951	0.09%	0.04%	2,332	71,274,320	2	29,000
All Large Systems	2,332	71,274,320	2	28,951	0.09%	0.04%	2,332	71,274,320	2	29,000
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	0	0	0	0	0.00%	0.00%	0	0	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Systems										
All Water Systems	3,484	195,180,649	3	30,829	0.09%	0.02%	66,187	252,493,852	14	40,900

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

Exhibit 4-13: Cylindrospermopsin National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population Served Data – Detections > HRL (0.6 µg/L)

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > HRL (0.6 µg/L)		Percent With At Least One Detection > HRL (0.6 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > HRL (0.6 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	0	0	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	798	3,602,504	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	798	3,602,504	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	0	0	0	0	0.00%	0.00%	0	0	0	0
Surface Water	2,332	71,274,320	1	10,174	0.04%	0.01%	2,332	71,274,320	1	10,200
All Large Systems	2,332	71,274,320	1	10,174	0.04%	0.01%	2,332	71,274,320	1	10,200
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	0	0	0	0	0.00%	0.00%	0	0	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Systems										
All Water Systems	3,484	195,180,649	1	10,174	0.03%	0.01%	66,187	252,493,852	1	10,200

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

4.4.2.2 Supplemental Data Sources

4.4.2.2.1 State Monitoring Data, 2010-2022

Because there is no available national database that receives and stores all relevant data regarding the occurrence of regulated and unregulated contaminants in public drinking water systems, the EPA gathered data from state drinking water monitoring websites in support of national occurrence assessments. Supplemental data of cyanotoxin occurrence in finished drinking water is very limited. Three states were found to have cyanotoxin monitoring programs: Ohio, Oregon, and Vermont. Other limited *ad hoc* sampling results were found for several other states. The monitoring data from each state/entity are limited and not necessarily representative of occurrence in the state/entity. These occurrence findings are also summarized below.

Ohio

Data were obtained from the Ohio EPA's Historical Algal Toxin Results page as reported by various PWSs from 2010 to 2022 (Ohio EPA, 2022a; Ohio EPA, 2022b). As of June 1, 2016, Ohio required PWSs using surface water sources to conduct routine monitoring of cyanotoxins. Therefore, the data from June 1, 2016, onward represents all surface water PWS monitoring while the occurrence data prior to June 1, 2016, are not as complete or representative compared to data after June 1, 2016. Further details describing the monitoring and reporting are found in the state administrative code (Ohio Administrative Code 3723-90) and are partly based on the current Harmful Algal Bloom Strategy (Ohio EPA, 2020). The Ohio sampling program focuses on total microcystins but some cylindrospermopsin results were also available. A summary of finished water cylindrospermopsin sampling results is presented in Exhibit 4-14.

Exhibit 4-14. Ohio Finished Water Sampling Results for Cylindrospermopsin, 2010-2022

Years ¹	Detection Frequency (detections are results $\geq$ reporting level)				Concentration Values (of detections, in $\mu\text{g/L}$)				
	No. of Samples	No. of Samples with Detections	No. of Sites	No. of Sites with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
June 2010 – December 2019	184	0	61	0	--	--	--	--	--
August 2020 – August 2022	1	0	1	0	--	--	--	--	--

¹ Source: For 2010-2019 data, see Ohio EPA (2022a). For 2020-2022 data, see Ohio EPA (2022b).

-- = No data or detections in this category

Oregon

In December 2018, the Oregon Health Authority (OHA) implemented rules requiring that PWSs using surface water sources that are prone to HABs conduct sampling of cyanotoxins in raw water once every two weeks from May through October (see Oregon Administrative Rules 333-061-0510 to -0580). If detections of total microcystins or cylindrospermopsin greater than or equal to 0.3 $\mu\text{g/L}$ are identified in raw water samples, PWSs must initiate weekly sampling of

finished water at entry points to the distribution system. Further details of monitoring requirements are described in OHA (2023). In the available data for cylindrospermopsin (2018 to 2022), a total of 4,044 samples were collected from 100 PWSs. There were no detections of cylindrospermopsin in the 266 finished water samples from 15 PWSs (OHA, 2022).

Vermont

Since 2015, the Drinking Water and Groundwater Protection Division of the Vermont Agency of Natural Resources has collaborated with the Vermont Department of Health to offer free analysis of cyanotoxin sampling in the raw and finished water of the 22 Lake Champlain-sourced PWSs (VT DEC, 2022). Sampling for these 22 PWSs is conducted for the 12 weeks from July through September with one sample collected at one finished water location and one raw water location per week. The MRL for reported samples ranged from 0.05 µg/L to 0.5 µg/L. Records are available for sampling conducted from 2014 to 2017. Over this four year period, a total of 645 finished water samples were collected at the 22 PWSs for cylindrospermopsin. There was one detection in finished water in 2017 with a concentration of 0.12 µg/L, which is less than the HRL of 0.6 µg/L.

Illinois

Drinking water occurrence data for cylindrospermopsin were available on the Illinois state Drinking Water Watch website. Results are presented in Exhibit 4-15. Comprehensive information about methods used and reporting levels is not available for the state data. Minimum detected concentrations are reported in Exhibit 4-15; these minimum values may be indicative of reporting levels used. Illinois had cylindrospermopsin data from 45 PWSs from 2020 - 2022. Overall, detected concentrations ranged from 0.05 µg/L to 0.1 µg/L. There were no reported detections greater than the HRL of 0.6 µg/L.

Exhibit 4-15: Illinois Sampling Results for Cylindrospermopsin, 2020-2022

Source Water Type	Detection Frequency (detections are results ≥ reporting level)				Concentration Values (of detections, in µg/L)				
	No. of Samples	No. of Samples with Detections	No. of Systems	No. of Systems with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
Ground Water	0	0	0	0	--	--	--	--	--
Surface Water	368	12	45	1	0.05	0.06	0.098	0.1	0.1

Source: Data downloaded by the EPA from the Illinois Drinking Water Watch website.

-- = No data or detections in this category

Miscellaneous State Sampling and Do Not Drink Advisories

Exhibit 4-16 presents a summary of available “Do Not Drink” advisories throughout the country over the past several years.

Exhibit 4-16: Summary of Miscellaneous State Sampling and “Do Not Drink” Advisories

State	Year	Description of Event
Oregon	2018	The city of Salem found cylindrospermopsin in treated drinking water (Detroit Reservoir). Multiple "do not drink" advisories were issued for vulnerable populations (City of Salem OR, 2018).
Florida	2021	The city of West Palm Beach issued a Do Not Drink advisory to vulnerable populations after cylindrospermopsin was detected above the health advisory level (WPB, 2021).

4.4.2.2.2 *Water Systems’ Consumer Confidence Reports (CCRs), 2018-2021*

CCRs are annual water quality reports that CWSs are required to provide to their customers. These reports summarize information on water sources, detected contaminants, and system compliance with the EPA drinking water standards; they may also include general educational material. Under the CCR Rule (40 CFR Subpart O), CWSs with 15 or more connections or serving at least 25 year-round residents must prepare and distribute a CCR to all billing units or service connections every year. Systems serving 100,000 or more residents are also required to post their current CCRs on a publicly accessible Internet site.

The EPA reviewed CCRs published by the 25 systems that serve over one million customers (as identified in the Safe Drinking Water Information System / Federal version, or SDWIS/Fed, from the fourth quarter 2021 data) for unregulated contaminant occurrence information for the years 2018 through 2021. Data on cylindrospermopsin were available from CCRs prepared by four CWSs: one system in California (Los Angeles), one system in New York (New York City), one system in Pennsylvania (Philadelphia), and one system in Texas (Dallas).

The Los Angeles Department of Water and Power discussed cylindrospermopsin monitoring as part of UCMR 4 in its 2020 and 2021 CCRs. No detections of cylindrospermopsin were reported.

New York City included data on cylindrospermopsin monitoring in its 2018 and 2019 CCRs. Monitoring was conducted as part of the UCMR 4 program. New York City is served by a large system of surface water networks in New York state. No detections of cylindrospermopsin were reported.

The Philadelphia Water Department included data on cylindrospermopsin in its 2020 and 2021 CCRs. Monitoring was conducted as part of the UCMR 4 program. Philadelphia is served by two surface water sources, the Schuylkill and the Delaware Rivers. Sampling locations and the number of samples collected were not reported. No detections of cylindrospermopsin were reported in the 2020 or the 2021 CCR.

The City of Dallas included data on cylindrospermopsin monitoring in its 2018 CCR. Monitoring was conducted as part of the UCMR 4 program. Dallas is served by seven surface water sources. The number of samples and location of samples was not reported. In 2018, cylindrospermopsin was not detected in any sample.

4.4.2.2.3 *Additional Source Water and Drinking Water Studies*

Szlag et al. (2015) looked at the occurrence of microcystin, anatoxin-a, and cylindrospermopsin in five different drinking water treatment plants in five states: California, Texas, Oklahoma, Florida, and Vermont. The researchers observed the plants for 12 to 16 weeks

during the spring and summer and used the thresholds for cyanobacteria cell density in the WHO risk management framework that includes an Alert Level 1 (for concentrations exceeding 2,000 cyanobacteria cells/mL) and an Alert Level 2 (for concentrations exceeding 100,000 cyanobacteria cells/mL). The method detection limit for cylindrospermopsin was 0.25 µg/L. No cyanotoxins were found in any of the finished water samples at any of the plants. In raw water samples, microcystin was frequently detected, cylindrospermopsin was detected once (in Oklahoma), and anatoxin-a was not detected. Four of the five plants (in California, Texas, Florida, Oklahoma) often exceeded the WHO Alert Level 1 for cyanobacteria cell density in raw water samples. Raw water in the California plant exceeded the WHO Alert Level 2 twice, and raw water in the Texas plant exceeded the WHO Alert Level 2 once. Szlag et al. (2015) did not find a correlation between the amount of toxin-producer cyanobacteria and the levels of toxins.

A survey conducted in 2000 in Florida (Burns, 2008) found cylindrospermopsin in raw drinking water and in nine finished drinking water samples at concentrations ranging from 8 µg/L to 97 µg/L.

Boyer (2008) accessed the occurrence and distribution of toxic cyanobacterial blooms in New York and the Lower Great Lakes from 2000 to 2004. More than 2,500 samples were collected from over 1,000 sites at 81 different New York lakes, including large lakes, intermediate-sized bodies of water, and smaller impoundments and lakes. Samples were collected at a variety of times throughout the growing season (June-October), with the bulk of the samples collected in late July and early September. Between 2000 and 2004, more than 1,000 samples were collected from 81 different lakes across New York state. With a reporting limit of 0.01 µg/L, cylindrospermopsin was detected in 8 (2%) of 366 samples, with a max concentration of less than 0.25 µg/L. Samples taken on two research cruises on Lake Erie during 2000-2004 were also tested for cylindrospermopsin. Cylindrospermopsin was not detected in 40 samples during one cruise, but was detected in 15% of 13 samples during another cruise, with a max concentration of 0.18 µg/L.

A report by the American Water Works Association (AWWA, 2016a) examined cyanotoxin occurrence in multiple states. Of 16 drinking water systems interviewed, 8 (50%) reported having monitored for cylindrospermopsin, and 2 (13%) reported having detected it. States were also contacted to provide occurrence data, and the most robust data were obtained from Ohio, covering the period 2010-2015. In Ohio, cylindrospermopsin was detected in 1 out of 270 source water samples, with a concentration of 0.11 µg/L, and cylindrospermopsin was detected in none of 179 treated drinking water samples. Detection limits ranged from 0.05 to 5 µg/L.

Farrer et al. (2015) studied cyanobacteria and cyanotoxin occurrence in drinking water and recreational water in Oregon. Cyanobacteria capable of producing anatoxin-a, microcystin, and cylindrospermopsin were found in freshwater bodies throughout Oregon. From 2009 to 2014, Oregon issued 88 recreational HAB advisories, of which 78 were based on cell counts and 10 on toxin results. During that same period, cylindrospermopsin was detected in one sample above its recreational guideline value of 6.0 µg/L. Farrer et al. (2015) reported that cyanotoxin levels in finished drinking water in Oregon never exceeded drinking water guidelines.

4.5 Analytical Methods

The EPA has developed one analytical method for the analysis of cylindrospermopsin in drinking water:

- EPA Method 545, *Determination of Cylindrospermopsin and Anatoxin-a in Drinking Water by Liquid Chromatography Electrospray Ionization Tandem Mass Spectrometry (LC/ESI-MS/MS)*, has a Lowest Concentration Minimum Reporting Level (LCMRL) of 0.063 µg/L. Mean recoveries in reagent water, chlorinated groundwater (total hardness = 325 mg/L (as CaCO₃); free chlorine = 0.69 mg/L; total chlorine = 0.97 mg/L; conductivity = 798 µS) and moderate total organic carbon (TOC) chlorinated surface water (total hardness = 142 mg/L (as CaCO₃); free chlorine = 0.64 mg/L; total chlorine = 1.14 mg/L; conductivity = 344 µS; TOC = 3.04 mg/L) range from 98.0 to 126 percent, with relative percent differences of 1.6 to 11 percent (USEPA, 2015c).

Laboratories participating in UCMR 4 were required to use EPA Method 545 and were required to report cylindrospermopsin values at or above the EPA-defined MRL of 0.09 µg/L (81 FR 92666; USEPA, 2016a). The MRL was set based on the capability of multiple laboratories at the time.

One or more non-EPA methods not discussed here might also be applicable to this contaminant in drinking water.

4.6 Treatment Technologies

The EPA evaluates whether suitable treatment technologies are available prior to promulgating a final NPDWR. The preliminary summary of treatment technology availability presented here represents the results of a May 2022 literature search.

Although management of cyanobacteria blooms in source water can be an important part of an integrated cyanotoxin management approach, source water treatment is not covered in this review of treatment technologies.

An important consideration when treating for cyanotoxins in drinking water is whether the cyanotoxins are contained within the intact cyanobacteria cell (intracellular) or dissolved in the water (extracellular). It is generally a good idea to remove as many intact cells as possible, to prevent the release of intracellular toxins. Treatments that are effective for removing intact cyanobacterial cells include conventional treatment (coagulation, sedimentation, and filtration), flotation (e.g., dissolved air flotation), and membrane filtration. Pre-oxidation is not recommended unless the dosage is sufficient to both lyse the cells and chemically inactivate the cyanotoxins (AWWA, 2016b).

The following treatment technologies may be effective for treating cylindrospermopsin in water: chlorine, powder activated carbon (PAC), ozone, photocatalysis, biological degradation and membrane filtration. An overview of cylindrospermopsin treatment options is provided by Chorus and Welker (2021).

Chlorine is effective at oxidizing cylindrospermopsin. The effectiveness of chlorine oxidation of cylindrospermopsin is pH dependent, with greater effectiveness at lower pH (USEPA, 2016b). Westrick et al. (2010 as cited in USEPA, 2015d) confirmed that cylindrospermopsin can be effectively oxidized by chlorine when the pH ranges from 6 to 9. Senogles et al. (2000) found in bench-scale experiments that a 5 mg/L dose of chlorine could degrade over 99 percent of 80 µg/L extracellular cylindrospermopsin following a contact time of 60 minutes. Chlorine doses of 2 and 3 mg/L degraded the same concentration of cylindrospermopsin by 30%. Most of the degradation took place within the first minute of contact time. Ho et al. (2008) found that 0.3, 1.0, and 1.5 mg/L chlorine at a chlorine exposure of

3 mg-min/L completely oxidized 20 µg/L cylindrospermopsin in two samples of surface water. Rodríguez et al. (2007) found that in a sample of filtered surface water at pH of 8, 1.5 mg/L chlorine could completely eliminate 415 µg/L of purified cylindrospermopsin. Cheng et al. (2009) found in bench-scale experiments that 1 mg/L of free chlorine, at pH 8, could remove 20 µg/L cylindrospermopsin, yielding a 1.7-minute half life for cylindrospermopsin.

PAC is also effective for removing cylindrospermopsin. Ho et al. (2008) found that to reduce the concentration of cylindrospermopsin in water from 5 µg/L to less than 1 µg/L, 30 minutes of contact time was needed using 33 mg/L PAC, and 60 minutes using 25 mg/L PAC. Subsequently, Ho et al. (2011) found in jar tests of unfiltered raw water that in order to reduce cylindrospermopsin concentrations from 20 µg/L to less than 1 µg/L, the necessary PAC doses were 25 mg/L in waters with 5.0 mg/L dissolved organic carbon and 50 mg/L in waters with 3.9 and 4.3 mg/L dissolved organic carbon, regardless of the length of contact time (30, 45, or 60 minutes). USEPA (2015d) notes that the PAC doses that are required for cyanotoxin removal, generally in excess of 20 mg/L, are higher than what is typically used in drinking water treatment.

Ozone is highly reactive with cylindrospermopsin. Alvarez et al. (2010 as cited in USEPA, 2015d) found that ozone is effective at doses of 0.5 – 1.1 mg/L under most water quality conditions and contact times. Cheng et al. (2009) found in bench-scale experiments that ozone exposure as low as 1 mg-min/L could completely remove 20 µg/L cylindrospermopsin. Yan et al. (2016), in dose testing of deionized water samples, found that 62.5 µM ozone in solution at pH 7 could effectively degrade 20 µg/L cylindrospermopsin after 24 hours. Wu et al. (2015) investigated titanium dioxide as an ozonation catalyst and found that at a pH of 7 in deionized water, an ozone concentration of 2 mg/L and a titanium dioxide concentration of 500 mg/L achieved a 98.9 percent removal rate for 2.5 mg/L cylindrospermopsin.

Photocatalysis may also be an effective treatment option for removing cylindrospermopsin from water. Senogles et al. (2001) showed that ultraviolet (UV) irradiation with a 0.1 g/L dose of titanium dioxide (Degussa P-25) as a photocatalyst produced the best degradation rate for extracellular cylindrospermopsin at an initial concentration of 100 µg/L, with a half-life of 16 minutes. The authors found that elevated concentrations of dissolved organic carbon concentration may reduce transmissivity and increase half-life. Pinho et al. (2015) conducted a lab-scale study using finished water dosed with approximately 70 µg/L cell suspension of *Cylindrospermopsis raciborskii*, at pH between 6.0 and 6.5, and found that a 50 percent removal efficiency could be achieved with a titanium dioxide dose of 200 mg/L and solar exposure of 8.7 kJUV/L by photoreactor. In bench-scale experiments with purified cylindrospermopsin in an aqueous solution, El-Sheikh et al. (2017) found a 100 percent degradation efficiency for cylindrospermopsin within 15 minutes using ultraviolet-visible irradiation and a titanium dioxide photocatalyst (0.25 g/L) that was 61.8 percent anatase and 38.2 percent brookite.

Biological degradation of cylindrospermopsin has been demonstrated. Smith et al. (2008) found that cylindrospermopsin concentrations between 13 to 76 µg/L could be completely degraded by aquatic organisms in 7 to 17 days. At lower initial cylindrospermopsin concentrations, complete degradation was not achieved, implying that a threshold concentration of cylindrospermopsin is necessary to induce its own degradation (Smith et al., 2008). Westrick et al. (2010 as cited in USEPA, 2015d) reports seasonal variability in the ability of biological active slow sand filtration to degrade cyanotoxins, with 95 percent removal of extracellular microcystins and cylindrospermopsin in the summer but less than 65 percent in the autumn.

Nanofiltration and reverse osmosis can be effective for removing extracellular cyanotoxins. Removal rates of 90-100 percent have been reported for cylindrospermopsin using these techniques. Results are affected by membrane material, pore size and water quality (USEPA, 2015d).

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Chapter 5: Ethoprop

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Abbreviations

AChE	Acetylcholinesterase
BMD	Benchmark Dose
BMD ₁₀	Benchmark Dose at 10 Percent Inhibition*
BMDL ₁₀	Lower Bound of 95 Percent Confidence Interval on BMD ₁₀ *
BW	Body Weight
CASRN	Chemical Abstracts Service Registry Number
CCL 5	Fifth Contaminant Candidate List
CCR	Consumer Confidence Report
CDR	Chemical Data Reporting
ChE	Cholinesterase
CSF	Cancer Slope Factor
CWS	Community Water System
DL	Detection Limit
DWI	Drinking Water Intake
DWI-BW	Drinking Water Intake Adjusted for Body Weight
DWW	Drinking Water Watch
EF	Exposure Factor
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA SF	Food Quality Protection Act Safety Factor
HED	Health Effects Division
HHRA	Human Health Risk Assessments
HRL	Health Reference Levels
IREL	Interim Reregistration Eligibility Decision
IUR	Inventory Update Reporting
K _H	Henry's Law Constant
K _{oc}	Organic Carbon Partitioning Coefficient
K _{ow}	Octanol/Water Partitioning Coefficient
LADWP	Los Angeles Department of Water & Power
LCMRL	Lowest Concentration Minimum Reporting Level
LT-MDL	Long-Term Method Detection Level
MAC	Maximum Acceptable Concentration
MDL	Method Detection Limit
MRL	Minimum Reporting Level
NAWQA	National Water-Quality Assessment
NCFAP	National Center for Food and Agricultural Policy
ND	Not Detected
NIRS	National Inorganics and Radionuclides Survey
NPDWR	National Primary Drinking Water Rule
NPS	National Pesticide Survey
NTNCWS	Non-Transient Non-Community Water System
NWIS	National Water Information System
OGWDW	Office of Ground Water and Drinking Water
OPP	Office of Pesticide Programs
PAD	Population Adjusted Dose

PDP	Pesticide Data Program
PMP	Pilot Monitoring Program
PND	Post-Natal Day
POD	Point of Departure
POD/UF	Point of Departure / Uncertainty Factor
PRD	Pesticide Re-evaluation Division
PWD	Philadelphia Water Department
PWS	Public Water System
RBC	Red Blood Cell
RD 5	Fifth Regulatory Determination
RfD	Reference Dose
RSC	Relative Source Contribution
RSD	Relative Standard Deviation
RUP	Restricted Use Pesticide
SD	Standard Deviation
SDWA	Safe Drinking Water Act
SDWIS/Fed	Safe Drinking Water Information System / Federal Version
SIM	Selected Ion Monitoring
ssPAD	Steady-State Population-Adjusted Dose
STORET	Storage and Retrieval Data System
SYR 2	Second Six-Year Review
SYR 3	Third Six-Year Review
SYR 4	Fourth Six-Year Review
TDI	Tolerable Daily Intake
TiO ₂	Titanium Dioxide
TOC	Total Organic Carbon
TRI	Toxic Release Inventory
UCM	Unregulated Contaminant Monitoring
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 1	First Unregulated Contaminant Monitoring Rule
UCMR 2	Second Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 4	Fourth Unregulated Contaminant Monitoring Rule
UF	Uncertainty Factor
UF _A	Interspecies Uncertainty Factor
UF _H	Intraspecies Uncertainty Factor
USDA	United States Department of Agriculture
USGS	United States Geological Survey
VOC	Volatile Organic Compound
WQP	Water Quality Portal
ZnO	Zinc Oxide

*These definitions apply only within this chapter.

Chapter 5: Ethoprop

The U.S. Environmental Protection Agency (EPA) is evaluating ethoprop, a contaminant on the fifth Contaminant Candidate List (CCL 5), as a candidate for regulation under the fifth Regulatory Determination process (RD 5). Information on the CCL 5 process is found in Chapter 1. Background on data sources used to evaluate CCL 5 chemicals is found in Chapter 2.

This chapter presents information and analysis specific to ethoprop, including background information on the contaminant, information on contaminant sources and environmental fate, an analysis of health effects, an analysis of occurrence in ambient and drinking water, and information about the availability of analytical methods and treatment technologies.

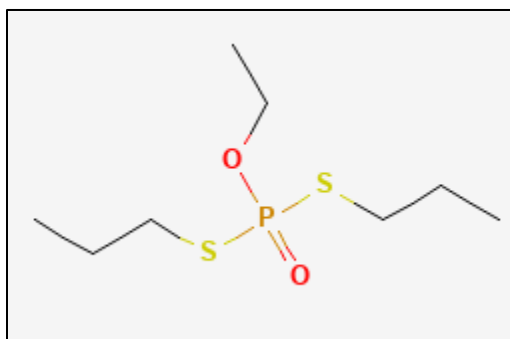
5.1 Contaminant Background and Chemical and Physical Properties

Ethoprop is an organophosphate (phosphorodithioate) pesticide. It is used as an insecticide and nematicide on vegetables, fruits and other plants, including potatoes, sweet potatoes, beans, cucumbers, cabbage, pineapples, bananas, plantains, tobacco and ornamentals. Synonyms for ethoprop include ethoprophos, prophos and *O*-ethyl *S,S*-dipropyl phosphorodithioate (NCBI, 2023). Ethoprop was first registered in the United States in 1967 (USEPA, 2006).

The EPA's Office of Pesticide Programs (OPP) released an Addendum to the 2001 Ethoprop Interim Reregistration Eligibility Decision (IRED) in February of 2006, which was finalized in July of 2006 (USEPA, 2006). Subsequent to the EPA changing from the pesticide reregistration process to the current Registration Review process, the EPA published a Summary Document for Ethoprop in December of 2008 and a Final Work Plan for Ethoprop in May of 2009 (USEPA, 2008; USEPA, 2009a). Three EPA-registered formulations containing $\geq 15\%$ active ingredient are Restricted Use Pesticides (RUP) (USEPA, 2022a).

Exhibit 5-1 presents the structural formula for ethoprop. Physical and chemical properties and other reference information are listed in Exhibit 5-2.

Exhibit 5-1: Chemical Structure of Ethoprop



Source: NCBI, 2023

Exhibit 5-2: Physical and Chemical Properties of Ethoprop

Property	Data
Chemical Abstracts Service Registry Number (CASRN)	13194-48-4 (NCBI, 2023)
EPA Pesticide Chemical Code	041101 (NCBI, 2023)
Chemical Formula	C ₈ H ₁₉ O ₂ PS ₂ (NCBI, 2023)
Molecular Weight	242.3 g/mol (NCBI, 2023)
Color/Physical State	Pale yellow liquid/oil (NCBI, 2023)
Boiling Point	187 to 196 °F at 0.2 mmHg (NCBI, 2023)
Melting Point	-13 °C (NCBI, 2023)
Density	1.094 g/mL (NCBI, 2023)
Freundlich Adsorption Coefficient	--
Vapor Pressure	0.00035 mmHg at 78.8 °F (NCBI, 2023)
Henry's Law Constant (K _H)	1.62 x 10 ⁻⁷ atm-m ³ /mole (NCBI, 2023)
Octanol/Water Partitioning Coefficient (log K _{ow})	3.59 @ 21 °C (NCBI, 2023)
Organic Carbon Partitioning Coefficient (K _{oc})	70-120 L/kg (NCBI, 2023)
Solubility in Water	750 mg/L @ 20-25 °C (NCBI, 2023); 843 ppm @ 21 °C (USEPA, 2015a)
Other Solvents	Soluble in most organic solvents (e.g., >300,000 mg/kg in acetone, ethanol, xylene, 1,2-dichloroethane, diethyl ether, ethyl acetate, petroleum spirit, cyclohexane; NCBI, 2023)

Note: Many of these properties are temperature-dependent. Values are given for properties at 20-25°C unless otherwise noted. Due to varying experimental conditions, and due to the variabilities associated with modeling, standard information sources may provide a range of values. Where more than one value was available from these sources, one value was selected for this table based on best professional judgment.

5.2 Sources and Environmental Fate

5.2.1 Production, Use, and Release

No data on production of ethoprop are available from the EPA's Inventory Update Reporting (IUR) and Chemical Data Reporting (CDR) programs. Data on industrial releases are available from the EPA's Toxics Release Inventory (TRI). In addition, several sources provide information about quantities of ethoprop used in agriculture. Additional information about these sources is provided in Chapter 2.

Toxics Release Inventory (TRI)

The EPA established TRI in 1987 in response to Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). EPCRA Section 313 requires the reporting of annual information on toxic chemical releases from facilities that meet specific criteria. This reported information is maintained in a database accessible through TRI Explorer (USEPA, 2023a).

Although TRI can provide a general idea of release trends, it has limitations. Not all facilities are required to report all releases. Facilities are generally required to report releases if they manufacture or process more than 25,000 pounds of a chemical or use more than 10,000 pounds per year. Reporting requirements have changed over time (e.g., reporting thresholds have increased or decreased), so conclusions about temporal trends should be drawn with caution. TRI

data are meant to reflect releases and should not be used to estimate general public exposure to a chemical (USEPA, 2022b).

TRI data for ethoprop from the years 1995-2022 are summarized in Exhibit 5-3 (USEPA, 2023a). Through 2010, on-site releases to land dominated reported total releases, varying between tens of thousands of pounds and hundreds of thousands of pounds. After 2010, there were no more reported on-site releases to land. Over the course of the entire period, there were sporadically on-site air emissions and off-site releases, and there were no on-site surface water discharges or underground injections.

Exhibit 5-3: Environmental Releases of Ethoprop in the United States, 1995-2022 (pounds)

Year	On-Site Air Emissions	On-Site Surface Water Discharges	On-Site Underground Injection	On-site Releases to Land	Off-site Disposal or Other Releases	Total On- and Off-site Disposal or Other Releases
1995	506	0	0	174,290	.	174,796
1996	866	0	0	108,933	250	110,049
1997	26	0	0	132,926	.	132,952
1998	34	0	0	116,444	6	116,484
1999	1	0	0	121,886	27	121,914
2000	46	0	0	104,984	.	105,030
2001	7	0	0	77,376	500	77,883
2002	7	0	0	121,928	.	121,935
2003	7	0	0	114,867	.	114,874
2004	6,212	0	0	71,574	.	77,786
2005	1,062	0	0	102,997	.	104,059
2006	79	0	0	133,592	.	133,671
2007	160	0	0	48,067	84	48,311
2008	273	0	0	44,324	.	44,597
2009	123	0	0	59,241	.	59,364
2010	44	0	0	35,616	.	35,660
2011	65	0	0	0	.	65
2012	90	0	0	0	.	90
2013	31	0	0	0	525	556
2014	15	0	0	0	.	15
2015	.	.	.	.	.	.
2016	.	.	.	.	.	.
2017	10	0	0	0	.	10
2018	1	0	0	0	.	1
2019	<1	0	0	0	.	<1
2020	10	0	0	0	.	10

Year	On-Site Air Emissions	On-Site Surface Water Discharges	On-Site Underground Injection	On-site Releases to Land	Off-site Disposal or Other Releases	Total On- and Off-site Disposal or Other Releases
2021	10	0	0	0	11,092	11,102
2022	12	0	0	0	8,855	8,867

Source: USEPA, 2023a

Note: A decimal point indicates that one or more facilities either left an applicable field blank or certified in streamlined reporting that annual release did not exceed 500 pounds, and that otherwise no releases were reported.

Exhibit 5-4 presents an expanded summary of total releases and total surface water discharges that includes the count of states reporting releases (USEPA, 2023a). Note that for the purposes of TRI, “state” counts include the District of Columbia and U.S. territories in addition to the 50 states. No states had reported surface water discharges of ethoprop from 1995 to 2022. No more than 4 states had any reported releases of ethoprop in a given year.

Exhibit 5-4: Summary of Total Releases and Total Surface Water Discharges of Ethoprop, 1995-2022

Year	On-Site Surface Water Discharges (in pounds)	Count of States with Surface Water Discharges	Total Releases (in pounds)	Count of States with Releases
1995	0	0	174,796	4
1996	0	0	110,049	4
1997	0	0	132,952	3
1998	0	0	116,484	4
1999	0	0	121,914	3
2000	0	0	105,030	3
2001	0	0	77,883	3
2002	0	0	121,935	3
2003	0	0	114,874	3
2004	0	0	77,786	4
2005	0	0	104,059	3
2006	0	0	133,671	2
2007	0	0	48,311	3
2008	0	0	44,597	2
2009	0	0	59,364	3
2010	0	0	35,660	2
2011	0	0	65	1
2012	0	0	90	1
2013	0	0	556	4
2014	0	0	15	2
2015	.	0	.	0
2016	.	0	.	0

Year	On-Site Surface Water Discharges (in pounds)	Count of States with Surface Water Discharges	Total Releases (in pounds)	Count of States with Releases
2017	0	0	10	2
2018	0	0	1	1
2019	0	0	<1	1
2020	0	0	10	1
2021	0	0	11,102	1
2022	0	0	8,867	3

Source: USEPA, 2023a

Note: A decimal point indicates that one or more facilities either left an applicable field blank or certified in streamlined reporting that annual release did not exceed 500 pounds, and that otherwise no releases were reported. For the purpose of counting states with releases, a decimal point was treated as a zero.

EPA Pesticide Industry Sales and Usage Report

The EPA’s Pesticide Industry Sales and Usage reports state that the amount of ethoprop active ingredient used in the United States was <1 million pounds in 2012 (USEPA, 2017).

National Center for Food and Agricultural Policy (NCFAP) Pesticide Use Database

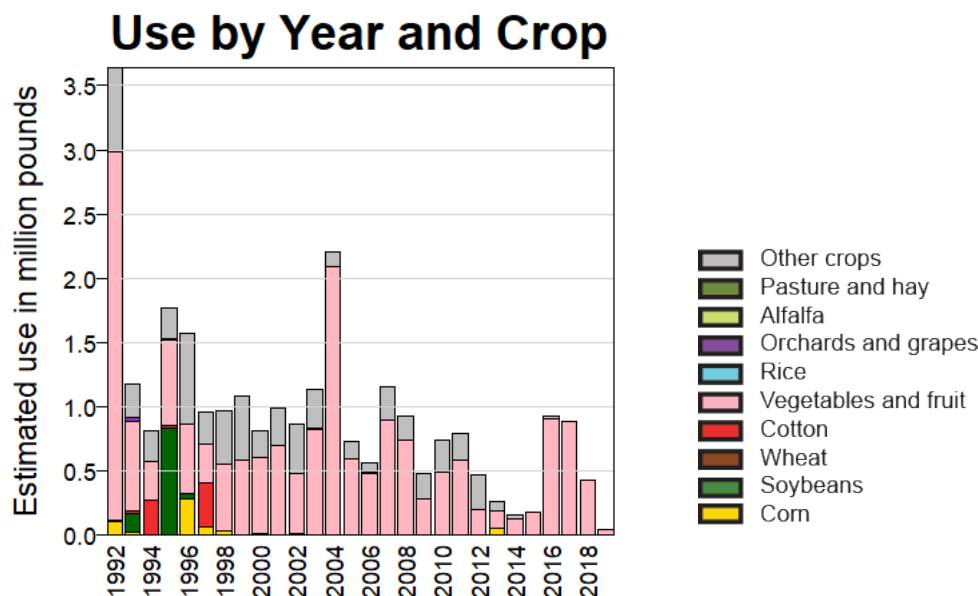
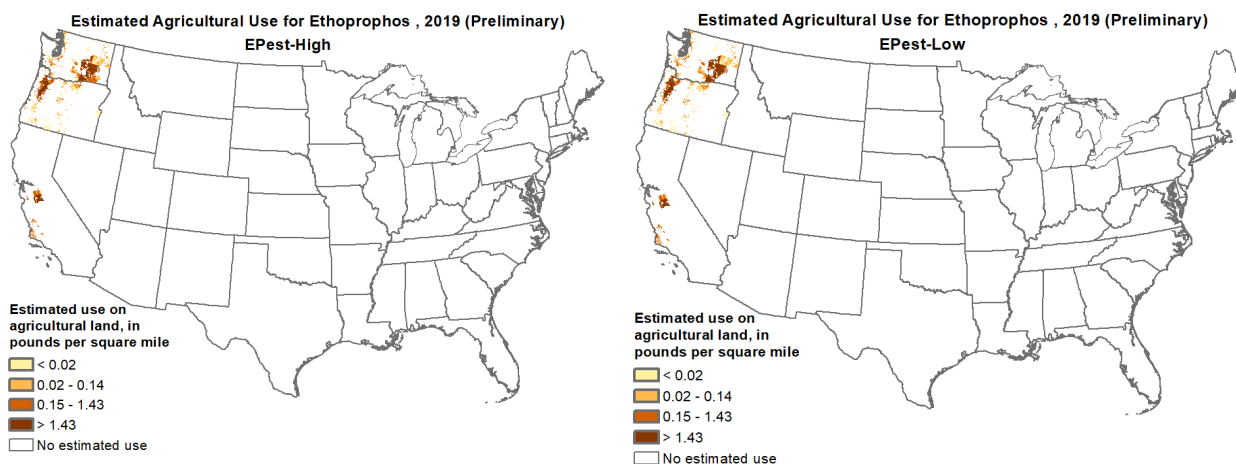
The National Center for Food and Agricultural Policy (NCFAP) maintains a national Pesticide Use Database, primarily for herbicides. Pesticide use estimates are based on state-level commercial agriculture usage patterns and state-level crop acreage. NCFAP listed uses of ethoprop on 9 crops totaling approximately 1.45 million pounds active ingredient per year in 27 states in 1992. In 1997, NCFAP listed uses of ethoprop on 10 crops totaling approximately 1.01 million pounds active ingredient per year in 25 states (NCFAP, 2000).

United States Geological Survey (USGS) Pesticide Use Maps

The United States Geological Survey (USGS) produces estimates of annual national pesticide use for over 200 compounds. USGS pesticide use maps show the average annual pesticide use intensity expressed as average weight (in pounds) of a pesticide applied to each square mile of agricultural land in a county. The USGS maps are created using data from NCFAP and county-level information on harvested crop acreage from the Census of Agriculture (USGS, 2023).

Exhibit 5-5 shows the geographic distribution of estimated annual ethoprop use in the United States in 2019. The differences between the “low” and “high” estimates primarily reflect assumptions made when data on usage of a pesticide were unavailable from a crop reporting district (i.e., an assumption of no pesticide usage or an assumption that usage was comparable to neighboring districts). A breakdown of use by crop from year to year is also included below, using the “high” assumption. Ethoprop is mostly used on vegetables and fruit. Estimated usage has declined, unevenly, over the past few decades. The map indicates that ethoprop usage in 2019 was limited to the Pacific Northwest and California (USGS, 2023).

Exhibit 5-5: Estimated Annual Agricultural Use of Ethoprop, 2019



Source: USGS, 2023

5.2.2 Environmental Fate

As discussed in Chapter 2, the measures used by the EPA to assess mobility include (where available) the organic carbon partitioning coefficient (K_{oc}), log octanol-water partitioning coefficient ($\log K_{ow}$), Henry's Law Constant (K_H), water solubility, and vapor pressure. A vapor pressure of 0.00038 mm Hg at 20-25 degrees C indicates that ethoprop will exist in the vapor phase if it is released to the atmosphere. Photochemically-produced hydroxyl radicals will degrade ethoprop in air with a half-life of 5.6 hours. K_{oc} values of 70-120 L/kg suggest that ethoprop will have high mobility in soil (implying high mobility in water as well); however, ethoprop is not expected to volatilize from dry or wet soil surfaces. With a K_H of 1.62×10^{-7} atm-m³/mol, volatilization from water is not expected to be an important removal mechanism (NCBI, 2023).

Under aerobic conditions, half-lives of ethoprop in soil, due primarily to biodegradation, in various studies are reported to be 3-4 days, 5-12 days, 3-56 days, 2-12 weeks, 12 days at 20 °C to 89 days at 2 °C, 16 days at 20 °C to 144 days at 2 °C, 73 days at 20 °C to 347 days at 6 °C and 10.9-28.8 days. Temperature and the sterile/non-sterile nature of the soils were primary factors in the magnitude of observed half-lives (NCBI, 2023).

Hydrolysis half-lives of ethoprop in distilled water, river water, brackish water and sea water range from 25-133 days. Photolysis half-lives of ethoprop range from 4.7-12.3 days depending on the degree of sunlight (NCBI, 2023). Bioconcentration of ethoprop in aquatic organisms is expected to be low (NCBI, 2023).

5.3 Health Effects

5.3.1 Health Assessment Identification

Ethoprop is a currently registered pesticide chemical under the EPA’s Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (USEPA, 2015a). For currently registered pesticide chemicals, the RD 5 Protocol provides that toxicity information from EPA OPP Health Effects Division (HED) Human Health Risk Assessments (HHRAs) are to be used as the basis for calculating health reference levels (HRLs). (See Section B.5.1.1 of the RD 5 Protocol, found in Appendix B of this document.) Therefore, the EPA reviewed the toxicity information in the HHRA for ethoprop (USEPA, 2015a; USEPA, 2015b). The OPP health assessment provides a toxicity value relevant to chronic oral toxicity and was published prior to the cutoff date of January 2023.

Exhibit 5-6 provides a summary overview of the OPP health assessment data reviewed and selected for ethoprop under RD 5.

Exhibit 5-6: OPP Health Assessment Supporting Current FIFRA Registration for Ethoprop

Health Assessment ^a	Oral Reference Value	POD Type	Noncancer Critical Study	Oral Cancer Slope Factor ^b	Cancer Critical Study	Cancer Descriptor
<i>EPA OPP Human Health Risk Assessment^c (USEPA, 2015a; USEPA, 2015b)</i>	<i>0.000065^d</i>	<i>BMDL₁₀</i>	<i>Chartier et al. (2005)</i>	0.0281	Williams (1992)	S ^e

Notes: POD = point of departure; BMDL₁₀ = lower bound of the 95 percent confidence interval on the benchmark dose level associated with a 10 percent response.

^a Selected health assessment and chronic toxicity value and supporting information are bolded and italicized.

^b Cancer slope factors (CSFs) are expressed in (mg/kg/day)⁻¹ unless otherwise specified.

^c The EPA OPP considers this health assessment “final” at the time of publication in the Federal Register.

^d The oral reference value, in units of mg/kg/day, is a steady-state population-adjusted dose (ssPAD) (USEPA, 2015a).

^e In the 2015 HHRA, OPP HED classified ethoprop as “Likely to be carcinogenic to humans” by following the EPA’s 2005 *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005) and calculated an oral cancer slope factor (USEPA, 2015a). However, since publishing the 2015 HHRA, OPP HED has updated the cancer classification for ethoprop to “Suggestive Evidence of Carcinogenic Potential” (USEPA 2023b). Both designations were determined by following the process described in the EPA’s 2005 *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005). The EPA has further determined that quantification of risk using a non-linear approach (i.e., the reference dose, or RfD) will adequately account for all chronic toxicity, including any potential carcinogenicity, that could result from exposure to ethoprop (USEPA, 2023b).

5.3.2 Health Assessment Selection

The health assessment selected for ethoprop under RD 5 is the 2015 EPA OPP HHRA (USEPA 2015a; USEPA, 2015b) because it supported the most recent FIFRA registration decision for ethoprop. The 2015 EPA OPP HHRA (USEPA, 2015a) provided both cancer and noncancer toxicity values for ethoprop: an oral reference value and an oral cancer slope factor (CSF). In 2023, OPP’s Pesticide Re-evaluation Division (PRD) requested that HED conduct exposure assessments for ethoprop to estimate human health risks resulting from registered uses (USEPA, 2023b). The cancer classification was then changed from “Likely to be Carcinogenic to Humans” to “Suggestive Evidence of Carcinogenic Potential” based on the presence of thyroid C-cell tumors in male F344 rats (USEPA, 2005; USEPA, 2023b). Although the study showed suggestive cancer effects from exposure to ethoprop, there were no concerns for mutagenicity. As a result, HED recommended using a non-linear (i.e., reference dose, or RfD) approach as a protective measure of carcinogenic risk and did not conduct a new cancer assessment (USEPA, 2023b).

Therefore, the EPA selected the non-cancer oral reference value provided in the 2015 EPA OPP HHRA as the basis for derivation of an HRL under RD 5 (USEPA 2015a). See Section B.5.1.2 of the RD 5 Protocol, in Appendix B of this document, for the decision logic that was applied to health assessment selection for RD 5 chemicals.

5.3.3 Health Reference Level (HRL) Development

HRLs are non-regulatory health-based toxicity values, expressed as concentrations in drinking water, that are used by the Agency to evaluate occurrence data for a contaminant when making decisions about regulatory determinations. See Section B.6.1.1 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA’s approach for deriving HRLs for chemicals.

5.3.3.1 Oral Reference Value

In the 2015 EPA HHRA (USEPA, 2015a), OPP selected a repeat dosing rat study (Chartier et al. 2005) as the critical study to derive the oral reference value. In this study, six Wistar “young adult” rats (eight to ten weeks old) of each sex per group, and ten preweanling pups (aged post-natal day 11, or PND 11, at the start of dosing) of each sex per group, were exposed to ethoprop via gavage for 11 consecutive days in doses of 0, 0.25, 0.5, or 1 mg/kg/day. Blood and brain samples were collected after the final dose to measure effects on plasma cholinesterase (ChE), erythrocyte (i.e., red blood cell, or RBC) acetylcholinesterase (AChE), and brain AChE (Chartier et al. 2005; USEPA, 2015a).

At the high dose level (1 mg/kg/day), both sexes of adult rats and pups experienced a statistically significant decrease in plasma ChE and RBC AChE activity, and brain AChE activity was significantly reduced in pups and adult females compared to the controls (Chartier et al. 2005). Plasma ChE activity was significantly reduced in all rats exposed to the mid-dose level (0.5 mg/kg/day), and RBC AChE activity was reduced significantly in the adult and male pup groups. There was a significant reduction of brain AChE activity in both sexes of pups in the mid-dose and low-dose (0.025 mg/kg/day) groups, and plasma ChE activity was significantly reduced in pups and adult females exposed to the lowest dose of ethoprop (Chartier et al. 2005).

OPP conducted benchmark dose (BMD) modeling to determine dosages associated with 10 percent inhibition (BMD₁₀) of RBC AChE in male pup rats, as this was the most sensitive endpoint analyzed (USEPA, 2015a). A lower bound of the 95 percent confidence interval on the BMD₁₀, or BMDL₁₀, of 0.0653 mg/kg/day was calculated for this critical effect as a point of departure (POD) for quantifying toxicity in humans (USEPA, 2015a). A total uncertainty factor (UF) of 1,000 was applied to the POD: an interspecies UF (UF_A) of 10, an intraspecies UF (UF_H) of 10, and a Food Quality Protection Act safety factor (FQPA SF) of 10 to account for uncertainty in the human dose-response relationship for neurodevelopmental effects (USEPA, 2015a). After applying the total UF, the oral reference value (a steady-state population-adjusted dose, or ssPAD) was calculated to be 0.000065 mg/kg/day. The EPA selected this oral reference value (0.000065 mg/kg/day) from the 2015 EPA OPP HHRA (USEPA, 2015a) to derive an HRL for ethoprop.

5.3.3.2 Exposure Factor Selection

In prioritizing the contaminants of greatest public health concern for regulatory determination, Section 1412(b)(1)(C) of the Safe Drinking Water Act (SDWA) requires the Agency to consider “among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water compared to the general population.” One way that the EPA considers potentially sensitive populations or life stages (i.e., populations or life stages that may be more susceptible or sensitive to a chemical exposure) is during the selection of exposure factors (EFs) for the development of HRLs.

Drinking water intake rate adjusted for body weight (DWI-BW) is the EF used to derive HRLs for RD 5 (USEPA, 2019). EFs are input values intended to protect the general population, including sensitive populations or life stages, from adverse effects resulting from exposure to a contaminant. The Agency selects an appropriate DWI-BW for each chemical by reviewing the critical effect and study used for HRL derivation and identifying the interval of exposure (for example, see USEPA, 2022c; USEPA, 2022d). Since the critical effect represents the most sensitive adverse effect observed in the best available studies for a given chemical, it is reasonable to assume that the interval of exposure in the critical study could inform the selection of a DWI-BW protective of sensitive populations. When multiple potentially sensitive populations or life stages are identified based on the interval of exposure in the study used for HRL derivation, the EPA selects the population or life stage with the highest DWI-BW because it is the most health protective. See Section B.6.1.2 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA’s EF selection process.

In the critical study (Chartier et al. 2005) selected in the 2015 EPA OPP HHRA (USEPA, 2015a), male and female preweanling rats were exposed to ethoprop for 11 consecutive days, beginning on PND 11. Following the decision logic described in Section B.6.1.2 of the RD 5 Protocol, the EPA selected a corresponding human life stage. The EPA determined that rodents from birth through three weeks old are in the growth stage between birth and weaning and approximately correspond to the neonatal and infancy life stages in humans (Ghasemi et al., 2021; Wang et al., 2020). Therefore, the EPA used the DWI-BW representing the 90th percentile consumers-only two-day average of direct and indirect community water consumption for infants (birth to < 1 year), which equals 0.143 L/kg/day (USEPA, 2019), to derive the HRL for ethoprop.

5.3.3.3 Relative Source Contribution

Relative source contribution (RSC) is used to account for exposure via non-drinking water routes when deriving health-based drinking water concentrations for contaminants with threshold effects (noncarcinogens and nonlinear carcinogens). RSC is defined as the portion (percentage) of an individual's exposure attributed to drinking water rather than other sources (e.g., food, ambient air). A 20 percent RSC is used for all RD 5 contaminants, consistent with past practice for regulatory determinations, to derive the HRL because (1) HRLs are developed prior to completing the exposure assessment; and (2) a 20 percent RSC is the lowest RSC that can be applied for deriving health-based drinking water concentrations according to EPA guidance (USEPA, 2000), and it therefore produces the most health protective HRL. Should a contaminant proceed to a National Primary Drinking Water Regulation (NPDWR), a full exposure analysis is conducted, and an RSC is derived following the Exposure Decision Tree approach described in the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000).

5.3.3.4 HRL Calculation

Exhibit 5-7 summarizes the critical study and toxicity information from the qualifying health assessment and the EF (DWI-BW) and RSC that the EPA used to derive the HRL for ethoprop.

Exhibit 5-7: Basis of HRL for Ethoprop

Selected Health Assessment	Critical Study	Interval of Exposure	Critical Effect	Oral Toxicity Value	RSC	Target Population	Exposure Factor
EPA OPP Human Health Risk Assessment (USEPA, 2015a; USEPA, 2015b)	Chartier et al. (2005)	11 days; beginning at 11 days of age	Inhibition of RBC AChE in male rats	0.000065 mg/kg/day	0.2 (20%)	Infants (birth to <1 year)	0.143 L/kg/day

The EPA calculates HRLs for contaminants with a threshold dose-response, including ethoprop, as follows:

$$HRL = \frac{RfD}{DWI-BW} * RSC$$

where:

RfD = Reference dose (mg/kg/day), an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. It is derived in the selected qualifying health assessment and is based on the critical effect and study identified in that assessment. Other values that can be used in place of an RfD in this equation can include a maximum acceptable concentration (MAC), minimal risk level, point of departure / uncertainty factor (POD/UF), population-adjusted dose (PAD), or tolerable daily intake (TDI).

DWI-BW = Drinking water intake (DWI), adjusted for body weight (BW), in units of liter per kilogram body weight per day (L/kg/day).

RSC = Relative source contribution, the percentage of the total exposure attributed to drinking water sources (USEPA, 2000), where the remainder of the exposure is allocated to other routes or sources. For HRL derivation in RD 5, an RSC of 20 percent is used for all contaminants.

Using an oral reference value of 0.000065 mg/kg/day (USEPA, 2015a; USEPA, 2015b), a DWI-BW of 0.143 L/kg/day (USEPA, 2019), and a 20 percent RSC to account for non-drinking-water sources of exposure (USEPA, 2000), the HRL for ethoprop is calculated as follows:

$$HRL = \frac{0.000065 \text{ mg/kg/day}}{0.143 \text{ L/kg/day}} * 0.2$$

$$HRL = 0.0000909 \text{ mg/L}$$

or

$$HRL = 0.0909 \text{ } \mu\text{g/L}$$

Following HRL derivation practices, the HRL for ethoprop is 0.09 $\mu\text{g/L}$ after rounding to one significant figure.

5.4 Occurrence

This section presents data on the occurrence of ethoprop in ambient water and drinking water in the United States. As described in Section 5.3, an HRL of 0.09 $\mu\text{g/L}$ was calculated for ethoprop based on non-carcinogenic effects. HRLs are risk-derived concentrations against which the EPA evaluates the occurrence data to determine if contaminants occur at levels of potential public health concern. Occurrence data from various sources presented below are analyzed with respect to the HRL and one-half the HRL. When possible, estimates of the population exposed at concentrations above the HRL and one-half the HRL are presented.

For additional background information about data sources used to evaluate occurrence, please refer to Chapter 2.

5.4.1 Occurrence in Ambient Water

Lakes, rivers, and aquifers are the ambient sources of most drinking water. Contaminant occurrence in ambient water provides information on the potential for contaminants to adversely affect drinking water supplies. Occurrence data for ethoprop in ambient water are available from the USGS National Water-Quality Assessment (NAWQA) program, the USGS National Water Information System (NWIS) database, the EPA's legacy Storage and Retrieval Data System (STORET), and several published studies. When sources of information on ambient occurrence also include limited finished water data, those finished water data are summarized here as well.

5.4.1.1 United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) Ambient Water Analyses

USGS instituted the NAWQA program in 1991 to examine ambient water quality status and trends in the United States. The NAWQA program generates high quality contaminant occurrence and other water quality parameter data for significant watersheds and aquifers across the nation. The program collects data on surface water and groundwater chemistry, hydrology, land use, stream habitat, and aquatic life in parts of nearly all 50 states. The program is designed to apply nationally consistent methods to provide a uniform basis for contaminant occurrence comparisons and assessments among study basins across the country and over time. The occurrence assessments can also serve to facilitate interpretation of natural and anthropogenic factors affecting national water quality. For more detailed information on NAWQA program design and implementation, refer to Leahy and Thompson (1994) and Hamilton et al. (2004).

The process of sampling, analysis, and data synthesis is divided into cycles of approximately ten years: Cycle 1 covered 1991-2001, Cycle 2 covered 2002-2012, and Cycle 3 covered 2013-2023. Study units are sampled and analyzed on a staggered schedule within each cycle. Each NAWQA cycle begins with a two-year startup phase for planning and retroactive analysis, followed by a three-year intensive data collection phase, and finally a five-year phase for analyzing the data, developing reports, and continuing a low level of monitoring (NRC, 2012).

The EPA downloaded NAWQA data from the Water Quality Portal (WQP) in September 2023 (WQP, 2023). The EPA's analysis of the NAWQA data is a simple, non-parametric occurrence analysis that provides summary statistics to characterize contaminant occurrence. The EPA included in the analysis all samples that could be classified as groundwater and surface water, and also the limited number of samples labeled as finished water. Other types of samples (e.g., from soil, sediment, and wastewater) were excluded. The EPA calculated detection frequencies as the percentage of samples and the percentage of sites with at least one detection. (A detection is an analytical result equal to or greater than the reporting level.) No weighting was applied. The EPA determined the minimum and maximum detected concentrations and calculated other descriptive statistics including the median, 90th percentile, and 99th percentile concentrations (based only on samples with detections). Reporting levels varied over time during the NAWQA program.

The results of the EPA's analysis of NAWQA data downloaded from WQP are presented in Exhibit 5-8 through Exhibit 5-10. In all three cycles, ethoprop was found more frequently in surface water samples (with detection frequencies ranging from 1.47 percent to 2.03 percent) than in groundwater samples (with detection frequencies ranging from 0 percent to 0.04 percent). Surface water generally also had higher concentrations than groundwater. No groundwater concentrations exceeded the ethoprop HRL of 0.09 µg/L. In each cycle, there were surface water concentrations in excess of the HRL; the highest concentration observed was 5.75 µg/L. The NAWQA data for ethoprop included 2 finished water samples in Cycle 1 and 63 samples in Cycle 2. There were no ethoprop detections in finished water.

Note that there may be some overlap between the NAWQA data assessment presented here and summaries of individual NAWQA studies presented below.

Exhibit 5-8: Ethoprop NAWQA Data – Summary of Detected Concentrations

Site Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90 th Percentile	99 th Percentile	Maximum
Cycle 1 (1991 - 2001)					
Finished Water	--	--	--	--	--
Groundwater	0.009	0.009	0.009	0.009	0.009
Surface Water	0.001	0.011	0.105	0.756	1.95
All Sites	0.001	0.011	0.103	0.755	1.95
Cycle 2 (2002 - 2012)					
Finished Water	--	--	--	--	--
Groundwater	0.006	0.0075	0.0084	0.0089	0.009
Surface Water	0.00045	0.0235	0.122	0.585	5.75
All Sites	0.00045	0.0230	0.119	0.584	5.75
Cycle 3 (2013 - 2023)					
Groundwater	--	--	--	--	--
Surface Water	0.00042	0.00762	0.0822	0.539	0.861
All Sites	0.00042	0.00762	0.0822	0.539	0.861

Source: WQP, 2023

"--" = No detections in this category

Exhibit 5-9: Ethoprop NAWQA Data – Summary of Samples

Site Type	No. of Samples	Detection Frequency (detections are results $\geq$ reporting level)					
		No. of Samples with Detections	Percent Samples with Detections	No. of Samples with Detections $> \frac{1}{2}$ HRL	Percent Samples with Detections $> \frac{1}{2}$ HRL	No. of Samples with Detections $>$ HRL	Percent Samples with Detections $>$ HRL
Cycle 1 (1991 - 2001)							
Finished Water	2	0	0.00%	0	0.00%	0	0.00%
Groundwater	6,382	1	0.02%	0	0.00%	0	0.00%
Surface Water	15,242	245	1.61%	46	0.30%	28	0.18%
All Sites	21,626	246	1.14%	46	0.21%	28	0.13%
Cycle 2 (2002 - 2012)							
Finished Water	63	0	0.00%	0	0.00%	0	0.00%
Groundwater	4,540	2	0.04%	0	0.00%	0	0.00%
Surface Water	8,412	124	1.47%	38	0.45%	20	0.24%
All Sites	13,015	126	0.97%	38	0.29%	20	0.15%
Cycle 3 (2013 - 2023)							
Groundwater	1,882	0	0.00%	0	0.00%	0	0.00%
Surface Water	14,110	287	2.03%	53	0.38%	28	0.20%
All Sites	15,992	287	1.79%	53	0.33%	28	0.18%

Source: WQP, 2023

Exhibit 5-10: Ethoprop NAWQA Data – Summary of Sites

Site Type	No. of Sites	Detection Frequency (detections are results ≥ reporting level)					
		No. of Sites with Detections	Percent Sites with Detections	No. of Sites with Detections > ½ HRL	Percent Sites with Detections > ½ HRL	No. of Sites with Detections > HRL	Percent Sites with Detections > HRL
Cycle 1 (1991 - 2001)							
Finished Water	2	0	0.00%	0	0.00%	0	0.00%
Groundwater	5,508	1	0.02%	0	0.00%	0	0.00%
Surface Water	1,845	81	4.39%	16	0.87%	9	0.49%
All Sites	7,355	82	1.11%	16	0.22%	9	0.12%
Cycle 2 (2002 - 2012)							
Finished Water	52	0	0.00%	0	0.00%	0	0.00%
Groundwater	2,999	2	0.07%	0	0.00%	0	0.00%
Surface Water	205	11	5.37%	3	1.46%	3	1.46%
All Sites	3,256	13	0.40%	3	0.09%	3	0.09%
Cycle 3 (2013 - 2023)							
Groundwater	1,764	0	0.00%	0	0.00%	0	0.00%
Surface Water	481	28	5.82%	6	1.25%	5	1.04%
All Sites	2,245	28	1.25%	6	0.27%	5	0.22%

Source: WQP, 2023

NAWQA Pesticide National Synthesis Project, 1992-2001

The NAWQA Pesticide National Synthesis Project is a national-scale assessment of the occurrence and behavior of pesticides in streams and groundwater of the United States and the potential for pesticides to adversely affect drinking water supplies or aquatic ecosystems. The Pesticide National Synthesis analysis is based on Cycle 1 data from NAWQA study units (Gilliom et al., 2007). Cycle 1 began in 1991, and the date range of the data is given as 1992-2001. Data for surface water and groundwater are presented separately, and results in each category are subdivided by land use category. Land use categories include agricultural, urban, mixed (deeper aquifers of regional extent in the case of groundwater), and undeveloped.

Over the course of Cycle 1, some NAWQA analytical methods were improved or changed. Hence, detection thresholds varied over time for some compounds. USGS used the maximum Long-Term Method Detection Level (LT-MDL) for each analyte as a uniform reporting threshold. The maximum LT-MDL for ethoprop was 0.002 µg/L (Gilliom et al., 2007).

In NAWQA stream samples (Exhibit 5-11), ethoprop was found at frequencies ranging from 0.70 percent of samples in undeveloped areas to 0.62 percent of samples in mixed land use settings, 0.91 percent of samples in urban areas, and 2.90 percent of samples in agricultural settings. The 95th percentile concentration was less than the maximum LT-MDL in all settings. The highest surface water concentration was 0.455 µg/L.

Exhibit 5-11: USGS National Synthesis Summary of NAWQA Monitoring of Ethoprop in Streams, 1992-2001

Land Use Type	Number of Sites	Number of Samples	Detection Frequency (Samples)	Concentration Values (among all samples, in µg/L)		
				Median	95 th Percentile	Maximum
Agricultural	83	1,996	2.90%	ND	ND	0.455
Mixed	65	1,381	0.62%	ND	ND	0.052
Undeveloped	8	144	0.70%	ND	ND	0.019
Urban	30	807	0.91%	ND	ND	0.124

Source: Gilliom et al., 2007

ND = not detected (concentration is less than the maximum LT-MDL and is expected to be less than any higher percentile concentration shown in the table).

In NAWQA groundwater samples (Exhibit 5-12), ethoprop was found at frequencies of 0 percent of samples in undeveloped areas, 0 percent in mixed land use settings, 0 percent in urban areas, and 0.07 percent in agricultural settings. The 95th percentile concentrations were less than the maximum LT-MDL in all settings. The highest groundwater concentration was 0.009 µg/L.

Exhibit 5-12: USGS National Synthesis Summary of NAWQA Monitoring of Ethoprop in Groundwater, 1992-2001

Land Use Type	Number of Wells	Detection Frequency	Concentration Values (among all samples, in µg/L)		
			Median	95 th Percentile	Maximum
Agricultural	1,401	0.07%	ND	ND	0.009
Mixed	2,728	0.00%	ND	ND	ND
Undeveloped	34	0.00%	ND	ND	ND
Urban	854	0.00%	ND	ND	ND

Source: Gilliom et al., 2007

ND = not detected (concentration is less than the maximum LT-MDL and is expected to be less than any higher percentile concentration shown in the table).

5.4.1.2 National Water Information System (NWIS) Data

NWIS is the nation's principal repository of water resources data collected by USGS from more than 1.9 million sites in all U.S. states and territories (USGS, 2022). All USGS water quality and flow data are stored in NWIS, including site characteristics, streamflow, groundwater level, precipitation, and chemical analyses of water, sediment, and biological media, though not all parameters are available for every site. NWIS houses the NAWQA data and includes other USGS data from a range of unspecified projects. NWIS encompasses many more samples at many more sites than are involved in the NAWQA Program. Although NWIS is comprised of primarily ambient water data, some finished drinking water data are included as well. This section presents analyses of non-NAWQA data in NWIS, downloaded from the WQP in

September 2023 (WQP, 2023). These data do not overlap with the NAWQA results presented above.

The results of the non-NAWQA NWIS ethoprop analysis are presented in Exhibit 5-13. Ethoprop was detected in 168 (0.5 percent) of 33,672 samples at 98 (0.9 percent) of 10,958 sites. Ethoprop was detected more frequently and at higher concentrations in surface water than in groundwater. The highest reported concentration, 7.7 µg/L, observed in groundwater, exceeded the HRL. Ethoprop was detected in finished water in 1 of 16 samples at 1 of 8 sites; the detected concentration (0.006 µg/L) did not exceed ½ the HRL. Note that the NWIS data are presented as downloaded; potential outliers were not evaluated or excluded from the analysis.

Exhibit 5-13: Ethoprop NWIS Data, 1991-2023

Sample Media Type	Detection Frequency (detections are results ≥ reporting level)				Concentration Values (of detections, in µg/L)				
	No. of Samples	No. of Samples with Detections	No. of Sites	No. of Sites with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
Finished Water	16	1	8	1	0.006	0.006	0.006	0.006	0.006
Groundwater	13,123	7	7,844	7	0.00114	0.003	0.099	0.103	0.103
Surface Water	20,533	160	3,130	90	0.0002	0.016	0.141	2.38	7.7
Total	33,672	168	10,958	98	0.0002	0.016	0.140	2.28	7.7

Source: WQP, 2023

Note that some NWIS sites are associated with multiple sample media types, so site counts might not add up to totals.

5.4.1.3 Storage and Retrieval (STORET) Data

From its launch in 1999 until it was decommissioned in June 2018, the EPA's STORET Data Warehouse was collaboratively populated with raw biological, chemical, and physical data from surface water and groundwater sampling by federal, state and local agencies, Native American Tribes, volunteer groups, academics, and others. Legacy STORET data, as well as more current STORET data, are accessible through the WQP.

STORET data are from monitoring locations in all 50 states as well as multiple territories and jurisdictions of the United States. STORET's data quality limitations include variations in the extent of national coverage and data completeness from parameter to parameter. Data may have been collected as part of targeted, rather than randomized, monitoring. This section presents analyses of STORET data, downloaded from the WQP in September 2023 (WQP, 2023). The EPA reviewed STORET groundwater data from wells and springs and surface water data from lakes, rivers/streams, and reservoirs. The STORET data set also included limited data from public water systems (PWSs). The database does not specify whether PWS sampling was conducted before or after treatment.

The results of the STORET analysis for ethoprop are presented in Exhibit 5-14 through Exhibit 5-16. Samples were collected between 1991 and 2017. Ethoprop was detected in 3 (0.25 percent) of surface water samples from 3 (0.84 percent) of 357 sites and in none of 24 groundwater samples from 16 sites. The highest reported concentration, 0.385 µg/L, is greater than the HRL of 0.09 µg/L.

Exhibit 5-14: Ethoprop STORET Data – Summary of Detected Concentrations

Source Water Type	Concentration Value of Detections (µg/L)			
	Minimum	Median	90 th Percentile	Maximum
Groundwater	--	--	--	--
Surface Water	0.021	0.038	0.281	0.385
Total	0.021	0.038	0.281	0.385

Source: WQP, 2023

"--" = No detections in this category

Exhibit 5-15: Ethoprop STORET Data – Summary of Samples and Sites

Source Water Type	Total Number of Samples	Samples with Detections		Total Number of Sites	Sites with Detections	
		Number	Percent		Number	Percent
Groundwater	24	0	0.00%	16	0	0.00%
Surface Water	1,191	3	0.25%	357	3	0.84%
Total	1,215	3	0.25%	373	3	0.80%

Source: WQP, 2023

Exhibit 5-16: Ethoprop STORET Data – Summary of States

Source Water Type	Total Number of States	States with Detections	
		Number	Percent
Groundwater	3	0	0%
Surface Water	11	2	18%
Total¹	11	2	18%

Source: WQP, 2023

¹ The number of states with groundwater data plus the number of states with surface water data may not equal the "Total" number of states providing data because some states provided both groundwater and surface water data.

5.4.1.4 Additional Ambient Water Studies

Kingsbury et al. (2021) evaluated groundwater-quality samples collected from 2017 to 2019 as part of the third cycle of USGS's NAWQA Program. Six types of well network studies were conducted: principal aquifer study networks; major aquifer study networks; land-use study networks; vertical flow-path study networks; enhanced trends networks; and modeling support studies. The reporting level used for ethoprop was 0.0025 µg/L. Ethoprop was not detected in any of the 470 samples at 464 sites.

Erickson et al. (2019) conducted a study to assess groundwater quality in the United States glacial aquifer system using groundwater samples gathered from approximately 39,000 wells from 2005 to 2013. Data were derived from three sources: the USGS NWIS, the EPA's

Safe Drinking Water Information System (SDWIS), and numerous agencies and organizations at the state, regional, and local level. No detections of ethoprop exceeded the “high” benchmark of 1 µg/L or the “moderate” benchmark of 0.1 µg/L in 1,449 analyses.

5.4.2 Occurrence in Drinking Water

Data sources reviewed by the EPA for information on contaminant occurrence in drinking water included: the EPA’s first, second, third, and fourth Unregulated Contaminant Monitoring Rules (UCMR 1, UCMR 2, UCMR 3, UCMR 4); Rounds 1 and 2 of the EPA’s Unregulated Contaminant Monitoring (UCM) program that preceded the Unregulated Contaminant Rule (UCMR); the EPA’s National Inorganics and Radionuclides Survey (NIRS); and a range of others as discussed in Chapter 2. Among the sources reviewed, the following sources had data and information on ethoprop occurrence in drinking water and are discussed in this section:

- The EPA’s Fourth Unregulated Contaminant Monitoring Rule (UCMR 4).
- State drinking water monitoring programs.
- Consumer Confidence Reports (CCRs) from PWSs.
- National Pesticide Survey (NPS).
- United States Department of Agriculture (USDA) Pesticide Data Program (PDP).
- USGS Pilot Monitoring Program (PMP).
- Additional source water and drinking water studies.

Note that there may be some overlap as sources with different purposes and audiences may have reported the same underlying data. UCMR 4 is a nationally representative data source. Other data sources profiled in this section are considered “supplemental” sources. Also note that the ambient water section, above, presents some limited finished water data and miscellaneous data from PWSs found in ambient water data sources.

5.4.2.1 Primary Data Sources

5.4.2.1.1 *The EPA’s Fourth Unregulated Contaminant Monitoring Rule (UCMR 4), 2018-2020*

The UCMR program was designed to provide a national assessment of the occurrence of select unregulated contaminants in PWSs. UCMR 4 was published on December 20, 2016 (USEPA, 2016a) and required monitoring for 30 chemical contaminants between 2018 and 2020. Data reporting continued into 2021.

UCMR 4 Assessment Monitoring occurrence data are available for ethoprop. For UCMR 4, all large and very large community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) (serving between 10,001 and 100,000 people and serving more than 100,000 people, respectively), plus a statistically representative national sample of 800 small CWSs and NTNCWSs (serving 10,000 people or fewer), were required to conduct Assessment Monitoring during a 12-month period between January 2018 and December 2020.¹ Surface water and groundwater under the direct influence of surface water (GWUDI) sampling points were

¹ Only 797 small systems submitted results for ethoprop.

monitored four times during the applicable year of monitoring. Groundwater sampling points were monitored twice during the applicable year of monitoring. See USEPA (2016a) and USEPA (2024a) for more information on the UCMR 4 study design and data analysis.

The design of UCMR 4 permits estimation of national occurrence by multiplying the total number of systems (or population served) in the nation in a system size category by the percent of systems (or population served) found to exceed a specified threshold in the sample. This extrapolation methodology is applied to small systems. Because all large and very large systems were required to participate in the UCMR 4 Assessment Monitoring, national occurrence estimates in these size categories can be developed using survey census figures rather than extrapolation. Total national occurrence is estimated by summing the extrapolated figures for small systems and the census figures for the large and very large systems.

Exhibit 5-17 through Exhibit 5-21 provide an overview of ethoprop occurrence results from UCMR 4 Assessment Monitoring. The minimum reporting level (MRL) used for ethoprop in the UCMR 4 survey was 0.03 µg/L. Exhibit 5-17 shows a statistical summary of ethoprop concentrations by system size and source water type (including the minimum, median, 90th percentile, 99th percentile, and maximum). Exhibit 5-18 presents a sample-level summary of the results. Exhibit 5-19 through Exhibit 5-21 show system-level results, including national extrapolations, at three thresholds: detections, ½ the HRL, and the HRL. Detections are evaluated on a “greater than or equal to” basis ($\geq$ the MRL), while health-based thresholds are evaluated in terms of exceedances ($> \frac{1}{2}$ HRL and $>$ HRL).

As a reminder that the figures from large and very large systems represent a census of systems in those categories, results in those categories are labeled “CENSUS” in the exhibits below. No extrapolation was necessary in these categories, as it was for the small systems, to derive national estimates of occurrence. National estimates of occurrence are reported separately in each system size and source water category, and also in the aggregate.

A total of 37,276 UCMR 4 samples for ethoprop were collected from 5,028 systems. Ethoprop was detected in only five samples (0.01 percent), with concentrations ranging from 0.0326 µg/L to 0.21 µg/L. The detections were found at five water systems, representing 0.10 percent of systems participating in the monitoring program. All reported detections were in systems serving more than 10,000 people. Three systems serving 75,032 people reported at least one detection of ethoprop greater than ½ the HRL of 0.045 µg/L and 1 system serving nearly 15,000 people reported at least one detection of ethoprop greater than the HRL of 0.09 µg/L.

Exhibit 5-17: Ethoprop Occurrence Data from UCMR 4 Assessment Monitoring – Summary of Reported Concentrations

Source Water Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90th Percentile	99th Percentile	Maximum
Small Systems (serving $\leq$ 10,000 people)					
Groundwater	--	--	--	--	--
Surface Water	--	--	--	--	--
All Small Systems	--	--	--	--	--
Large Systems (serving 10,001 - 100,000 people) -- CENSUS					
Groundwater	0.047	0.047	0.047	0.047	0.047
Surface Water	0.0326	0.059	0.180	0.207	0.21

Source Water Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90th Percentile	99th Percentile	Maximum
All Large Systems	0.0326	0.053	0.165	0.205	0.21
Very Large Systems (serving > 100,000 people) -- CENSUS					
Groundwater	--	--	--	--	--
Surface Water	0.041	0.041	0.041	0.041	0.041
All Very Large Systems	0.041	0.041	0.041	0.041	0.041
All Systems					
All Water Systems	0.0326	0.047	0.150	0.204	0.21

Source: USEPA, 2024a

"--" = No detections in this category

Exhibit 5-18: Ethoprop National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of Samples

Source Water Type	Total # of Samples	Samples with Detections ≥ MRL (0.03 µg/L)		Samples with Detections > ½ HRL (0.045 µg/L)		Samples with Detections > HRL (0.09 µg/L)	
		Number	Percent	Number	Percent	Number	Percent
Small Systems (serving ≤ 10,000 people)							
Groundwater	1,896	0	0.00%	0	0.00%	0	0.00%
Surface Water	1,360	0	0.00%	0	0.00%	0	0.00%
All Small Systems	3,256	0	0.00%	0	0.00%	0	0.00%
Large Systems (serving 10,001 - 100,000 people) -- CENSUS							
Groundwater	10,948	1	0.01%	1	0.01%	0	0.00%
Surface Water	15,702	3	0.02%	2	0.01%	1	0.01%
All Large Systems	26,650	4	0.02%	3	0.01%	1	0.00%
Very Large Systems (serving > 100,000 people) -- CENSUS							
Groundwater	2,057	0	0.00%	0	0.00%	0	0.00%
Surface Water	5,313	1	0.02%	0	0.00%	0	0.00%
All Very Large Systems	7,370	1	0.01%	0	0.00%	0	0.00%
All Systems							
All Water Systems	37,276	5	0.01%	3	0.01%	1	0.00%

Source: USEPA, 2024a

Exhibit 5-19: Ethoprop National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population – All Reported Detections

Source Water Type	UCMR 4 Sample		Number With At Least One Detection $\geq$ MRL (0.03 $\mu\text{g/L}$)		Percent With At Least One Detection $\geq$ MRL (0.03 $\mu\text{g/L}$)		National Inventory ¹		National Estimate of Number With At Least One Detection $\geq$ MRL (0.03 $\mu\text{g/L}$) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving $\leq 10,000$ people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,468	37,653,948	1	33,000	0.07%	0.09%	1,468	37,653,948	1	33,000
Surface Water	2,340	71,511,793	3	89,605	0.13%	0.13%	2,340	71,511,793	3	89,600
All Large Systems	3,808	109,165,741	4	122,605	0.11%	0.11%	3,808	109,165,741	4	123,000
Very Large Systems (serving $> 100,000$ people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	1	218,667	0.28%	0.18%	354	120,303,825	1	219,000
All Very Large Systems	423	137,063,500	1	218,667	0.24%	0.16%	423	137,063,500	1	219,000
All Systems										
All Water Systems	5,028	249,079,866	5	341,272	0.10%	0.14%	67,732	307,144,948	5	341,000

Source: USEPA, 2024a

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

Exhibit 5-20: Ethoprop National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population Served Data – Detections > ½ the HRL (0.045 µg/L)

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > ½ HRL (0.045 µg/L)		Percent With At Least One Detection > ½ HRL(0.045 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > ½ HRL (0.045 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,468	37,653,948	1	33,000	0.07%	0.09%	1,468	37,653,948	1	33,000
Surface Water	2,340	71,511,793	2	42,032	0.09%	0.06%	2,340	71,511,793	2	42,000
All Large Systems	3,808	109,165,741	3	75,032	0.08%	0.07%	3,808	109,165,741	3	75,000
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,028	249,079,866	3	75,032	0.06%	0.03%	67,732	307,144,948	3	75,000

Source: USEPA, 2024a

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

Exhibit 5-21: Ethoprop National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population Served Data – Detections > HRL (0.09 µg/L)

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > HRL (0.09 µg/L)		Percent With At Least One Detection > HRL (0.09 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > HRL (0.09 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,468	37,653,948	0	0	0.00%	0.00%	1,468	37,653,948	0	0
Surface Water	2,340	71,511,793	1	14,999	0.04%	0.02%	2,340	71,511,793	1	15,000
All Large Systems	3,808	109,165,741	1	14,999	0.03%	0.01%	3,808	109,165,741	1	15,000
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,028	249,079,866	1	14,999	0.02%	0.01%	67,732	307,144,948	1	15,000

Source: USEPA, 2024a

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

5.4.2.2 Supplemental Data Sources

5.4.2.2.1 *State Monitoring Data, 2018*

Because there is no available national database that receives and stores all relevant data regarding the occurrence of regulated and unregulated contaminants in public drinking water systems, the EPA gathered data from state drinking water monitoring websites in support of national occurrence assessments. Data were gathered from 38 states/entities. For 28 of the 38 states, data were available through the Drinking Water Watch (DWW) portal on the state's website. Available data for other states/entities that had been submitted to the EPA through the Second, Third, and Fourth Six-Year Review efforts (SYR2, SYR3, and SYR4) were also evaluated. As part of the Six-Year Reviews, some states submitted PWS occurrence data for unregulated contaminants along with requested data on regulated contaminants. For all rounds of the Six-Year Review, these unregulated data provide varying degrees of completeness in their coverage of the states/entities and are not necessarily representative of occurrence in those states/entities. For more details on data compiled under SYR2, SYR3, and SYR4, refer to USEPA (2009b), USEPA (2016b), and USEPA (2024b), respectively.

Drinking water occurrence data for ethoprop were available on state websites from one state: Vermont. One ethoprop non-detection sample result from 2018 was reported from Vermont.

5.4.2.2.2 *Water Systems' Consumer Confidence Reports (CCRs), 2018-2021*

CCRs are annual water quality reports that CWSs are required to provide to their customers. These reports summarize information on water sources, detected contaminants, and system compliance with EPA drinking water standards; they may also include general educational material. Under the CCR Rule (40 CFR Subpart O), CWSs with 15 or more connections or serving at least 25 year-round residents must prepare and distribute a CCR to all billing units or service connections every year. Systems serving 100,000 or more residents are also required to post their current CCRs on a publicly accessible Internet site.

The EPA reviewed CCRs published by the 25 systems that serve over one million customers (as identified in the Safe Drinking Water Information System / Federal version, or SDWIS/Fed, from the fourth quarter 2021 data) for unregulated contaminant occurrence information for the years 2018 through 2021. Data on ethoprop were available from CCRs prepared by five CWSs: one system in California (Los Angeles), one system in Colorado (Denver), two systems in New York (Suffolk County and New York City), and one system in Pennsylvania (Philadelphia). Monitoring results from all five systems showed no detections of ethoprop.

Los Angeles Department of Water & Power (LADWP) included data on ethoprop monitoring for UCMR 4 in its 2020 and 2021 CCRs. LADWP is served by multiple surface water and groundwater sources. The sampling was conducted in 2018-2019. Ethoprop was not detected.

Denver Water included data on ethoprop monitoring for UCMR 4 in its 2018 CCR. Denver Water is served by the South Platte River and other surface water sources. An average ethoprop concentration of "0 µg/L" was reported for treatment plant effluent.

Suffolk County, New York, included data on ethoprop in its 2018-2021 CCRs. Suffolk County is served by groundwater from four major aquifers beneath Long Island. In all 4 years, ethoprop was monitored for but was not detected.

New York City included data on ethoprop in four CCRs covering 2018 through 2021. New York City is served by a large system of surface water networks in New York state. In all 4 years, ethoprop was monitored for but was not detected.

The Philadelphia Water Department (PWD) included data on ethoprop in three CCRs covering 2019 through 2021. PWD is served by surface water from the Schuylkill and Delaware rivers. In all 3 years, ethoprop was monitored for but was not detected.

5.4.2.2.3 *National Pesticide Survey (NPS), 1988-1990*

In 1990, the EPA completed a national survey of pesticides in drinking water wells. The purpose of the NPS was to determine the national occurrence frequencies and concentrations of select pesticides in the nation's drinking water wells and to improve the EPA's understanding of how pesticide occurrence in groundwater correlates with patterns of pesticide usage and groundwater vulnerability. The survey included 566 CWS wells and 783 rural domestic wells. Sampling was conducted between 1988 and 1990. The survey targeted areas representing a variety of pesticide usage levels and groundwater vulnerability. The survey was designed to provide a statistically reliable estimate of pesticide occurrence in the nation's drinking water wells. It was not designed to provide statistically valid results at the state or local level. Wells were sampled for 101 pesticides, 25 pesticide degradates, and nitrate (USEPA, 1990). At a reporting level of 0.060 µg/L, ethoprop was not detected in the survey (USEPA, 1990).

5.4.2.2.4 *United States Department of Agriculture (USDA) Pesticide Data Program (PDP), 2001-2013*

The USDA PDP maintains a national pesticide residue database. PDP was initiated in 1991 to collect representative data on pesticide residues in the United States food supply, following a rigorous statistical design. Sampling and testing have been conducted on fruits and vegetables, select grains, milk, and (between 2001 and 2013) drinking water (USDA, 2022).

The PDP drinking water project was initiated at CWSs in New York and California in 2001. Since then, the drinking water sampling program has expanded, though a somewhat changing mix of states is sampled each year. At one time or another, CWSs in 29 states and the District of Columbia have contributed raw or finished water data or both to the program (USDA, 2023). The CWSs selected for sampling tend to be small and medium-sized systems (primarily CWSs serving under 50,000), systems served by surface water, and systems located in regions of heavy agriculture. Sampling of raw ("untreated") water in addition to finished water began in 2004; sampling of raw and finished drinking water was discontinued after 2013. Note that temporal trends cannot be evaluated based on these data since the list of CWSs included in the project varied from year to year (USDA, 2022; USDA, 2023).

Ethoprop was included in the USDA PDP (Exhibit 5-22) (USDA, 2022). Ethoprop was not detected in any of the 2,741 raw water samples. Ethoprop was detected in 1 (0.02%) of 4,469 finished water samples, with a concentration of 0.027 µg/L. No detected concentrations exceeded one-half the HRL or the HRL. The reported limits of detection ranged from 0.003 to 0.017 µg/L.

Exhibit 5-22: Summary of Ethoprop PDP Data, 2001-2013

Year	Raw/ Finished	Total Number of Samples	Number of Detections	Percent of Detections	Minimum Value of Detections (µg/L)	Maximum Value of Detections (µg/L)
2001	Finished	283	0	0.00%	N/A	N/A
2002	Finished	669	0	0.00%	N/A	N/A
2003	Finished	794	0	0.00%	N/A	N/A
2004	Finished	381	0	0.00%	N/A	N/A
	Raw	381	0	0.00%	N/A	N/A
2005	Finished	369	0	0.00%	N/A	N/A
	Raw	371	0	0.00%	N/A	N/A
2006	Finished	368	0	0.00%	N/A	N/A
	Raw	369	0	0.00%	N/A	N/A
2007	Finished	369	0	0.00%	N/A	N/A
	Raw	364	0	0.00%	N/A	N/A
2008	Finished	310	0	0.00%	N/A	N/A
	Raw	309	0	0.00%	N/A	N/A
2009	Finished	306	0	0.00%	N/A	N/A
	Raw	306	0	0.00%	N/A	N/A
2010	Finished	280	1	0.4%	0.027	0.027
	Raw	279	0	0.00%	N/A	N/A
2011	Finished	119	0	0.00%	N/A	N/A
	Raw	120	0	0.00%	N/A	N/A
2012	Finished	178	0	0.00%	N/A	N/A
	Raw	199	0	0.00%	N/A	N/A
2013	Finished	43	0	0.00%	N/A	N/A
	Raw	43	0	0.00%	N/A	N/A

Source: USDA, 2022

N/A = not applicable (no detections in this category).

5.4.2.2.5 United States Geological Survey (USGS) Pilot Monitoring Program (PMP), 1999

In 1999, the PMP was initiated by USGS and the EPA to provide information on pesticide concentrations in drinking water. The program focused on small drinking water supply reservoirs in areas with high pesticide use in order to test the sampling approach in areas where pesticides are probably present (Blomquist et al., 2001). Sampling sites represented a variety of geographic regions as well as different cropping patterns. The ideal site candidates were mostly small reservoirs located in high pesticide-use areas with a high runoff potential. Twelve water-supply reservoirs considered vulnerable to pesticide contamination were selected from the list of candidates. These 12 sites were located in California, Indiana, Louisiana, Missouri, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, and Texas.

Samples were collected quarterly throughout the year and at weekly or biweekly intervals following the primary pesticide-application periods. Water samples were collected from the raw-

water intake and from finished drinking water taps prior to entering the distribution system. At some sites, samples were also collected at the reservoir outflow.

Ethoprop was an analyte in the PMP. At a method reporting level of 0.003 µg/L, ethoprop was not detected in any of the 323 samples from raw water sites or any of the 228 samples from finished water sites (Blomquist et al., 2001).

5.4.2.2.6 *Additional Source Water and Drinking Water Studies*

Note that there may be some overlap between the NAWQA data assessment presented earlier in the ambient water occurrence section and the summaries of NAWQA studies presented below.

Water Quality in Public-Supply Wells (Toccalino et al., 2010), 1993-2007

To assess risks posed by contaminants in public-supply wells, water samples were collected from source (untreated) groundwater from 932 public-supply wells located in parts of 40 NAWQA Study Units in 41 states (Toccalino et al., 2010). Each well was sampled once between 1993 and 2007. The public wells sampled in this study represented 629 unique PWSs, constituting 0.5 percent of the approximately 140,000 groundwater-supplied PWSs, but serving nearly 25 percent of the population served by groundwater PWSs in the United States. The reporting levels used for ethoprop in this study ranged from 0.002 µg/L to 0.006 µg/L. Ethoprop was reported as detected in 1 (0.15 percent) of a total of 647 samples. Results from this study are presented in Exhibit 5-23 and Exhibit 5-24.

Exhibit 5-23: Ethoprop Data from Public-Supply Wells (Toccalino et al., 2010) – Summary of Reported Concentrations

Source Water Type	Concentration Values (µg/L)				
	Minimum	Median	90 th Percentile	99 th Percentile	Maximum
Groundwater Only	0.0056	0.0056	0.0056	0.0056	0.0056

Source: Toccalino et al., 2010

Exhibit 5-24: Ethoprop Data from Public-Supply Wells (Toccalino et al., 2010) – Summary of Samples

Source Water Type	Number of Samples	All Reported Detections		Detections > ½ HRL (0.045 µg/L)		Detections > HRL (0.09 µg/L)	
		Number	Percent	Number	Percent	Number	Percent
Groundwater Only	647	1	0.15%	0	0.00%	0	0.00%

Source: Toccalino et al., 2010

Water Quality in Domestic Wells (DeSimone, 2009), 1991-2004

Between 1991 and 2004, USGS assessed water quality from domestic wells across the United States using NAWQA data (DeSimone, 2009). The program included the analysis of major ions, trace elements, nutrients, radon, and organic compounds (pesticides and volatile

organic compounds or VOCs) at approximately 2,100 domestic wells (private drinking water wells) across 48 states, covering 30 regional aquifers. In addition, USGS summarized data from wells sampled for NAWQA agricultural land-use assessment studies to provide an indication of the potential effects of agricultural land-use practices on the groundwater in the aquifers studied. Reporting thresholds for ethoprop varied; the most common thresholds were 0.002 and 0.003 µg/L. Ethoprop was not detected in any of the 2,115 samples from aquifer studies or in the 425 samples from agricultural land-use studies.

Water Quality in Carbonate Aquifers (Lindsey et al., 2008), 1993-2005

As part of the NAWQA program, Lindsey et al. (2008) assessed the water quality in carbonate aquifers, which account for 22 percent of the groundwater pumped by the nation's PWSs. From 1993 to 2005, the study analyzed 1,042 wells and springs across 12 aquifer systems and 20 states for major ions, radon, nutrients, pesticides, and VOCs. Reporting levels varied. Ethoprop was not detected in any of the 992 samples.

5.5 Analytical Methods

The EPA has published three analytical methods that are available for the analysis of ethoprop in drinking water:

- EPA Method 507, Revision 2.1, *Determination of Nitrogen- and Phosphorus-Containing Pesticides in Water by Gas Chromatography With a Nitrogen-Phosphorus Detector*. Has a method detection limit (MDL) of 0.021 µg/L. Mean recoveries in reagent water and two synthetic waters (artesian spring water and reagent water fortified with 1 mg/L fulvic acid) range from 79.0 to 108 percent, with standard deviations (SDs) of 3.0 to 7.0 µg/L and a relative standard deviation (RSD) of 3.0 percent (USEPA, 1995a).
- EPA Method 525.2, Revision 2.0, *Determination of Organic Compounds in Drinking Water by Liquid-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry*, has MDLs that range from 0.048 to 0.19 µg/L. Mean recoveries in reagent water and tap water range from 122 to 138 percent, with RSDs of 2.3 to 10.0 percent (USEPA, 1995b).
- EPA Method 525.3, Version 1.0, *Determination of Semivolatile Organic Chemicals in Drinking Water by Solid Phase Extraction and Capillary Column Gas Chromatography/Mass Spectrometry (GC/MS)* has Detection limits (DLs) that range from 0.0048 to 0.13 µg/L in Full Scan mode and a DL of 0.0082 µg/L in Selected Ion Monitoring (SIM) mode. The Lowest Concentration Minimum Reporting Levels (LCMRLs) generated by the laboratories that helped to develop the method range from 0.12 to 0.39 µg/L in Full Scan mode and 0.0084 to 0.036 µg/L in SIM mode. Mean recoveries in reagent water, finished water from groundwater with a hardness of 290 to ≥350 mg/L (as calcium carbonate) and finished drinking water from surface water with total organic carbon (TOC) of 2.4 to 2.8 mg/L range from 85.9 to 122 percent, with RSDs of 0.6 to 21.0 percent for Full Scan mode. Mean recoveries in reagent water, finished water from groundwater with a hardness of 325 to 393 mg/L (as calcium carbonate) and finished drinking water from surface water with TOC of 2.0 to 2.52 mg/L and a hardness of 137 mg/L (as calcium carbonate) range from 89.4 to 112 percent, with RSDs of 1.0 to 19.0 percent for SIM mode (USEPA, 2012).

Laboratories participating in UCMR 4 were required to use EPA Method 525.3 and were required to report ethoprop values at or above the EPA-defined MRL of 0.03 µg/L (81 FR 92666; USEPA, 2016a). The MRL was set based on the capability of multiple laboratories at the time.

5.6 Treatment Technologies

The EPA evaluates whether suitable treatment technologies are available prior to promulgating a final NPDWR. The preliminary summary of treatment technology availability presented here represents the results of a December 2023 literature search.

Nassar et al. (2023) investigated the effectiveness of hydrochar-loaded iron nanoparticles in removing ethoprop and other organophosphorus insecticides from aqueous solutions in batch experiments. The adsorption technology was found to be effective. “Almost all” ethoprop was successfully removed from environmental water samples spiked with initial concentrations of 0.5 and 1 mg/L. The removal efficiency slightly declined after treatment of samples spiked with 1.5 mg/L. In a direct comparison, granular activated carbon removed <78% of ethoprop while the prepared hydrochar removed >90%.

Fenoll et al. (2012) studied heterogeneous photocatalysis of ethoprop and other pesticides in aqueous suspensions with a variety of semiconductor materials, such as zinc oxide (ZnO), titanium dioxide (TiO₂), tungsten (VI) oxide (WO₃), tin (IV) oxide (SnO₂), and zinc sulphide (ZnS). The experiments were carried out at pilot plant scale using compound parabolic collectors under natural sunlight. The study showed that ZnO and TiO₂ strongly enhanced photodegradation. With ZnO, it took 118.7 minutes to achieve a 90% reduction in ethoprop concentration. With TiO₂, it took 354.7 minutes.

Abdeen & Mohammad (2014) studied the elimination of ethoprop from aqueous solutions using chitosan, a natural biosorbent. Ethoprop removals of 85.693% to 89.234% were observed at the bench scale, using chitosan doses of 0.02 to 0.1 g/100ml.

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Chapter 6: Microcystins

A chapter from:

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EPA Report 815-R-26-002

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Abbreviations

ADD	Acceptable Daily Dose
ALP	Alkaline Phosphatase
AWWA	American Water Works Association
AWWARF	American Water Works Association Research Foundation
BW	Body Weight
CASRN	Chemical Abstracts Service Registry Number
CCL 5	Fifth Contaminant Candidate List
CCR	Consumer Confidence Reports
CDC	Centers for Disease Control and Prevention
CDR	Chemical Data Reporting
CWS	Community Water System
DOC	Dissolved Organic Carbon
D _{ow}	Octanol/Water Distribution Ratio
DWGWD	Drinking Water and Groundwater Protection Division
DWI	Drinking Water Intake
DWI-BW	Drinking Water Intake Rate Adjusted For Body Weight
DWTP	Drinking Water Treatment Plant
EF	Exposure Factors
ELISA	Enzyme-Linked Immunosorbent Assay
EPA	U.S. Environmental Protection Agency
GAC	Granular Activated Carbon
GWUDI	Groundwater Under the Influence of Surface Water
HAB	Harmful Algal Bloom
HABISS	Harmful Algal Bloom-Related Illness Surveillance System
HRL	Health Reference Level
IARC	International Agency for Research on Cancer
IUR	Inventory Update Reporting
K _H	Henry's Law Constant
K _{oc}	Organic Carbon Partitioning Coefficient
K _{ow}	Octanol/Water Partitioning Coefficient
LCMRL	Lowest Concentration Minimum Reporting Level
LDH	Lactate Dehydrogenase
LOAEL	Lowest-Observed-Adverse-Effect Level
MAC	Maximum Acceptable Concentration
MRDL	Maximum Residual Disinfectant Level
MRL	Minimum Reporting Level
NAWQA	National Water-Quality Assessment
NIRS	National Inorganics and Radionuclides Survey
NLA	National Lakes Assessment
NOAEL	No-Observed-Adverse-Effect Level
NOM	Natural Organic Material
NORS	National Outbreak Reporting System
NPDWR	National Primary Drinking Water Regulation
NTNCWS	Non-Transient Non-Community Water System
NWIS	USGS National Water Information System
OGWDW	Office of Ground Water and Drinking Water

OHA	Oregon Health Authority
OHHABS	One Health Harmful Algal Bloom System
OW	Office of Water
PAC	Powder Activated Carbon
PAD	Population Adjusted Dose
PAS	Periodic Acid-Schiff
pK _a	Acid Dissociation Constant
POD	Point of Departure
POD/UF	Point of Departure / Uncertainty Factor
PWS	Public Water System
RD 5	Fifth Regulatory Determination
RfD	Reference Dose
RPD	Relative Percentage Difference
RSC	Relative Source Contribution
SDWA	Safe Drinking Water Act
SDWIS/Fed	Safe Drinking Water Information System / Federal version
STORET	Storage and Retrieval Data System
TDI	Tolerable Daily Intake
TOC	Total Organic Carbon
TRI	Toxic Release Inventory
UCM	Unregulated Contaminant Monitoring
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 1	First Unregulated Contaminant Monitoring Rule
UCMR 2	Second Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 4	Fourth Unregulated Contaminant Monitoring Rule
UF	Uncertainty Factor
UF _A	Interspecies Uncertainty Factor
UF _D	Database Uncertainty Factor
UF _H	Intraspecies Uncertainty Factor
UF _L	LOAEL-to-NOAEL Extrapolation Uncertainty Factor
USGS	United States Geological Survey
VDH	Vermont Department of Health
WBDOS	Waterborne Disease and Outbreak Surveillance System
WHO	World Health Organization
WQP	Water Quality Portal
WRF	Water Research Foundation

Chapter 6: Microcystins

The U.S. Environmental Protection Agency (EPA) is evaluating microcystins, a contaminant on the fifth Contaminant Candidate List (CCL 5), as a candidate for regulation under the fifth Regulatory Determination process (RD 5). Information on the CCL 5 process is found in Chapter 1. Background on data sources used to evaluate CCL 5 chemicals is found in Chapter 2.

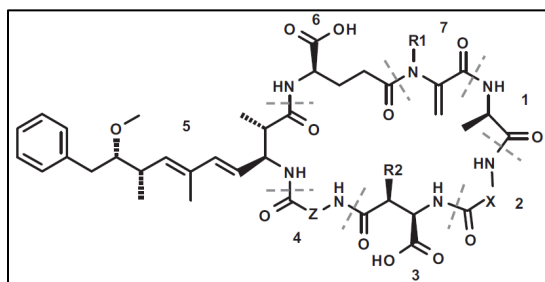
This chapter presents information and analysis specific to microcystins, including background information on the contaminant, information on contaminant sources and environmental fate, an analysis of health effects, an analysis of occurrence in ambient and drinking water, and information about the availability of analytical methods and treatment technologies.

6.1 Contaminant Background and Chemical and Physical Properties

Microcystins are toxins naturally produced and released by cyanobacteria. Cyanobacteria, sometimes referred to as blue-green algae, are photosynthetic bacteria that are nearly ubiquitous in freshwater and marine environments. Harmful algal blooms (HABs) of cyanobacteria in freshwater environments can release quantities of cyanotoxins, including microcystins.

Microcystins are monocyclic heptapeptides with seven amino acids joined end-to-end and then head to tail, resulting in large cyclic compounds with molecular weights that can range from 800 to 1,100 grams/mol (USEPA, 2015a). See Exhibit 6-1 for a general representation of the chemical structure of microcystins. The locations marked “X” and “Z” in the structure can be filled by different amino acids. Microcystins exist in multiple forms (congeners), based on variations in amino acid composition at these two locations and on methylation/demethylation at selected sites in the cyclipeptide. There are approximately 100 known microcystin congeners (USEPA, 2015a).

Exhibit 6-1: General Chemical Structure of Microcystins



Source: Chorus and Welker, 2021

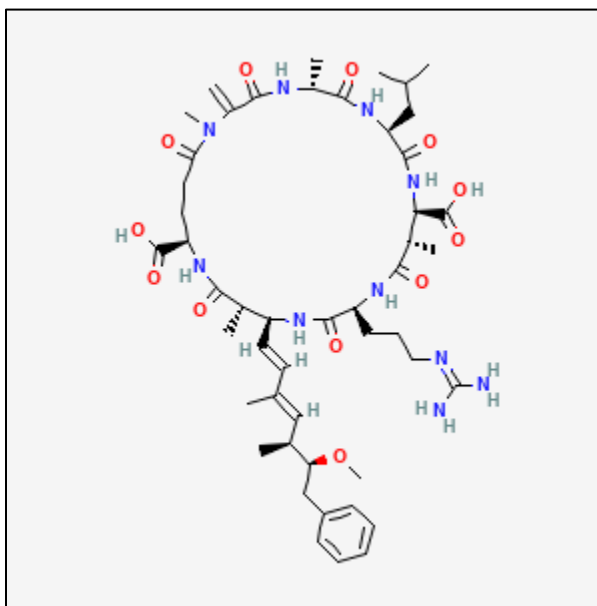
Microcystins are generally distinguished using letters that refer to the two variable amino acids. The six most common microcystin congeners, as reported in USEPA (2015b), are listed in Exhibit 6-2, along with the amino acids that give them their identity. Microcystin-LR, which includes leucine (L) and arginine (R) amino acids, is the most common congener and also the most intensively studied (USEPA, 2015a). Synonyms for microcystin-LR include cyanoginosin LR (NCBI, 2022a). Exhibit 6-3 shows a representation of the chemical structure of microcystin-LR.

Exhibit 6-2. Amino Acid Composition of Select Microcystin Congeners

Microcystin Congener	Amino Acid in Position X	Amino Acid in Position Z
microcystin-LR	Leucine	Arginine
microcystin-RR	Arginine	Arginine
microcystin-YR	Tyrosine	Arginine
microcystin-LA	Leucine	Alanine
microcystin-LY	Leucine	Tyrosine
microcystin-LF	Leucine	Phenylalanine

Source: USEPA 2015b.

Note: X and Z refer to specific sites in the microcystin monocyclic heptapeptide structure (see Exhibit 6-1).

Exhibit 6-3: Chemical Structure of Microcystin-LR

Source: NCBI, 2022a

Physical and chemical properties and other reference information for selected microcystin congeners (the same six listed in Exhibit 6-2) are presented in Exhibit 6-4.

Exhibit 6-4: Physical and Chemical Properties of Six Microcystins

Property	microcystin-LA	microcystin-LF	microcystin-LR	microcystin-LY	microcystin-RR	microcystin-YR
Chemical Abstracts Service Registry Number (CASRN)	96180-79-9 (NCBI, 2022b)	154037-70-4 (NCBI, 2022c)	101043-37-2 (NCBI, 2022a)	123304-10-9 (NCBI, 2022d)	111755-37-4 (NCBI, 2022e)	101064-48-6 (NCBI, 2022f)
Chemical Formula	C ₄₆ H ₆₇ N ₇ O ₁₂ (NCBI, 2022b)	C ₅₂ H ₇₁ N ₇ O ₁₂ (NCBI, 2022c)	C ₄₉ H ₇₄ N ₁₀ O ₁₂ (NCBI, 2022a)	C ₅₂ H ₇₁ N ₇ O ₁₃ (NCBI, 2022d)	C ₄₉ H ₇₅ N ₁₃ O ₁₂ (NCBI, 2022e)	C ₅₂ H ₇₂ N ₁₀ O ₁₃ (NCBI, 2022f)
Molecular Weight	910.1 g/mol (NCBI, 2022b)	986.2 (NCBI, 2022c)	995.2 g/mol (NCBI, 2022a)	1002.2 (NCBI, 2022d)	1038.2 (NCBI, 2022e)	1045.2 (NCBI, 2022f)
Color/Physical State	--	--	Clear or white solid (NCBI, 2022a)	--	--	--
Boiling Point	--	--	--	--	--	--
Melting Point	--	--	--	--	--	--
Density	--	--	1.29 g/mL (NCBI, 2022a)	--	--	--
Freundlich Adsorption Coefficient	--	--	--	--	--	--
Vapor Pressure	--	--	--	--	--	--
Henry's Law Constant (K _H)	--	--	--	--	--	--
Octanol/Water Partitioning Coefficient (log K _{ow})	--	3.95 at pH 7 (WHO, 2020)	2.54 at pH 7 (WHO, 2020) Octanol/water distribution ratio (log D _{ow}) of -4.70 at pH 7.4 (Abbas et al., 2020)	--	1.7 at pH 7 (WHO, 2020)	2.25 at pH 7 (WHO, 2020)
Organic Carbon Partitioning Coefficient (K _{oc})	--	--	--	--	--	--
Acid Dissociation Constant (pK _a)	--	--	pKa1 2.09 pKa2 2.19 pKa3 12.48 (NCBI, 2022a)	--	--	--
Solubility in Water	--	--	Highly soluble in water (NCBI, 2022a)	--	--	--
Other Solvents	--	--	1 mg/mL in ethanol. 10mg/mL in ethanol, dimethyl sulfoxide & dimethylformamide (NCBI, 2022a)	--	--	--

Note: "--" indicates that no information was found.

Note: Many of these properties are temperature-dependent. Values are given for properties at 20-25°C unless otherwise noted. Due to varying experimental conditions, and due to the variabilities associated with modeling, standard information sources may provide a range of values. Where more than one value was available from these sources, one value was selected for this table based on best professional judgment.

6.2 Sources and Environmental Fate

Because microcystins are naturally produced in the environment and not industrially produced, no data are available on production of microcystins from the EPA's Inventory Update

Reporting (IUR) and Chemical Data Reporting (CDR) programs, and no data are available on industrial releases of microcystins from the EPA's Toxics Release Inventory (TRI).

6.2.1 Natural Sources

The following cyanobacteria genera are known to include microcystin-producing species: *Dolichospermum* (previously *Anabaena*), *Fischerella*, *Gloeotrichia*, *Microcystis*, *Nodularia*, *Nostoc*, *Oscillatoria*, and *Planktothrix* (USEPA, 2015a; USEPA, 2024a). Microcystins are the most common cyanotoxins found worldwide, and they have been reported in surface waters in most of the United States (Funari and Testai, 2008 as cited in USEPA, 2015a).

For the most part, microcystins are not released into surrounding waters by healthy living cyanobacterial cells. Release of microcystins generally results from senescence or lysis. Laboratory studies suggest that less than 10 percent of total microcystins can be expected to be extracellular in healthy cyanobacterial cultures (Chorus and Welker, 2021).

Cyanotoxin production is influenced by environmental conditions that favor the growth of particular cyanobacterial species and strains. Factors that affect cyanobacterial growth, cyanobacteria population dynamics, and the development of blooms include nutrient concentrations, light intensity, water turbidity, temperature, competing bacteria and phytoplankton, pH, and turbulence (mixing). The concentrations of cyanotoxins released from a bloom will depend on the composition of the bloom and environmental and ecosystem influences on bloom dynamics (USEPA, 2015b).

6.2.2 Environmental Fate

Microcystins are readily soluble in water. Microcystin-LR, for example, has a solubility of greater than 1,000 mg/L (Rivasseau et al. 1998; NCBI, 2022a). Based on an analysis of contaminant properties (in particular, the n-octanol/water distribution ratio expressed as log D_{ow} , which is related to log K_{ow}), de Maagd et al. (1999) find that the tendency of microcystins to partition from water to sediments or suspended particulate matter or to bioconcentrate is expected to be relatively low at pH values of 6-9, which is the pH range at which cyanobacteria flourish. As log K_{ow} varies from one congener to another (see Exhibit 6-4, the tendency to sorb may also vary. Field and treatment studies confirm that adsorption does occur (USEPA, 2015a; USEPA, 2015b). The extent of adsorption will depend on the adsorption medium; experiments show little or no sorption to sandy soil (O'Reilly et al., 2011).

Microcystins are very stable chemicals, resistant to hydrolysis in the neutral pH range and resistant to extreme heat (Chorus and Welker, 2021). Persistence of up to 2-3 months has been reported in cultures enriched with water and bacteria from a river and up to 6 months in dry scum (Jones and Orr, 1994; Jones et al., 1995).

Microcystins are subject to slow photochemical breakdown and isomerization in full sunlight. Photodegradation of microcystins can take as long as six weeks. The process is sped up in the presence of water-soluble cell pigments (phycobiliproteins) and naturally occurring humic substances. It is inhibited in deeper and turbid water (Chorus and Welker, 2021; USEPA, 2015a).

Biodegradation is an important fate mechanism. Dozens of natural aquatic bacteria from diverse ecosystems are capable of degrading microcystins (de la Cruz et al., 2011; Li et al., 2017). The majority of microcystin-degrading bacterial strains have been identified as belonging to the genera *Sphingomonas* and *Sphingopyxis* (Li et al. 2017). Bacterial degradation of

microcystins is predominately aerobic, although a few bacteria capable of anaerobic degradation have been isolated (Li et al., 2017).

Chorus and Welker (2021) note that biodegradation of microcystins often begins with an initial lag phase, which can last for as little as two days or as long as several weeks, during which time there is little loss of microcystin. Factors affecting the duration of the lag phase appear to include the concentration of dissolved microcystin, climatic conditions, and possibly previous bloom history of the source water. After the lag phase, biodegradation can be quick. Many researchers have found half-lives in the range of 0.2 to 5 days for various microcystin congeners, according to Chorus and Welker (2021). Other researchers have reported half-lives of 4 to 14 days; longer half-lives are associated with flowing streams and shorter half-lives with lakes, possibly suggesting that microbial communities have differing degradation capabilities in different habitats (Edwards et al., 2008). The rate of microcystin biodegradation also depends on temperature, and can vary depending on the size of the microbial population capable of degradation and the initial microcystin concentration (Park et al., 2001; Bourne et al., 2006; both as cited in Chorus and Welker 2021).

Bioconcentration of microcystins in aquatic animals is well documented (Liang et al., 2011). Microcystins have been found in aquatic vertebrates and invertebrates (Chorus and Welker, 2021) and have the potential for bioconcentration and bioaccumulation (Machado et al. 2017), despite the observation by de Maagd et al. (1999) about partitioning and bioconcentration noted above.

6.3 Health Effects

6.3.1 Health Assessment Identification

In order to identify qualifying health assessments for microcystins (specifically, microcystin congeners microcystin-LA, microcystin-LW, microcystin-RR, microcystin-YR and microcystin-LR), the EPA conducted a systematic web-based search of the EPA and other authoritative sources, as described in Section B.5.1.1 of the RD 5 Protocol, found in Appendix B of this document.

Exhibit 6-5 provides a summary overview of qualifying health assessments for microcystins (i.e., health assessments from qualifying sources that provide a toxicity value relevant to chronic oral toxicity) that were published prior to the search cut-off date of January 2023. An assessment can present a noncancer oral toxicity value, a cancer oral toxicity value, or both. Information about the health assessment selected for microcystins under RD 5 is **bolded** and *italicized* in Exhibit 6-5.

Exhibit 6-5: Qualifying Health Assessments Identified for Microcystins

Health Assessment ^a	Oral Reference Value ^b	POD Type	Noncancer Critical Study	Oral Cancer Slope Factor ^c	Cancer Critical Study	Cancer Descriptor
<i>EPA Office of Water (OW) Health Effects Support Document (USEPA, 2015a)</i>	<i>0.00005^{d,e}</i>	<i>LOAEL</i>	<i>Heinze, 1999</i>	–	–	1 ^f
Health Canada Drinking Water Quality Guidelines (HC, 2017)	0.000056 ^d	LOAEL	Heinze, 1999	–	–	–
World Health Organization (WHO) Provisional Drinking Water Guideline (WHO, 2020)	0.00004 ^d	NOAEL	Fawell et al., 1999	–	–	2B ^g

Notes: POD = point of departure; LOAEL = lowest-observed-adverse-effect level; NOAEL = no-observed-adverse-effect level; dash (–) = not applicable.

^a Selected health assessment and chronic toxicity value and supporting information are bolded and italicized.

^b Oral reference values are expressed in mg/kg/day unless otherwise specified; “oral reference value” can refer to the acceptable daily dose (ADD), maximum acceptable concentration (MAC), minimal risk level, point of departure / uncertainty factor (POD/UF), population-adjusted dose (PAD), reference dose (RfD), or tolerable daily intake (TDI).

^c Cancer slope factors are expressed in (mg/kg/day)⁻¹ unless otherwise specified.

^d Oral reference values were derived for microcystin-LR because of all microcystins it is the congener with the majority of toxicological data available; since microcystin-LR is also one of the most potent congeners, these reference values are believed to be protective against exposure to all microcystins (including both free and cell bound) that may be present in drinking water.

^e This oral reference dose is an RfD based on liver effects in rats orally exposed to microcystin-LR (USEPA, 2015a).

^f This “inadequate information to assess carcinogenic potential” cancer descriptor was determined by following the process described in the EPA’s 2005 *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005).

^g Microcystins are classified as Group 2B (possibly carcinogenic to humans) by the International Agency for Research on Cancer (IARC, 2010) based on tumor promotional activity mediated via protein phosphatase inhibition (WHO 2020). Microcystin-LR is “possibly carcinogenic to humans based on inadequate evidence of carcinogenicity in both animals and humans but sufficient evidence for tumor promotion in animals,” according to IARC’s classification of carcinogens.

6.3.2 Health Assessment Selection

The health assessment selected for microcystins under RD 5 is the 2015 EPA OW Health Effects Support Document (USEPA, 2015a). This is an EPA health assessment that uses the best available science in its evaluation of noncancer risk for microcystins. Although the Health Canada Drinking Water Quality Guideline (HC, 2017) and World Health Organization (WHO) Provisional Drinking Water Guidelines (WHO, 2020) are more recent health assessments, they do not derive a toxicity value based on a more recent critical study or use better available science in their evaluations of noncancer risk for microcystins. See Section B.5.1.2 of the RD 5 Protocol, in Appendix B of this document, for the decision logic that was applied to health assessments selection for RD 5 chemicals.

6.3.3 Health Reference Level (HRL) Development

Health reference levels (HRLs) are non-regulatory health-based toxicity values, expressed as concentrations in drinking water, that are used by the Agency to evaluate occurrence data for a contaminant when making decisions about regulatory determinations. See Section B.6.1.1 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA’s approach for deriving HRLs for chemicals. The input values used to derive the HRL for microcystins are described below.

6.3.3.1 Oral Reference Value

In the 2015 EPA Office of Water (OW) Health Effects Support Document (USEPA, 2015a), the EPA selected a short-term oral toxicity study in rats (Heinze, 1999) as the critical study to derive a point of departure (POD) for the oral reference value. In this study, doses of 0, 50, and 150 µg/kg/day of microcystin-LR (commercial product, purity not reported) were administered in the drinking water of 11-week-old male hybrid rats (n = 10 per dose) for 28 days. The dose estimates in this study were not adjusted to account for the 3 to 7 percent of unconsumed drinking water over the experimental period. Rats were sacrificed after the exposure period to record liver, kidney, adrenal, thymus and spleen weights. Hematology, serum biochemistry, and histopathology of liver and kidneys were also evaluated (Heinze, 1999).

A 38 percent increase in leukocyte counts were observed in the high dose group (150 µg/kg/day) relative to control after hematological evaluation. Significantly increased mean alkaline phosphatase (ALP) and lactate dehydrogenase (LDH) levels were observed in both treatment groups (84 percent elevation in LDH and 34 percent elevation in ALP at 50 µg/kg/day relative to control, and 100 percent elevation in LDH and 33 elevation in ALP at 150 µg/kg/day relative to control). A dose-dependent increase in absolute and relative liver weights was also observed in both dose groups relative to control (8.8 grams): 9.70 grams and 17 percent elevation at 50 µg/kg/day, and 10.51 grams and 26 percent elevation at 150 µg/kg/day. Lesions indicative of cell damage were spread diffusely throughout the parenchyma, characterized by increases in cell volume, mitochondria, cell necrosis, Kupffer cells activation, and increased levels of periodic acid-Schiff (PAS)-positive substances. Liver lesions were present in both treatment groups, with increased severity at the dose of 150 µg/kg/day. No other statistically significant effects were reported (Heinze, 1999).

A lowest-observed-adverse-effect level (LOAEL) of 50 µg/kg/day for liver effects in rats orally exposed to microcystin-LR was the critical effect selected to derive an oral reference value in the 2015 EPA OW Health Effects Support Document. This was considered the “most appropriate basis for quantitation as it was a common finding among oral toxicology studies” (USEPA, 2015a). Since microcystin-LR is one of the most potent microcystin congeners and the majority of microcystin toxicity data comes from studying this congener, microcystin-LR was used as a surrogate for deriving an oral reference value for all microcystins (USEPA, 2015a). A total uncertainty factor (UF) of 1000 was applied to the POD: an intraspecies UF (UF_H) of 10, an interspecies UF (UF_A) of 10, LOAEL-to-NOAEL extrapolation UF (UF_L) of 3, and a database UF (UF_D) of 3. After applying the total UF, the oral reference value (a reference dose, or RfD) was calculated to be 0.00005 mg/kg/day (USEPA, 2015a). The EPA selected this oral reference value (0.00005 mg/kg/day) from the EPA OW Health Effects Support Document (USEPA, 2015a) to derive an HRL for RD 5.

6.3.3.2 Exposure Factor Selection

In prioritizing the contaminants of greatest public health concern for regulatory determination, Section 1412(b)(1)(C) of the Safe Drinking Water Act (SDWA) requires the Agency to consider “among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water compared to the general population.” One way that the EPA considers potentially sensitive populations or life stages (i.e., populations or life stages

that may be more susceptible or sensitive to a chemical exposure) is during the selection of exposure factors (EFs) for the development of HRLs.

Drinking water intake rate adjusted for body weight (DWI-BW) is the EF used to derive HRLs for RD 5 (USEPA, 2019). EFs are input values intended to protect the general population, including sensitive populations or life stages, from adverse effects resulting from exposure to a contaminant. The Agency selects an appropriate DWI-BW for each chemical by reviewing the critical effect and study used for HRL derivation and identifying the interval of exposure (for example, see USEPA, 2022a; USEPA, 2022b). Since the critical effect represents the most sensitive adverse effect observed in the best available studies for a given chemical, it is reasonable to assume that the interval of exposure in the critical study could inform the selection of a DWI-BW protective of sensitive populations. When multiple potentially sensitive populations or life stages are identified based on the interval of exposure in the study used for HRL derivation, the EPA selects the population or life stage with the highest DWI-BW because it is the most health protective. See Section B.6.1.2 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA's EF selection process.

The critical study (Heinze, 1999) selected in the 2015 EPA OW Health Effects Support Document for microcystins (USEPA, 2015a) measured toxicity in rats orally exposed to microcystin-LR in drinking water for 28 days, where exposure started at the age of 11 weeks (Heinze, 1999). Following the decision logic described in Section B.6.1.2 of the RD 5 Protocol, the EPA selected a corresponding human life stage. The EPA determined that for a study like this one, observing effects in adult rodents after initiating exposure post-adolescence (rodents aged 10 weeks or older), the potential corresponding human age range is adults 21 years and older. Although windows of development can vary by species and strain, various rat and mouse studies indicate that adulthood development begins at about 70 days (Ghasemi et al., 2021; Wang et al., 2020). Therefore, the EPA used the DWI-BW representing the 90th percentile consumers-only, two-day average, direct and indirect community water consumption for adults (21 years and older), which equals 0.0336 L/kg/day (USEPA, 2019), to derive the HRL for microcystins.

6.3.3.3 Relative Source Contribution

Relative source contribution (RSC) is used to account for exposure via non-drinking water routes when deriving health-based drinking water concentrations for contaminants with threshold effects (noncarcinogens and nonlinear carcinogens). RSC is defined as the portion (percentage) of an individual's exposure attributed to drinking water rather than other sources (e.g., food, ambient air). A 20 percent RSC is used for all RD 5 contaminants, consistent with past practice for regulatory determinations, to derive the HRL because (1) HRLs are developed prior to completing the exposure assessment; and (2) a 20 percent RSC is the lowest RSC that can be applied for deriving health-based drinking water concentrations according to the EPA guidance (USEPA, 2000), and it therefore produces the most health protective HRL. Should a contaminant proceed to a National Primary Drinking Water Regulation (NPDWR), a full exposure analysis is conducted, and an RSC is derived following the Exposure Decision Tree approach described in the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000).

6.3.3.4 HRL Calculation

Exhibit 6-6 summarizes the critical study and toxicity information from the qualifying health assessment and the EF (DWI-BW) and RSC that the EPA used to derive the HRL for microcystins.

Exhibit 6-6: Basis of HRL for Microcystins

Selected Health Assessment	Critical Study	Interval of Exposure	Critical Effect	Oral Toxicity Value	RSC	Target Population	Exposure Factor
EPA OW Health Effects Support Document (USEPA, 2015a)	Heinze (1999)	28 days; beginning at 11 weeks of age	Hepatotoxicity in rats	0.00005 mg/kg/day	0.2 (20%)	Adults (21 years and older)	0.0336 L/kg/day

The EPA calculates HRLs for contaminants with a threshold dose-response, including microcystins, as follows:

$$HRL = \frac{RfD}{DWI-BW} * RSC$$

Where:

RfD = Reference dose (mg/kg/day), an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. It is derived in the selected qualifying health assessment and is based on the critical effect and study identified in that assessment. Other values that can be used in place of an RfD in this equation can include a maximum acceptable concentration (MAC), minimal risk level, point of departure / uncertainty factor (POD/UF), population-adjusted dose (PAD), or tolerable daily intake (TDI).

DWI-BW = Drinking water intake (DWI), adjusted for body weight (BW), in units of liter per kilogram body weight per day (L/kg/day).

RSC = Relative source contribution, the percentage of the total exposure attributed to drinking water sources (USEPA, 2000), where the remainder of the exposure is allocated to other routes or sources. For HRL derivation in RD 5, an RSC of 20 percent is used for all contaminants.

Using an oral reference value of 0.00005 mg/kg/day (USEPA, 2015a), a DWI-BW of 0.0336 L/kg/day (USEPA, 2019) and a 20 percent RSC to account for non-water sources of exposure (USEPA, 2000), the HRL for microcystins is calculated as follows:

$$HRL = \frac{0.00005 \text{ mg/kg/day}}{0.0336 \text{ L/kg/day}} * 0.2$$

$$HRL = 0.000298 \text{ mg/L}$$

or

$$HRL = 0.298 \text{ } \mu\text{g/L}$$

Following HRL derivation practices, the HRL for microcystins is 0.3 µg/L after rounding to one significant figure.

6.4 Occurrence

This section presents data on the occurrence of microcystins in ambient water and drinking water in the United States. As described in Section 6.3, an HRL of 0.3 µg/L was calculated for microcystins based on non-carcinogenic effects. HRLs are risk-derived concentrations against which the EPA evaluates the occurrence data to determine if contaminants occur at levels of potential public health concern. Occurrence data from various sources presented below are analyzed with respect to the HRL and one-half the HRL. When possible, estimates of the population exposed at concentrations above the HRL and one-half the HRL are presented.

For additional background information about data sources used to evaluate occurrence, please refer to Chapter 2.

6.4.1 Occurrence in Ambient Water

Lakes, rivers, and aquifers are the ambient sources of most drinking water. Contaminant occurrence in ambient water provides information on the potential for contaminants to adversely affect drinking water supplies. Occurrence data for microcystins in ambient water are available from the United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) program, the USGS National Water Information System (NWIS) database, the EPA's legacy Storage and Retrieval Data System (STORET), and several published studies. When sources of information on ambient occurrence also include limited finished water data, those finished water data are summarized here as well.

6.4.1.1 United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) Ambient Water Analyses

USGS instituted the NAWQA program in 1991 to examine ambient water quality status and trends in the United States. The NAWQA program generates high quality contaminant occurrence and other water quality parameter data for significant watersheds and aquifers across the nation. The program collects data on surface water and groundwater chemistry, hydrology, land use, stream habitat, and aquatic life in parts of nearly all 50 states. The program is designed to apply nationally consistent methods to provide a uniform basis for contaminant occurrence comparisons and assessments among study basins across the country and over time. The occurrence assessments can also serve to facilitate interpretation of natural and anthropogenic factors affecting national water quality. For more detailed information on NAWQA program design and implementation, refer to Leahy and Thompson (1994) and Hamilton et al. (2004).

The process of sampling, analysis, and data synthesis is divided into cycles of approximately ten years: Cycle 1 covered 1991-2001, Cycle 2 covered 2002-2012, and Cycle 3 covered 2013-2023. Study units are sampled and analyzed on a staggered schedule within each cycle. Each NAWQA cycle begins with a two-year startup phase for planning and retroactive analysis, followed by a three-year intensive data collection phase, and finally a five-year phase for analyzing the data, developing reports, and continuing a low level of monitoring (NRC, 2012).

The EPA downloaded NAWQA data from the Water Quality Portal (WQP) in September 2023 (WQP, 2023). The EPA's analysis of the NAWQA data is a simple, non-parametric

occurrence analysis that provides summary statistics to characterize contaminant occurrence. The EPA included in the analysis all samples that could be classified as groundwater and surface water, and also the limited number of samples labeled as finished water. Other types of samples (e.g., from soil, sediment, and wastewater) were excluded. The EPA calculated detection frequencies as the percentage of samples and the percentage of sites with at least one detection. (A detection is an analytical result equal to or greater than the reporting level.) No weighting was applied. The EPA determined the minimum and maximum detected concentrations and calculated other descriptive statistics including the median, 90th percentile, and 99th percentile concentrations (based only on samples with detections). Reporting levels varied over time during the NAWQA program.

No sampling for microcystins was conducted during Cycle 1. In Cycle 2, one groundwater sample was tested and microcystins were found not to be present. In Cycle 3, microcystins were detected in 2 (8.70 percent) of 23 surface water samples from 1 (20 percent) of five sites. Both detections had a value of 0.1 µg/L, which is less than the microcystins HRL of 0.3 µg/L (WQP, 2023).

Exhibit 6-7: Microcystins NAWQA Data – Summary of Detected Concentrations

Site Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90 th Percentile	99 th Percentile	Maximum
Cycle 2 (2002 - 2012)					
Groundwater	--	--	--	--	--
Surface Water	--	--	--	--	--
All Sites	--	--	--	--	--
Cycle 3 (2013 - 2023)					
Groundwater	--	--	--	--	--
Surface Water	0.1	0.1	0.1	0.1	0.1
All Sites	0.1	0.1	0.1	0.1	0.1

Source: WQP, 2023

-- = No data or detections in this category

Exhibit 6-8: Microcystins NAWQA Data – Summary of Samples

Site Type	No. of Samples	Detection Frequency (detections are results ≥ reporting level)					
		No. of Samples with Detections	Percent Samples with Detections	No. of Samples with Detections > ½ HRL	Percent Samples with Detections > ½ HRL	No. of Samples with Detections > HRL	Percent Samples with Detections > HRL
Cycle 2 (2002 - 2012)							
Groundwater	1	0	0.00%	0	0.00%	0	0.00%
Surface Water	0	0	n/a	0	n/a	0	n/a
All Sites	1	0	0.00%	0	0.00%	0	0.00%

Site Type	No. of Samples	Detection Frequency (detections are results ≥ reporting level)					
		No. of Samples with Detections	Percent Samples with Detections	No. of Samples with Detections > ½ HRL	Percent Samples with Detections > ½ HRL	No. of Samples with Detections > HRL	Percent Samples with Detections > HRL
Cycle 3 (2013 - 2023)							
Groundwater	0	0	n/a	0	n/a	0	n/a
Surface Water	23	2	8.70%	0	0.00%	0	0.00%
All Sites	23	2	8.70%	0	0.00%	0	0.00%

Source: WQP, 2023

Exhibit 6-9: Microcystins NAWQA Data – Summary of Sites

Site Type	No. of Sites	Detection Frequency (detections are results ≥ reporting level)					
		No. of Sites with Detections	Percent Sites with Detections	No. of Sites with Detections > ½ HRL	Percent Sites with Detections > ½ HRL	No. of Sites with Detections > HRL	Percent Sites with Detections > HRL
Cycle 2 (2002 - 2012)							
Groundwater	1	0	0.00%	0	0.00%	0	0.00%
Surface Water	0	0	n/a	0	n/a	0	n/a
All Sites	1	0	0.00%	0	0.00%	0	0.00%
Cycle 3 (2013 - 2023)							
Groundwater	0	0	n/a	0	n/a	0	n/a
Surface Water	5	1	20.00%	0	0.00%	0	0.00%
All Sites	5	1	20.00%	0	0.00%	0	0.00%

Source: WQP, 2023

6.4.1.2 National Water Information System (NWIS) Data

NWIS is the nation's principal repository of water resources data collected by USGS from more than 1.9 million sites in all U.S. states and territories (USGS, 2022). All USGS water quality and flow data are stored in NWIS, including site characteristics, streamflow, groundwater level, precipitation, and chemical analyses of water, sediment, and biological media, though not all parameters are available for every site. NWIS houses the NAWQA data and includes other USGS data from a range of unspecified projects. NWIS encompasses many more samples at many more sites than are involved in the NAWQA Program. Although NWIS is comprised of primarily ambient water data, some finished drinking water data are included as well. This section presents analyses of non-NAWQA data in NWIS, downloaded from the WQP in September 2023 (WQP, 2023). These data do not overlap with the NAWQA results presented above.

The results of the non-NAWQA NWIS analysis of microcystins data are presented in Exhibit 6-10. Microcystins were detected in approximately 20 percent of samples (211 out of 1,056) at approximately 36 percent of sites (65 out of 181). All of the samples were from surface water. The median detected concentration, 0.3 $\mu\text{g/L}$, was equal to the HRL. The highest reported

concentration was 110 µg/L. Note that the NWIS data are presented as downloaded; potential outliers were not evaluated or excluded from the analysis.

Exhibit 6-10: Microcystins NWIS Data, 1991-2023

Sample Media Type	Detection Frequency (detections are results ≥ reporting level)				Concentration Values (of detections, in µg/L)				
	No. of Samples	No. of Samples with Detections	No. of Sites	No. of Sites with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
Groundwater	0	0	0	0	--	--	--	--	--
Surface Water	1,056	211	181	65	0.1	0.3	40.9	79.7	110
Total	1,056	211	181	65	0.1	0.3	40.9	79.7	110

Source: WQP, 2023

-- = No data or detections in this category

6.4.1.3 Storage and Retrieval (STORET) Data

From its launch in 1999 until it was decommissioned in June 2018, the EPA's STORET Data Warehouse was collaboratively populated with raw biological, chemical, and physical data from surface water and groundwater sampling by federal, state and local agencies, Native American Tribes, volunteer groups, academics, and others. Legacy STORET data, as well as more current data, are accessible through the WQP.

STORET data are from monitoring locations in all 50 states as well as multiple territories and jurisdictions of the United States. STORET's data quality limitations include variations in the extent of national coverage and data completeness from parameter to parameter. Data may have been collected as part of targeted, rather than randomized, monitoring. This section presents analyses of STORET data, downloaded from the WQP in September 2023 (WQP, 2023). The EPA reviewed STORET groundwater data from wells and springs and surface water data from lakes, rivers/streams, and reservoirs. The STORET data set also included limited data from public water systems (PWSs). The database does not specify whether PWS sampling was conducted before or after treatment.

The results of the STORET analysis for microcystins are presented in Exhibit 6-11 through Exhibit 6-13. Samples were collected between 2005 and 2022. Microcystins were found in 7,319 (91.44 percent) of 8,004 samples, at 1,331 (92.49 percent) of 1,439 sites. All of the samples were from surface water. The median detected concentration, 0.33 µg/L, exceeded the HRL of 0.3 µg/L. The highest reported concentration was 80,000 µg/L. Note that the STORET data are presented as downloaded; potential outliers were not evaluated or excluded from the analysis.

Exhibit 6-11: Microcystins STORET Data – Summary of Detected Concentrations

Source Water Type	Concentration Value of Detections (µg/L)			
	Minimum	Median	90 th Percentile	Maximum
Groundwater	--	--	--	--
Surface Water	0.01252	0.33	5.54	80,000
Total	0.01252	0.33	5.54	80,000

Source: WQP, 2023

"--" = No data or detections in this category

Exhibit 6-12: Microcystins STORET Data – Summary of Samples and Sites

Source Water Type	Total Number of Samples	Samples with Detections		Total Number of Sites	Sites with Detections	
		Number	Percent		Number	Percent
Groundwater	--	--	--	--	--	--
Surface Water	8,004	7,319	91.44%	1,439	1,331	92.49%
Total	8,004	7,319	91.44%	1,439	1,331	92.49%

Source: WQP, 2023

Exhibit 6-13: Microcystins STORET Data – Summary of States

Source Water Type	Total Number of States	States with Detections	
		Number	Percent
Groundwater	--	--	--
Surface Water	48	48	100%
Total¹	48	48	100%

Source: WQP, 2023

¹ The number of states with groundwater data plus the number of states with surface water data may not equal the "Total" number of states providing data because some states provided both groundwater and surface water data.

6.4.1.4 Additional Ambient Water Studies

The National Lakes Assessment (NLA) is part of the National Aquatic Resource Surveys, a series of statistically-based assessments designed to provide the public and decision-makers with nationally consistent and representative information on the condition of the nation's waters. The 2007 NLA report (USEPA, 2009) presented information gathered from sampling of 49,546 lakes across the country. Microcystins were present in 29.5 percent of man-made lakes and 30.6 percent of natural lakes, and were present at "levels of concern" in 1 percent of lakes overall. Microcystin levels fluctuated by region. Microcystins were present in 5 percent of lakes in the Western Mountains region, 9 percent of Northern Appalachian lakes, 21 percent of Southern Plains lakes, 23 percent of lakes in the Xeric region, 23 percent of Upper Midwest lakes, 25 percent of Southern Appalachian lakes, 35 percent of Coastal Plains lakes, 67 percent of Temperate Plains lakes, and 75 percent of Northern Plains lakes. The 2012 NLA (USEPA, 2016a) found microcystins in 39 percent of the nation's lakes, an increase since 2007. Fewer

than 1 percent of lakes were assigned to the “most disturbed” or “moderately disturbed” condition categories. According to the 2017 report (USEPA, 2022c), microcystin was detected in 21 percent of lakes. Regional detection rates were reported as 25 percent in the Coastal Plains, 2 percent in the Northern Appalachians, 58 percent in the Northern Plains, 10 percent in the Southern Appalachians, 19 percent in the Southern Plains, 29 percent in the Temperate Plains, 25 percent in the Upper Midwest, 3 percent in the Western Mountains, and 15 percent in the Xeric region. The minimum detection level was 0.1 µg/L. The EPA’s recreational criterion (8 µg/L) was exceeded in 2% of lakes (4,400 lakes).

A total of 18 states voluntarily adopted use of the One Health Harmful Algal Bloom System (OHHABS) and entered 421 reports during 2016–2018 (Roberts et al., 2020). The majority of events occurred during May–October (98 percent) and in freshwater bodies (90 percent). Microcystins were reported as present in 291 of the 421 HABs. Of the 35 HABs where multiple cyanotoxins were found, microcystins were present in 33.

Graham et al. (2020) conducted a study of 11 large river sites located throughout the United States that were sampled during June to September of 2017 to determine the occurrence of cyanobacteria with known cyanotoxin producing strains, cyanotoxin synthetase genes, and cyanotoxins. Cyanobacteria were present in the algal communities of all rivers and many of the cyanobacterial genera identified have known cyanotoxin-producing strains. Eutrophic rivers located in the midcontinent region of the United States had the highest algal biomass, abundance of cyanotoxin synthetase genes, and cyanotoxin occurrence. Higher occurrence in these midcontinent rivers may be a result of eutrophication-related shifts in algal community composition, either within the rivers or upstream reservoirs. Of the cyanobacteria identified in the river samples, microcystin producing strains were detected in 91 percent of rivers and were present in over 70 percent of samples, though the microcystin cyanotoxin itself was only detected at low levels (0.18–0.38 µg/L) in three samples from two midcontinent rivers (the Kansas and Mississippi Rivers). Additional details and findings from this research effort are published in Linz et al. (2023) and Zhang et al. (2023).

Weirich (2017) studied water samples from 39 lakes across North America, South America, Europe, and Africa. From 2008 to 2014, 2 to 68 samples were taken from each lake to create cyanotoxin profiles. Microcystin-LR and microcystin-RR were the most frequently detected microcystins, found in 19.8 percent and 12.1 percent of samples, respectively. The highest cyanotoxin concentration was for microcystin-LR, detected in Lake Winnebago, Wisconsin at 38.25 µg/L.

Eleven freshwater HAB-associated outbreaks that occurred in 2009 or 2010 were reported to the Centers for Disease Control and Prevention (CDC) by New York, Ohio, and Washington (Hilborn et al., 2014). The reporting was voluntary and conducted through CDC’s Waterborne Disease and Outbreak Surveillance System (WBDOS) via the National Outbreak Reporting System (NORS) and the Harmful Algal Bloom-Related Illness Surveillance System (HABISS). Microcystins were detected in all eight investigations where they were tested, at widely ranging concentrations (0.2 to >2,000 µg/L).

USGS and the National Park Service assessed Kabetogama Lake in Voyageurs National Park in northern Minnesota for microcystin levels from 2008 to 2009 (Christensen et al., 2011). Of the 14 cyanobacterial bloom samples, 11 had detectable microcystin levels, 7 had microcystin levels exceeding the 1.0 µg/L WHO guideline for finished drinking water, and 2 were in the WHO high risk recreational exposure category for exceeding 20 µg/L microcystin. The maximum microcystin concentration was 110 µg/L in 2009.

Jacoby and Kann (2007) summarized information on cyanobacteria in the Pacific Northwest region of the United States and Canada. Idaho, Northern California, Oregon, Washington, and British Columbia had recorded toxic bloom events that led to animal illness, waterbody closure, and public health concerns. Microcystins are the most commonly reported cyanotoxin in the region and have been identified at concentrations between <1 µg/L to 30 mg/L. Jacoby and Kann (2007) collected information about the location, date, cyanobacterial species observed, and cyanotoxin concentration of toxic events. The study concluded that few or none of the water systems studied had systemic monitoring programs for cyanotoxins.

6.4.2 Occurrence in Drinking Water

Data sources reviewed by the EPA for information on contaminant occurrence in drinking water included: the EPA's first, second, third, and fourth Unregulated Contaminant Monitoring Rules (UCMR 1, UCMR 2, UCMR 3, UCMR 4); Rounds 1 and 2 of the EPA's Unregulated Contaminant Monitoring (UCM) program that preceded the Unregulated Contaminant Monitoring Rule (UCMR); the EPA's National Inorganics and Radionuclides Survey (NIRS); and a range of others as discussed in Chapter 2. Among the sources reviewed, the following had data and information on total microcystins occurrence in drinking water and are discussed in this section:

- The EPA's Fourth Unregulated Contaminant Monitoring Rule (UCMR 4).
- State drinking water monitoring programs.
- Consumer Confidence Reports (CCRs) from PWSs.
- Additional source water and drinking water studies.

Note that there may be some overlap, as sources with different purposes and audiences may have reported the same underlying data. UCMR 4 is a national data source. Other data sources profiled in this section are considered "supplemental" sources.

6.4.2.1 Primary Data Sources

6.4.2.1.1 *The USEPA's Fourth Unregulated Contaminant Monitoring Rule (UCMR 4)*

The UCMR program was designed to provide a national assessment of the occurrence of select unregulated contaminants in PWSs. UCMR 4 was published on December 20, 2016 (81 FR 92666; USEPA, 2016b) and required monitoring for 30 chemical contaminants between 2018 and 2020. Data reporting continued into 2021.

Monitoring consisted of sampling finished drinking water in PWSs that use surface water or groundwater under the influence of surface water (GWUDI). Groundwater systems were excluded from cyanotoxin monitoring. The sampling was conducted at two groups of PWSs: (a) all large systems serving more than 10,000 people (a census of large PWSs) including all community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) and (b) a nationally representative, randomly selected group of approximately 800 small CWSs and NTNCWSs (small systems serve 10,000 or fewer people).¹ Monitoring

¹ Only 798 small systems submitted results for microcystins.

occurred twice a month for four consecutive months from March through November (for a total of eight sampling events).² Sampling was conducted at entry points to the distribution system.

In addition to analytical sample results, UCMR 4 reporting required systems to provide information related to source water conditions and cyanobacteria / cyanotoxin occurrence and treatment, including: bloom occurrence, possible bloom treatment, and details on changes in source water quality conditions. Those additional data are not summarized in this report. See USEPA (2016b) and USEPA (2024b) for more information on the UCMR 4 study design and data analysis.

The design of UCMR 4 permits estimation of national occurrence by multiplying the total number of systems (or population served) in the nation in a system size category by the percent of systems (or population served) found to exceed a specified threshold in the sample. This extrapolation methodology is applied to small systems. Because all large and very large systems were required to participate in the UCMR 4 Assessment Monitoring, national occurrence estimates in these size categories can be developed using survey census figures rather than extrapolation. Total national occurrence is estimated by summing the extrapolated figures for small systems and the census figures for the large and very large systems.

Exhibit 6-14 through Exhibit 6-18 provide an overview of total microcystins occurrence results from UCMR 4 Assessment Monitoring. The minimum reporting level (MRL) used for total microcystins in the UCMR 4 survey was 0.3 µg/L. Exhibit 6-14 shows a statistical summary of total microcystins concentrations by system size and source water type (including the minimum, median, 90th percentile, 99th percentile, and maximum). Exhibit 6-15 presents a sample-level summary of the results. Exhibit 6-16 through Exhibit 6-18 show system-level results, including national extrapolations, at three thresholds: detections, ½ the HRL, and the HRL. Detections are evaluated on a “greater than or equal to” basis ($\geq$ the MRL), while health-based thresholds are evaluated in terms of exceedances ($> \frac{1}{2}$ HRL, and $>$ HRL).

As a reminder that the figures from large and very large systems represent a census of systems in those categories, results in those categories are labeled “CENSUS” in the exhibits below. No extrapolation was necessary in these categories, as it was for the small systems, to derive national estimates of occurrence. National estimates of occurrence are reported separately in each system size and source water category, and also in the aggregate.

Total microcystins was detected in 0.02 percent of UCMR 4 samples. Reported total microcystins concentrations ranged from 0.32 µg/L to 0.83 µg/L. A total of 35,000 samples for total microcystins were collected from 3,485 systems. Of these systems, 7 (0.20 percent of systems, serving 0.06 percent of the PWS-served population) reported at least one detection of total microcystins. Extrapolating these findings suggests that an estimated 29 PWSs serving nearly 133,000 people nationally have at least one detection of total microcystins. All detections were greater than ½ the HRL and the HRL.

When a system tested positive for total microcystins, it was required to report testing results for six individual microcystin congeners as well. The handful of reported results for individual microcystin congeners are presented in the accompanying UCMR 4 report (USEPA, 2024b).

2 This was an increased sampling frequency and a more narrow monitoring timeframe than for the 20 additional chemical contaminants monitored under UCMR 4.

Exhibit 6-14: Total Microcystins Occurrence Data from UCMR 4 Assessment Monitoring - Summary of Detected Concentrations

Source Water Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90th Percentile	99th Percentile	Maximum
Small Systems (serving ≤ 10,000 people)					
Groundwater	--	--	--	--	--
Surface Water	0.32	0.355	0.383	0.389	0.39
All Small Systems	0.32	0.355	0.383	0.389	0.39
Large Systems (serving 10,001 - 100,000 people) -- CENSUS					
Groundwater	-	-	-	-	-
Surface Water	0.33	0.367	0.720	0.819	0.83
All Large Systems	0.33	0.367	0.720	0.819	0.83
Very Large Systems (serving > 100,000 people) -- CENSUS					
Groundwater	--	--	--	--	--
Surface Water	--	--	--	--	--
All Very Large Systems	--	--	--	--	--
All Systems					
All Water Systems	0.32	0.367	0.676	0.815	0.83

Source: USEPA, 2024b

"--" = No data or detections in this category

Exhibit 6-15: Total Microcystins National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of Samples

Source Water Type	Total # of Samples	Samples with Detections ≥ MRL (0.3 µg/L)		Samples with Detections > ½ HRL (0.15 µg/L)		Samples with Detections > HRL (0.3 µg/L)	
		Number	Percent	Number	Percent	Number	Percent
Small Systems (serving ≤ 10,000 people)							
Groundwater	0	0	0.00%	0	0.00%	0	0.00%
Surface Water	6,630	2	0.03%	2	0.03%	2	0.03%
All Small Systems	6,630	2	0.03%	2	0.03%	2	0.03%
Large Systems (serving 10,001 - 100,000 people) -- CENSUS							
Groundwater	0	0	0.00%	0	0.00%	0	0.00%
Surface Water	22,780	6	0.03%	6	0.03%	6	0.03%
All Large Systems	22,780	6	0.03%	6	0.03%	6	0.03%
Very Large Systems (serving > 100,000 people) -- CENSUS							
Groundwater	0	0	0.00%	0	0.00%	0	0.00%
Surface Water	5,590	0	0.00%	0	0.00%	0	0.00%
All Very Large Systems	5,590	0	0.00%	0	0.00%	0	0.00%
All Systems							
All Water Systems	35,000	8	0.02%	8	0.02%	8	0.02%

Source: USEPA, 2024b

Exhibit 6-16: Total Microcystins National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population – Detections

Source Water Type	UCMR 4 Sample		Number With At Least One Detection ≥ MRL (0.3 µg/L)		Percent With At Least One Detection ≥ MRL (0.3 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection ≥ MRL (0.3 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	0	0	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	798	3,602,504	2	2,463	0.25%	0.07%	9,624	22,859,068	24	15,600
All Small Systems	798	3,602,504	2	2,463	0.25%	0.07%	63,501	60,915,707	24	15,600
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	0	0	0	0	0.00%	0.00%	0	0	0	0
Surface Water	2,333	71,281,856	5	117,262	0.21%	0.16%	2,333	71,281,856	5	117,000
All Large Systems	2,333	71,281,856	5	117,262	0.21%	0.16%	2,333	71,281,856	5	117,000
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	0	0	0	0	0.00%	0.00%	0	0	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Systems										
All Water Systems	3,485	195,188,185	7	119,725	0.20%	0.06%	66,188	252,501,388	29	133,000

Source: USEPA, 2024b

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

Exhibit 6-17: Total Microcystins National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population Served Data – Detections > ½ the HRL (0.15 µg/L)

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > ½ HRL (0.15 µg/L)		Percent With At Least One Detection > ½ HRL (0.15 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > ½ HRL (0.15 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	0	0	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	798	3,602,504	2	2,463	0.25%	0.07%	9,624	22,859,068	24	15,600
All Small Systems	798	3,602,504	2	2,463	0.25%	0.07%	63,501	60,915,707	24	15,600
Large Systems (serving 10,001 – 100,000 people) – CENSUS										
Groundwater	0	0	0	0	0.00%	0.00%	0	0	0	0
Surface Water	2,333	71,281,856	5	117,262	0.21%	0.16%	2,333	71,281,856	5	117,000
All Large Systems	2,333	71,281,856	5	117,262	0.21%	0.16%	2,333	71,281,856	5	117,000
Very Large Systems (serving > 100,000 people) – CENSUS										
Groundwater	0	0	0	0	0.00%	0.00%	0	0	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Systems										
All Water Systems	3,485	195,188,185	7	119,725	0.20%	0.06%	66,188	252,501,388	29	133,000

Source: USEPA, 2024b

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

Exhibit 6-18: Total Microcystins National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population Served Data – Detections > HRL (0.3 µg/L)

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > HRL (0.3 µg/L)		Percent With At Least One Detection > HRL (0.3 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > HRL (0.3 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	0	0	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	798	3,602,504	2	2,463	0.25%	0.07%	9,624	22,859,068	24	15,600
All Small Systems	798	3,602,504	2	2,463	0.25%	0.07%	63,501	60,915,707	24	15,600
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	0	0	0	0	0.00%	0.00%	0	0	0	0
Surface Water	2,333	71,281,856	5	117,262	0.21%	0.16%	2,333	71,281,856	5	117,000
All Large Systems	2,333	71,281,856	5	117,262	0.21%	0.16%	2,333	71,281,856	5	117,000
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	0	0	0	0	0.00%	0.00%	0	0	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Systems										
All Water Systems	3,485	195,188,185	7	119,725	0.20%	0.06%	66,188	252,501,388	29	133,000

Source: USEPA, 2024b

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

6.4.2.2 Supplemental Data Sources

6.4.2.2.1 State Monitoring Data, 2010-2022

Because there is no available national database that receives and stores all relevant data regarding the occurrence of regulated and unregulated contaminants in public drinking water systems, the EPA gathered data from state drinking water monitoring websites in support of national occurrence assessments. Supplemental data of cyanotoxin occurrence in finished drinking water is very limited. Three states were found to have cyanotoxin monitoring programs: Ohio, Oregon, and Vermont. Other limited *ad hoc* sampling results were found for several other states. The monitoring data from each state/entity are limited and not necessarily representative of occurrence in the state/entity. These occurrence findings are also summarized below.

Ohio

Data were obtained from the Ohio EPA's Historical Algal Toxin Results page as reported by various PWSs from 2010 to 2022 (Ohio EPA, 2022a; Ohio EPA, 2022b). As of June 1, 2016, Ohio required PWSs using surface water sources to conduct routine monitoring of cyanotoxins. Therefore, the data from June 1, 2016, onward represents all surface water PWS monitoring while the occurrence data prior to June 1, 2016, are not as complete or representative compared to data after June 1, 2016. Further details describing the monitoring and reporting are found in the state administrative code (Ohio Administrative Code 3723-90) and are partly based on the current Harmful Algal Bloom Strategy (Ohio EPA, 2020). The Ohio sampling program focuses on total microcystins. A summary of finished water sampling results is presented in Exhibit 6-19.

Exhibit 6-19. Ohio Finished Water Sampling Results for Total Microcystins, 2010-2022

Years ¹	Detection Frequency (detections are results $\geq$ reporting level)				Concentration Values (of detections, in $\mu\text{g/L}$)				
	No. of Samples	No. of Samples with Detections	No. of Sites	No. of Sites with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
January 2010 – July 2020	11,776	31	132	10	0.054	0.477	3.4	3.56	3.56
August 2020 – August 2022	3,084	0	67	0	--	--	--	--	--

¹ Source: For 2010-2019 data, see Ohio EPA (2022a). For 2020-2022 data, see Ohio EPA (2022b).

-- = No detections in this category

Oregon

In December 2018, the Oregon Health Authority (OHA) implemented rules requiring that PWSs using surface water sources that are prone to harmful algal blooms conduct sampling of cyanotoxins in raw water once every two weeks from May through October (see Oregon Administrative Rules 333-061-0510 to -0580). If detections of total microcystins or cylindrospermopsin greater than or equal to 0.3 $\mu\text{g/L}$ are identified in raw water samples, PWSs must initiate weekly sampling of finished water at entry points to the distribution system. Further details of monitoring requirements are described in OHA (2023). In the available data for total

microcystins (2018 to 2022), a total of 4,139 samples were collected from 100 PWSs. Of the 288 finished water samples from 15 PWSs, only one detection was reported for microcystins. This detection was equal to 0.36 µg/L (OHA, 2022).

Vermont

Since 2015, the Drinking Water and Groundwater Protection Division (DWGWPD) of the Vermont Agency of Natural Resources has collaborated with the Vermont Department of Health (VDH) to offer free analysis of cyanotoxin sampling in the raw and finished water of the 22 Lake Champlain-sourced public water systems (VT DEC, 2022). Sampling for these 22 PWSs is conducted for the 12 weeks from July through September with one sample collected at one finished water location and one raw water location per week. The MRL for reported samples is 0.16 µg/L. Records are available for sampling conducted from 2014 to 2022. (Note that the 2022 sampling season was not fully completed at the time of writing this report.) Over this 8-year period, a total of 1,689 finished water samples were collected at the 22 PWSs for total microcystins. There were no detections in finished water samples but there were eight detections at or above the MRL in raw water locations.

Illinois

Drinking water occurrence data for microcystins were available on the Illinois state Drinking Water Watch website. Results are presented in Exhibit 6-20. Comprehensive information about methods used and reporting levels is not available for the state data. However, the minimum detected concentrations reported in Exhibit 6-20 may be indicative of reporting levels used. Illinois had microcystins data from 45 PWSs from 2020 - 2022 (the time of data download). Overall, detected concentrations ranged from 0.16 µg/L to 3.39 µg/L. All detections were greater than ½ the HRL (0.15 µg/L). Seventeen systems reported a total of 41 detections greater than the HRL of 0.3 µg/L.

Exhibit 6-20: Illinois Sampling Results for Total Microcystins, 2020-2022

Source Water Type	Detection Frequency (detections are results ≥ reporting level)				Concentration Values (of detections, in µg/L)				
	No. of Samples	No. of Samples with Detections	No. of Systems	No. of Systems with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
Ground Water	0	0	0	0	--	--	--	--	--
Surface Water	367	64	45	25	0.16	0.37	1.05	3.19	3.39

Source: Data downloaded by the EPA from Illinois Drinking Water Watch website.

-- = No detections in this category

Miscellaneous State Sampling and Do Not Drink Advisories

Exhibit 6-21 presents a summary of available “Do Not Drink” advisories throughout the country over the past several years.

Exhibit 6-21: Summary of Miscellaneous State Sampling and “Do Not Drink” Advisories

State	Year	Description of Event
California	2021	Microcystin was detected (15.09-4,490 µg/L) in Clear Lake source waters well above the health advisory level (15.09-4,490 ppb). A Do Not Drink advisory was issued for houses pulling directly from source water. Fill stations for houses from Golden State Water Company and Mt. Konocti MW were set up (BVR, 2021).
California	2022	Microcystin was detected (0.39 - 147.81 µg/L) in Clear Lake source waters well above the health advisory level. A Do Not Drink advisory was issued for houses pulling directly from source water. Fill stations were set up (BVR, 2022).
Iowa	2016	Microcystin was detected in the drinking water of the City of Des Moines below lower health advisory level (<i>Des Moines Register</i> , 2016). No specific concentrations values were reported in this source.
Iowa	2018	The City of Greenfield issued a "do not drink" advisory due to unusually high turbidity levels in the water. Test results showed that the city did not have dangerous levels of microcystin (Eller, 2018). No specific concentrations values were reported in this source.
Kansas	2018	The City of Norton issued an advisory due to a visible bloom on Lake Sebelius. Microcystin levels were as high as 1 µg/L (KDHE, 2018).
Kansas	2019	The City of Carbondale issued a do not drink advisory due to low levels of microcystins in finished drinking water (Grabauskas, 2019).
New York	2016	Detectable levels of microcystins were found in the treated drinking water from the City of Auburn and the City of Owasco. Levels ranged from 0.16 to 0.121 µg/L. No advisories issued since levels below the EPA's health advisory level (Hannagan, 2016).
New York	2017	Blue green algae was reportedly found in samples taken from the Village public drinking water from Skaneateles Lake in Syracuse. The algae was at levels below health advisory limits. An advisory was issued in the City of Syracuse for those who draw water from Skaneateles Lake through private intakes (Village of Skaneateles, 2017). No specific concentrations values were reported in this source.
New York	2018	A "do not drink" advisory was issued for the cities of Rushville and Middlesex. The advisory issued for all consumers due to a visible bloom in Canandaigua Lake. Microcystin was detected at 0.66 µg/L (NY DOH, 2018).
Ohio	2013	Carroll Township, OH shut down its municipal water supplies for two days due to microcystin concentrations greater than 1 µg/L (Wynne and Stumpf, 2015).
Ohio	2014	The city of Toledo, Ohio issued a "do not drink or boil advisory" to nearly 500,000 customers in response to the presence of total microcystins in the city's finished drinking water at levels up to 2.50 µg/L. The presence of the toxins was due to a cyanobacterial bloom near Toledo's drinking water intake located in Lake Erie. The advisory was lifted two days later, after treatment adjustments led to the reduction of the cyanotoxin concentrations to concentrations below the WHO guideline value of 1 µg/L in all samples from the treatment plant and distribution system (Gebhardt, 2014).
Oregon	2018	The City of Salem found low levels of microcystin in treated drinking water (Detroit Reservoir). Multiple "do not drink" advisories were issued over the course of 6 weeks from late May 2018 to early July 2018 (City of Salem OR, 2018). Levels of microcystins in 70 drinking water samples ranged from 0.0021 µg/L to 2.3746 µg/L (Urness et al., 2018).
Texas	2016	The City of Ingleside issued a 13-day "do not drink" advisory due to detections of microcystin in their drinking water distribution system (AWWA, 2016a). No specific concentrations values were reported in this source.

6.4.2.2.2 Water Systems' Consumer Confidence Reports (CCRs), 2018-2021

CCRs are annual water quality reports that CWSs are required to provide to their customers. These reports summarize information on water sources, detected contaminants, and system compliance with EPA drinking water standards; they may also include general educational material. Under the CCR Rule (40 CFR Subpart O), CWSs with 15 or more connections or serving at least 25 year-round residents must prepare and distribute a CCR to all

billing units or service connections every year. Systems serving 100,000 or more residents are also required to post their current CCRs on a publicly accessible Internet site.

The EPA reviewed CCRs published by the 25 systems that serve over one million customers (as identified in the Safe Drinking Water Information System / Federal version, or SDWIS/Fed, from the fourth quarter 2021 data) for unregulated contaminant occurrence information for the years 2018 through 2021. Data on total microcystins were available from CCRs prepared by five CWSs: one system in California (Los Angeles), one system in New York (New York City), one system in Ohio (Columbus), one system in Pennsylvania (Philadelphia), and one system in Texas (Dallas).

The Los Angeles Department of Water and Power discussed on total microcystins monitoring as part of UCMR 4 in its 2020 and 2021 CCRs. No detections of on total microcystins were reported.

New York City included data on total microcystins monitoring in its 2018 and 2019 CCRs. Monitoring was conducted as part of the UCMR 4 program. New York City is served by a large system of surface water networks in New York state. No detections of total microcystins were reported.

The City of Columbus, Ohio listed microcystins its 2018, 2019, 2020, and 2021 CCR as an analyte that is not found in their drinking water. The City of Columbus water system uses surface water from the Scioto River and Big Walnut Creek, as well as groundwater sources. Microcystins was not detected in any samples.

The Philadelphia Water Department included data on microcystin in its 2020 and 2021 CCRs. Monitoring was conducted as part of the UCMR 4 program. Philadelphia is served by two surface water sources, the Schuylkill and the Delaware Rivers. Sampling locations and the number of samples collected were not reported. No detections of total microcystins were reported.

The City of Dallas included data on microcystin monitoring in its 2018 CCR. Monitoring was conducted as part of the UCMR 4 program. Dallas is served by seven surface water sources. The number of samples and location of samples was not reported. In 2018, total microcystins were not detected in any sample.

6.4.2.2.3 *Additional Source Water and Drinking Water Studies*

Szlag et al. (2015) looked at the occurrence of microcystin, anatoxin-a, and cylindrospermopsin in five different drinking water treatment plants in five states: California, Texas, Oklahoma, Florida, and Vermont. The researchers observed the plants for 12 to 16 weeks during the spring and summer and used the thresholds in the WHO risk management framework that includes an Alert Level 1 (for concentrations exceeding 2,000 cyanobacteria cells/mL) and an Alert Level 2 (for concentrations exceeding 100,000 cyanobacteria cells/mL). The method detection limit for individual microcystin congeners was 0.25 µg/L. No cyanotoxins were found in any of the finished water samples at any of the plants. In raw water samples, microcystin was frequently detected, cylindrospermopsin was detected once (in Oklahoma), and anatoxin-a was not detected. Four of the five plants (in California, Texas, Florida, Oklahoma) often exceeded the WHO Alert Level 1 in raw water samples. Raw water in the California plant exceeded the WHO action level 2 twice, and raw water in the Texas plant exceeded the WHO Alert Level 2 once. Szlag et al. (2015) did not find a correlation between the amount of toxin-producer cyanobacteria and the levels of toxins.

Miller et al. (2017) summarized cyanotoxin occurrence on Lake Erie. Microcystins were detected at 16 of 25 surface water sampling locations on Lake Erie in the 2010-2015 timeframe (N ranging from 1 to 52). Overall, the mean concentration was 126.9 µg/L and the highest was 3,144 µg/L. With the two highest values removed as outliers, the mean would be 1.81 µg/L. Microcystins were detected at 18 of 21 drinking water intakes in Lake Erie (N ranging from 1 to 1,377). Overall, the mean concentration was 1.04 µg/L and the highest was 340 µg/L. Among the nine drinking water treatment plants (DWTPs) in Ohio reporting detectable levels of microcystins, six draw surface water from Lake Erie. Among these six, the highest microcystin concentrations ranged from 0.23 to 3.56 µg/L. Elsewhere in the state, the highest concentration was 11 µg/L.

Trautman (2018) studied microcystin levels in 28 treatment plants in Iowa from July 11, 2016 to June 26, 2017. The 28 treatment plants were from 26 community public water supply systems, of which 22 used surface water sources and 6 used groundwater sources under direct influence of surface water. Researchers collected samples weekly and collected additional samples when microcystin was detected. There was at least one detection of microcystin in raw water for 27 of the 51 weeks studied. Of the 22 systems using surface water, 15 had at least one sample above the detection limit of 0.3 µg/L total microcystin in raw water (maximum: >5 µg/L), but no finished water sample had detectable microcystin levels. Of the systems using GWUDI sources, none experienced a microcystin detection in raw water or finished water.

The American Water Works Association Research Foundation (AWWARF), now the Water Research Foundation (WRF), sponsored a study on the occurrence of cyanobacterial toxins in source and treated drinking waters from 24 public water systems in the United States and Canada in 1996-1998 (Carmichael, 2000). Of 677 samples tested, 539 (80 percent) were positive for microcystins. Microcystin levels in excess of 1 µg/L were found in 29 (4.3 percent) of the samples, including in two finished water samples.

A survey conducted in 1999 in Florida (Burns, 2008; Williams et al., 2001) reported that microcystins were present in all 87 samples of Florida water tested. Sampling the next year focused on raw and finished drinking water; microcystins were found in both raw and finished water, with finished water concentrations as high as 12.5 µg/L.

Boyer (2008) assessed the occurrence and distribution of toxic cyanobacterial blooms in New York and the Lower Great Lakes from 2000 to 2004. More than 2,500 samples were collected from over 1,000 sites at 81 different New York lakes, including large lakes, intermediate-sized bodies of water, and smaller impoundments and lakes. Samples were collected at a variety of times throughout the growing season (June-October), with the bulk of the samples collected in late July and early September. Between 2000 and 2004, more than 1,000 samples were collected from 81 different lakes across New York state. With a reporting limit of 0.01 µg/L, microcystins were detected in 1,223 (53%) of 2,286 samples, with a maximum concentration of <0.25 µg/L. Samples were also taken on five different research cruises on Lake Erie during 2000-2004. Microcystins were detected in 7-85% of Lake Erie samples (N ranging from 13 to 119), with a maximum concentration of 21 µg/L.

During the summer of 2003, a survey was conducted to test for microcystins in 33 drinking water treatment plants in the Northeast and Midwest (Haddix et al., 2007). Microcystins were detected in 87% of 206 raw water samples, with a mean concentration of 0.307 µg/L and a maximum concentration of 5.646 µg/L, and in 30% of 77 finished water samples, with a mean concentration of 0.036 µg/L and a maximum concentration of 0.36 µg/L. Detection limits ranged from 0.15 µg/L for microcystin-LR to 0.44 µg/L for microcystin-YR.

Microcystin-LR was monitored in 2005 and 2006 in Lake Ontario and other lakes and ponds within its watershed (Makarewicz et al., 2009). With a detection limit of 0.003 µg/L, microcystin-LR was detected in 91.6% of 581 samples in and around Lake Ontario and in 100% of 98 samples collected at inland lakes. In and around Lake Ontario, means ranged from 0.006 µg/L (offshore/nearshore sites) to 0.084 µg/L (bay/harbor sites) and the highest observed concentration was 7.034 µg/L. In the inland lakes, some of which are sources of drinking water, the mean concentration was 1.136 µg/L and the highest observed concentration was 20.394 µg/L.

A report by the American Water Works Association (AWWA, 2016a) examined cyanotoxin occurrence in multiple states. Of 16 drinking water systems interviewed, all reported having monitored for microcystins, and 14 (88%) reported having detected them. States were also contacted to provide occurrence data, and the most robust data were obtained from Ohio, covering the period 2010-2015. In Ohio, microcystins were detected in 1,877 out of 4,162 source water samples, with an average concentration of 25 µg/L and a maximum of 20,000 µg/L, and microcystins were detected in 32 of 2,243 treated drinking water samples, with an average concentration of 1.33 µg/L and a maximum of 11 µg/L. Detection limits ranged from 0.01 to 0.6 µg/L.

Solomon et al. (2022) explored the effect of harmful algal blooms on private drinking water intakes from June to November 2021 in Clear Lake, California. Of the 17 public drinking water systems with source lake water intakes tested for microcystins, none had exceedances of the EPA health advisory level of 0.3 µg/L in finished water. Sampling was also performed at 46 homes with private lake water intakes (surface water) of private wells (groundwater) within 50 feet of the lake. Microcystins were not detected in samples of tap water from 15 homes with private wells. Microcystins were detected in samples from 22 of 31 homes with lake water intakes. Concentrations at or above 0.3 µg/L were found in 18 homes, and the highest microcystins concentration was 3.9 µg/L.

Farrer et al. (2015) studied cyanobacteria and cyanotoxin occurrence in drinking water and recreational water in Oregon. Cyanobacteria capable of producing anatoxin-a, microcystin, and cylindrospermopsin were found in freshwater bodies throughout Oregon. From 2009 to 2014, Oregon issued 88 recreational harmful algal bloom advisories, of which 78 were based on cell counts and 10 on toxin results. During that same period, microcystin was detected 14 times above its recreational water guideline value of 10.0 µg/L. Farrer et al. (2015) reported that cyanotoxin levels in finished drinking water in Oregon never exceeded drinking water guidelines.

Karner et al. (2001) evaluated microcystins occurrence in raw and finished drinking water in Wisconsin from five water treatment plants and their two water sources, Rainbow Lake and Lake Winnebago, in 1998 and 1999. During the 1998 sampling period (July-September 1998), the weekly average raw water microcystin concentration ranged from 0.585 to 1.216 µg/L, and the weekly average finished water microcystin concentration ranged from 0.0028 to 0.0054 µg/L. The highest raw water value was 6.1 µg/L, and the highest finished water value was 0.017 µg/L. During the 1999 sampling period (August-October 1999), raw water microcystin concentrations were lower, ranging from 0.123 to 0.993 µg/L. The finished water microcystin concentrations ranged from no detection (<0.002 µg/L) to 0.022 µg/L.

6.5 Analytical Methods

The EPA has published two analytical methods that are available for the analysis of microcystins in drinking water. EPA Method 546 is used for the analysis of total microcystins, and EPA Method 544 is used for the analysis of the 6 microcystin congeners.

- EPA Method 546, *Determination of Total Microcystins and Nodularins in Drinking Water and Ambient Water by Adda Enzyme-Linked Immunosorbent Assay*, is for the determination of total microcystins in finished drinking water and in ambient water using enzyme-linked immunosorbent assay (ELISA). EPA Method 546 measures the total concentration based on detection of a characteristic feature common to microcystin and nodularin congeners (structural variants), specifically, the Adda amino acid side chain: (4E,6E)-3- amino-9-methoxy-2,6,8-trimethyl-10-phenyldeca-4,6-dienoic acid (Fischer et al., 2001). EPA Method 546 summarizes method performance data for a single microcystin congener: MC-LR. The Lowest Concentration Minimum Reporting Level (LCMRL) is 0.26 µg/L. Mean recoveries in reagent water and drinking water (total organic carbon (TOC) = 3.0 mg/L, pH = 7.55, free chlorine = 0.89 mg/L, total chlorine = 1.17 mg/L, hardness = 126 mg/L as CaCO₃) range from 93.4 to 117 percent, with relative percent differences (RPDs) of 5.1 to 12 percent (USEPA, 2016c).
- EPA Method 544, *Determination of Microcystins and Nodularin in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry*, is for the determination of six microcystin congeners: microcystin-LA; microcystin-LF; microcystin-LR; microcystin-LY; microcystin-RR; and microcystin-YR. EPA Method 544 has the following LCMRLs:

Microcystin-LA: 2.9 ng/L

Microcystin-LF: 3.5 ng/L

Microcystin-LR: 6.6 ng/L

Microcystin-LY: 4.6 ng/L

Microcystin-RR: 5.6 ng/L

Microcystin-YR: 22 ng/L

Recoveries and RPDs in reagent water, finished drinking water from a groundwater source (TOC = 0.48 mg/L and hardness = 360 mg/L as CaCO₃) and finished drinking water from a surface water source (TOC = 2.49 mg/L and hardness = 137 mg/L as CaCO₃) are:

Microcystin-LA: Recoveries of 81.8 to 112 percent with RPDs of 0.9 to 6.0 percent

Microcystin-LF: Recoveries of 85.0 to 104 percent with RPDs of 2.1 to 8.7 percent

Microcystin-LR: Recoveries of 85.5 to 117 percent with RPDs of 1.7 to 7.4 percent

Microcystin-LY: Recoveries of 83.8 to 106 percent with RPDs of 2.3 to 6.8 percent

Microcystin-RR: Recoveries of 92.1 to 116 percent with RPDs of 0.9 to 9.8 percent

Microcystin-YR: Recoveries of 82.4 to 114 percent with RPDs of 5.3 to 14 percent (USEPA, 2015c)

In addition to the two EPA-developed methods, Ohio EPA Method 701.0 and 701.0-A, version 2.4 are available for the determination of total (intracellular and extracellular)

microcystins-ADDA in surface water, groundwater and finished drinking water using an ELISA analytical methodology (Ohio EPA, 2021). An earlier version of the method, version 2.3 (Ohio EPA, 2018), lists a reporting limit of 0.30 µg/L. Version 2.4 (Ohio EPA, 2021) only lists the following dilution-based adjusted reporting limits:

- 2x dilution, reporting limit = 0.6 µg/L
- 5x dilution, reporting limit = 1.5 µg/L
- 10x dilution, reporting limit = 3.0 µg/L
- 20x dilution, reporting limit = 6.0 µg/L

From this list of values, it can be inferred that the reporting limit with no dilution for version 2.4 is 0.3 µg/L, just as it had been in version 2.3.

Laboratories participating in UCMR 4 were required to use EPA Method 544 and EPA Method 546 (81 FR 92666; USEPA, 2016b). Using EPA Method 546, participants were required to report total microcystins values at or above the EPA-defined MRL of 0.3 µg/L. If a reporting threshold of 0.3 µg/L for total microcystins using EPA Method 546 was exceeded, participants were required to report values for the six microcystin congeners at or above the following EPA-defined MRLs using EPA Method 544:

- Microcystin-LA: 0.008 µg/L
- Microcystin-LF: 0.006 µg/L
- Microcystin-LR: 0.02 µg/L
- Microcystin-LY: 0.009 µg/L
- Microcystin-RR: 0.006 µg/L
- Microcystin-YR: 0.02 µg/L

The MRLs were set based on the capability of multiple laboratories at the time.

One or more non-EPA methods not discussed here might also be applicable to this contaminant in drinking water.

6.6 Treatment Technologies

The EPA evaluates whether suitable treatment technologies are available prior to promulgating a final NPDWR. The preliminary summary of treatment technology availability presented here represents the results of a May 2022 literature search.

Although management of cyanobacteria blooms in source water can be an important part of an integrated cyanotoxin management approach, source water treatment is not covered in this review of treatment technologies.

An important consideration when treating for cyanotoxins in drinking water is whether the cyanotoxins are contained within the intact cyanobacteria cell (intracellular) or dissolved in the water (extracellular). It is generally a good idea to remove as many intact cells as possible, to prevent the release of intracellular toxins. Treatments that are effective for removing intact cyanobacterial cells include conventional treatment (coagulation, sedimentation, and filtration), flotation (e.g., dissolved air flotation), and membrane filtration. Pre-oxidation is not recommended unless the dosage is sufficient to both lyse the cells and chemically inactivate the cyanotoxins (AWWA, 2016b).

The following treatment technologies may be effective for treating microcystins in water: granular activated carbon (GAC), powder activated carbon (PAC), chlorine, ozone, permanganate, biological degradation and membrane filtration.

Adsorption by GAC and PAC has been shown to be effective at removing microcystins (AWWA, 2016b; USEPA, 2016d). Newcombe and Nicholson (2004) reported that PAC with pores between 2 and 50 nm can adsorb dissolved microcystins, but results vary by congener. For example, at an initial concentration of 5 µg/L and 30-minute contact time, microcystin-RR could be reduced by approximately 90 percent but microcystin-LA could only be reduced by approximately 10 percent by using wood-based PAC (Newcombe and Nicholson, 2004). USEPA (2015d) notes that wood-based PAC has been demonstrated to be the most effective at removing microcystins, but that PAC doses that are required for cyanotoxin removal, generally in excess of 20 mg/L, are higher than what is typically used in drinking water treatment. Walker (2015 as cited in USEPA, 2016d) confirmed that wood-based or lignite-type carbon, with pores between 2 and 50 nm, was effective for removing microcystins, and that wood-based GAC is generally effective for cyanotoxin removal. Alvarez et al. (2010 as cited in USEPA, 2015d) reports that for GAC an empty bed contact time of no less than 10 minutes is recommended for adequate microcystin-LR removal in most cases.

Bogialli et al. (2013) evaluated the removal of microcystins in a conventional drinking water treatment plant using post-filtration GAC. After 12 months of being fully operative, the system was able to reduce the concentration of microcystins from 2.8 µg/L to 0.006 µg/L. Lambert et al. (1996) also evaluated the removal of microcystins at a water treatment plant using conventional filtration followed by GAC adsorption. Incremental removal of 14-60% and 43-60% of microcystin-LR was observed across filtration and GAC, respectively. This was found for influent concentrations of microcystin-LR of up to 1.4 µg/L (filter) and 0.6 µg/L (GAC). The authors noted that high TOC levels (25-30 mg/L) in the raw water and lack of treatment optimization for TOC removal could explain the relatively low levels of microcystin removal compared with previous studies. No information on the characteristics of the activated carbon used was provided in either study.

Chlorine and ozone have both been shown to be effective oxidants for the destruction of microcystins. The efficiency of chlorination and ozonation is dependent on the chemical characteristics of the water, including pH and dissolved organic carbon (DOC) (Chorus and Welker, 2021). For microcystin-LR, the desirable pH range for the most efficient oxidation with free chlorine is between 6 and 8. A pH below 6 may result in the risk of cell stress or lysis, while a pH of above 8 presents a risk of unreasonably high contact times potentially resulting in plants exceeding the maximum residual disinfectant level (MRDL) for free chlorine (USEPA, 2016d). Ho et al. (2006) reported that chlorination contact times of up to 25 mg-min/L were required to oxidize 20 µg/L microcystins to below 1.0 µg/L; efficacy varied depending on the microcystin congener, the pH and the concentration and character of natural organic material (NOM) in the water (conventionally treated water from South Australia utilities). Rositano et al. (2001) reported 100 percent destruction of 20 µg/L microcystin-LR and 20 µg/L microcystin-LA in four surface water samples after 5 minutes with ozone at doses of 0.5-1.1 mg/L, with pH ranging from 7.1 to 7.8 and DOC ranging from 4.6 to 15.5. Alvarez et al. (2010 as cited in USEPA, 2015d) found that ozone is effective at doses of 0.5 – 1.1 mg/L under most water quality conditions and contact times.

Potassium permanganate has also been reported to be effective at destroying microcystins, independent of pH (USEPA, 2016d). Walker (2015 as cited in USEPA, 2016d)

reports that studies using doses of approximately 1 mg/L have resulted in significant microcystins reduction, while Chorus and Welker (2021) indicate that most studies report a dose of 1-2 mg/L to be very effective. One study reported microcystin-LR removal from initial levels between 0.89 to 2.44 mg/L to levels below 1 µg/L after 2 hours of contact time with 1-1.25 mg/L potassium permanganate, with water at a DOC of 6.7 and a pH of 7.3 (Rodríguez et al., 2007).

Biological degradation is an effective method for removing and inactivating microcystins (Chorus and Welker, 2021). Ho et. al (2012 as cited in USEPA, 2016d) notes that efficiency of biological degradation is dependent on water temperature, the abundance of specific bacteria capable of degrading the cyanotoxins present, the concentration of the target cyanotoxins, and the presence of organic matter and metals in the source water. In a full-scale slow sand filter study with pulsed application of dissolved microcystins, Grützmacher et al. (2002) reported achieving a microcystin elimination rate of over 95 percent after 33 hours, corresponding to a half life of approximately 1 hour in the filter bed. Lower rates of elimination were seen at lower temperatures. Westrick et al. (2010 as cited in USEPA, 2015d) reports seasonal variability in the ability of biological active slow sand filtration to degrade cyanotoxins, with 95 percent removal of extracellular microcystins and cylindrospermopsin in the summer but less than 65 percent in the autumn. Newcombe et al. (2003) reported 100 percent biodegradation of microcystin-LR and microcystin-LA at initial concentrations of approximately 130 µg/L and 150 µg/L, respectively, after nine days in a batch bioreactor in the presence of microorganisms removed from a GAC pilot filter sample. Wang et al. (2007) reported biological degradation in conventional GAC filters as an efficient removal mechanism, and attributed the increase they observed in microcystin removal efficiency after 38 days to biodegradation. One challenging aspect of using biological degradation is the lag period during which microorganisms are acclimating to the conditions of the treatment environment or multiplying to the point at which they will be effective, which can range from days to more than a year (Chorus and Welker, 2021).

Nanofiltration and reverse osmosis can be effective for removing extracellular cyanotoxins. Westrick et al. (2010 as cited in USEPA, 2015d) reports removal rates from 82 to 100 percent for a range of microcystins using these techniques. Results are affected by membrane material, pore size and water quality (USEPA, 2015d).

6.7 References

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Chapter 7: Molybdenum

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Abbreviations

ADD	Acceptable Daily Dose
ATSDR	Agency for Toxic Substances and Disease Registry
BW	Body Weight
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CCL 5	Fifth Contaminant Candidate List
CCR	Consumer Confidence Report
CDC	Centers for Disease Control and Prevention
CDR	Chemical Data Reporting
CWS	Community Water System
CWSS	Community Water System Survey
DWI	Drinking Water Intake
DWI-BW	Drinking Water Intake Rate Adjusted for Body Weight
DWW	Drinking Water Watch
EF	Exposure Factor
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
GWUDI	Groundwater Under the Direct Influence of Surface Water
HRL	Health Reference Levels
iMRL	Intermediate-Duration Oral Minimal Risk Level
IOC	Inorganic Chemical
IRIS	Integrated Risk Information System
IUR	Inventory Update Reporting
LOAEL	Lowest-Observed-Adverse-Effect Level
LOD	Limit of Detection
MAC	Maximum Acceptable Concentration
MDL	Method Detection Limit
MRL	Minimum Reporting Level
NAWQA	National Water-Quality Assessment
ND	No Detection
NIRS	National Inorganics and Radionuclides Survey
NOAEL	No-Observed-Adverse-Effect Level
NPDWR	National Primary Drinking Water Regulation
NTNCWS	Non-Transient Non-Community Water System
NWIS	USGS National Water Information System
OGWDW	Office of Ground Water and Drinking Water
PAD	Population-Adjusted Dose
POD	Point of Departure
POD/UF	Point of Departure / Uncertainty Factor
PWS	Public Water Systems
RD 5	Fifth Regulatory Determination
RfD	Reference Dose
ROS	Regression on Ordered Statistics
RPD	Relative Percent Differences
RSC	Relative Source Contribution
SDWA	Safe Drinking Water Act

SDWIS	Safe Drinking Water Information System
SDWIS/Fed	Safe Drinking Water Information System / Federal Version
SM	Standard Methods
STORET	Storage and Retrieval Data System
SYR2	Second Six-Year Review
SYR3	Third Six-Year Review
SYR4	Fourth Six-Year Review
TDI	Tolerable Daily Intake
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
UCM	Unregulated Contaminant Monitoring
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 1	First Unregulated Contaminant Monitoring Rule
UCMR 2	Second Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 4	Fourth Unregulated Contaminant Monitoring Rule
UF	Uncertainty Factor
UF _A	Interspecies Uncertainty Factor
UF _H	Intraspecies Uncertainty Factor
UF _S	Subchronic-to-Chronic Uncertainty Factor
USGS	United States Geological Survey
VOC	Volatile Organic Compound
WHO	World Health Organization
WQP	Water Quality Portal

Chapter 7: Molybdenum

The U.S. Environmental Protection Agency (EPA) is evaluating molybdenum, a contaminant on the fifth Contaminant Candidate List (CCL 5), as a candidate for regulation under the fifth Regulatory Determination process (RD 5). Information on the CCL 5 process is found in Chapter 1. Background on data sources used to evaluate CCL 5 chemicals is found in Chapter 2.

This chapter presents information and analysis specific to molybdenum, including background information on the contaminant, information on contaminant sources and environmental fate, an analysis of health effects, an analysis of occurrence in ambient and drinking water, and information about the availability of analytical methods and treatment technologies.

7.1 Contaminant Background and Chemical and Physical Properties

Molybdenum is a naturally occurring element (chemical symbol Mo, atomic number 42) and a transition metal in Group Six of the periodic table), which also includes chromium, tungsten, and seaborgium. Molybdenum, especially in the form of molybdenum trioxide, is commonly used in metallurgy, including in alloys with cast iron, steel and superalloys. Molybdenum compounds are also used in catalysts, lubricants, and pigments. Of the 33 known isotopes of molybdenum, seven are found in nature: ^{92}Mo (15.86 percent abundance), ^{94}Mo (9.12 percent), ^{95}Mo (15.7 percent), ^{96}Mo (16.5 percent), ^{97}Mo (9.45 percent), ^{98}Mo (23.75 percent), and ^{100}Mo (9.62 percent) (ATSDR, 2020; NCBI, 2024a).

There are also several radioactive isotopes with atomic masses 83-91, 93, 99, and 101-115. Notable among these is ^{99}Mo , a beta particle emitter with a radioactive half-life of 65.976 hours that is used to produce technetium-99m ($^{99\text{m}}\text{Tc}$) for medical scans (ATSDR, 2020). Since drinking water contamination by radioactive isotopes, including beta particle emitters, is covered under the existing radionuclides rule, this document deals only with nonradioactive properties and the occurrence of “total” molybdenum in the environment.

Molybdenum constitutes approximately 0.0001 percent (1ppm) of the earth’s crust, ranking as the 53rd most abundant element of the earth’s crust, and it is the most abundant transition metal in seawater (ASTDR, 2020; Wedepohl, 1995; Smedley and Kinniburgh, 2017). Molybdenum is not found in nature in its pure metallic form, but is found in minerals, primarily as oxide or sulfide compounds. Molybdenum can exist in oxidation states from -2 to +6; it is most commonly found in oxidation state +6 (Mo(VI)), for example in molybdenum trioxide and molybdates, and in oxidation state +4 (Mo(IV)), for example in molybdenite. Molybdenite is the most common mineral from which commercial molybdenum is obtained. Mining and milling of crude ore produce molybdenite concentrate which can be converted to technical-grade molybdenum trioxide, the base of production for a variety of chemical compounds (ATSDR, 2020).

Physical and chemical properties and other reference information for elemental molybdenum and select molybdenum compounds are listed in Exhibit 7-1. Exhibit 7-2 and Exhibit 7-3, in the following section, identify some additional molybdenum-containing compounds that are produced industrially.

Exhibit 7-1: Physical and Chemical Properties of Molybdenum and Selected Molybdenum Compounds

Property	Elemental Molybdenum	Molybdenite (Molybdenum disulfide)	Molybdenum trioxide	Disodium Molybdate
Chemical Abstracts Service Registry Number (CASRN)	7439-98-7 (ASTDR, 2020)	1309-56-4/1317-33-5 (natural mineral form); 12612-50-9 (synthetic form) (ASTDR, 2020)	1313-27-5 (ASTDR, 2020)	7631-95-0 (ASTDR, 2020)
Chemical Formula	Mo (ASTDR, 2020)	MoS ₂ (ASTDR, 2020)	MoO ₃ (ASTDR, 2020)	Na ₂ MoO ₄ (ASTDR, 2020)
Molecular Weight	95.94 g/mol (ASTDR, 2020)	160.07 g/mol (ASTDR, 2020)	143.95 g/mol (ASTDR, 2020)	205.92 g/mol (ASTDR, 2020)
Color/ Physical State	Dull gray powder (ASTDR, 2020)	Black crystalline solid (ASTDR, 2020)	White to slightly blue crystalline solid (ASTDR, 2020)	White crystalline powder (ASTDR, 2020)
Boiling Point	4,612°C (ASTDR, 2020)	2,375°C (ACS, 2020)	1,155°C (ASTDR, 2020)	N/A (ASTDR, 2020)
Melting Point	2,617°C (ASTDR, 2020)	>1,600°C (rhombohedral crystal); did not melt at 1,800°C (ASTDR, 2020)	801°C (ASTDR, 2020)	687°C (ASTDR, 2020)
Density	10.22 g/cm ³ (ASTDR, 2020)	5.05 g/cm ³ (ASTDR, 2020)	4.692 g/cm ³ at 21°C (ASTDR, 2020)	3.5 g/cm ³ (ASTDR, 2020)
Freundlich Adsorption Coefficient	--	--	--	--
Vapor Pressure	No data at 20 °C (ASTDR, 2020)	--	--	--
Solubility in Water	5.5–12 mg/L at 20°C and pH of 3.5– 4.3 (ASTDR, 2020)	Insoluble (ASTDR, 2020)	490 mg/L at 28°C (ASTDR, 2020)	840,000 mg/L at 100°C (NCBI, 2024b)
Other Solvents	Dissolved by a mixture of concentrated nitric and concentrated hydrofluoric acids (ASTDR, 2020)	Dissolves only in strongly oxidizing acids (ASTDR, 2020)	Soluble in aqueous alkali and ammonia (ASTDR, 2020)	--

Note: "--" indicates that no information was found.

Note: Many of these properties are temperature-dependent. Values are given for properties at 20-25°C unless otherwise noted. Due to varying experimental conditions, and due to the variabilities associated with modeling, standard information sources may provide a range of values. Where more than one value was available from these sources, one value was selected for this table based on best professional judgment.

7.2 Sources and Environmental Fate

7.2.1 Natural Sources

Molybdenum is a naturally occurring trace element necessary for plant and animal life as a micronutrient. Molybdenum exists in the environment predominantly as a component of minerals, including oxide or sulfide compounds. Among the most important naturally occurring molybdenum-bearing minerals are molybdenite (molybdenum disulfide), powellite (calcium molybdate), wulfenite (lead molybdate), ferrimolybdite (a hydrous iron molybdate), and ilsemanite (a molybdenum oxide) (ASTDR, 2020). As noted above, molybdenum is the 53rd most abundant element of the earth's crust and is present in seawater (Wedepohl, 1995; Smedley and Kinniburgh, 2017). It can also be naturally present in trace amounts in soils, sediments, and fresh waters (Smedley and Kinniburgh, 2017).

Naturally occurring molybdenum gets into the atmosphere from volcanic activity, ocean spray, wildfires, primary biogenic particles, and air erosion of dusts and soils. Weathering of bedrock, atmospheric deposition, and volcanic ash are sources of naturally occurring molybdenum in soils and environmental waters (Wong et al., 2021; Smedley and Kinniburgh, 2017).

7.2.2 Production, Use, and Release

The United States produces molybdenum domestically from mining operations in Colorado, Arizona, Montana, Nevada, and Utah, and also imports molybdenum. Total U.S. mine production of molybdenum concentrate fell from a recent high of 51,100 metric tons in 2020 to 42,000 metric tons in 2022. U.S. production in 2022 accounted for approximately 17% of total global molybdenum production. The United States exported 53,000 metric tons in 2022 and imported 33,000 metric tons. Estimated apparent consumption in the United States stood at 22,000 metric tons (USGS, 2023).

The product of mining and milling of crude ore is molybdenite. Purified molybdenite can be used directly as a solid or in coatings bonded onto metal surfaces, and can also be used in the desulfurization of petroleum (see discussion of catalytic applications below), but most molybdenite is converted to molybdenum trioxide (ATSDR, 2020). Molybdenum trioxide may in turn be converted to other commercial intermediate products such as ferromolybdenum and metal powder (USGS, 2023). Most molybdenum (as molybdenum trioxide or ferromolybdenum) is used as an alloying agent in cast iron, steel, and superalloys, to enhance hardenability, strength, and resistance to wear and corrosion. In 2018, metallurgical applications accounted for approximately 89% of total United States molybdenum consumption (USGS, 2021). Non-metallurgical applications for molybdenum compounds include catalysts, lubricants, and pigments. Molybdenum-based catalysts have important applications to the petroleum and plastics industries, notably in the desulfurization of petroleum, petrochemicals, and coal-derived liquids. Catalysis accounts for most (over 70%, according to one estimate) of the non-metallurgical use of molybdenum (USGS, 2021).

Demand for molybdenum will continue into the future as there is little potential for substitution in its metallurgical and catalytic applications (USGS, 2021; USGS, 2023). Molybdenum is increasingly important in green technology, especially in the manufacture of biofuels, catalysts, ethanol, solar panels, and wind turbines (USGS, 2021).

Production data for molybdenum compounds are available from the EPA's Inventory Update Reporting (IUR) and Chemical Data Reporting (CDR) programs, and industrial release data for one molybdenum compound, molybdenum trioxide, are available from the EPA's Toxics Release Inventory (TRI), as described below. Additional information about these sources is provided in Chapter 2.

Inventory Update Reporting (IUR) and Chemical Data Reporting (CDR) Programs

Under the authority of the Toxic Substances Control Act (TSCA), the EPA gathers information on production (including both manufacture and importation) of industrial chemicals. Under IUR, producers provided information once every four years from 1986 to 2006. Since 2012, producers have continued to provide information in accordance with the CDR Rule, which superseded the IUR in 2011. Under CDR, producers collect annual production data and report it once every four years. Results are generally presented to the public in terms of production ranges. Sometimes (e.g., to protect confidential business information) the production ranges are withheld.

Until 2006, the IUR regulation required manufacturers and importers of organic chemical substances included on the TSCA Chemical Substance Inventory to report on chemicals produced (i.e., manufactured or imported) in amounts of 10,000 pounds or more at a single site. In 2006, the minimum threshold for reporting was increased to 25,000 pounds and reporting began for inorganic chemicals (USEPA, 2008a). Among changes made under CDR, a two-tier system of reporting thresholds was implemented, with 25,000 pounds as the threshold for some contaminants and 2,500 pounds as the threshold for others (USEPA, 2020). As a result of program modifications, the results from 2006 and later might not be directly comparable to results from earlier years. Under CDR, every four years manufacturers and importers are required to report annual data from each of the previous four years, provided that the thresholds of 2,500 or 25,000 pounds are met during at least one of the four years (USEPA, 2020).

Exhibit 7-2 presents the publicly available information on production of molybdenum and 32 molybdenum compounds in the United States as reported under IUR. Currently, only data from the 2006 reports (representing calendar year 2005 production) are available for download; data from earlier years are not publicly available. The compound produced in the greatest quantity (in the range of 1 billion pounds and greater) in 2005, according to available data, was molybdenum oxide (MoO_3).

Exhibit 7-3 presents the publicly available production data for molybdenum and molybdenum compounds in the United States from 2011 to 2019 as reported under CDR. Twenty-one compounds were produced or imported in quantities greater than one million pounds in at least one year. Only one compound, molybdenum oxide (MoO_3), was produced in quantities greater than 100 million pounds.

When considering the molybdenum contribution from complex compounds such as those listed in the tables below, it is important to remember that molybdenum is only a fraction of the total poundage reported. For example, molybdenum zinc oxide is approximately 43 percent molybdenum by weight (96 out of 225 g/mol), while ammonium octamolybdate (listed in the tables below as “molybdate ($\text{Mo}_8\text{O}_{264}$), ammonium (1:4)”) is approximately 61 percent molybdenum by weight (768 out of 1,256 g/mol). Dissociation of molybdenum and molybdenum species from compounds listed in the table may pose health risks, and some of the compounds themselves may be of health concern.

Exhibit 7-2: IUR Reported Annual Production (Manufacture and Importation) of Molybdenum Compounds in the United States, 2005 (pounds)

Chemical Name and CASRN	Production in Calendar Year 2005
Ammonium molybdenum oxide 11098-84-3	1 to < 10 million
Ammonium molybdenum oxide ($(\text{NH}_4)_2\text{Mo}_2\text{O}_7$) 27546-07-2	1 to < 10 million
Bismuth molybdenum oxide ($\text{Bi}_2\text{Mo}_3\text{O}_{12}$) 13595-85-2	< 500,000
C.I. Basic Violet 1, molybdatephosphate 67989-22-4	< 500,000
C.I. Basic Violet 1, molybdatesilicate 68647-35-8	< 500,000
C.I. Basic Violet 1, molybdatetungstatephosphate 1325-82-2	< 500,000

Chemical Name and CASRN	Production in Calendar Year 2005
Cerium molybdenum oxide ($\text{Ce}_2\text{Mo}_3\text{O}_{12}$) 13454-70-1	< 500,000
Cobalt molybdenum hydroxide oxide phosphate 68130-37-0	1 to < 10 million
Cobalt molybdenum nickel oxide ($\text{CoMo}_2\text{NiO}_8$) 68016-03-5	< 500,000
Cobalt molybdenum oxide (CoMoO_4) 13762-14-6	1 to < 10 million
Iron molybdenum oxide 11115-97-2	1 to < 10 million
Iron molybdenum oxide ($\text{Fe}_2\text{Mo}_3\text{O}_{12}$) 13769-81-8	500,000 to < 1 million
Magnesium molybdenum oxide 12013-21-7	< 500,000
Molybdate ($\text{Mo}_7\text{O}_{24}^{6-}$), ammonium (1:6) 12027-67-7	1 to < 10 million
Molybdate ($\text{Mo}_8\text{O}_{26}^{4-}$), ammonium (1:4) 12411-64-2	1 to < 10 million
Molybdate (MoO_4^{2-}), ammonium (1:2), (T-4)- 13106-76-8	1 to < 10 million
Molybdate (MoO_4^{2-}), calcium (1:1), (T-4)- 7789-82-4	< 500,000
Molybdate (MoO_4^{2-}), sodium (1:2), (T-4)- 7631-95-0	1 to < 10 million
Molybdate(3-), tetracosamolybdododecaoxo[12-phosphato(3-)- molybdododecaphosphato]dodeca-, cobalt(2+) (2:3)12263-08-0	1 to < 10 million
Molybdate(3-), tetracosamolybdododecaoxo[12-phosphato(3-)- molybdododecaphosphato]dodeca-, hydrogen (1:3) 12026-57-2	500,000 to < 1 million
Molybdenum 7439-98-7	1 billion and greater
Molybdenum nickel hydroxide oxide phosphate 68130-36-9	10 to < 50 million
Molybdenum nickel oxide (MoNiO_4) 14177-55-0	1 to < 10 million
Molybdenum oxide (MoO_2) 18868-43-4	1 to < 10 million
Molybdenum oxide (MoO_3) 1313-27-5	1 billion and greater
Molybdenum sulfide (MoS_2) 1317-33-5	50 to < 100 million
Molybdenum zinc oxide 61583-60-6	< 500,000
Molybdenum, bis(N,N-ditridecylcarbamodithioato-kappa.S,kappa.S')dioxodi- molybdo-, branched 253873-84-6	< 500,000
Molybdenum, bis[N,N-bis(2-ethylhexyl)carbamodithioato- kappa.S,kappa.S']dioxodi-molybdo-, branched 90901-24-9	< 500,000

Chemical Name and CASRN	Production in Calendar Year 2005
Molybdenum, bis[O,O-bis(2-ethylhexyl) phosphorodithioato- .kappa.S,.kappa.S']dioxodi-.mu.-thioxodi-, (Mo-Mo) 72030-25-2	< 500,000
Xanthylum, 3,6-bis(ethylamino)-9-[2-(methoxycarbonyl)phenyl]-2,7-dimethyl-, molybdatephosphate 68310-07-6	< 500,000
Xanthylum, 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethyl-, molybdatesilicate (1:?) 63022-06-0	< 500,000
Xanthylum, 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethyl-, molybdatetungstatephosphate 12224-98-5	< 500,000

Source: USEPA, 2022a

Exhibit 7-3: CDR Reported Annual Production (Manufacture and Importation) of Molybdenum Compounds in the United States, 2011-2019 (pounds)

Chemical Name and CASRN	2011	2012	2013	2014	2015	2016	2017	2018	2019
1-Tetradecanaminium, N,N-dimethyl-N-tetradecyl-, hexa-.mu.-oxotetra-.mu.3-oxodi-.mu.5-oxotetradecaooxooctamolybdate(4-) (4:1) 117342-25-3	CBI	50,466	45,372	59,194	0	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical
Aluminum molybdenum oxide (Al ₂ Mo ₃ O ₁₂) 15123-80-5	2,463,000	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M
Amides, coco, N,N-bis(hydroxyethyl), reaction products with coco monoglycerides and molybdenum oxide (MoO ₃) 445409-27-8	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	1M - <20M	1M - <20M	1M - <20M	1M - <20M
Ammonium molybdenum oxide ((NH ₄) ₂ Mo ₂ O ₇) 27546-07-2	>16,440,925	1M - <20M	1M - <20M	1M - <20M	10M - <50M	10M - <50M	10M - <50M	10M - <50M	10M - <50M
Ammonium molybdenum tungsten nickel hydroxide maleate (PROVISIONAL) 261144	No Data for Chemical	<1M	<1M	<1M	<1M	<1M	<1M	<1M	<1M
Bismuth molybdenum oxide (Bi ₂ Mo ₃ O ₁₂) 13595-85-2	CBI	<1M	<1M	<1M	<1M	94,835	124,559	102,301	<1M
C.I. Basic Violet 1, molybdatephosphate 67989-22-4	CBI	<1M	<1M	<1M	<1M	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical
C.I. Basic Violet 1, molybdatetungstatephosphate 1325-82-2	CBI	100,000 - <500,00	<1M	100,000 - <500,00	100,000 - <500,00	100,000 - <500,00	<1M	<1M	<1M
Cerium molybdenum oxide (Ce ₂ Mo ₃ O ₁₂) 13454-70-1	CBI	<1M	<1M	<1M	<1M	<1M	<1M	<1M	<1M
Cobalt molybdenum hydroxide oxide phosphate 68130-37-0	CBI	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M

Chemical Name and CASRN	2011	2012	2013	2014	2015	2016	2017	2018	2019
Cobalt molybdenum nickel oxide (CoMo2NiO8) 68016-03-5	CBI	131,146	480,892	0	100,191	<1M	<1M	<1M	<1M
Cobalt molybdenum oxide (CoMoO4) 13762-14-6	>156,000	1M - <20M	1M - <20M	<1M	<1M	<1M	1M - <20M	1M - <20M	1M - <20M
Ethanaminium, N-[4-[bis(4-(diethylamino)phenyl)methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, molybdatephosphate 68814-02-8	CBI	<1M	<1M	<1M	<1M	<1M	<1M	<1M	<1M
Ethanaminium, N-[4-[bis(4-(diethylamino)phenyl)methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, molybdatetungstatephosphate 1325-88-8	No Data for Chemical	<1M	<1M	<1M	<1M	67,000	73,000	53,000	54,000
Ethanedioic acid, reaction products with ethylene glycol and molybdenum oxide (MoO3) 71786-59-9	No Data for Chemical	26,510	31,540	37,658	26,222	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical
Hexanoic acid, 2-ethyl-, molybdenum salt (1:?) 34041-09-3	1,400,000	1,100,000	1,300,000	700,000	1M - <20M	1M - <20M	<1M	<1M	1M - <20M
Iron molybdenum oxide 11115-97-2	67,511	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical
Iron molybdenum oxide (Fe2Mo3O12) 13769-81-8	CBI	500,000 - <1M	100,000 - <500,00	100,000 - <500,00	100,000 - <500,00	100,000 - <500,00	500,000 - <1M	100,000 - <500,00	100,000 - <500,00
Magnesium molybdenum oxide 12013-21-7	CBI	<1M	<1M	<1M	<1M	<1M	<1M	<1M	<1M
Molybdate (Mo7O246-), ammonium (1:6) 12027-67-7	>2,300,000	3,412,213	2,544,051	1,546,134	3,285,275	1M - <20M	1M - <20M	1M - <20M	1M - <20M
Molybdate (Mo8O264-), ammonium (1:4) 12411-64-2	1,834,739	809,828	1,052,203	1,153,825	1,708,689	1,792,259	1,827,590	1,890,173	2,131,700
Molybdate (MoO42-), ammonium (1:2), (T-4)- 13106-76-8	CBI	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M	<1M	<1M
Molybdate (MoO42-), calcium (1:1), (T-4)- 7789-82-4	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	0	11,253	17,838	21,805
Molybdate (MoO42-), disodium, dihydrate, (T-4)- 10102-40-6	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	<1M	<1M	<1M	<1M
Molybdate (MoO42-), hydrogen (1:2), (T-4)- 7782-91-4	5,233,515	<1M	<1M	<1M	<1M	<1M	<1M	<1M	<1M
Molybdate (MoO42-), sodium (1:2), (T-4)- 7631-95-0	12,330,315	9,303,748	7,492,805	6,405,437	10,451,572	1M - <10M	1M - <10M	1M - <10M	1M - <10M
Molybdenum 7439-98-7	>8,478,869	10M - <50M	10M - <50M	10M - <50M	10M - <50M	1M - <10M	10M - <50M	10M - <50M	10M - <50M
Molybdenum alkylamine complex (PROVISIONAL) 155498	CBI	<1M	<1M	<1M	<1M	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical

Chemical Name and CASRN	2011	2012	2013	2014	2015	2016	2017	2018	2019
Molybdenum nickel hydroxide oxide phosphate 68130-36-9	CBI	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M
Molybdenum nickel oxide (MoNiO ₄) 14177-55-0	CBI	1M - <10M	1M - <10M	1M - <10M	1M - <10M	1M - <20M	1M - <20M	1M - <10M	1M - <10M
Molybdenum oxide (MoO ₂) 18868-43-4	CBI	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M	1M - <20M	<1M	<1M
Molybdenum oxide (MoO ₃) 1313-27-5	>165,067, 662	100M - <250M	100M - <250M	100M - <250M	100M - <250M	100M - <250M	100M - <250M	100M - <250M	100M - <250M
Molybdenum sulfide (MoS ₂) 1317-33-5	>1,977,873	1M - <10M	1M - <10M	1M - <10M	1M - <10M	10M - <50M	10M - <50M	10M - <50M	10M - <50M
Molybdenum sulfide (MoS ₃) 12033-29-3	440,000	<1M	<1M	<1M	<1M	<1M	<1M	<1M	<1M
Molybdenum zinc oxide 61583-60-6	No Data for Chemical	1M - <20M	<1M	1M - <20M	<1M	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical
Molybdenum zinc oxide (Mo ₂ Zn ₃ O ₉) 22914-58-5	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	48,500	52,500	50,100	58,500
Molybdenum zinc oxide (MoZnO ₄) 13767-32-3	No Data for Chemical	32,000	41,000	41,000	50,000	71,647	67,176	87,733	104,108
Molybdenum(1+), tris(carbamodithioato- .kappa.S,.kappa.S')tris[.mu.- (disulfur-.kappa.S,.kappa.S':.kappa.S,.kappa.S')]-.mu.3-thioxotri-, N,N,N',N',N'',N''-hexacoco alkyl derivs., salts with N,N- dicocoalkylcarbamodithioates (1:1) 1928735-59-4	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	2,326,215	2,278,217	1,191,182	1,339,478
Molybdenum, [N,N-bis(2-ethylhexyl)carbamodithioato- .kappa.S,.kappa.S'][(N,N-ditridecylcarbamodithioato- .kappa.S,.kappa.S')dioxodi-.mu.-thioxodi- , branched 253873-83-5	CBI	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical
Molybdenum, bi/s(2-ethylhexyl)carbamodithioate bis(2-ethylhexyl)carbamothioate oxo thioxo complexes 68954-53-0	No Data for Chemical	48,363	69,808	73,544	96,083	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical
Molybdenum, bis(N,N-dibutylcarbamodithioato- .kappa.S,.kappa.S')di-.mu.-oxodioxodi-, sulfurized 68412-26-0	CBI	1M - <20M	<1M	<1M	<1M	<1M	<1M	<1M	<1M
Molybdenum, bis(N,N-ditridecylcarbamodithioato- .kappa.S,.kappa.S')dioxodi-.mu.-thioxodi- , branched 253873-84-6	CBI	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical
Molybdenum, bis[N,N-bis(2-ethylhexyl)carbamodithioato- .kappa.S,.kappa.S']dioxodi-.mu.-thioxodi- 90901-24-9	CBI	<1M	<1M	<1M	<1M	189,271	405,390	537,919	621,513

Chemical Name and CASRN	2011	2012	2013	2014	2015	2016	2017	2018	2019
Molybdenum, bis[O,O-bis(2-ethylhexyl)phosphorodithioato- κ .S, κ .S']dioxodi- μ -thioxodi-, (Mo-Mo) 72030-25-2	CBI	<1M	<1M	<1M	<1M	<1M	<1M	<1M	<1M
Molybdenum, borate neodecanoate oxo complexes 1003300-72-8	No Data for Chemical	<1M	<1M	<1M	<1M	<1M	<1M	<1M	<1M
Molybdenum, N,N-bis(C11-14-branched and linear alkyl)carbamodithioate oxo thioxo complexes 906665-74-5	CBI	<1M	<1M	<1M	<1M	<1M	<1M	<1M	<1M
Organomolybdenum complex of organic amide (PROVISIONAL) 162482	CBI	1M - <20M	1M - <20M	1M - <20M	1M - <20M	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical
Reaction product of ethoxylated fatty amines and ammonium molybdate (PROVISIONAL) 155318	CBI	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical
Vinylimidazole (VIMA) grafted poly alpha olefin (PAO) complexed with molybdenum borate neodecanoate (PROVISIONAL) 264870	No Data for Chemical	<1M	<1M	<1M	<1M	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical
Xanthylum, 3,6-bis(ethylamino)-9-[2-(methoxycarbonyl)phenyl]-2,7-dimethyl-, molybdatephosphate 68310-07-6	No Data for Chemical	<1M	<1M	<1M	<1M	<1M	<1M	<1M	<1M
Xanthylum, 3,6-bis(ethylamino)-9-[2-(methoxycarbonyl)phenyl]-2,7-dimethyl-, molybdatesilicate 75627-12-2	169,766	160,164	205,192	157,621	205,165	<1M	<1M	<1M	<1M
Xanthylum, 9-(2-carboxyphenyl)-3,6-bis(diethylamino)-, molybdatephosphate 63022-09-3	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	No Data for Chemical	<1M	<1M	<1M	<1M
Xanthylum, 9-[2-(ethoxycarbonyl)phenyl]-3,6-bis(ethylamino)-2,7-dimethyl-, molybdatesilicate (1:?) 63022-06-0	CBI	<1M	<1M	<1M	<1M	25,000 - <100,00	100,000 - <500,00	100,000 - <500,00	100,000 - <500,00

Source: USEPA, 2022a

M = million; CBI = Confidential Business Information

Toxics Release Inventory (TRI)

The EPA established TRI in 1987 in response to Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). EPCRA Section 313 requires the reporting of annual information on toxic chemical releases from facilities that meet specific criteria. This

reported information is maintained in a database accessible through TRI Explorer (USEPA, 2023a).

Although TRI can provide a general idea of release trends, it has limitations. Not all facilities are required to report all releases. Facilities are generally required to report releases if they manufacture or process more than 25,000 pounds of a chemical or use more than 10,000 pounds per year. Reporting requirements have changed over time (e.g., reporting thresholds have increased or decreased), so conclusions about temporal trends should be drawn with caution. TRI data are meant to reflect releases and should not be used to estimate general public exposure to a chemical (USEPA, 2022b).

TRI data are available for one molybdenum compound, molybdenum trioxide. TRI data for molybdenum trioxide from the years 1988-2022 are summarized in Exhibit 7-4 (USEPA, 2023a). Off-site releases, ranging from hundreds of thousands to millions of pounds, have contributed the largest share of releases of molybdenum trioxide followed by on-site releases to land (which has been released in large quantities especially since 1998). On-site underground injections have been consistently in the hundreds of thousands of pounds per year, and surface water discharges almost always in the tens of thousands of pounds. On-site air emissions have ranged from tens of thousands to hundreds of thousands of pounds per year.

Exhibit 7-4: Environmental Releases of Molybdenum Trioxide in the United States, 1988-2022 (pounds)

Year	On-Site Air Emissions	On-Site Surface Water Discharges	On-Site Underground Injection	On-site Releases to Land	Off-site Disposal or Other Releases	Total On- and Off-site Disposal or Other Releases
1988	111,195	138,771	197,115	96,488	573,624	1,117,193
1989	115,774	124,535	173,270	108,014	840,637	1,362,230
1990	67,448	102,887	170,650	48,870	528,611	918,466
1991	95,420	80,585	134,965	23,165	536,841	870,976
1992	112,819	59,691	162,705	42,651	338,610	716,476
1993	180,494	61,969	202,775	32,449	447,889	925,576
1994	177,836	40,139	161,340	71,819	393,773	844,907
1995	179,060	27,305	333,730	77,604	1,029,058	1,646,757
1996	191,095	27,499	209,900	60,386	626,806	1,115,686
1997	223,699	39,645	276,580	64,093	407,866	1,011,883
1998	220,657	36,330	302,005	948,394	723,652	2,231,038
1999	115,280	38,305	117,120	672,703	1,369,752	2,313,160
2000	92,324	26,976	148,950	864,716	1,539,668	2,672,634
2001	75,079	24,759	120,500	658,902	1,126,527	2,005,767
2002	70,169	23,067	142,300	961,313	701,846	1,898,695
2003	82,849	32,882	237,607	607,583	1,058,385	2,019,307
2004	105,819	36,162	218,322	481,544	996,069	1,837,916
2005	97,650	29,897	270,672	603,347	711,195	1,712,762
2006	125,213	40,330	300,562	608,837	1,168,627	2,243,569
2007	113,250	35,720	248,542	391,494	507,389	1,296,394

Year	On-Site Air Emissions	On-Site Surface Water Discharges	On-Site Underground Injection	On-site Releases to Land	Off-site Disposal or Other Releases	Total On- and Off-site Disposal or Other Releases
2008	119,692	45,848	198,987	396,925	948,290	1,709,743
2009	76,936	91,385	184,744	281,722	588,593	1,223,380
2010	94,091	40,063	250,998	344,966	671,993	1,402,111
2011	115,876	38,189	258,773	194,363	574,394	1,181,594
2012	95,778	39,548	221,934	301,713	679,728	1,338,701
2013	112,358	23,039	175,127	262,723	374,883	948,130
2014	107,313	52,603	128,373	172,077	580,101	1,040,467
2015	97,808	34,138	186,869	301,271	1,094,198	1,714,284
2016	70,012	37,956	189,975	481,496	1,135,331	1,914,770
2017	84,516	35,238	186,108	854,679	865,014	2,025,556
2018	77,237	37,984	246,569	602,579	1,488,559	2,452,928
2019	73,015	33,284	258,990	430,557	1,367,884	2,163,731
2020	69,213	28,439	267,179	862,041	1,075,900	2,302,772
2021	69,240	39,683	274,697	465,039	914,530	1,763,189
2022	84,666	38,320	221,584	496,967	1,012,040	1,853,577

Source: USEPA, 2023a

Note: A decimal point indicates that one or more facilities either left an applicable field blank or certified in streamlined reporting that annual release did not exceed 500 pounds, and that otherwise no releases were reported.

Exhibit 7-5 presents an expanded summary of total releases and total surface water discharges that includes the count of states reporting releases (USEPA, 2023a). Note that for the purposes of TRI, “state” counts include the District of Columbia and U.S. territories in addition to the 50 states. Surface water discharges of molybdenum trioxide were reported from between 8 and 21 states per year. Reported releases of any kind came from between 24 and 36 states per year.

Exhibit 7-5: Summary of Total Releases and Total Surface Water Discharges of Molybdenum Trioxide, 1988-2022

Year	On-Site Surface Water Discharges (in pounds)	Count of States with Surface Water Discharges	Total Releases (in pounds)	Count of States with Releases
1988	138,771	8	1,117,193	24
1989	124,535	9	1,362,230	27
1990	102,887	13	918,466	29
1991	80,585	12	870,976	28
1992	59,691	14	716,476	30
1993	61,969	15	925,576	30
1994	40,139	15	844,907	29
1995	27,305	15	1,646,757	30

Year	On-Site Surface Water Discharges (in pounds)	Count of States with Surface Water Discharges	Total Releases (in pounds)	Count of States with Releases
1996	27,499	14	1,115,686	29
1997	39,645	14	1,011,883	28
1998	36,330	16	2,231,038	32
1999	38,305	16	2,313,160	31
2000	26,976	18	2,672,634	33
2001	24,759	17	2,005,767	32
2002	23,067	16	1,898,695	30
2003	32,882	18	2,019,307	32
2004	36,162	17	1,837,916	35
2005	29,897	19	1,712,762	36
2006	40,330	21	2,243,569	35
2007	35,720	19	1,296,394	33
2008	45,848	17	1,709,743	30
2009	91,385	19	1,223,380	28
2010	40,063	16	1,402,111	32
2011	38,189	18	1,181,594	31
2012	39,548	18	1,338,701	30
2013	23,039	19	948,130	33
2014	52,603	18	1,040,467	33
2015	34,138	15	1,714,284	28
2016	37,956	14	1,914,770	30
2017	35,238	14	2,025,556	32
2018	37,984	16	2,452,928	31
2019	33,284	14	2,163,731	32
2020	28,439	16	2,302,772	33
2021	39,683	16	1,763,189	28
2022	38,320	14	1,853,577	29

Source: USEPA, 2023a

7.2.3 Environmental Fate

Naturally occurring molybdenum enters the atmosphere via volcanic activity, ocean spray, wildfires, primary biogenic particles, and air erosion of dusts and soils. Molybdenum also is released to air by industrial and agricultural activity and from vehicle braking (Wong et al., 2021). The main source of molybdenum in the atmosphere is coal combustion. Molybdenum released to the air is subject to wet and dry deposition (ATSDR, 2020).

Molybdenum is naturally present in soils, and additional molybdenum may be added by weathering and atmospheric deposition and by direct human activity such as application of molybdenum and phosphate fertilizers (Wong et al., 2021). In soils molybdenum may be found in a dissolved fraction, occluded with aluminum, iron, and manganese oxides, in solid phases (e.g., as molybdenite, powellite, ferrimolybdate, or wulfenite), or associated with organic compounds (Redd et al., 2009). Concentrations of molybdenum are highest in the topsoil layer

due to strong binding to natural organic matter. The primary form of molybdenum in wet soil is the molybdate anion, MoO_4^{2-} (ATSDR, 2020). The molybdate anion can sorb to positively charged metal oxides, clay minerals, dissolved organic compounds, and carbonates (Kaiser et al., 2005). Adsorption of molybdenum is dependent on the pH of the soil, with maximum absorption occurring when pH is in the range of 2-5 (ATSDR, 2020).

Molybdenum enters freshwater resources (surface and groundwater) from the natural weathering of rocks and soils and from atmospheric deposition (Wong et al., 2021; Smedley and Kinniburgh, 2017). Anthropogenic sources of molybdenum in water include effluents from molybdenum, uranium, and copper mining and milling operations, oil production and oil refining operations, and coal-fired power plants. Speciation and adsorption of molybdenum in environmental waters is affected by the pH of the water and the composition and redox conditions of the sediment. Molybdenum is predominantly found in water as the molybdate anion. When pH is greater than 6.5, the molybdate anion may be the sole molybdenum species present. Under low redox conditions, the anion can be reduced to molybdenite. Molybdenum is generally more mobile in water under alkaline conditions, increasing bioavailability. Low pH favors adsorption, as does the presence of sediment with low redox potential and high iron and organic matter content (ATSDR, 2020).

7.3 Health Effects

7.3.1 Health Assessment Identification

In order to identify qualifying health assessments for molybdenum, the EPA conducted a systematic web-based search of the EPA and other authoritative sources, as described in Section B.5.1.1 of the RD 5 Protocol, found in Appendix B of this document.

Exhibit 7-6 provides a summary overview of qualifying health assessments for molybdenum (i.e., health assessments from qualifying sources that provide a toxicity value relevant to chronic oral toxicity) that were published prior to the search cut-off date of January 2023. An assessment can present a noncancer oral toxicity value, a cancer oral toxicity value, or both. Information about the health assessment selected for molybdenum under RD 5 is bolded and italicized in Exhibit 7-6.

Exhibit 7-6: Qualifying Health Assessments Identified for Molybdenum

Health Assessment^a	Oral Reference Value^b	POD Type	Noncancer Critical Study	Oral Cancer Slope Factor^c	Cancer Critical Study	Cancer Descriptor
EPA Integrated Risk Information System (IRIS) Chemical Assessment Summary (USEPA, 1992)	0.005	LOAEL	Koval'skiy et al. (1961)	–	–	–
World Health Organization (WHO) Guidelines for Drinking Water Quality (WHO, 2011)	0.07 ^d	NOAEL	USEPA (1979)	–	–	–
<i>Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profile (ATSDR, 2020)</i>	<i>0.06^e</i>	<i>NOAEL</i>	<i>Murray et al. (2014)</i>	–	–	–

Notes: POD = point of departure; LOAEL = lowest-observed-adverse-effect level; NOAEL = no-observed-adverse-effect level; dash (–) = not applicable.

^a Selected health assessment and chronic toxicity value and supporting information are bolded and italicized.

^b Oral reference values are expressed in mg/kg/day unless otherwise specified; “oral reference value” can refer to the acceptable daily dose (ADD), maximum acceptable concentration (MAC), minimal risk level, point of departure / uncertainty factor (POD/UF), population-adjusted dose (PAD), reference dose (RfD), or tolerable daily intake (TDI).

^c Cancer slope factors are expressed in (mg/kg/day)⁻¹ unless otherwise specified.

^d This oral reference value is in units of mg/L.

^e This oral reference value is an intermediate-duration oral minimal risk level (iMRL); ATSDR did not derive a chronic-duration oral minimal risk level because the chronic oral database was insufficient (ATSDR, 2020). ATSDR's iMRL of 0.06 mg/kg-day is based on a NOAEL of 17 mg/kg/day, a total uncertainty factor (UF) of 100, and a modifying factor of 3. The EPA applied an additional UF of 3 for extrapolation from subchronic to chronic exposure.

7.3.2 Health Assessment Selection

The health assessment selected for molybdenum under RD 5 is the 2020 Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profile (ATSDR, 2020). This is the most recent health assessment identified for molybdenum that derives an oral toxicity value, and it uses the best available science in its evaluation of noncancer risk. The ATSDR's oral toxicity value is based on a more recent critical study (Murray et al., 2014) than those used by previous EPA and non-EPA health assessments (USEPA, 1992; WHO, 2011). See Section B.5.1.2 of the RD 5 Protocol, in Appendix B of this document, for the decision logic that was applied to health assessment selection for RD 5 chemicals.

7.3.3 Health Reference Level (HRL) Development

Health reference levels (HRLs) are non-regulatory health-based toxicity values, expressed as concentrations in drinking water, that are used by the Agency to evaluate occurrence data for a contaminant when making decisions about regulatory determinations. See Section B.6.1.1 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA's approach for deriving HRLs for chemicals. The input values used to derive the HRL for molybdenum are described below.

7.3.3.1 Oral Reference Value

In the 2020 ATSDR Toxicological Profile (ATSDR, 2020), ATSDR selected a 90-day toxicity study in rats (Murray et al. 2014) as the critical study to derive a point of departure (POD) for the intermediate-duration oral reference value. In this study, sodium molybdate dihydrate was administered daily at doses of 0, 5, 17 and 60 mg/kg/day in the diets of male and female Sprague-Dawley rats (20 per group for the control and high dose groups and 10 per group for the low and mid-dose groups). The rats were approximately nine weeks old at the start of dosing (Murray et al. 2014). Throughout the treatment period, the authors measured body weight, food consumption, hematology and blood chemistry, vaginal cytology, estrus cycles, and sperm counts (Murray et al. 2014). Following oral exposure to molybdenum for 90 days, 10 animals per group were necropsied, and a number of endpoints were evaluated, including measuring of organ weights and histopathological evaluation (Murray et al. 2014). The remaining 10 control and high dose animals were necropsied after a 60-day recovery period that followed the 90 days of dosing (Murray et al. 2014).

Final body weights of the high dose group decreased significantly in males compared to controls. Although the male high dose group showed significant increases in body weight at each weekly measure during the recovery period, absolute body weights remained below that of controls. In the same male high dose group, significant decreases in absolute brain, liver, heart, spleen, and pituitary weights were observed, as well as decreased food conversion efficiency. Histopathological examination of the kidneys revealed a slight diffuse hyperplasia in the proximal tubules of 2 of 10 female rats in the high dose group, however, no renal lesions were noted after the recovery period (Murray et al. 2014).

ATSDR identified a 17 mg/kg/day no-observed-adverse-effect level (NOAEL) for renal effects in female rats as the critical effect and POD because this was the most sensitive endpoint measured in the Murray et al. (2014) study. A total uncertainty factor (UF) of 100 was applied to the POD: an interspecies UF (UF_A) of 10, and an intraspecies UF (UF_H) of 10. A modifying factor of 3 was also applied to account for a data gap, the lack of reproductive/developmental studies in sensitive subpopulations with marginal copper diets. After applying the total UF and modifying factor, the intermediate-duration oral reference value (an intermediate-duration oral minimum risk level, or iMRL) was calculated to be 0.06 mg/kg/day. According to ATSDR, this intermediate-duration oral reference value is “based on the assumption of healthy dietary levels of molybdenum and copper and represents the level of exposure above and beyond the normal diet” (ATSDR, 2020). ATSDR did not derive a chronic-duration oral reference value. The EPA’s definition of chronic exposure is repeated exposure (oral, dermal, or inhalation) for *more* than approximately 90 days to 2 years (USEPA, 2023b). In order to derive a chronic oral reference value for molybdenum, the EPA applied an UF of 3 to the intermediate-duration oral reference value, per Agency guidelines (USEPA, 2002), for extrapolation from subchronic to chronic exposure duration (UFs). The EPA selected a UFs of 3 rather than 10 because the critical study’s subchronic exposure duration of 90 days is very close to a chronic exposure duration (>90 days) and due to the absence of available data on differences in toxicity after subchronic versus chronic exposure durations. With the UFs applied, the oral reference value that the EPA used to derive the HRL for molybdenum was 0.02 mg/kg/day.

7.3.3.2 Exposure Factor Selection

In prioritizing the contaminants of greatest public health concern for regulatory determination, Section 1412(b)(1)(C) of the Safe Drinking Water Act (SDWA) requires the Agency to consider “among other factors of public health concern, the effect of such

contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water compared to the general population.” One way that the EPA considers potentially sensitive populations or life stages (i.e., populations or life stages that may be more susceptible or sensitive to a chemical exposure) is during the selection of exposure factors (EFs) for the development of HRLs.

Drinking water intake rate adjusted for body weight (DWI-BW) is the EF used to derive HRLs for RD 5 (USEPA, 2019a). EFs are input values intended to protect the general population, including sensitive populations or life stages, from adverse effects resulting from exposure to a contaminant. The Agency selects an appropriate DWI-BW for each chemical by reviewing the critical effect and study used for HRL derivation and identifying the interval of exposure (for example, see USEPA, 2022c; USEPA, 2022d). Since the critical effect represents the most sensitive adverse effect observed in the best available studies for a given chemical, then it is reasonable to assume that the interval of exposure in the critical study could inform the selection of a DWI-BW protective of sensitive subpopulations. When multiple potentially sensitive subpopulations or life stages are identified based on the interval of exposure in the study used for HRL derivation, the EPA selects the population or life stage with the highest DWI-BW because it is the most health protective. See Section B.6.1.2 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA’s EF selection process.

In the critical study (Murray et al., 2014) selected in the 2020 ATSDR Toxicological Profile for molybdenum (ATSDR, 2020), rats were exposed to dietary sodium molybdate dihydrate for approximately 90 days, with exposure starting at approximately 9 weeks of age. Following the decision logic described in Section B.6.1.2 of the RD 5 Protocol, the EPA selected a corresponding human life stage. Rats and mice at 9 weeks old are in the developmental stage approximately corresponding to a human life stage between juvenile or later childhood and adolescence (Ghasemi et al., 2021; Wang et al., 2020). For the purpose of evaluating environmental exposures, the EPA defines childhood in humans as the period from conception through adolescence, until 21 years of age (USEPA, 2021). Therefore, the EPA used the DWI-BW representing the 90th percentile consumers-only, two-day average, direct and indirect community water consumption for children (birth to <21 years), which equals 0.0343 L/kg/day (USEPA, 2019a), to derive the HRL for molybdenum.

7.3.3.3 Relative Source Contribution

Relative source contribution (RSC) is used to account for exposure via non-drinking water routes when deriving health-based drinking water concentrations for contaminants with threshold effects (noncarcinogens and nonlinear carcinogens). RSC is defined as the portion (percentage) of an individual’s exposure attributed to drinking water rather than other sources (e.g., food, ambient air). A 20 percent RSC is used for all RD 5 contaminants, consistent with past practice for regulatory determinations, to derive the HRL because (1) HRLs are developed prior to completing the exposure assessment; and (2) a 20 percent RSC is the lowest RSC that can be applied for deriving health-based drinking water concentrations according to EPA guidance (USEPA, 2000), and it therefore produces the most health protective HRL. Should a contaminant proceed to a National Primary Drinking Water Regulation (NPDWR), a full exposure analysis is conducted, and an RSC is derived following the Exposure Decision Tree approach described in the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000).

7.3.3.4 HRL Calculation

Exhibit 7-7 summarizes the critical study and toxicity information from the qualifying health assessment and the EF (DWI-BW) and RSC that the EPA used to derive the HRL for molybdenum.

Exhibit 7-7: Basis of HRL for Molybdenum

Selected Health Assessment	Critical Study	Interval of Exposure	Critical Effect	Oral Toxicity Value	RSC	Target Population	Exposure Factor
ATSDR Toxicological Profile (ATSDR, 2020)	Murray et al. (2014)	90 days; beginning at approximately 9 weeks of age	Renal proximal tubule hyperplasia in female rats	0.06 mg/kg/day	0.2 (20%)	Children (birth to <21 years)	0.0343 L/kg/day

The EPA calculates HRLs for contaminants with a threshold dose-response, including molybdenum, as follows:

$$HRL = \frac{RfD}{DWI-BW} * RSC$$

where:

RfD = Reference dose (mg/kg/day), an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. It is derived in the selected qualifying health assessment and is based on the critical effect and study identified in that assessment. Other values that can be used in place of an RfD in this equation can include a maximum acceptable concentration (MAC), minimal risk level, point of departure / uncertainty factor (POD/UF), population-adjusted dose (PAD), or tolerable daily intake (TDI).

DWI-BW = Drinking water intake (DWI), adjusted for body weight (BW), in units of liter per kilogram body weight per day (L/kg/day).

RSC = Relative source contribution, the percentage of the total exposure attributed to drinking water sources (USEPA, 2000), where the remainder of the exposure is allocated to other routes or sources. For HRL derivation in RD 5, an RSC of 20 percent is used for all contaminants.

Using an intermediate-duration oral reference value of 0.06 mg/kg/day (ATSDR, 2020) with an additional subchronic-to-chronic UF of 3, a DWI-BW of 0.0343 L/kg/day (USEPA, 2019a), and a 20 percent RSC to account for non-drinking-water sources of exposure (USEPA, 2000), the HRL for molybdenum is calculated as follows:

$$HRL = \frac{\left(\frac{0.06 \text{ mg/kg/day}}{3} \right)}{0.0343 \text{ L/kg/day}} * 0.2$$

$$HRL = \frac{0.02 \text{ mg/kg/day}}{0.0343 \text{ L/kg/day}} * 0.2$$

$$HRL = 0.116618 \text{ mg/L}$$

or

$$HRL = 116.6 \text{ } \mu\text{g/L}$$

Following HRL derivation practices, the HRL for molybdenum is 100 $\mu\text{g/L}$ after rounding to one significant figure.

7.4 Occurrence

This section presents data on the occurrence of molybdenum in ambient water and drinking water in the United States. As described in Section 7.3, an HRL of 100 $\mu\text{g/L}$ was calculated for molybdenum based on non-carcinogenic effects. HRLs are risk-derived concentrations against which the EPA evaluates the occurrence data to determine if contaminants occur at levels of potential public health concern. Occurrence data from various sources presented below are analyzed with respect to the HRL and one-half the HRL. When possible, estimates of the population exposed at concentrations above the HRL and one-half the HRL are presented.

For additional background information about data sources used to evaluate occurrence, please refer to Chapter 2.

7.4.1 Occurrence in Ambient Water

Lakes, rivers, and aquifers are the ambient sources of most drinking water. Contaminant occurrence in ambient water provides information on the potential for contaminants to adversely affect drinking water supplies. Occurrence data for molybdenum in ambient water are available from the United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) program, the USGS National Water Information System (NWIS) database, the EPA's legacy Storage and Retrieval Data System (STORET), and one published study. When sources of information on ambient occurrence also include limited finished water data, those finished water data are summarized here as well.

7.4.1.1 United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) Ambient Water Analyses

USGS instituted the NAWQA program in 1991 to examine ambient water quality status and trends in the United States. The NAWQA program generates high quality contaminant occurrence and other water quality parameter data for significant watersheds and aquifers across the nation. The program collects data on surface water and groundwater chemistry, hydrology, land use, stream habitat, and aquatic life in parts of nearly all 50 states. The program is designed to apply nationally consistent methods to provide a uniform basis for contaminant occurrence comparisons and assessments among study basins across the country and over time. The occurrence assessments can also serve to facilitate interpretation of natural and anthropogenic factors affecting national water quality. For more detailed information on NAWQA program design and implementation, refer to Leahy and Thompson (1994) and Hamilton et al. (2004).

The process of sampling, analysis, and data synthesis is divided into cycles of approximately ten years: Cycle 1 covered 1991-2001, Cycle 2 covered 2002-2012, and Cycle 3 covered 2013-2023. Study units are sampled and analyzed on a staggered schedule within each cycle. Each NAWQA cycle begins with a two-year startup phase for planning and retroactive analysis, followed by a three-year intensive data collection phase, and finally a five-year phase for analyzing the data, developing reports, and continuing a low level of monitoring (NRC, 2012).

The EPA downloaded NAWQA data from the Water Quality Portal (WQP) in September 2023 (WQP, 2023). The EPA's analysis of the NAWQA data is a simple, non-parametric occurrence analysis that provides summary statistics to characterize contaminant occurrence. The EPA included in the analysis all samples that could be classified as groundwater and surface water, and also the limited number of samples labeled as finished water. Other types of samples (e.g., from soil, sediment, and wastewater) were excluded. The EPA calculated detection frequencies as the percentage of samples and the percentage of sites with at least one detection. (A detection is an analytical result equal to or greater than the reporting level.) No weighting was applied. The EPA determined the minimum and maximum detected concentrations and calculated other descriptive statistics including the median, 90th percentile, and 99th percentile concentrations (based only on samples with detections). Reporting levels varied over time during the NAWQA program.

The results of the EPA's analysis of NAWQA data downloaded from WQP are presented in Exhibit 7-8 through Exhibit 7-10. Across the three cycles, the sample detection rate for molybdenum in groundwater ranged from 52.50 percent to 83.51 percent, while the sample detection rate in surface water ranged from 44.71 percent to 100 percent. The highest concentrations tended to be found in groundwater. The HRL was exceeded by a single surface water sample (in Cycle 1), and by 0.12 percent to 0.26 percent of groundwater samples across the three cycles. The highest reported groundwater concentration was 4,730 µg/L and the highest reported surface water concentration was 157 µg/L. Note that the NAWQA data are presented as downloaded; potential outliers were not evaluated or excluded from the analysis. Two finished water samples were included in the Cycle 2 data. Molybdenum was detected in both finished water samples; the concentrations (0.214 µg/L and 0.687 µg/L) did not exceed the HRL or ½ the HRL.

Note that there may be some overlap between the NAWQA data assessment presented here and summaries of individual NAWQA studies presented below.

Exhibit 7-8: Molybdenum NAWQA Data – Summary of Detected Concentrations

Site Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90 th Percentile	99 th Percentile	Maximum
Cycle 1 (1991 - 2001)					
Groundwater	0.1	2.66	13.0	61.2	4,730
Surface Water	0.1	2.72	11.0	34.0	157
All Sites	0.1	2.67	12.0	51.0	4,730
Cycle 2 (2002 - 2012)					
Finished Water	0.214	0.451	0.592	0.678	0.687
Groundwater	0.01	0.964	7.25	32.1	208
Surface Water	0.119	2.01	9.53	23.3	28.6

Site Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90 th Percentile	99 th Percentile	Maximum
All Sites	0.01	1.14	7.72	31.0	208
Cycle 3 (2013 - 2023)					
Groundwater	0.014	0.854	6.86	29.3	226
Surface Water	0.051	0.492	3.10	5.08	5.5
All Sites	0.014	0.839	6.74	29.0	226

Source: WQP, 2023

Exhibit 7-9: Molybdenum NAWQA Data – Summary of Samples

Site Type	No. of Samples	Detection Frequency (detections are results ≥ reporting level)					
		No. of Samples with Detections	Percent Samples with Detections	No. of Samples with Detections > 1/2 HRL	Percent Samples with Detections > 1/2 HRL	No. of Samples with Detections > HRL	Percent Samples with Detections > HRL
Cycle 1 (1991 - 2001)							
Groundwater	3,440	1,806	52.50%	33	0.96%	9	0.26%
Surface Water	3,572	1,597	44.71%	4	0.11%	1	0.03%
All Sites	7,012	3,403	48.53%	37	0.53%	10	0.14%
Cycle 2 (2002 - 2012)							
Finished Water	2	2	100.00%	0	0.00%	0	0.00%
Groundwater	4,608	3,716	80.64%	20	0.43%	8	0.17%
Surface Water	638	621	97.34%	0	0.00%	0	0.00%
All Sites	5,248	4,339	82.68%	20	0.38%	8	0.15%
Cycle 3 (2013 - 2023)							
Groundwater	3,335	2,785	83.51%	9	0.27%	4	0.12%
Surface Water	50	50	100.00%	0	0.00%	0	0.00%
All Sites	3,385	2,835	83.75%	9	0.27%	4	0.12%

Source: WQP, 2023

Exhibit 7-10: Molybdenum NAWQA Data – Summary of Sites

Site Type	No. of Sites	Detection Frequency (detections are results ≥ reporting level)					
		No. of Sites with Detections	Percent Sites with Detections	No. of Sites with Detections > 1/2 HRL	Percent Sites with Detections > 1/2 HRL	No. of Sites with Detections > HRL	Percent Sites with Detections > HRL
Cycle 1 (1991 - 2001)							
Groundwater	3,076	1,642	53.38%	32	1.04%	9	0.29%
Surface Water	478	295	61.72%	2	0.42%	1	0.21%
All Sites	3,554	1,937	54.50%	34	0.96%	10	0.28%
Cycle 2 (2002 - 2012)							
Finished Water	2	2	100.00%	0	0.00%	0	0.00%

Site Type	No. of Sites	Detection Frequency (detections are results $\geq$ reporting level)					
		No. of Sites with Detections	Percent Sites with Detections	No. of Sites with Detections > 1/2 HRL	Percent Sites with Detections > 1/2 HRL	No. of Sites with Detections > HRL	Percent Sites with Detections > HRL
Groundwater	3,126	2,609	83.46%	15	0.48%	5	0.16%
Surface Water	39	37	94.87%	0	0.00%	0	0.00%
All Sites	3,167	2,648	83.61%	15	0.47%	5	0.16%
Cycle 3 (2013 - 2023)							
Groundwater	3,125	2,629	84.13%	9	0.29%	4	0.13%
Surface Water	12	12	100.00%	0	0.00%	0	0.00%
All Sites	3,137	2,641	84.19%	9	0.29%	4	0.13%

Source: WQP, 2023

7.4.1.2 National Water Information System (NWIS) Data

NWIS is the nation's principal repository of water resources data collected by USGS from more than 1.9 million sites in all U.S. states and territories (USGS, 2022). All USGS water quality and flow data are stored in NWIS, including site characteristics, streamflow, groundwater level, precipitation, and chemical analyses of water, sediment, and biological media, though not all parameters are available for every site. NWIS houses the NAWQA data and includes other USGS data from a range of unspecified projects. NWIS encompasses many more samples at many more sites than are involved in the NAWQA Program. Although NWIS is comprised of primarily ambient water data, some finished drinking water data are included as well. This section presents analyses of non-NAWQA data in NWIS, downloaded from the WQP in September 2023 (WQP, 2023). These data do not overlap with the NAWQA results presented above.

The results of the non-NAWQA NWIS molybdenum analysis are presented in Exhibit 7-11. Molybdenum was detected in approximately 61 percent of samples from about 71 percent of sites. The highest reported groundwater concentration (28,000 $\mu\text{g/L}$) and the highest reported surface water concentration (42,000 $\mu\text{g/L}$) exceeded the HRL, but the 99th percentile concentrations did not. Note that the NWIS data are presented as downloaded; potential outliers were not evaluated or excluded from the analysis. The NWIS data for molybdenum include 47 finished water samples from 29 sites. Molybdenum was detected in 38 (81 percent) of the finished water samples and at 28 (97 percent) of the sites. The highest reported finished water concentration (52.5 $\mu\text{g/L}$) exceeds the $\frac{1}{2}$ HRL threshold but not the HRL.

Exhibit 7-11: Molybdenum NWIS Data, 1991-2023

Sample Media Type	Detection Frequency (detections are results $\geq$ reporting level)				Concentration Values (of detections, in $\mu\text{g/L}$)				
	No. of Samples	No. of Samples with Detections	No. of Sites	No. of Sites with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
Finished Water	47	38	29	28	0.197	10.0	41.8	51.6	52.5

Sample Media Type	Detection Frequency (detections are results $\geq$ reporting level)				Concentration Values (of detections, in $\mu\text{g/L}$)				
	No. of Samples	No. of Samples with Detections	No. of Sites	No. of Sites with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
Groundwater	30,539	21,002	16,965	12,150	0.01	2.09	16.3	91.8	28,000
Surface Water	54,357	30,834	5,186	3,629	0.01	1.33	8.13	65.8	42,000
Total	84,943	51,874	22,058	15,728	0.01	1.64	10.0	80.0	42,000

Source: WQP, 2023

Note that some NWIS sites are associated with multiple sample media types, so site counts might not add up to totals.

7.4.1.3 Storage and Retrieval (STORET) Data

From its launch in 1999 until it was decommissioned in June 2018, the EPA's STORET Data Warehouse was collaboratively populated with raw biological, chemical, and physical data from surface water and groundwater sampling by federal, state and local agencies, Native American Tribes, volunteer groups, academics, and others. Legacy STORET data, as well as more current STORET data, are accessible through the WQP.

STORET data are from monitoring locations in all 50 states as well as multiple territories and jurisdictions of the United States. STORET's data quality limitations include variations in the extent of national coverage and data completeness from parameter to parameter. Data may have been collected as part of targeted, rather than randomized, monitoring. This section presents analyses of STORET data, downloaded from the WQP in September 2023 (WQP, 2023). The EPA reviewed STORET groundwater data from wells and springs and surface water data from lakes, rivers/streams, and reservoirs. The STORET data set also included limited data from public water systems (PWSs). The database does not specify whether PWS sampling was conducted before or after treatment.

The results of the STORET analysis for molybdenum are presented in Exhibit 7-12 through Exhibit 7-14. These molybdenum samples were collected between 1991 and 2023. Molybdenum was found in 9,208 (52.11 percent) of 17,671 samples, at 1,107 (34.41 percent) of 3,217 sites. Molybdenum was found more frequently in surface water than groundwater. The highest reported concentration, 50,000 $\mu\text{g/L}$, was found in surface water. The highest groundwater concentration, 50 $\mu\text{g/L}$, is equal to $\frac{1}{2}$ the HRL. Note that the STORET data are presented as downloaded; potential outliers were not evaluated or excluded from the analysis.

Exhibit 7-12: Molybdenum STORET Data – Summary of Detected Concentrations

Source Water Type	Concentration Value of Detections ($\mu\text{g/L}$)			
	Minimum	Median	90 th Percentile	Maximum
Groundwater	0.00216	6.3	44	50
Surface Water	0.00053	5.5	207	50,000
Total	0.00053	5.5	79.2	50,000

Source: WQP, 2023

Exhibit 7-13: Molybdenum STORET Data – Summary of Samples and Sites

Source Water Type	Total Number of Samples	Samples with Detections		Total Number of Sites	Sites with Detections	
		Number	Percent		Number	Percent
Groundwater	1,358	275	20.25%	625	97	15.52%
Surface Water	16,313	8,933	54.76%	2,592	1,010	38.97%
Total	17,671	9,208	52.11%	3,217	1,107	34.41%

Source: WQP, 2023

Exhibit 7-14: Molybdenum STORET Data – Summary of States

Source Water Type	Total Number of States	States with Detections	
		Number	Percent
Groundwater	11	6	55%
Surface Water	31	18	58%
Total¹	33	19	58%

Source: WQP, 2023

¹ The number of states with groundwater data plus the number of states with surface water data may not equal the “Total” number of states providing data because some states provided both groundwater and surface water data.

7.4.1.4 Additional Ambient Water Studies

Erickson et al. (2019) conducted a study to assess groundwater quality in the United States glacial aquifer system using groundwater samples gathered from approximately 39,000 wells from 2005 to 2013. Data were derived from three sources: the USGS NWIS, the EPA’s Safe Drinking Water Information System (SDWIS), and numerous agencies and organizations at the state, regional, and local level. Molybdenum was evaluated against a “high” benchmark of 40 µg/L and a “moderate” benchmark of 20 µg/L. The high benchmark was exceeded in 0.7 percent (area weighted) and 1.5 percent (population weighted) of 2,262 analyses from wells in the water supply interval. Concentrations between the moderate and high benchmarks were found in 2.9 percent (area weighted) and 4.2 percent (population weighted) of the 2,262 analyses.

7.4.2 Occurrence in Drinking Water

Data sources reviewed by the EPA for information on contaminant occurrence in drinking water included: the EPA’s first, second, third, and fourth Unregulated Contaminant Monitoring Rules (UCMR 1, UCMR 2, UCMR 3, UCMR 4); Rounds 1 and 2 of the EPA’s Unregulated Contaminant Monitoring (UCM) program that preceded the Unregulated Contaminant Rule (UCMR); the EPA’s National Inorganics and Radionuclides Survey (NIRS); and a range of others as discussed in Chapter 2. Among the sources reviewed, the following sources had data and information on molybdenum occurrence in drinking water and are discussed in this section:

- The EPA’s Third Unregulated Contaminant Monitoring Rule (UCMR 3).
- The EPA’s National Inorganics and Radionuclides Survey (NIRS).

- State drinking water monitoring programs.
- Consumer Confidence Reports (CCRs) from PWSs.
- The EPA’s Community Water System Survey (CWSS).
- Additional source water and drinking water studies.

Note that there may be some overlap, as sources with different purposes and audiences may have reported the same underlying data. UCMR 3 and NIRS are national data sources. Other sources profiled in this section are considered “supplemental” sources. Also note that the presentation of NAWQA and NWIS results in the ambient water section, above, includes some finished water data.

7.4.2.1 Primary Data Sources

7.4.2.1.1 *The EPA’s Third Unregulated Contaminant Monitoring Rule (UCMR 3), 2013 - 2015*

UCMR 3 monitoring, designed to provide nationally representative contaminant occurrence data, was conducted from 2013 through 2015. UCMR 3 List 1 Assessment Monitoring occurrence data are available for molybdenum. For UCMR 3, all large and very large community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) (serving between 10,001 and 100,000 people and serving more than 100,000 people, respectively), plus a statistically representative national sample of 800 small CWSs and NTNCWSs (serving 10,000 people or fewer), were required to conduct Assessment Monitoring during a 12-month period between January 2013 and December 2015.¹ Surface water and groundwater under the direct influence of surface water (GWUDI) sampling points were monitored four times during the applicable year of monitoring. Groundwater sampling points were monitored twice during the applicable year of monitoring. See USEPA (2012) and USEPA (2019b) for more information on the UCMR 3 study design and data analysis.

The design of UCMR 3 permits estimation of national occurrence by multiplying the total number of systems (or population served) in the nation in a system size category by the percent of systems expected to exceed a specified threshold. An extrapolation methodology is applied to small systems because not all small systems were required to participate in the UCMR 3 Assessment Monitoring. Because all large and very large systems were required to participate in the UCMR 3 Assessment Monitoring, national estimates of occurrence in these size categories can be done using survey census figures rather than extrapolation. Total national occurrence is estimated by summing the extrapolated figures for small systems and the census figures for the large and very large systems.

Exhibit 7-15 through Exhibit 7-19 provide an overview of molybdenum occurrence results from UCMR 3 Assessment Monitoring. Laboratories participating in UCMR 3 were required to report values at or above minimum reporting levels (MRLs) defined by the EPA. The MRLs are established to ensure reliable and consistent results from the array of laboratories needed for a national monitoring program and are set based on the capability of multiple commercial laboratories prior to the beginning of each UCMR round. The MRL used for molybdenum in the UCMR 3 survey was 1 µg/L (77 FR 26072; USEPA, 2012). Exhibit 7-15 shows a statistical summary of molybdenum concentrations by system size and source water type

¹ Only 799 small systems submitted Assessment Monitoring results.

(including the minimum, median, 90th percentile, 99th percentile, and maximum). Exhibit 7-16 presents a sample-level summary of the results. Exhibit 7-17 through Exhibit 7-19 show system-level results, including national extrapolations, at three thresholds: detections, ½ the HRL, and the HRL. Detections are evaluated on a “greater than or equal to” basis ($\geq$ the MRL), while health-based thresholds are evaluated in terms of exceedances ($> \frac{1}{2}$ HRL, and $>$ HRL).

As noted above, UCMR 3 monitoring was required at a representative sample of small systems and at all large and very large systems. As a reminder that the figures from large and very large systems represent a census of systems in those categories, results in those categories are labeled “CENSUS” in the exhibits below. No extrapolation was necessary in these categories, as it was for the small systems, to derive national estimates of occurrence in these exhibits. National estimates of occurrence are reported separately in each system size and source water category, and also in the aggregate.

A total of 62,986 finished water samples for molybdenum were collected from 4,922 systems. Molybdenum was detected in 40.29 percent of UCMR 3 samples. Reported molybdenum concentrations ranged from 1 µg/L (the MRL) to 196 µg/L. About 52 percent of systems reported at least one detection of molybdenum. Extrapolating these findings suggests that an estimated 657 PWSs serving 895,000 people nationally have at least one detection of molybdenum greater than ½ the HRL and 216 PWSs serving 240,000 people nationally have at least one detection of molybdenum greater than the HRL.

Exhibit 7-15: Molybdenum Occurrence Data from UCMR 3 Assessment Monitoring - Summary of Reported Concentrations

Source Water Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90th Percentile	99th Percentile	Maximum
Small Systems (serving ≤ 10,000 people)					
Groundwater	1	2.66	12.0	96.8	180
Surface Water	1	1.90	6.84	24.5	37.9
All Small Systems	1	2.30	9.12	61.4	180
Large Systems (serving 10,001 - 100,000 people) -- CENSUS					
Groundwater	1	2.60	10.1	41.0	190
Surface Water	1	2.08	6.20	24.0	196
All Large Systems	1	2.30	7.70	31.0	196
Very Large Systems (serving > 100,000 people) -- CENSUS					
Groundwater	1	2.60	8.54	16.7	19
Surface Water	1	2.80	5.80	13.0	33
All Very Large Systems	1	2.70	6.10	14.7	33
All Systems					
All Water Systems	1	2.40	7.50	29.0	196

Source: USEPA, 2018

Exhibit 7-16: Molybdenum National Occurrence Measures Based on UCMR 3 Assessment Monitoring Data – Summary of Samples

Source Water Type	Total # of Samples	Samples with Detections ≥ MRL (1 µg/L)		Samples with Detections > 1/2 HRL (50 µg/L)		Samples with Detections > HRL (100 µg/L)	
		Number	Percent	Number	Percent	Number	Percent
Small Systems (serving ≤ 10,000 people)							
Groundwater	3,238	1,261	38.94%	26	0.80%	9	0.28%
Surface Water	2,697	959	35.56%	0	0.00%	0	0.00%
All Small Systems	5,935	2,220	37.41%	26	0.44%	9	0.15%
Large Systems (serving 10,001 - 100,000 people) -- CENSUS							
Groundwater	18,766	7,786	41.49%	51	0.27%	3	0.02%
Surface Water	27,345	10,184	37.24%	25	0.09%	12	0.04%
All Large Systems	46,111	17,970	38.97%	76	0.16%	15	0.03%
Very Large Systems (serving > 100,000 people) -- CENSUS							
Groundwater	2,863	673	23.51%	0	0.00%	0	0.00%
Surface Water	8,077	4,514	55.89%	0	0.00%	0	0.00%
All Very Large Systems	10,940	5,187	47.41%	0	0.00%	0	0.00%
All Systems							
All Water Systems	62,986	25,377	40.29%	102	0.16%	24	0.04%

Source: USEPA, 2018

Exhibit 7-17 : Molybdenum National Occurrence Measures Based on UCMR 3 Assessment Monitoring Data – Summary of System and Population – All Reported Detections

Source Water Type	UCMR 3 Sample		Number With At Least One Detection $\geq$ MRL (1 μ g/L)		Percent With At Least One Detection $\geq$ MRL (1 μ g/L)		National Inventory ¹		National Estimate of Number With At Least One Detection $\geq$ MRL (1 μ g/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving $\leq$ 10,000 people)										
Groundwater	527	1,498,845	269	764,198	51.04%	50.99%	55,700	38,730,597	28,400	19,700,000
Surface Water	272	1,250,215	123	583,779	45.22%	46.69%	9,728	20,007,917	4,400	9,340,000
All Small Systems	799	2,749,060	392	1,347,977	49.06%	49.03%	65,428	58,738,514	32,800	29,100,000
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,455	37,187,791	785	20,892,841	53.95%	56.18%	1,455	37,187,791	785	20,900,000
Surface Water	2,260	69,619,878	1,103	35,160,852	48.81%	50.50%	2,260	69,619,878	1,100	35,200,000
All Large Systems	3,715	106,807,669	1,888	56,053,693	50.82%	52.48%	3,715	106,807,669	1,890	56,100,000
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	68	16,355,951	45	11,654,011	66.18%	71.25%	68	16,355,951	45	11,700,000
Surface Water	340	115,158,260	221	74,792,203	65.00%	64.95%	340	115,158,260	221	74,800,000
All Very Large Systems	408	131,514,211	266	86,446,214	65.20%	65.73%	408	131,514,211	266	86,400,000
All Systems										
All Water Systems	4,922	241,070,940	2,546	143,847,884	51.73%	59.67%	69,551	297,060,394	35,000	172,000,000

Source: USEPA, 2018

¹ The national inventory numbers presented here are from a freeze of the December 2010 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data, the same freeze that was used to develop the sampling frame to select small systems for participation in UCMR 3. The small system counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. Note that although all large and very large systems were required to conduct UCMR 3 Assessment Monitoring, data might not have been received from every large and very large system.

² National estimates for the small systems are generated by multiplying the UCMR 3 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 3 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

**Exhibit 7-18: Molybdenum National Occurrence Measures Based on UCMR 3 Assessment Monitoring Data –
Summary of System and Population Served Data – Detections > ½ the HRL (50 µg/L)**

Source Water Type	UCMR 3 Sample		Number With At Least One Detection > ½ HRL (50 µg/L)		Percent With At Least One Detection > ½ HRL (50 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > ½ HRL (50 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	527	1,498,845	6	11,849	1.14%	0.79%	55,700	38,730,597	634	306,200
Surface Water	272	1,250,215	0	0	0.00%	0.00%	9,728	20,007,917	0	0
All Small Systems	799	2,749,060	6	11,849	0.75%	0.43%	65,428	58,738,514	634	306,200
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,455	37,187,791	17	489,215	1.17%	1.32%	1,455	37,187,791	17	489,000
Surface Water	2,260	69,619,878	6	99,123	0.27%	0.14%	2,260	69,619,878	6	99,100
All Large Systems	3,715	106,807,669	23	588,338	0.62%	0.55%	3,715	106,807,669	23	588,000
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	68	16,355,951	0	0	0.00%	0.00%	68	16,355,951	0	0
Surface Water	340	115,158,260	0	0	0.00%	0.00%	340	115,158,260	0	0
All Very Large Systems	408	131,514,211	0	0	0.00%	0.00%	408	131,514,211	0	0
All Systems										
All Water Systems	4,922	241,070,940	29	600,187	0.59%	0.25%	69,551	297,060,394	657	895,000

Source: USEPA, 2018

¹ The national inventory numbers presented here are from a freeze of the December 2010 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data, the same freeze that was used to develop the sampling frame to select small systems for participation in UCMR 3. The small system counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. Note that although all large and very large systems were required to conduct UCMR 3 Assessment Monitoring, data might not have been received from every large and very large system.

² National estimates for the small systems are generated by multiplying the UCMR 3 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 3 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

**Exhibit 7-19: Molybdenum National Occurrence Measures Based on UCMR 3 Assessment Monitoring Data –
Summary of System and Population Served Data – Detections > HRL (100 µg/L)**

Source Water Type	UCMR 3 Sample		Number With At Least One Detection > HRL (100 µg/L)		Percent With At Least One Detection > HRL (100 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > HRL (100 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	527	1,498,845	2	3,686	0.38%	0.25%	55,700	38,730,597	211	95,200
Surface Water	272	1,250,215	0	0	0.00%	0.00%	9,728	20,007,917	0	0
All Small Systems	799	2,749,060	2	3,686	0.25%	0.13%	65,428	58,738,514	211	95,200
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,455	37,187,791	3	103,431	0.21%	0.28%	1,455	37,187,791	3	103,000
Surface Water	2,260	69,619,878	2	41,561	0.09%	0.06%	2,260	69,619,878	2	41,600
All Large Systems	3,715	106,807,669	5	144,992	0.13%	0.14%	3,715	106,807,669	5	145,000
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	68	16,355,951	0	0	0.00%	0.00%	68	16,355,951	0	0
Surface Water	340	115,158,260	0	0	0.00%	0.00%	340	115,158,260	0	0
All Very Large Systems	408	131,514,211	0	0	0.00%	0.00%	408	131,514,211	0	0
All Systems										
All Water Systems	4,922	241,070,940	7	148,678	0.14%	0.06%	69,551	297,060,394	216	240,000

Source: USEPA, 2018

¹ The national inventory numbers presented here are from a freeze of the December 2010 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data, the same freeze that was used to develop the sampling frame to select small systems for participation in UCMR 3. The small system counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. Note that although all large and very large systems were required to conduct UCMR 3 Assessment Monitoring, data might not have been received from every large and very large system.

² National estimates for the small systems are generated by multiplying the UCMR 3 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 3 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

7.4.2.1.2 *National Inorganics and Radionuclides Survey (NIRS), 1984-1986*

NIRS was conducted by the EPA to provide data on the occurrence of a select set of radionuclides and inorganic chemicals (IOCs). It provides contaminant occurrence data from 989 community water systems (CWSs) served by groundwater sources. Each of these randomly selected PWSs was sampled a single time between 1984 and 1986. Selection of the PWSs was designed so that the contaminant occurrence results from these PWSs would be representative of national occurrence of contaminants in groundwater systems. Further description of the NIRS survey can be found in Longtin (1988) and USEPA (2008b).

NIRS was structured as a stratified, random sampling of the nation's community groundwater supplies as they existed in the mid-1980s. A random selection of systems from each of several size categories was included, in proportion to the number of PWSs that existed in those size categories nationally. The sampling frame used in NIRS was designed to be representative of groundwater supplies on a national basis, but not necessarily on a state-by-state, regional, or other geographic basis. The resulting sample of systems represents approximately 2 percent of the nation's community groundwater supply in each system size category. Since there are many more small than large PWSs in the United States, most of the NIRS data are from smaller systems. The data are from 49 states (there are no data from Hawaii), as well as Puerto Rico.

Results of the NIRS are presented in Exhibit 7-20 through Exhibit 7-23. The first two exhibits summarize all detections. Molybdenum was monitored with a reporting level of 6 µg/L. Approximately 7.79 percent of groundwater PWSs had detections of molybdenum (i.e., concentrations at or above the reporting level). These detections occurred in systems serving about 6.21 percent of the population served by the PWSs. Detected concentrations ranged from 6.07 µg/L to 180.7 µg/L.

The development of the NIRS data set enables extrapolation of contaminant occurrence in groundwater on a nationwide scale. To extrapolate, the percentage of groundwater systems (or percentage of population served) observed to exceed a specified threshold is multiplied by the total national number of groundwater systems (or the total national population served). The total number of groundwater systems (and population served) is calculated in two ways in the tables below: as the total number of CWSs served by groundwater, and as the sum of CWSs and non-transient non-community water systems (NTNCWSs) served by groundwater. NTNCWSs are public water systems that regularly supply water to at least 25 of the same people at least six months per year, but not year-round. Some examples are schools, factories, office buildings, and hospitals that have their own water systems. See Chapter 2 for additional information on national extrapolations. The results of this national extrapolation are presented in Exhibit 7-21 through Exhibit 7-23.

Exhibit 7-20: Molybdenum Occurrence Data from the NIRS Database – Summary of Detected Concentrations

Source Water Type	Total Number of Samples	Number of Detections	Percent of Detections	Concentration Value of Detections (µg/L)				
				Minimum	Median	90 th Percentile	99 th Percentile	Maximum
Groundwater Only	989	77	7.79%	6.07	10.0	31.8	106	180.7

Source: EPA data

Exhibit 7-21: Molybdenum Occurrence Data from the NIRS Database – Summary of System and Population Served Data – All Detections

Source Water Type	Total Number		Detections					
			Number		Percent		National Extrapolation ¹	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Groundwater Only	989	1,482,133	77	92,095	7.79%	6.21%	3,120 (CWS only)	5,790,000 (CWS only)
							4,630 (CWS + NTNCWS)	6,120,000 (CWS + NTNCWS)

Source: EPA data

¹ National extrapolations are generated by multiplying the NIRS national statistical sample findings of system/population percentages and national system/population inventory numbers for groundwater-sourced PWSs developed from the EPA's SDWIS, the CWSS, and UCMR (see Chapter 2 for discussion). The inventory numbers are: 93.1 million people served by 40,106 groundwater CWSs, and 98.5 million people served by 59,405 CWSs + NTNCWSs.

Exhibit 7-22: Molybdenum Data from the NIRS Database – Summary of System and Population Served Data – Detections > ½ the HRL

Source Water Type	Total Number		Detections > ½ HRL (50 µg/L)					
			Number		Percent		National Extrapolation ¹	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Groundwater Only	989	1,482,133	4	14,790	0.40%	1.00%	162 (CWS only)	929,000 (CWS only)
							240 (CWS + NTNCWS)	983,000 (CWS + NTNCWS)

Source: EPA data

¹ National extrapolations are generated by multiplying the NIRS national statistical sample findings of system/population percentages and national system/population inventory numbers for groundwater-sourced PWSs developed from the EPA's SDWIS, the CWSS, and UCMR (see Chapter 2 for discussion). The inventory numbers are: 93.1 million people served by 40,106 groundwater CWSs, and 98.5 million people served by 59,405 CWSs + NTNCWSs.

Exhibit 7-23: Molybdenum Data from the NIRS Database – Summary of System and Population Served Data – Detections > HRL

Source Water Type	Total Number		Detections > HRL (100 µg/L)					
			Number		Percent		National Extrapolation ¹	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Groundwater Only	989	1,482,133	1	69	0.10%	0.00%	41 (CWS only)	4,340 (CWS only)
							60 (CWS + NTNCWS)	4,590 (CWS + NTNCWS)

Source: EPA data

¹ National extrapolations are generated by multiplying the NIRS national statistical sample findings of system/population percentages and national system/population inventory numbers for groundwater-sourced PWSs developed from the EPA's SDWIS, the CWSS, and UCMR (see Chapter 2 for discussion). The inventory numbers are: 93.1 million people served by 40,106 groundwater CWSs, and 98.5 million people served by 59,405 CWSs + NTNCWSs.

7.4.2.2 Supplemental Data Sources

7.4.2.2.1 State Monitoring Data, 1990-2022

Because there is no available national database that receives and stores all relevant data regarding the occurrence of regulated and unregulated contaminants in public drinking water systems, the EPA gathered data from state drinking water monitoring websites in support of national occurrence assessments. Data were gathered from 28 states. For 24 of the 28 states, data were available through the Drinking Water Watch (DWW) portal on the state's website. Available data for other states/entities that had been submitted to the EPA through the Second, Third, and Fourth Six-Year Review efforts (SYR2, SYR3, and SYR4) were also evaluated. As part of the Six-Year Reviews, some states submitted PWS occurrence data for unregulated contaminants along with requested data on regulated contaminants. For all rounds of the Six-Year Review, these unregulated data provide varying degrees of completeness in their coverage of the states/entities and are not necessarily representative of occurrence in those states/entities. For more details on data compiled under SYR2, SYR3, and SYR4, refer to USEPA (2009a), USEPA (2016), and USEPA (2024), respectively.

Drinking water occurrence data for molybdenum were available on state websites from 13 states: Alaska, California, Delaware, Idaho, Illinois, Iowa, Maryland, Montana, Nevada, New Mexico, Ohio, Wisconsin, and West Virginia. Results are presented in Exhibit 7-24 through Exhibit 7-26. Results are broken down into two different time periods: 1990-2011, and 2012-2022. Comprehensive information about methods used and reporting levels is not available for the state data. However, minimum detected concentrations reported in Exhibit 7-24 may be indicative of reporting levels used.

As noted above, the monitoring data from each state/entity are limited and not necessarily representative of occurrence in the state/entity. The number of PWSs per state with molybdenum data ranges from only 1 PWS from Idaho in the 2012-2022 time period to 1,223 PWSs in the Illinois 1990-2011 time period. Overall, detected concentrations ranged from 0.001 µg/L to 263,000 µg/L.

Exhibit 7-24: Molybdenum State Drinking Water Website Occurrence Data – Summary of Detected Concentrations

State (Date Range)	Source Water Type	Concentration Value of Detections (µg/L)				
		Minimum	Median	90th Percentile	99th Percentile	Maximum
Date Range: 1990-2011						
Alaska (2001-2005)	Groundwater	3.53	3.53	3.53	3.53	3.53
	Surface Water	--	--	--	--	--
	Total	3.53	3.53	3.53	3.53	3.53
California (1995-2011)	Groundwater	0.4	4.00	18.1	46.1	79
	Surface Water	0.005	4.00	12.0	63.4	83
	Total	0.005	4.00	14.3	53.0	83
Illinois (1990-2011)	Groundwater	0.001	24.3	39.0	95.0	280
	Surface Water	0.009	29.0	70.8	82.0	110
	Total	0.001	25.0	48.6	88.5	280
Montana (2000-2011)	Groundwater	--	--	--	--	--
	Surface Water	1.3	1.50	1.66	1.70	1.7
	Total	1.3	1.50	1.66	1.70	1.7
New Mexico (2002)	Groundwater	50	50	50	50	50
	Surface Water	--	--	--	--	--
	Total	50	50	50	50	50
Nevada (1993-2011)	Groundwater	1	3.55	5.02	12.9	22
	Surface Water	1	5.00	5.90	7.00	26
	Total	1	5.00	5.89	7.00	26
Ohio (1999-2011)	Groundwater	1	11.0	51.0	68.2	70
	Surface Water	1	7.50	12.0	15.0	15
	Total	1	8.00	37.8	65.9	70
Wisconsin (2000-2006)	Groundwater	8	8	8	8	8
	Surface Water	--	--	--	--	--
	Total	8	8	8	8	8
West Virginia (2000-2011)	Groundwater	1.4	1.70	1.94	1.99	2
	Surface Water	--	--	--	--	--
	Total	1.4	1.70	1.94	1.99	2

State (Date Range)	Source Water Type	Concentration Value of Detections (µg/L)				
		Minimum	Median	90th Percentile	99th Percentile	Maximum
Date Range: 2012-2022						
California (2012-2022)	Groundwater	0.011	3.07	17.5	80.0	230
	Surface Water	0.039	3.00	7.50	17.0	59
	Unknown	2	3.70	6.00	7.76	8
	Total	0.011	3.04	8.30	49.9	230
Iowa (2016-2022)	Groundwater	1	2.50	3.90	6.68	7.4
	Surface Water	--	--	--	--	--
	Total	1	2.50	3.90	6.68	7.4
Idaho (2022)	Groundwater	--	--	--	--	--
	Surface Water	263,000	263,000	263,000	263,000	263,000
	Total	263,000	263,000	263,000	263,000	263,000
Illinois (2012-2022)	Groundwater	1.6	23.6	30.6	37.4	43.4
	Surface Water	20.7	36.3	70.4	73.2	73.5
	Total	1.6	25.4	59.6	72.7	73.5
Nevada (2012-2022)	Groundwater	2	5.90	7.36	9.50	9.6
	Surface Water	2.2	5.00	8.00	9.80	10
	Total	2	5.60	8.08	9.90	10
Ohio (2012-2021)	Groundwater	2.4	2.4	2.4	2.4	2.4
	Surface Water	--	--	--	--	--
	Total	2.4	2.4	2.4	2.4	2.4
Wisconsin (2013-2018)	Groundwater	4.32	100	104	109	110
	Surface Water	--	--	--	--	--
	Total	4.32	100	104	109	110
West Virginia (2012-2022)	Groundwater	2.2	2.20	2.20	2.20	2.2
	Surface Water	2.6	2.60	2.60	2.60	2.6
	Total	2.2	2.40	2.56	2.60	2.6

Source: Data provided to the EPA by states and downloaded by the EPA from state websites

--" = No detections in this category

Note: States with occurrence data but no detections do not appear in this table.

Exhibit 7-25: Molybdenum State Drinking Water Occurrence Data – Summary of Samples

State (Date Range)	Source Water Type	Total Number of Samples	All Detections		Detections > ½ HRL (50 µg/L)		Detections > HRL (100 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
Date Range: 1990-2011								
Alaska (2001-2005)	Groundwater	6	1	16.67%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	6	1	16.67%	0	0.00%	0	0.00%
California (1995-2011)	Groundwater	1,171	590	50.38%	3	0.26%	0	0.00%
	Surface Water	2,675	1,132	42.32%	15	0.56%	0	0.00%
	Total	3,846	1,722	44.77%	18	0.47%	0	0.00%
Delaware (2006)	Groundwater	2	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	2	0	0.00%	0	0.00%	0	0.00%
Illinois (1990-2011)	Groundwater	10,102	727	7.20%	27	0.27%	5	0.05%
	Surface Water	1,811	233	12.87%	62	3.42%	1	0.06%
	Total	11,913	960	8.06%	89	0.75%	6	0.05%
Montana (2000-2011)	Groundwater	6	0	0.00%	0	0.00%	0	0.00%
	Surface Water	5	2	40.00%	0	0.00%	0	0.00%
	Total	11	2	18.18%	0	0.00%	0	0.00%
New Mexico (2002)	Groundwater	1	1	100.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	1	1	100.00%	0	0.00%	0	0.00%
Nevada (1993-2011)	Groundwater	110	70	63.64%	0	0.00%	0	0.00%
	Surface Water	872	452	51.83%	0	0.00%	0	0.00%
	Total	982	522	53.16%	0	0.00%	0	0.00%
Ohio (1999-2011)	Groundwater	93	31	33.33%	4	4.30%	0	0.00%
	Surface Water	55	38	69.09%	0	0.00%	0	0.00%
	Total	148	69	46.62%	4	2.70%	0	0.00%
Wisconsin (2000-2006)	Groundwater	5	1	20.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	5	1	20.00%	0	0.00%	0	0.00%

State (Date Range)	Source Water Type	Total Number of Samples	All Detections		Detections > ½ HRL (50 µg/L)		Detections > HRL (100 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
West Virginia (2000-2011)	Groundwater	5	2	40.00%	0	0.00%	0	0.00%
	Surface Water	80	0	0.00%	0	0.00%	0	0.00%
	Total	85	2	2.35%	0	0.00%	0	0.00%
Date Range: 2012-2022								
California (2012-2022)	Groundwater	562	457	81.32%	20	3.56%	2	0.36%
	Surface Water	3,059	1,680	54.92%	2	0.07%	0	0.00%
	Unknown	17	13	76.47%	0	0.00%	0	0.00%
	Total	3,638	2,150	59.10%	22	0.60%	2	0.05%
Iowa (2016-2022)	Groundwater	30	25	83.33%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	30	25	83.33%	0	0.00%	0	0.00%
Idaho (2022)	Groundwater	1	1	100.00%	1	100.00%	1	100.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	1	1	100.00%	1	100.00%	1	100.00%
Illinois (2012-2022)	Groundwater	2,889	79	2.73%	0	0.00%	0	0.00%
	Surface Water	319	38	11.91%	15	4.70%	0	0.00%
	Total	3,208	117	3.65%	15	0.47%	0	0.00%
Maryland (2017)	Groundwater	1	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	1	0	0.00%	0	0.00%	0	0.00%
Nevada (2012-2022)	Groundwater	70	22	31.43%	0	0.00%	0	0.00%
	Surface Water	710	5	0.70%	0	0.00%	0	0.00%
	Total	780	27	3.46%	0	0.00%	0	0.00%
Ohio (2012-2021)	Groundwater	3	1	33.33%	0	0.00%	0	0.00%
	Surface Water	2	0	0.00%	0	0.00%	0	0.00%
	Total	5	1	20.00%	0	0.00%	0	0.00%
Wisconsin (2013-2018)	Groundwater	14	8	57.14%	6	42.86%	2	14.29%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	14	8	57.14%	6	42.86%	2	14.29%

State (Date Range)	Source Water Type	Total Number of Samples	All Detections		Detections > ½ HRL (50 µg/L)		Detections > HRL (100 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
West Virginia (2012-2022)	Groundwater	8	1	12.50%	0	0.00%	0	0.00%
	Surface Water	18	1	5.56%	0	0.00%	0	0.00%
	Total	26	2	7.69%	0	0.00%	0	0.00%

Source: Data provided to the EPA by states and downloaded by the EPA from state websites

Exhibit 7-26: Molybdenum State Drinking Water Occurrence Data – Summary of Systems

State (Date Range)	Source Water Type	Total Number of Systems	Systems with Detections		Systems with Detections > ½ HRL (50 µg/L)		Systems with Detections > HRL (100 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
Date Range: 1990-2011								
Alaska (2001-2005)	Groundwater	5	1	20.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	5	1	20.00%	0	0.00%	0	0.00%
California (1995-2011)	Groundwater	144	92	63.89%	3	2.08%	0	0.00%
	Surface Water	71	50	70.42%	4	5.63%	0	0.00%
	Total	207	136	65.70%	7	3.38%	0	0.00%
Delaware (2006)	Groundwater	2	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	2	0	0.00%	0	0.00%	0	0.00%
Illinois (1990-2011)	Groundwater	1,020	268	26.27%	18	1.76%	5	0.49%
	Surface Water	203	48	23.65%	8	3.94%	1	0.49%
	Total	1,223	316	25.84%	26	2.13%	6	0.49%
Montana (2000-2011)	Groundwater	4	0	0.00%	0	0.00%	0	0.00%
	Surface Water	3	2	66.67%	0	0.00%	0	0.00%
	Total	7	2	28.57%	0	0.00%	0	0.00%
New Mexico (2002)	Groundwater	1	1	100.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	1	1	100.00%	0	0.00%	0	0.00%

State (Date Range)	Source Water Type	Total Number of Systems	Systems with Detections		Systems with Detections > ½ HRL (50 µg/L)		Systems with Detections > HRL (100 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
Nevada (1993-2011)	Groundwater	13	7	53.85%	0	0.00%	0	0.00%
	Surface Water	8	8	100.00%	0	0.00%	0	0.00%
	Total	21	15	71.43%	0	0.00%	0	0.00%
Ohio (1999-2011)	Groundwater	21	9	42.86%	2	9.52%	0	0.00%
	Surface Water	6	5	83.33%	0	0.00%	0	0.00%
	Total	27	14	51.85%	2	7.41%	0	0.00%
Wisconsin (2000-2006)	Groundwater	3	1	33.33%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	3	1	33.33%	0	0.00%	0	0.00%
West Virginia (2000-2011)	Groundwater	3	1	33.33%	0	0.00%	0	0.00%
	Surface Water	13	0	0.00%	0	0.00%	0	0.00%
	Total	16	1	6.25%	0	0.00%	0	0.00%
Date Range: 2012-2022								
California (2012-2022)	Groundwater	69	47	68.12%	4	5.80%	2	2.90%
	Surface Water	73	50	68.49%	1	1.37%	0	0.00%
	Unknown	1	1	100.00%	0	0.00%	0	0.00%
	Total	143	98	68.53%	5	3.50%	2	1.40%
Iowa (2016-2022)	Groundwater	3	2	66.67%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	3	2	66.67%	0	0.00%	0	0.00%
Idaho (2022)	Groundwater	0	0	0.00%	0	0.00%	0	0.00%
	Surface Water	1	1	100.00%	1	100.00%	1	100.00%
	Total	1	1	100.00%	1	100.00%	1	100.00%
Illinois (2012-2022)	Groundwater	519	23	4.43%	0	0.00%	0	0.00%
	Surface Water	64	7	10.94%	2	3.13%	0	0.00%
	Total	583	30	5.15%	2	0.34%	0	0.00%
Maryland (2017)	Groundwater	1	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	1	0	0.00%	0	0.00%	0	0.00%

State (Date Range)	Source Water Type	Total Number of Systems	Systems with Detections		Systems with Detections > ½ HRL (50 µg/L)		Systems with Detections > HRL (100 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
Nevada (2012-2022)	Groundwater	10	6	60.00%	0	0.00%	0	0.00%
	Surface Water	8	3	37.50%	0	0.00%	0	0.00%
	Total	18	9	50.00%	0	0.00%	0	0.00%
Ohio (2012-2021)	Groundwater	3	1	33.33%	0	0.00%	0	0.00%
	Surface Water	2	0	0.00%	0	0.00%	0	0.00%
	Total	5	1	20.00%	0	0.00%	0	0.00%
Wisconsin (2013-2018)	Groundwater	5	3	60.00%	1	20.00%	1	20.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	5	3	60.00%	1	20.00%	1	20.00%
West Virginia (2012-2022)	Groundwater	4	1	25.00%	0	0.00%	0	0.00%
	Surface Water	12	1	8.33%	0	0.00%	0	0.00%
	Total	16	2	12.50%	0	0.00%	0	0.00%

Source: Data provided to the EPA by states and downloaded by the EPA from state websites

7.4.2.2.2 *Water Systems' Consumer Confidence Reports (CCRs), 2018-2021*

CCRs are annual water quality reports that CWSs are required to provide to their customers. These reports summarize information on water sources, detected contaminants, and system compliance with the EPA drinking water standards; they may also include general educational material. Under the CCR Rule (40 CFR Subpart O), CWSs with 15 or more connections or serving at least 25 year-round residents must prepare and distribute a CCR to all billing units or service connections every year. Systems serving 100,000 or more residents are also required to post their current CCRs on a publicly accessible Internet site.

The EPA reviewed CCRs published by the 25 systems that serve over one million customers (as identified in the Safe Drinking Water Information System / Federal version, or SDWIS/Fed, from the fourth quarter 2021 data) for unregulated contaminant occurrence information for the years 2018 through 2021. Data on molybdenum were available from CCRs prepared by seven CWSs: two systems in California (Los Angeles and East Bay Municipal Utility District), one system in Missouri (Missouri American Water), two systems in New York (Suffolk County and New York City), and two systems in Ohio (City of Cleveland and City of Columbus).

The Los Angeles Department of Water and Power included data on molybdenum in its 2018 and 2019 CCRs. These CCRs presents results from UCMR 3 monitoring, completed several years earlier. Los Angeles is served by a large system of surface and groundwater sources. Molybdenum concentrations, in samples gathered at three locations, ranged from 3 to 10 µg/L.

The East Bay Municipal Utility District included data on molybdenum in its 2018 CCR. Monitoring was conducted as part of the UCMR 3 program. The East Bay Municipal Utility

District is served by one surface water source, the Pardee Reservoir. Data were reported for five locations; the number of samples collected was not reported. Molybdenum concentrations ranged from <1 ppb to 1 ppb.

Missouri American Water included data on molybdenum in its 2021 CCR. Missouri American Water is served by two surface water sources, the Missouri and Meramec Rivers. In 2021, molybdenum was monitored for but not detected.

Suffolk County, New York, included data on molybdenum, in its 2018-2021 CCRs. Suffolk County is served by groundwater from four major aquifers beneath Long Island.

- The 2018 CCR presented results for 27 distribution areas. The number of samples of molybdenum varied from 2 to 560 depending on the distribution area; molybdenum concentrations ranged from ND (no detection) to 1.1 µg/L.
- The 2019 CCR presented results for 27 distribution areas. The number of samples of molybdenum varied from 2 to 581 depending on the distribution area; molybdenum concentrations ranged from ND to 2.0 µg/L.
- The 2020 CCR presented results for 27 distribution areas. The number of samples of molybdenum varied from 2 to 523 depending on the distribution area; molybdenum concentrations ranged from ND to 1.1 µg/L.
- The 2021 CCR presented results for 27 distribution areas. The number of samples of molybdenum varied from 2 to 565 depending on the distribution area; molybdenum concentrations ranged from ND to 1.1 µg/L.

New York City included data on molybdenum in its 2018 CCR. New York City is served by a large system of surface water networks in New York state. In 2018, molybdenum was monitored for but was not detected.

Cleveland Water included data on molybdenum in two CCRs covering 2020 and 2021. Cleveland is served by one surface water source, Lake Erie. Samples were collected from one surface water source. The number of samples collected was not reported. Molybdenum had an average concentration of “NA” (No Value Required or Available) for both years.

The City of Columbus, Ohio included data on molybdenum, in its 2018 CCR. This CCR presents results from UCMR 3 monitoring, completed several years earlier. The City of Columbus water system uses surface water from the Scioto River and Big Walnut Creek, as well as groundwater sources. Samples were collected from two surface water sources and one groundwater source. Data were reported from three sources for 2014 sampling; the number of samples was not reported. Molybdenum concentrations ranged from 4.1 ppb to 12 ppb.

7.4.2.2.3 *Community Water System Survey (CWSS), 2006*

The 2006 CWSS (USEPA, 2009b) gathered data on the financial and operating characteristics of a random sample of CWSs nationwide. All systems serving more than 500,000 people (94 systems in 2006) received the survey, and systems in that size category were asked questions about concentrations of unregulated contaminants in their raw and finished water. Of the 94 systems asked about unregulated contaminants, 58 systems (62 percent) responded to the survey, though not all of these systems answered every question. The EPA supplemented the data set by gathering additional information about contaminant occurrence at the 94 systems from publicly available sources (e.g., CCRs).

In the 2006 CWSS, two of the 94 systems serving more than 500,000 people reported monitoring data for molybdenum from two samples. Reporting levels were not specified in this survey.

7.4.2.2.4 Additional Source Water and Drinking Water Studies

Note that there may be some overlap between the NAWQA data assessment presented earlier in the ambient water occurrence section and the summaries of NAWQA studies presented below.

Datasets of Groundwater Quality (Kingsbury et al., 2021), 2017-2019

Kingsbury et al. (2021) evaluated groundwater-quality samples collected from 2017 to 2019 as part of the third cycle of USGS's NAWQA Program. Six types of well network studies were conducted: principal aquifer study networks; major aquifer study networks; land-use study networks; vertical flow-path study networks; enhanced trends networks; and modeling support studies. The reporting level used for molybdenum was 0.05 µg/L. Molybdenum was detected in 841 of 1,042 samples with detected concentrations ranging from 0.05 µg/L to 92.6 µg/L.

Trace Elements and Radon in Groundwater (Ayotte et al., 2011), 1992-2003

Ayotte et al. (2011) conducted an assessment as part of the NAWQA program, collecting water samples in ambient groundwater and drinking water aquifers to evaluate the occurrence of trace-element concentrations, including strontium. A total of 1,309 samples were collected between 1992 and 2003 across the United States from more than 40 principal and other aquifers. The reporting level was 1 µg/L. Molybdenum was detected in 57.6 percent of the 3,063 samples. The study used statistical analyses to estimate the median, 90th, and maximum concentrations of molybdenum of 1.0 µg/L, 8.0 µg/L, and 4,700 µg/L, respectively (Ayotte et al., 2011).

Water Quality in Public-Supply Wells (Toccalino et al., 2010), 1993-2007

To assess risks posed by contaminants in public-supply wells, water samples were collected from source (untreated) groundwater from 932 public-supply wells located in parts of 40 NAWQA Study Units in 41 states (Toccalino et al., 2010). Each well was sampled once between 1993 and 2007. Reporting levels for molybdenum ranged from 0.06 µg/L to 1 µg/L. Results from this study are presented in Exhibit 7-27 and Exhibit 7-28. Molybdenum was detected in approximately 77 percent of samples and was detected at concentrations greater than half the HRL in nearly 0.32 percent of samples.

Exhibit 7-27: Molybdenum Data from Public-Supply Wells (Toccalino et al., 2010) – Summary of Detected Concentrations

Source Water Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90 th Percentile	99 th Percentile	Maximum
Groundwater Only	0.105	2	7.89	30.3	89

Source: Toccalino et al., 2010

Exhibit 7-28: Molybdenum Data from Public-Supply Wells (Toccalino et al., 2010) – Summary of Samples

Source Water Type	Number of Samples	All Detections		Detections > ½ HRL (50 µg/L)		Detections > HRL (100 µg/L)	
		Number	Percent	Number	Percent	Number	Percent
Groundwater Only	628	485	77.2	2	0.32	0	0.00

Source: Toccalino et al., 2010

Water Quality in Domestic Wells (DeSimone, 2009), 1991-2004

USGS conducted an assessment of the quality of water from domestic wells across the United States using NAWQA data (DeSimone, 2009). The program included the analysis of major ions, trace elements, nutrients, radon, and organic compounds (pesticides and volatile organic compounds or VOCs) at approximately 2,100 domestic wells (private drinking water wells) across 48 states, covering 30 regional aquifers, between 1991 and 2004. In addition, USGS summarized data from wells sampled for NAWQA agricultural land-use assessment studies to provide an indication of the potential effects of agricultural land-use practices on the groundwater in the aquifers studied. Reporting thresholds varied; DeSimone censored the molybdenum data at a common reporting level of 1 µg/L. There was a total of 1,650 analyses for molybdenum in aquifer and agricultural land-use studies. Manganese was reported as detected in 921 (58.6 percent) of 1,572 analyses from aquifer studies and 49 (62.8 percent) of 78 analyses from agricultural land use studies. In 0.57 percent of wells, detected concentrations of molybdenum exceeded 40 µg/L (the study's human health benchmark for molybdenum).

Selected Trace Elements in Groundwater in the Glacial Aquifer System of the Northern United States (Groschen et al., 2009), 1991-2003

Using NAWQA data, Groschen et al. (2009) conducted an assessment of the occurrence and distribution of several contaminants in groundwater of the glacial aquifer system in the Northern United States, which underlies portions of New England, the Midwest, the Pacific Northwest, and Alaska. The study analyzed data collected from 1,590 monitoring wells and water supply wells sampled between 1991 and 2003. Reporting levels ranged from 0.2 µg/L to 60 µg/L. The results of the USGS analysis are presented in Exhibit 7-29 and Exhibit 7-30. Molybdenum was detected in 608 (71.8 percent) of a total of 847 samples. The maximum detected concentration was 304 µg/L.

Exhibit 7-29: Molybdenum Data from Northern United States Glacial Aquifer System (Groschen et al., 2009) – Summary of Detection Frequencies

Element	Number of Samples Analyzed	Number of Samples with Concentration ≥ any Reporting Level	Percent of Samples with Detection at any Reporting Level	Number of Samples with Concentration ≥ 1 µg/L	Percent of Samples with Detection ≥ 1 µg/L
Molybdenum	847	608	71.8	482	56.9

Source: Groschen et al., 2009

Exhibit 7-30: Molybdenum Data from Northern United States Glacial Aquifer System (Groschen et al., 2009) – Summary of Concentrations

Element Minimum Concentration (µg/L)		Mean Concentration (µg/L)	Maximum Concentration (µg/L)	Percentile Concentrations (µg/L) Estimated from Regression on Ordered Statistics (ROS)						
				5 th	10 th	25 th	50 th	75 th	90 th	95 th
Molybdenum	0.105	4.1	304	0.082	0.13	0.35	1.4	3.6	7.9	14

Source: Groschen et al., 2009

Note: the minimum, mean and maximum concentrations are measured values. The percentile concentrations are estimated statistically. In the report, USGS notes: "Regression on Ordered Statistics (ROS) techniques were used to estimate medians, percentiles, and other summary statistics. ROS was used to estimate the descriptive statistics for all elements because most elements had substantial portions of results reported as below detection (less than the reporting level)." Hence, the ROS-modeled summary statistics are sometimes less than the minimum measured concentrations or even the reporting levels. These are estimates based on the modeled probability distributions.

7.4.3 Other Data

The Centers for Disease Control and Prevention (CDC) National Report on Human Exposure to Environmental Chemicals

The Centers for Disease Control and Prevention's (CDC) *National Report on Human Exposure to Environmental Chemicals* (CDC, 2022) includes data on urine concentrations (µg/L) for molybdenum for the years 1999-2018. Results are presented in Exhibit 7-31. The 95th percentiles for the total of all age groups (not creatinine-corrected) ranged from 137 µg/L to 180 µg/L from 1999 through 2018. The 95th percentiles for the total of all age groups (creatinine-corrected) ranged from 117 µg/g_{creatinine} to 144 µg/g_{creatinine} from 1999 through 2018. The limit of detection (LOD) for molybdenum (not creatinine-corrected) ranged from 0.8 µg/L to 1.5 µg/L for the years 1999-2018. (The LOD does not apply to creatinine-corrected values.) These 95th percentile values cannot be compared to the HRL because the values represent urine concentrations, not water concentrations.

Exhibit 7-31: 95th Percentile of Urine Molybdenum Concentrations, 1999-2018

Year Range	Medium Analyzed	95 th Percentile of All Samples (not creatinine-corrected), in units of µg/L	Sample Size (not creatinine-corrected)	95 th Percentile of All Samples (creatinine-corrected), in units of µg/g _{creatinine}	Sample Size (creatinine-corrected)
1999-2000	Urine	180	2,257	144	2,257
2001-2002	Urine	165	2,690	130	2,689
2003-2004	Urine	138	2,558	120	2,558
2005-2006	Urine	158	2,576	132	2,576
2007-2008	Urine	163	2,627	137	2,627
2009-2010	Urine	160	2,848	143	2,848
2011-2012	Urine	146	2,504	130	2,502
2013-2014	Urine	139	2,664	117	2,663

Year Range	Medium Analyzed	95 th Percentile of All Samples (not creatinine-corrected), in units of µg/L	Sample Size (not creatinine-corrected)	95 th Percentile of All Samples (creatinine-corrected), in units of µg/g _{creatinine}	Sample Size (creatinine-corrected)
1999-2000	Urine	180	2,257	144	2,257
2001-2002	Urine	165	2,690	130	2,689
2003-2004	Urine	138	2,558	120	2,558
2005-2006	Urine	158	2,576	132	2,576
2007-2008	Urine	163	2,627	137	2,627
2009-2010	Urine	160	2,848	143	2,848
2015-2016	Urine	137	3,060	123	3,057
2017-2018	Urine	140	2,808	122	2,806

Source: CDC, 2022

7.5 Analytical Methods

The EPA has developed two analytical methods for the analysis of molybdenum in drinking water. In addition, Standard Methods (SM) has developed five methods for the analysis of molybdenum in drinking water (APHA, 2012):

- EPA Method 200.7, Revision 4.4, *Determination of Metals and Trace Elements in Water and Wastes by Inductively Coupled Plasma-Atomic Emission Spectrometry*, has a Method Detection Limit (MDL) of 4 µg/L. Mean recoveries in tap water, pond water, and well water range from 95 to 108 percent, with Relative Percent Differences (RPDs) of 0.5 to 10.5 percent (USEPA, 1994a).
- EPA Method 200.8, Revision 5.4, *Determination of Trace Elements in Waters by Inductively Coupled Plasma - Mass Spectrometry*, has MDLs that range from 0.01 to 0.3 µg/L. Mean recoveries in drinking water, pond water, and well water range from 98.6 to 104.2 percent, with RPDs of 1 to 5.7 percent (USEPA, 1994b).
- *Standard Methods for the Examination of Water and Wastewater*, 22nd Edition lists the following methods for the analysis of molybdenum: SM 3111 D, SM 3111 E, SM 3113 B, SM 3120 (B) and SM 3125 (B). Performance for the 3111 series methods (Atomic Adsorption Spectrometry/Direct Nitrous Oxide-Acetylene Flame Method or Extraction/ Direct Nitrous Oxide-Acetylene Flame Method) is provided in SM 3111 A: molybdenum has an Instrument Detection Limit of 0.1 mg/L a sensitivity of 0.5 mg/L and an optimal concentration range of 1-20 mg/L. Interlaboratory precision and bias measurements include a standard deviation of 1.1 µg/L, a relative standard deviation of 11.6 percent (via extracted determination) and a relative error of 1.3 percent (participants = 5). Single operator precision and bias measurements include a standard deviation of 1.0 µg/L, relative standard deviations of 10.5 percent (via extracted determination) and 0.9 percent (via direct determination; number of participants not indicated) and an acceptable range of 5.5-14.5 µg/L (participants = 5). Performance for the 3113 method (Electrothermal Atomic Adsorption Spectrometry) is provided in SM 3113 A: molybdenum has an Estimated Detection Level of 1 µg/L and an optimal concentration range of 3-60 µg/L.

SM 3120B (Inductively Coupled Plasma-Mass Spectrometry) has an Estimated Detection Level of 8 µg/L and an upper limit concentration of 100 mg/L. SM 3125B (Inductively Coupled Plasma-Mass Spectrometry) has an Instrument Detection Level of 0.003 µg/L (APHA, 2012).

Laboratories participating in UCMR 3 were required to use EPA Method 200.8 (or, alternatively, ASTM D5673–10 or SM 3125) and were required to report molybdenum, values at or above the EPA-defined MRL of 1 µg/L (77 FR 26072; USEPA, 2012). The MRL was set based on the capability of multiple laboratories at the time.

7.6 Treatment Technologies

The EPA evaluates whether suitable treatment technologies are available prior to promulgating a final NPDWR. The preliminary summary of treatment technology availability presented here represents the results of a January 2024 literature search.

A limited number of studies were found. These discuss ion exchange at full scale, and coagulation-filtration and nanoscale zero-valent iron with activated carbon at the bench scale.

Chen et al. (2020) evaluated simultaneous removal of arsenic and several co-contaminants, including molybdenum, from groundwater high in nitrate using full-scale ion exchange at a community water system in Idaho. The ion exchange system, using a strong base anionic resin, successfully reduced molybdenum concentrations to <0.1 µg/L in all but a few samples at the baseline regeneration setpoint of 422 bed volumes, indicating that molybdenum was highly preferred by this resin. At 714 bed volumes, molybdenum was still preferentially removed by the resin, with initial concentrations of 12.2 µg/L reduced to 0.7 µg/L.

Zhang et al. (2015) conducted bench-scale jar testing of coagulation-filtration for removal of molybdenum (as Mo(VI)) from lab-prepared water. The coagulants tested were ferric chloride and ferric sulfate. Ferric sulfate performed better than ferric chloride under acidic conditions (pH of 4-5), and about as well at higher pH values. Optimum removal efficiency by ferric sulfate, 94 percent, was achieved at pH of 5. The presence of calcium reduced Mo(VI) removal across all pH ranges. The mechanisms of interference by natural organic matter (represented in the study by dosed humic acids) were also investigated.

In China, Zhu et al. (2020) conducted experiments on the application of nanoscale zero-valent iron, supported by activated carbon, to raw water from a reservoir in Songxian County, Henan Province, that was contaminated with molybdenum from upstream mining operations. At a pH of 8.1, the predominant form of molybdenum in the raw water was Mo(VI). In bench-scale experiments of a fixed-bed column system containing nanoscale zero-valent iron and activated carbon, 74% of the original Mo(VI) was removed within the first 14 hours of operation. The raw water concentration of Mo(VI) was 1,603 µg/L, with a target effluent concentration of 70 µg/L (based on World Health Organization provisional guidelines). The breakthrough empty-bed volumes were between 800 and 1,110 and the empty-bed contact time was between 3 and 6 minutes.

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Chapter 8: Permethrin

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Abbreviations

aPAD	Acute Population-Adjusted Dose
BMD _{1SD}	Benchmark Dose at One Standard Deviation from Controls*
BMDL _{1SD}	Lower Bound of 95 Percent Confidence Interval on BMD _{1SD} *
BW	Body Weight
CASRN	Chemical Abstracts Service Registry Number
CCL 5	Fifth Contaminant Candidate List
CCR	Consumer Confidence Report
CDR	Chemical Data Reporting
CI	Confidence Interval
CWS	Community Water System
DL	Detection Limit
DL	Detection Limit
DWI	Drinking Water Intake
DWI-BW	Drinking Water Intake Adjusted for Body Weight
DWW	Drinking Water Watch
EF	Exposure Factor
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning And Community Right-to-Know Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GWUDI	Groundwater Under the Direct Influence of Surface Water
HED	Health Effects Division
HHRA	Human Health Risk Assessment
HRL	Health Reference Level
IUR	Inventory Update Reporting
K _H	Henry's Law Constant
K _{oc}	Organic Carbon Partitioning Coefficient
K _{ow}	Octanol/Water Partitioning Coefficient
LADWP	Los Angeles Department of Water & Power
LCMRL	Lowest Concentration Minimum Reporting Level
LT-MDL	Long-Term Method Detection Level
MAC	Maximum Acceptable Concentration
MDL	Method Detection Limit
MRL	Minimum Reporting Level
NAWQA	National Water-Quality Assessment
NCFAP	National Center for Food and Agricultural Policy
ND	No Detection
NIRS	National Inorganics and Radionuclides Survey
NPDWR	National Primary Drinking Water Regulation
NPS	National Pesticide Survey
NTNCWS	Non-Transient Non-Community Water System
NWIS	National Water Information System
OGWDW	Office of Ground Water and Drinking Water
OPP	Office of Pesticide Programs
PAC	Powdered Activated Carbon
PAD	Population-Adjusted Dose
PDP	Pesticide Data Program

PMP	Pilot Monitoring Program
POD	Point of Departure
POD/UF	Point of Departure / Uncertainty Factor
PWD	Philadelphia Water Department
PWS	Public Water System
RD 5	Fifth Regulatory Determination
RED	Reregistration Eligibility Decision
RfD	Reference Dose
RSC	Relative Source Contribution
RSD	Relative Standard Deviation
RUP	Restricted Use Pesticide
SDWA	Safe Drinking Water Act
SDWIS	Safe Drinking Water Information System
SDWIS/Fed	Safe Drinking Water Information System / Federal Version
SIM	Selected Ion Monitoring
STORET	Storage and Retrieval Data System
SYR2	Second Six-Year Review
SYR3	Third Six-Year Review
SYR4	Fourth Six-Year Review
TDI	Tolerable Daily Intake
TOC	Total Organic Carbon
TRI	Toxics Release Inventory
UCM	Unregulated Contaminant Monitoring
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 1	First Unregulated Contaminant Monitoring Rule
UCMR 2	Second Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 4	Fourth Unregulated Contaminant Monitoring Rule
UF	Uncertainty Factor
UF _A	Interspecies Uncertainty Factor
UF _H	Intraspecies Uncertainty Factor
USDA	United States Department of Agriculture
USGS	United States Geological Survey
VOC	Volatile Organic Compound
WQP	Water Quality Portal

*These definitions apply only within this chapter.

Chapter 8: Permethrin

The U.S. Environmental Protection Agency (EPA) is evaluating permethrin, a contaminant on the fifth Contaminant Candidate List (CCL 5), as a candidate for regulation under the fifth Regulatory Determination process (RD 5). Information on the CCL 5 process is found in Chapter 1. Background on data sources used to evaluate CCL 5 chemicals is found in Chapter 2.

This chapter presents information and analysis specific to permethrin, including background information on the contaminant, information on contaminant sources and environmental fate, an analysis of health effects, an analysis of occurrence in ambient and drinking water, and information about the availability of analytical methods and treatment technologies.

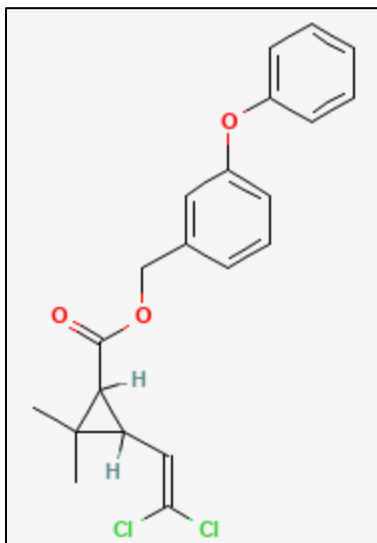
8.1 Contaminant Background and Chemical and Physical Properties

Permethrin is a pyrethroid pesticide and is used as an insecticide. Synonyms for permethrin include ambush, corsair, dragnet, ectiban, kafil, permasect, perthrine, pramex, and stomoxin (NCBI, 2023). Permethrin was first registered in the United States in 1979 (USEPA, 2011a).

The EPA's Office of Pesticide Programs (OPP) released a Reregistration Eligibility Decision (RED) for permethrin in April of 2006 (USEPA, 2006), and an amended RED in 2007 (USEPA, 2007). Subsequent to the EPA changing from the pesticide Reregistration process to the current Registration Review process, the EPA published a Summary Document for Permethrin (USEPA, 2011a) in June of 2011 and a Final Work Plan for Permethrin (USEPA, 2011b) in December of 2011. Twenty-two EPA-registered formulations containing ≥ 0.5 percent active ingredient are Restricted Use Pesticides (RUP) (USEPA, 2022a).

Exhibit 8-1 presents the structural formula for permethrin. Physical and chemical properties and other reference information are listed in Exhibit 8-2.

Exhibit 8-1: Chemical Structure of Permethrin



Source: NCBI, 2023

Exhibit 8-2: Physical and Chemical Properties of Permethrin

Property	Data
Chemical Abstracts Service Registry Number (CASRN)	52645-53-1 (NCBI, 2023)
EPA Pesticide Chemical Code	109701 (NCBI, 2023)
Chemical Formula	C ₂₁ H ₂₀ Cl ₂ O ₃ (NCBI, 2023)
Molecular Weight	391.3 g/mol (NCBI, 2023)
Color/Physical State	Pale brown liquid (NCBI, 2023)
Boiling Point	220 °C at 0.05 mm Hg (ATSDR, 2003; NCBI, 2023)
Melting Point	34-35 °C (ATSDR, 2003; NCBI, 2023)
Density	1.19-1.27 g/mL at 20 °C (ATSDR, 2003; NCBI, 2023)
Freundlich Adsorption Coefficient	--
Vapor Pressure	5.18 x 10 ⁻⁸ mm Hg at 25 °C (NCBI, 2003)
Henry's Law Constant (K _H)	1.9 x 10 ⁻⁶ atm·m ³ /mol at 25 °C (ATSDR, 2003)
Octanol/Water Partitioning Coefficient (log K _{ow})	6.5 (ATSDR, 2003; NCBI, 2023)
Organic Carbon Partitioning Coefficient (K _{oc})	10,471-86,000 L/kg (ATSDR, 2003; NCBI, 2023)
Solubility in Water	0.006 mg/L at 20 °C (ATSDR, 2003; NCBI, 2023)
Other Solvents	Soluble in organic solvents (ATSDR, 2003; NCBI, 2023)

Note: Many of these properties are temperature-dependent. Values are given for properties at 20-25°C unless otherwise noted. Due to varying experimental conditions, and due to the variabilities associated with modeling, standard information sources may provide a range of values. Where more than one value was available from these sources, one value was selected for this table based on best professional judgment.

8.2 Sources and Environmental Fate

8.2.1 Production, Use, and Release

No data on production of permethrin are available from the EPA's Inventory Update Reporting (IUR) and Chemical Data Reporting (CDR) programs. Data on industrial releases are available from the EPA's Toxics Release Inventory (TRI). In addition, several sources provide information about quantities of permethrin used in agriculture. Additional information about these sources is provided in Chapter 2.

Toxics Release Inventory (TRI)

The EPA established TRI in 1987 in response to Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). EPCRA Section 313 requires the reporting of annual information on toxic chemical releases from facilities that meet specific criteria. This reported information is maintained in a database accessible through TRI Explorer (USEPA, 2023).

Although TRI can provide a general idea of release trends, it has limitations. Not all facilities are required to report all releases. Facilities are generally required to report releases if they manufacture or process more than 25,000 pounds of a chemical or use more than 10,000 pounds per year. Reporting requirements have changed over time (e.g., reporting thresholds have increased or decreased), so conclusions about temporal trends should be drawn with caution. TRI data are meant to reflect releases and should not be used to estimate general public exposure to a chemical (USEPA, 2022b).

TRI data for permethrin from the years 1995-2022 are summarized in Exhibit 8-3 (USEPA, 2023). On-site air emissions reached into the thousands of pounds, and off-site disposal sometimes reached into the tens of thousands of pounds. On-site surface water discharges, underground injections, and releases to land were more sporadic, but when they did occur, the underground injections and releases to land occasionally dominated total releases.

Exhibit 8-3: Environmental Releases of Permethrin in the United States, 1997-2022 (pounds)

Year	On-Site Air Emissions	On-Site Surface Water Discharges	On-Site Underground Injection	On-site Releases to Land	Off-site Disposal or Other Releases	Total On- and Off-site Disposal or Other Releases
1995	1,299	37	0	250	751	2,337
1996	1,495	0	0	0	1,250	2,745
1997	4,208	14	0	0	1,019	5,241
1998	4,435	7	0	0	17,549	21,991
1999	2,593	0	0	31,000	1,013	34,606
2000	1,581	7	0	0	1,000	2,588
2001	1,372	0	0	0	1,000	2,372
2002	760	5	0	0	.	765
2003	186	0	0	83	49	318
2004	676	0	17,154	24	34	17,888
2005	422	5	26,652	13	6,975	34,067
2006	811	0	0	0	20	831
2007	347	0	0	0	317.3	665
2008	2,970	0	0	0	1,872	4,842
2009	1,643	0	0	0	1,402.6	3,046
2010	1,752	0	0	0	364	2,116
2011	955	0	0	0	34	989
2012	5,552	0	0	0	.	5,552
2013	7,911	0	0	0	774	8,685
2014	5,733	0	0	0	2,505	8,238
2015	4,396	0	0	0	1,050	5,446
2016	4,143	0	0	0	15,964.9	20,108
2017	13	0	0	162,729	12,302.9	175,045
2018	11	0	0	0	5	16
2019	11	0	0	0	.	11
2020	114	0	0	0	11,314	11,428
2021	19	0	0	15,895	1,400	17,314
2022	30	0	0	122,211	.	122,241

Source: USEPA, 2023

Note: A decimal point indicates that one or more facilities either left an applicable field blank or certified in streamlined reporting that annual release did not exceed 500 pounds, and that otherwise no releases were reported.

Exhibit 8-4 presents an expanded summary of total releases and total surface water discharges that includes the count of states reporting releases (USEPA, 2023). Note that for the purposes of TRI, “state” counts include the District of Columbia and U.S. territories in addition to the 50 states. No more than three states had reported surface water discharges of permethrin in a given year, and there have been no reported surface water discharges since 2005. The number of states with reported permethrin releases of any kind varied between 3 and 10.

Exhibit 8-4: Summary of Total Releases and Total Surface Water Discharges of Permethrin, 1995-2022

Year	On-Site Surface Water Discharges (in pounds)	Count of States with Surface Water Discharges	Total Releases (in pounds)	Count of States with Releases
1995	37	1	2,337	7
1996	0	0	2,745	6
1997	14	3	5,241	8
1998	7	3	21,991	8
1999	0	0	34,606	9
2000	7	1	2,588	10
2001	0	0	2,372	8
2002	5	1	765	6
2003	0	0	318	5
2004	0	0	17,888	7
2005	5	1	34,067	4
2006	0	0	831	5
2007	0	0	665	5
2008	0	0	4,842	4
2009	0	0	3,046	4
2010	0	0	2,116	5
2011	0	0	989	4
2012	0	0	5,552	4
2013	0	0	8,685	4
2014	0	0	8,238	4
2015	0	0	5,446	4
2016	0	0	20,108	4
2017	0	0	175,045	3
2018	0	0	16	3
2019	0	0	11	5
2020	0	0	11,428	7

Year	On-Site Surface Water Discharges (in pounds)	Count of States with Surface Water Discharges	Total Releases (in pounds)	Count of States with Releases
2021	0	0	17,314	7
2022	0	0	122,241	7

Source: USEPA, 2023

Note: A decimal point indicates that one or more facilities either left an applicable field blank or certified in streamlined reporting that annual release did not exceed 500 pounds, and that otherwise no releases were reported. For the purpose of counting states with releases, a decimal point was treated as a zero.

The EPA Pesticide Industry Sales and Usage Report

The EPA’s Pesticide Industry Sales and Usage reports state that the amount of permethrin active ingredient used in the United States was between 2 and 4 million pounds in 2009 and between 1 and 3 million pounds in 2012 (USEPA, 2017).

National Center for Food and Agricultural Policy (NCFAP) Pesticide Use Database

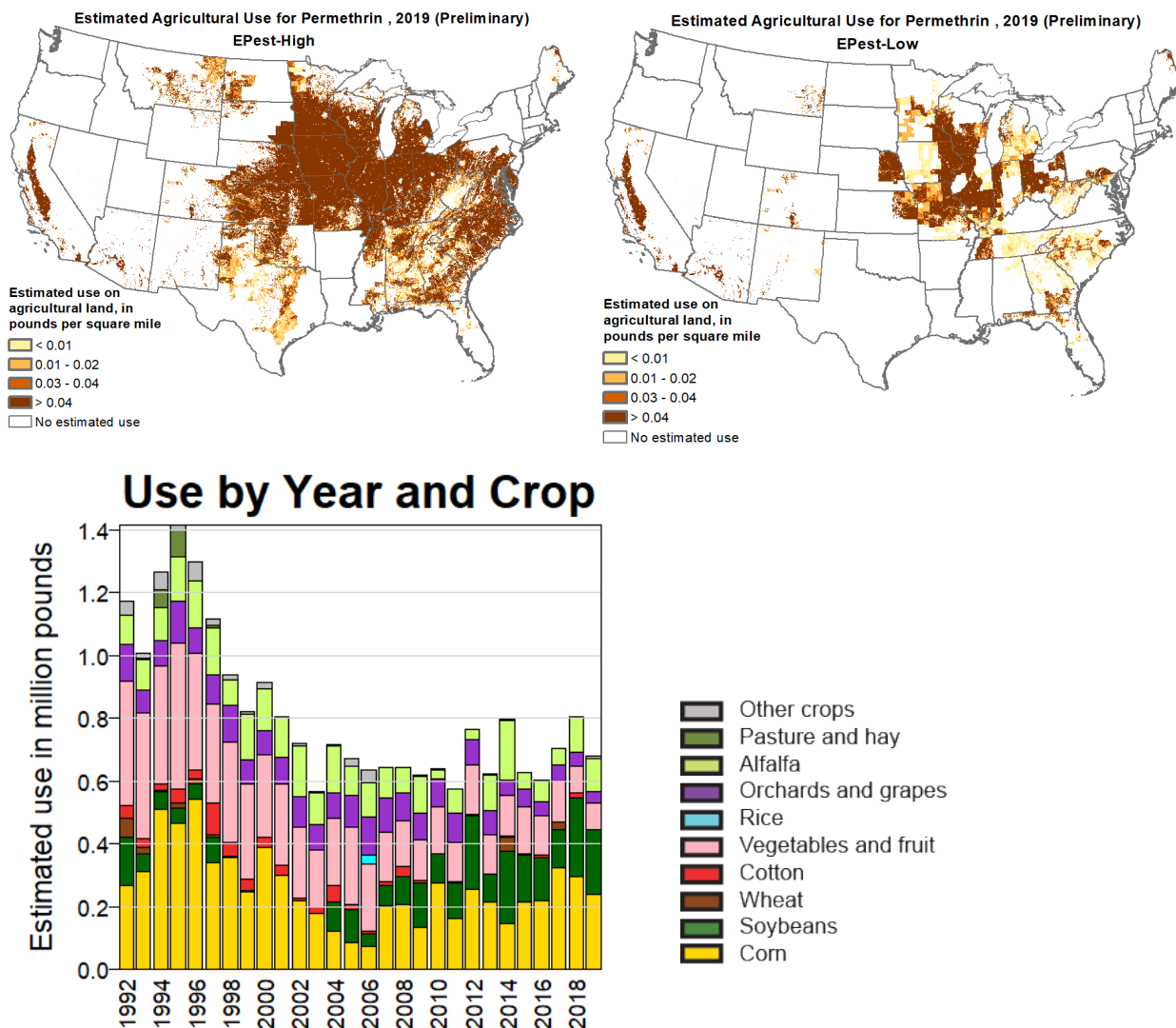
The National Center for Food and Agricultural Policy (NCFAP) maintains a national Pesticide Use Database, primarily for herbicides. Pesticide use estimates are based on state-level commercial agriculture usage patterns and state-level crop acreage. NCFAP listed uses of permethrin on 42 crops totaling approximately 1.07 million pounds active ingredient per year in 46 states in 1992. In 1997, NCFAP listed uses of permethrin on 39 crops totaling approximately 1.07 million pounds active ingredient per year in 48 states (NCFAP, 2000).

United States Geological Survey (USGS) Pesticide Use Maps

The United States Geological Survey (USGS) produces estimates of annual national pesticide use for over 200 compounds. USGS pesticide use maps show the average annual pesticide use intensity expressed as average weight (in pounds) of a pesticide applied to each square mile of agricultural land in a county. The USGS maps are created using data from NCFAP and county-level information on harvested crop acreage from the Census of Agriculture (USGS, 2023).

Exhibit 8-5 shows the geographic distribution of estimated annual permethrin use in the United States in 2019. The differences between the “low” and “high” estimates primarily reflect assumptions made when data on usage of a pesticide were unavailable from a crop reporting district (i.e., an assumption of no pesticide usage or an assumption that usage was comparable to neighboring districts). A breakdown of use by crop from year to year is also included below, using the “high” assumption. Permethrin usage declined from the mid-1990s to the mid-2000s and has held fairly steady since then in the range of around 600,000 to 800,000 pounds annually. Permethrin has been applied to a variety of crops, including corn, vegetables and fruit, alfalfa, orchards and grapes, and (increasingly in recent years) soybeans. The maps indicate that permethrin is most intensively used in the Midwest and in California’s Central Valley, and possibly even more widely, including in the South and the lower Great Plains (USGS, 2023).

Exhibit 8-5: Estimated Annual Agricultural Use of Permethrin, 2019



Source: USGS, 2023

8.2.2 Environmental Fate

As discussed in Chapter 2, the measures used by the EPA to assess mobility include (where available) the organic carbon partitioning coefficient (K_{oc}), log octanol-water partitioning coefficient ($\log K_{ow}$), Henry's Law Constant (K_H), water solubility, and vapor pressure. A vapor pressure of 5.18×10^{-8} mm Hg at 25 degrees C indicates that permethrin will exist in both the vapor phase and the particulate phase if it is released to the atmosphere. Vapor phase permethrin will degrade in the atmosphere due to reactions with photochemically-produced hydroxyl radicals and ozone, with estimated half-lives of 17 hours and 49 days, respectively. K_{oc} values of 10,471-86,000 L/kg suggest that permethrin will be of low mobility in soil. Permethrin will volatilize only slowly from dry soil surfaces and with a K_H of 1.9×10^{-6} atm-m³/mol at 25 degrees C, volatilization from water is expected to be slow (NCBI, 2023).

Permethrin is expected to be readily biodegradable. The half-life of permethrin in sediment/seawater is <2.5 days, with no change in permethrin concentration for 4 weeks under sterilized conditions, while the half-life of permethrin in a model ecosystem at 15-19 °C and a pH of 7.7 was 1.1-3.6 days. The United States Department of Agriculture (USDA) Pesticide Database reports an aerobic soil half-life of permethrin of 4-40 days (ATSDR, 2003).

At pH 5 and 7, permethrin is stable to hydrolysis, but at pH 9, the hydrolysis half-life is approximately 50 days. The cis- and trans- isomers of permethrin have photolysis half-lives of 27.1 and 19.6 hours, respectively. Bioconcentration of permethrin in aquatic organisms is expected to occur; however, the presence of dissolved organic matter in the water column may affect this process (ATSDR, 2003).

8.3 Health Effects

8.3.1 Health Assessment Identification

Permethrin is a currently registered pesticide chemical under the EPA's Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (USEPA, 2020a). For currently registered pesticide chemicals, the RD 5 Protocol provides that toxicity information from EPA OPP Health Effects Division (HED) Human Health Risk Assessments (HHRAs) are to be used as the basis for calculating health reference levels (HRLs). (See Section B.5.1.1 of the RD 5 Protocol, found in Appendix B of this document.) Therefore, the EPA reviewed the toxicity information in the HHRA for permethrin (USEPA, 2020a; USEPA, 2020b). The OPP health assessment provides a toxicity value relevant to chronic oral toxicity and was published prior to the cutoff date of January 2023.

Exhibit 8-6 provides a summary overview of the OPP health assessment data reviewed and selected for permethrin under RD 5.

Exhibit 8-6: OPP Health Assessment Supporting Current FIFRA Registration for Permethrin

Health Assessment ^a	Oral Reference Value	POD Type	Noncancer Critical Study	Oral Cancer Slope Factor	Cancer Critical Study	Cancer Descriptor
<i>EPA OPP Human Health Risk Assessment^b (USEPA, 2020a; USEPA, 2020b)</i>	<i>0.44^c</i>	<i>BMDL_{1SD}</i>	<i>Wolansky et al. (2006)</i>	–	–	S ^d

Notes: POD = point of departure; BMDL_{1SD} = lower bound of the 95 percent confidence interval on the benchmark dose associated with a difference of one standard deviation from controls; dash (–) = not applicable.

^a Selected health assessment and chronic toxicity value and supporting information are bolded and italicized.

^b The EPA OPP considers this health assessment “final” at the time of publication in the Federal Register.

^c The oral reference value, in units of mg/kg/day, is an acute population-adjusted dose (aPAD). Because repeated exposure does not result in a POD lower than that resulting from acute exposure, the aPAD is protective of chronic dietary risk and no chronic oral reference value was derived (USEPA, 2020b).

^d This “Sufficient evidence of carcinogenic potential” cancer descriptor was determined by following the process described in the EPA's 2005 *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005).

8.3.2 Health Assessment Selection

The health assessment selected for permethrin under RD 5 is the 2020 EPA OPP HHRA (USEPA 2020a; USEPA, 2020b) because it supported the most recent FIFRA registration

decision for permethrin. See Section B.5.1.2 of the RD 5 Protocol, in Appendix B of this document, for the decision logic that was applied to health assessment selection for RD 5 chemicals.

8.3.3 Health Reference Level (HRL) Development

HRLs are non-regulatory health-based toxicity values, expressed as concentrations in drinking water, that are used by the Agency to evaluate occurrence data for a contaminant when making decisions about regulatory determinations. See Section B.6.1.1 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA's approach for deriving HRLs for chemicals.

8.3.3.1 Oral Reference Value

In the 2020 EPA OPP HHRA (USEPA, 2020b), OPP selected an acute gavage study in rats (Wolansky et al., 2006) as the critical study to derive the oral reference value. In this study, male Long Evans rats (60-66 days old) were administered single doses of permethrin. There were nine doses, ranging from 0.1 to 200 mg/kg, plus a control group receiving the corn oil vehicle only (8-18 animals per dose group). After dosing, motor function was measured for one hour using maze tests. Wolansky et al. (2006) reported that the permethrin dose associated with a 30% decrease in motor activity (ED₃₀) was 42.66 mg/kg, with a standard error of ± 3.58 mg/kg and a 95 percent confidence interval (CI) of 35.60 to 49.70 mg/kg. They also reported a threshold dose (i.e., the highest dose level with no effect on activity observed) of 16.99 mg/kg, with a standard error of ± 3.82 mg/kg and a 95 percent CI of 9.50 to 24.48 mg/kg. Based on the statistically significant dose-related decreases in motor activity demonstrated in the Wolansky et al. (2006) study, OPP calculated a benchmark dose associated with one standard deviation difference from controls (BMD_{1SD}) of 63 mg/kg, and a lower bound of the 95 percent confidence interval on the BMD_{1SD} (BMDL_{1SD}) of 44 mg/kg (USEPA, 2020b).

The 44 mg/kg BMDL_{1SD} for decreased motor activity in rats orally exposed to permethrin (Wolansky et al., 2006) was identified by OPP as the critical effect and point of departure (POD) for dietary exposure, as this was the most sensitive endpoint available (USEPA, 2020b). Available data indicate that increased duration of exposure does not result in increasing toxicity; therefore the risk estimates derived from use of the acute study are protective of repeated/chronic exposures (USEPA, 2020b). A total uncertainty factor (UF) of 100 was applied to the POD: an intraspecies UF (UF_H) of 10 and an interspecies UF (UF_A) of 10. After applying the total UF, the oral reference value (an acute population-adjusted dose, or aPAD) was calculated to be 0.44 mg/kg/day (USEPA, 2020b). Following the approach described in the EPA's 2005 *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005), OPP classified permethrin as having "Suggestive Evidence of Carcinogenic Potential" based on lung adenomas in female mice. However, as noted above, the quantification of risk using a non-linear approach based on the acute toxicity data adequately accounts for all chronic toxicity, including carcinogenicity, that could result from exposure to permethrin (USEPA, 2020b). Therefore, the EPA selected this oral reference value (0.44 mg/kg/day) from the 2020 EPA OPP HHRA (USEPA, 2020b) to derive an HRL for permethrin.

8.3.3.2 Exposure Factor Selection

In prioritizing the contaminants of greatest public health concern for regulatory determination, Section 1412(b)(1)(C) of Safe Drinking Water Act (SDWA) requires the Agency

to consider “among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water compared to the general population.” One way that the EPA considers potentially sensitive populations or life stages (i.e., populations or life stages that may be more susceptible or sensitive to a chemical exposure) is during the selection of exposure factors (EFs) for the development of HRLs.

Drinking water intake rate adjusted for body weight (DWI-BW) is the EF used to derive HRLs for RD 5 (USEPA, 2019). EFs are input values intended to protect the general population, including sensitive populations or life stages, from adverse effects resulting from exposure to a contaminant. The Agency selects an appropriate DWI-BW for each chemical by reviewing the critical effect and study used for HRL derivation and identifying the interval of exposure (for example, see USEPA, 2022c; USEPA, 2022d). Since the critical effect represents the most sensitive adverse effect observed in the best available studies for a given chemical, it is reasonable to assume that the interval of exposure in the critical study could inform the selection of a DWI-BW protective of sensitive populations. When multiple potentially sensitive populations or life stages are identified based on the interval of exposure in the study used for HRL derivation, the EPA selects the population or life stage with the highest DWI-BW because it is the most health protective. See Section B.6.1.2 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA’s EF selection process.

In the critical study (Wolansky et al., 2006) selected for the 2020 EPA OPP HHRA (USEPA, 2020b), rats were approximately nine weeks old when they were acutely exposed to single doses of permethrin. Following the decision logic described in Section B.6.1.2 of the RD 5 Protocol, the EPA selected a corresponding human life stage. Six-week-old rats are in the developmental stage approximately corresponding to a human life stage between juvenile or later childhood and adolescence (Ghasemi et al., 2021; Wang et al., 2020). For the purpose of evaluating environmental exposures, the EPA defines childhood in humans as the period from conception through adolescence, until 21 years of age (USEPA, 2021). Therefore, the EPA used the DWI-BW representing the 90th percentile consumers-only, two-day average, direct and indirect community water consumption for children (birth to < 21 years), which equals 0.0343 L/kg/day (USEPA, 2019), to derive the HRL for permethrin.

8.3.3.3 Relative Source Contribution

Relative source contribution (RSC) is used to account for exposure via non-drinking water routes when deriving health-based drinking water concentrations for contaminants with threshold effects (noncarcinogens and nonlinear carcinogens). RSC is defined as the portion (percentage) of an individual’s exposure attributed to drinking water rather than other sources (e.g., food, ambient air). A 20 percent RSC is used for all RD 5 contaminants, consistent with past practice for regulatory determinations, to derive the HRL because (1) HRLs are developed prior to completing the exposure assessment; and (2) a 20 percent RSC is the lowest RSC that can be applied for deriving health-based drinking water concentrations according to EPA guidance (USEPA, 2000), and it therefore produces the most health protective HRL. Should a contaminant proceed to a National Primary Drinking Water Regulation (NPDWR), a full exposure analysis is conducted, and an RSC is derived following the Exposure Decision Tree approach described in the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000).

8.3.3.4 HRL Calculation

Exhibit 8-7 summarizes the critical study and toxicity information from the qualifying health assessment and the EF (DWI-BW) and RSC that the EPA used to derive the HRL for permethrin.

Exhibit 8-7: Basis of HRL for Permethrin

Selected Health Assessment	Critical Study	Interval of Exposure	Critical Effect	Oral Toxicity Value	RSC	Target Population	Exposure Factor
EPA OPP Human Health Risk Assessment (USEPA, 2020a; USEPA, 2020b)	Wolansky et al. (2006)	Acute (single dose); beginning at approximately 9 weeks of age	Decreased motor activity	0.44 mg/kg/day	0.2 (20%)	Children (birth to <21 years)	0.0343 L/kg/day

The EPA calculates HRLs for contaminants with a threshold dose-response, including permethrin, as follows:

$$HRL = \frac{RfD}{DWI-BW} * RSC$$

where:

RfD = Reference dose (mg/kg/day), an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. It is derived in the selected qualifying health assessment and is based on the critical effect and study identified in that assessment. Other values that can be used in place of an RfD in this equation can include a maximum acceptable concentration (MAC), minimal risk level, point of departure / uncertainty factor (POD/UF), population-adjusted dose (PAD), or tolerable daily intake (TDI).

DWI-BW = Drinking water intake (DWI), adjusted for body weight (BW), in units of liter per kilogram body weight per day (L/kg/day).

RSC = Relative source contribution, the percentage of the total exposure attributed to drinking water sources (USEPA, 2000), where the remainder of the exposure is allocated to other routes or sources. For HRL derivation in RD 5, an RSC of 20 percent is used for all contaminants.

Using an oral reference value of 0.44 mg/kg/day (USEPA, 2020a; USEPA, 2020b), a DWI-BW of 0.0343 L/kg/day (USEPA, 2019) and a 20 percent RSC to account for non-drinking-water sources of exposure (USEPA, 2000), the HRL for permethrin is calculated as follows:

$$HRL = \frac{0.44 \text{ mg/kg/day}}{0.0343 \text{ L/kg/day}} * 0.2$$

$$HRL = 2.566 \text{ mg/L}$$

or

$$HRL = 2566 \mu\text{g/L}$$

Following HRL derivation practices, the HRL for permethrin is 3,000 $\mu\text{g/L}$ after rounding to one significant figure.

8.4 Occurrence

This section presents data on the occurrence of permethrin in ambient water and drinking water in the United States. As described in Section 8.3, an HRL of 3,000 $\mu\text{g/L}$ was calculated for permethrin based on non-carcinogenic effects. HRLs are risk-derived concentrations against which the EPA evaluates the occurrence data to determine if contaminants occur at levels of potential public health concern. Occurrence data from various sources presented below are analyzed with respect to the HRL and one-half the HRL. When possible, estimates of the population exposed at concentrations above the HRL and one-half the HRL are presented.

For additional background information about data sources used to evaluate occurrence, please refer to Chapter 2.

8.4.1 Occurrence in Ambient Water

Lakes, rivers, and aquifers are the ambient sources of most drinking water. Contaminant occurrence in ambient water provides information on the potential for contaminants to adversely affect drinking water supplies. Occurrence data for permethrin in ambient water are available from the USGS National Water-Quality Assessment (NAWQA) program, the USGS National Water Information System (NWIS) database, the EPA's legacy Storage and Retrieval Data System (STORET), and several published studies. When sources of information on ambient occurrence also include limited finished water data, those finished water data are summarized here as well.

8.4.1.1 United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) Ambient Water Analyses

USGS instituted the NAWQA program in 1991 to examine ambient water quality status and trends in the United States. The NAWQA program generates high quality contaminant occurrence and other water quality parameter data for significant watersheds and aquifers across the nation. The program collects data on surface water and groundwater chemistry, hydrology, land use, stream habitat, and aquatic life in parts of nearly all 50 states. The program is designed to apply nationally consistent methods to provide a uniform basis for contaminant occurrence comparisons and assessments among study basins across the country and over time. The occurrence assessments can also serve to facilitate interpretation of natural and anthropogenic factors affecting national water quality. For more detailed information on NAWQA program design and implementation, refer to Leahy and Thompson (1994) and Hamilton et al. (2004).

The process of sampling, analysis, and data synthesis is divided into cycles of approximately ten years: Cycle 1 covered 1991-2001, Cycle 2 covered 2002-2012, and Cycle 3 covered 2013-2023. Study units are sampled and analyzed on a staggered schedule within each cycle. Each NAWQA cycle begins with a two-year startup phase for planning and retroactive analysis, followed by a three-year intensive data collection phase, and finally a five-year phase

for analyzing the data, developing reports, and continuing a low level of monitoring (NRC, 2012).

The EPA downloaded NAWQA data from the Water Quality Portal (WQP) in September 2023 (WQP, 2023). The EPA's analysis of the NAWQA data is a simple, non-parametric occurrence analysis that provides summary statistics to characterize contaminant occurrence. The EPA included in the analysis all samples that could be classified as groundwater and surface water, and also the limited number of samples labeled as finished water. Other types of samples (e.g., from soil, sediment, and wastewater) were excluded. The EPA calculated detection frequencies as the percentage of samples and the percentage of sites with at least one detection. (A detection is an analytical result equal to or greater than the reporting level.) No weighting was applied. The EPA determined the minimum and maximum detected concentrations and calculated other descriptive statistics including the median, 90th percentile, and 99th percentile concentrations (based only on samples with detections). Reporting levels varied over time during the NAWQA program.

The results of the EPA's analysis of NAWQA data downloaded from WQP are presented in Exhibit 8-8 through Exhibit 8-10. The data available include only surface water monitoring from Cycle 2 and Cycle 3. There were no detections in Cycle 2. In Cycle 3, permethrin was detected in 2 (3.33 percent) of 60 surface water samples. The highest concentration observed, 0.01 µg/L, is less than ½ the HRL of 3,000 µg/L.

Note that there may be some overlap between the NAWQA data assessment presented here and summaries of individual NAWQA studies presented below.

Exhibit 8-8: Permethrin NAWQA Data – Summary of Detected Concentrations

Site Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90 th Percentile	99 th Percentile	Maximum
Cycle 2 (2002 - 2012)					
Groundwater	--	--	--	--	--
Surface Water	--	--	--	--	--
All Sites	--	--	--	--	--
Cycle 3 (2013 - 2023)					
Groundwater	--	--	--	--	--
Surface Water	0.0077	0.00885	0.00954	0.00995	0.01
All Sites	0.0077	0.00885	0.00954	0.00995	0.01

Source: WQP, 2023

-- = No data or detections in this category

Exhibit 8-9: Permethrin NAWQA Data – Summary of Samples

Site Type	No. of Samples	Detection Frequency (detections are results $\geq$ reporting level)					
		No. of Samples with Detections	Percent Samples with Detections	No. of Samples with Detections $> \frac{1}{2}$ HRL	Percent Samples with Detections $> \frac{1}{2}$ HRL	No. of Samples with Detections $>$ HRL	Percent Samples with Detections $>$ HRL
Cycle 2 (2002 - 2012)							
Groundwater	0	0	n/a	0	n/a	0	n/a
Surface Water	2	0	0.00%	0	0.00%	0	0.00%
All Sites	2	0	0.00%	0	0.00%	0	0.00%
Cycle 3 (2013 - 2023)							
Groundwater	0	0	n/a	0	n/a	0	n/a
Surface Water	60	2	3.33%	0	0.00%	0	0.00%
All Sites	60	2	3.33%	0	0.00%	0	0.00%

Source: WQP, 2023

Exhibit 8-10: Permethrin NAWQA Data – Summary of Sites

Site Type	No. of Sites	Detection Frequency (detections are results $\geq$ reporting level)					
		No. of Sites with Detections	Percent Sites with Detections	No. of Sites with Detections $> \frac{1}{2}$ HRL	Percent Sites with Detections $> \frac{1}{2}$ HRL	No. of Sites with Detections $>$ HRL	Percent Sites with Detections $>$ HRL
Cycle 2 (2002 - 2012)							
Groundwater	0	0	n/a	0	n/a	0	n/a
Surface Water	2	0	0.00%	0	0.00%	0	0.00%
All Sites	2	0	0.00%	0	0.00%	0	0.00%
Cycle 3 (2013 - 2023)							
Groundwater	0	0	n/a	0	n/a	0	n/a
Surface Water	11	2	18.18%	0	0.00%	0	0.00%
All Sites	11	2	18.18%	0	0.00%	0	0.00%

Source: WQP, 2023

NAWQA Pesticide National Synthesis Project, 1992-2001

The NAWQA Pesticide National Synthesis Project is a national-scale assessment of the occurrence and behavior of pesticides in streams and groundwater of the United States and the potential for pesticides to adversely affect drinking water supplies or aquatic ecosystems. The Pesticide National Synthesis analysis is based on Cycle 1 data from NAWQA study units (Gilliom et al., 2007). Cycle 1 began in 1991, and the date range of the data is given as 1992-2001. Data for surface water and groundwater are presented separately, and results in each category are subdivided by land use category. Land use categories include agricultural, urban, mixed (deeper aquifers of regional extent in the case of groundwater), and undeveloped.

Over the course of Cycle 1, some NAWQA analytical methods were improved or changed. Hence, detection thresholds varied over time for some compounds. USGS used the

maximum Long-Term Method Detection Level (LT-MDL) for each analyte as a uniform reporting threshold. The maximum LT-MDL for cis-permethrin was 0.003 µg/L (Gilliom et al., 2007).

In NAWQA stream samples (Exhibit 8-11), cis-permethrin was found at frequencies of 0 percent of samples in undeveloped areas, 0 percent of samples in urban areas, 0.053 percent of samples in mixed land use settings, and 0.018 percent of samples in agricultural settings. The 95th percentile concentration was less than the maximum LT-MDL in all settings. The highest surface water concentration was 0.019 µg/L.

Exhibit 8-11: USGS National Synthesis Summary of NAWQA Monitoring of cis-Permethrin in Streams, 1992-2001

Land Use Type	Number of Sites	Number of Samples	Detection Frequency (Samples)	Concentration Values (among all samples, in µg/L)		
				Median	95 th Percentile	Maximum
Agricultural	83	2,003	0.18%	ND	ND	0.019
Mixed	65	1,385	0.53%	ND	ND	0.013
Undeveloped	8	144	0.00%	ND	ND	ND
Urban	30	813	0.00%	ND	ND	ND

Source: Gilliom et al., 2007

ND = not detected (concentration is less than the maximum LT-MDL and is expected to be less than any higher percentile concentration shown in the table).

In NAWQA groundwater samples (Exhibit 8-12), cis-permethrin was found at frequencies of 0 percent of samples in undeveloped areas, 0 percent in mixed land use settings, 0% in urban areas, and 0.14 percent in agricultural settings. The 95th percentile concentrations were less than the maximum LT-MDL in all settings. The highest groundwater concentration was 0.007 µg/L.

Exhibit 8-12: USGS National Synthesis Summary of NAWQA Monitoring of cis-Permethrin in Groundwater, 1992-2001

Land Use Type	Number of Wells	Detection Frequency	Concentration Values (among all samples, in µg/L)		
			Median	95 th Percentile	Maximum
Agricultural	1402	0.14%	ND	ND	0.007
Mixed	2728	0.00%	ND	ND	ND
Undeveloped	34	0.00%	ND	ND	ND
Urban	855	0.00%	ND	ND	ND

Source: Gilliom et al., 2007

ND = not detected (concentration is less than the maximum LT-MDL and is expected to be less than any higher percentile concentration shown in the table).

8.4.1.2 National Water Information System (NWIS) Data

NWIS is the nation’s principal repository of water resources data collected by USGS from more than 1.9 million sites in all U.S. states and territories (USGS, 2022). All USGS water quality and flow data are stored in NWIS, including site characteristics, streamflow, groundwater level, precipitation, and chemical analyses of water, sediment, and biological media, though not all parameters are available for every site. NWIS houses the NAWQA data and includes other USGS data from a range of unspecified projects. NWIS encompasses many more samples at many more sites than are involved in the NAWQA Program. Although NWIS is comprised of primarily ambient water data, some finished drinking water data are included as well. This section presents analyses of non-NAWQA data in NWIS, downloaded from the WQP in September 2023 (WQP, 2023). These data do not overlap with the NAWQA results presented above.

The results of the non-NAWQA NWIS permethrin analysis are presented in Exhibit 8-13. Permethrin was detected in approximately 0.46 percent of samples (6 of 1,312 samples) and at approximately 1.4 percent of sites (5 of 357 sites). There were no detections in groundwater. The highest concentration found in surface water, 0.0146 µg/L, was less than ½ the HRL of 3,000 µg/L.

Exhibit 8-13: Permethrin NWIS Data, 1991-2023

Sample Media Type	Detection Frequency (detections are results ≥ reporting level)				Concentration Values (of detections, in µg/L)				
	No. of Samples	No. of Samples with Detections	No. of Sites	No. of Sites with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
Groundwater	30	0	23	0	--	--	--	--	--
Surface Water	1,282	6	334	5	0.0044	0.0053	0.0108	0.0142	0.0146
Total	1,312	6	357	5	0.0044	0.0053	0.0108	0.0142	0.0146

Source: WQP, 2023

-- = No detections in this category

Note that some NWIS sites are associated with multiple sample media types, so site counts might not add up to totals.

8.4.1.3 Storage and Retrieval (STORET) Data / Water Quality Portal (WQP)

From its launch in 1999 until it was decommissioned in June 2018, the EPA’s STORET Data Warehouse was collaboratively populated with raw biological, chemical, and physical data from surface water and groundwater sampling by federal, state and local agencies, Native American Tribes, volunteer groups, academics, and others. Legacy STORET data, as well as more current STORET data, are accessible through the WQP.

STORET data are from monitoring locations in all 50 states as well as multiple territories and jurisdictions of the United States. STORET’s data quality limitations include variations in the extent of national coverage and data completeness from parameter to parameter. Data may have been collected as part of targeted, rather than randomized, monitoring. This section presents analyses of STORET data, downloaded from the WQP in September 2023 (WQP, 2023). The EPA reviewed STORET groundwater data from wells and springs and surface water data from lakes, rivers/streams, and reservoirs. The STORET data set also included limited data from

public water systems (PWSs). The database does not specify whether PWS sampling was conducted before or after treatment.

The results of the STORET analysis for permethrin are presented in Exhibit 8-14 through Exhibit 8-16. Samples were collected between 1994 and 2022. Of the 772 samples collected from 295 sites, permethrin was detected in 1 (0.13 percent of samples). The single surface water detection had a permethrin concentration of 0.348 µg/L, which is below ½ the HRL of 3,000 µg/L. STORET included no PWS samples for permethrin.

Exhibit 8-14: Permethrin STORET Data – Summary of Detected Concentrations

Source Water Type	Concentration Value of Detections (µg/L)			
	Minimum	Median	90 th Percentile	Maximum
Groundwater	--	--	--	--
Surface Water	0.348	0.348	0.348	0.348
Total	0.348	0.348	0.348	0.348

Source: WQP, 2023

-- = No detections in this category

Exhibit 8-15: Permethrin STORET Data – Summary of Samples and Sites

Source Water Type	Total Number of Samples	Samples with Detections		Total Number of Sites	Sites with Detections	
		Number	Percent		Number	Percent
Groundwater	34	0	0.00%	24	0	0.00%
Surface Water	738	1	0.14%	271	1	0.37%
Total	772	1	0.13%	295	1	0.34%

Source: WQP, 2023

Exhibit 8-16: Permethrin STORET Data – Summary of States

Source Water Type	Total Number of States	States with Detections	
		Number	Percent
Groundwater	3	0	0%
Surface Water	9	1	11%
Total¹	9	1	11%

Source: WQP, 2023

¹ The number of states with groundwater data plus the number of states with surface water data may not equal the "Total" number of states providing data because some states provided both groundwater and surface water data.

8.4.1.4 Additional Ambient Water Studies

Kingsbury et al. (2021) evaluated groundwater-quality samples collected from 2017 to 2019 as part of the third cycle of USGS's NAWQA Program. Six types of well network studies

were conducted: principal aquifer study networks; major aquifer study networks; land-use study networks; vertical flow-path study networks; enhanced trends networks; and modeling support studies. The reporting level used for cis-permethrin was 0.0021 µg/L. cis-Permethrin was detected in 1 of 462 samples with a detected concentration of 0.163 µg/L. The reporting level used for trans-permethrin was 0.0019 µg/L. trans-Permethrin was detected in 3 of 463 samples with detected concentrations ranging from 0.00564 µg/L to 0.183 µg/L.

Erickson et al. (2019) conducted a study to assess groundwater quality in the United States glacial aquifer system using groundwater samples gathered from approximately 39,000 wells from 2005 to 2013. Data were derived from three sources: the USGS NWIS, the EPA's Safe Drinking Water Information System (SDWIS), and numerous agencies and organizations at the state, regional, and local level. No detections of cis-permethrin exceeded the "high" benchmark of 4 µg/L or the "moderate" benchmark of 0.4 µg/L in 1,532 analyses. trans-Permethrin was also included in the study, but results were not presented due to insufficient data.

8.4.2 Occurrence in Drinking Water

Data sources reviewed by the Agency for information on contaminant occurrence in drinking water included: the EPA's first, second, third, and fourth Unregulated Contaminant Monitoring Rules (UCMR 1, UCMR 2, UCMR 3, UCMR 4); Rounds 1 and 2 of the Agency's Unregulated Contaminant Monitoring (UCM) program that preceded the Unregulated Contaminant Rule (UCMR); the EPA's National Inorganics and Radionuclides Survey (NIRS); and a range of others as discussed in Chapter 2. Among the sources reviewed, the following sources had data and information on permethrin occurrence in drinking water and are discussed in this section:

- The EPA's Fourth Unregulated Contaminant Monitoring Rule (UCMR 4).
- State drinking water monitoring programs.
- Consumer Confidence Reports (CCRs) from PWSs.
- National Pesticide Survey (NPS).
- USGS Pilot Monitoring Program (PMP).
- Additional source water and drinking water studies.

Note that there may be some overlap as sources with different purposes and audiences may have reported the same underlying data. UCMR 4 is a nationally representative data source. Other data sources profiled in this section are considered "supplemental" sources. Also note that the ambient water section, above, presents some limited finished water data and miscellaneous data from PWSs found in ambient water data sources.

8.4.2.1 Primary Data Sources

8.4.2.1.1 *The EPA's Fourth Unregulated Contaminant Monitoring Rule (UCMR 4), 2018-2020*

The UCMR program was designed to provide a national assessment of the occurrence of select unregulated contaminants in PWSs. UCMR 4 was published on December 20, 2016 (USEPA, 2016a) and required monitoring for 30 chemical contaminants between 2018 and 2020. Data reporting continued into 2021.

UCMR 4 Assessment Monitoring occurrence data are available for permethrin. For UCMR 4, all large and very large community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) (serving between 10,001 and 100,000 people and serving more than 100,000 people, respectively), plus a statistically representative national sample of 800 small CWSs and NTNCWSs (serving 10,000 people or fewer), were required to conduct Assessment Monitoring during a 12-month period between January 2018 and December 2020.¹ Surface water and groundwater under the direct influence of surface water (GWUDI) sampling points were monitored four times during the applicable year of monitoring. Groundwater sampling points were monitored twice during the applicable year of monitoring. See USEPA (2016a) and USEPA (2024a) for more information on the UCMR 4 study design and data analysis.

The design of UCMR 4 permits estimation of national occurrence by multiplying the total number of systems (or population served) in the nation in a system size category by the percent of systems (or population served) found to exceed a specified threshold in the sample. This extrapolation methodology is applied to small systems. Because all large and very large systems were required to participate in the UCMR 4 Assessment Monitoring, national occurrence estimates in these size categories can be developed using survey census figures rather than extrapolation. Total national occurrence is estimated by summing the extrapolated figures for small systems and the census figures for the large and very large systems.

Exhibit 8-17 through Exhibit 8-21 provide an overview of permethrin occurrence results from UCMR 4 Assessment Monitoring. The minimum reporting level (MRL) used for permethrin in the UCMR 4 survey was 0.04 µg/L. Exhibit 8-17 shows a statistical summary of permethrin concentrations by system size and source water type (including the minimum, median, 90th percentile, 99th percentile, and maximum). Exhibit 8-18 presents a sample-level summary of the results. Exhibit 8-19 through Exhibit 8-21 show system-level results, including national extrapolations, at three thresholds: detections, ½ the HRL, and the HRL. Detections are evaluated on a “greater than or equal to” basis ($\geq$ the MRL), while health-based thresholds are evaluated in terms of exceedances ($> \frac{1}{2}$ HRL and $>$ HRL).

As a reminder that the figures from large and very large systems represent a census of systems in those categories, results in those categories are labeled “CENSUS” in the exhibits below. No extrapolation was necessary in these categories, as it was for the small systems, to derive national estimates of occurrence. National estimates of occurrence are reported separately in each system size and source water category, and also in the aggregate.

A total of 37,291 UCMR 4 samples for permethrin were collected from 5,028 systems. Permethrin was detected in sixteen samples (0.04 percent), with concentrations ranging from 0.04 µg/L to 0.212 µg/L. The detections were found at thirteen systems, representing 0.26 percent of systems participating in the monitoring program. Extrapolating these findings suggests that an estimated 116 PWSs serving almost 1.5 million people nationally have detectable levels of permethrin. There were no exceedances of the HRL or ½ the HRL.

¹ Only 797 small systems submitted results for permethrin.

Exhibit 8-17: Permethrin Occurrence Data from UCMR 4 Assessment Monitoring – Summary of Reported Concentrations

Source Water Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90th Percentile	99th Percentile	Maximum
Small Systems (serving ≤ 10,000 people)					
Groundwater	0.047	0.047	0.047	0.047	0.047
Surface Water	--	--	--	--	--
All Small Systems	0.047	0.047	0.047	0.047	0.047
Large Systems (serving 10,001 - 100,000 people) -- CENSUS					
Groundwater	--	--	--	--	--
Surface Water	0.04	0.0464	0.0802	0.0818	0.082
All Large Systems	0.04	0.0464	0.0802	0.0818	0.082
Very Large Systems (serving > 100,000 people) -- CENSUS					
Groundwater	0.0559	0.164	0.202	0.211	0.212
Surface Water	0.048	0.057	0.064	0.066	0.066
All Very Large Systems	0.048	0.066	0.193	0.210	0.212
All Systems					
All Water Systems	0.04	0.0496	0.123	0.205	0.212

Source: USEPA, 2024a

"--" = No detections in this category

Exhibit 8-18: Permethrin National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of Samples

Source Water Type	Total # of Samples	Samples with Detections ≥ MRL (0.04 µg/L)		Samples with Detections > ½ HRL (1,500 µg/L)		Samples with Detections > HRL(3,000 µg/L)	
		Number	Percent	Number	Percent	Number	Percent
Small Systems (serving ≤ 10,000 people)							
Groundwater	1,896	1	0.05%	0	0.00%	0	0.00%
Surface Water	1,360	0	0.00%	0	0.00%	0	0.00%
All Small Systems	3,256	1	0.03%	0	0.00%	0	0.00%
Large Systems (serving 10,001 - 100,000 people) -- CENSUS							
Groundwater	10,954	0	0.00%	0	0.00%	0	0.00%
Surface Water	15,711	10	0.06%	0	0.00%	0	0.00%
All Large Systems	26,665	10	0.04%	0	0.00%	0	0.00%
Very Large Systems (serving > 100,000 people) -- CENSUS							
Groundwater	2,057	3	0.15%	0	0.00%	0	0.00%
Surface Water	5,313	2	0.04%	0	0.00%	0	0.00%
All Very Large Systems	7,370	5	0.07%	0	0.00%	0	0.00%
All Systems							
All Water Systems	37,291	16	0.04%	0	0.00%	0	0.00%

Source: USEPA, 2024a

Exhibit 8-19: Permethrin National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population – All Reported Detections

Source Water Type	UCMR 4 Sample		Number With At Least One Detection ≥ MRL (0.04 µg/L)		Percent With At Least One Detection ≥ MRL (0.04 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection ≥ MRL (0.04 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	518	1,540,255	1	3,750	0.19%	0.24%	53,877	38,056,639	104	92,700
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	1	3,750	0.13%	0.13%	63,501	60,915,707	104	92,700
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,468	37,653,948	0	0	0.00%	0.00%	1,468	37,653,948	0	0
Surface Water	2,340	71,511,793	9	313,176	0.38%	0.44%	2,340	71,511,793	9	313,000
All Large Systems	3,808	109,165,741	9	313,176	0.24%	0.29%	3,808	109,165,741	9	313,000
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	1	157,609	1.45%	0.94%	69	16,759,675	1	158,000
Surface Water	354	120,303,825	2	901,442	0.56%	0.75%	354	120,303,825	2	901,000
All Very Large Systems	423	137,063,500	3	1,059,051	0.71%	0.77%	423	137,063,500	3	1,060,000
All Systems										
All Water Systems	5,028	249,079,866	13	1,375,977	0.26%	0.55%	67,732	307,144,948	116	1,460,000

Source: USEPA, 2024a

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

**Exhibit 8-20: Permethrin National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data –
Summary of System and Population Served Data – Detections > ½ the HRL (1,500 µg/L)**

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > ½ HRL (1,500 µg/L)		Percent With At Least One Detection > ½ HRL (1,500 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > ½ HRL (1,500 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,468	37,653,948	0	0	0.00%	0.00%	1,468	37,653,948	0	0
Surface Water	2,340	71,511,793	0	0	0.00%	0.00%	2,340	71,511,793	0	0
All Large Systems	3,808	109,165,741	0	0	0.00%	0.00%	3,808	109,165,741	0	0
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,028	249,079,866	0	0	0.00%	0.00%	67,732	307,144,948	0	0

Source: USEPA, 2024a

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

**Exhibit 8-21: Permethrin National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data –
Summary of System and Population Served Data – Detections > HRL (3,000 µg/L)**

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > HRL (3,000 µg/L)		Percent With At Least One Detection > HRL (3,000 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > HRL (3,000 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,468	37,653,948	0	0	0.00%	0.00%	1,468	37,653,948	0	0
Surface Water	2,340	71,511,793	0	0	0.00%	0.00%	2,340	71,511,793	0	0
All Large Systems	3,808	109,165,741	0	0	0.00%	0.00%	3,808	109,165,741	0	0
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,028	249,079,866	0	0	0.00%	0.00%	67,732	307,144,948	0	0

Source: USEPA, 2024a

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

8.4.2.2 Supplemental Data Sources

8.4.2.2.1 *State Monitoring Data, 1990-2022*

Because there is no available national database that receives and stores all relevant data regarding the occurrence of regulated and unregulated contaminants in public drinking water systems, the EPA gathered data from state drinking water monitoring websites in support of national occurrence assessments. Data were gathered from 38 states/entities. For 28 of the 38 states, data were available through the Drinking Water Watch (DWW) portal on the state's website. Available data for other states/entities that had been submitted to the EPA through the Second, Third, and Fourth Six-Year Review efforts (SYR2, SYR3, and SYR4) were also evaluated. As part of the Six-Year Reviews, some states submitted PWS occurrence data for unregulated contaminants along with requested data on regulated contaminants. For all rounds of the Six-Year Review, these unregulated data provide varying degrees of completeness in their coverage of the states/entities and are not necessarily representative of occurrence in those states/entities. For more details on data compiled under SYR2, SYR3, and SYR4, refer to USEPA (2009), USEPA (2016b), and USEPA (2024b), respectively.

Drinking water occurrence data for permethrin (mixed, cis, trans) were available on state websites from six states: California, Illinois, Louisiana, Montana, Nevada, and Vermont. Drinking water occurrence data for cis-permethrin were available from one state website: California. Drinking water occurrence data for trans-permethrin were available on state websites from two states: California and New Mexico. Results are presented in Exhibit 8-22 and Exhibit 8-23 for permethrin (mixed, cis, trans), Exhibit 8-24 and Exhibit 8-25 for cis-permethrin, and Exhibit 8-26 and Exhibit 8-27 for trans-permethrin. Results are broken down into two different time periods: 1990-2011 and 2012-2022. Comprehensive information about methods used and reporting levels is not available for the state data.

As noted above, the monitoring data from each state/entity are limited and not necessarily representative of occurrence in the state/entity. The number of PWSs per state with permethrin data ranges from only 1 PWS from a single state such as Vermont and others to 33 PWSs from California for cis-permethrin in the 2012-2022 time period. There was only one reported detection of permethrin. It was from Louisiana and was equal to 10 µg/L.

Exhibit 8-22: Permethrin (Mixed, Cis, Trans) State Drinking Water Occurrence Data – Summary of Samples

State (Date Range)	Source Water Type	Total Number of Samples	All Detections		Detections > ½ HRL (1,500 µg/L)		Detections > HRL (3,000 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
Date Range: 1990-2011								
California (2011)	Groundwater	5	0	0.00%	0	0.00%	0	0.00%
	Surface Water	5	0	0.00%	0	0.00%	0	0.00%
	Total	10	0	0.00%	0	0.00%	0	0.00%

State (Date Range)	Source Water Type	Total Number of Samples	All Detections		Detections > ½ HRL (1,500 µg/L)		Detections > HRL (3,000 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
Louisiana (2005)	Groundwater	1	1	100.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	1	1	100.00%	0	0.00%	0	0.00%
Nevada (2002-2009)	Groundwater	17	0	0.00%	0	0.00%	0	0.00%
	Surface Water	17	0	0.00%	0	0.00%	0	0.00%
	Total	34	0	0.00%	0	0.00%	0	0.00%
Vermont (2007)	Groundwater	1	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	1	0	0.00%	0	0.00%	0	0.00%
Date Range: 2012-2022								
California (2012-2014)	Groundwater	3	0	0.00%	0	0.00%	0	0.00%
	Surface Water	7	0	0.00%	0	0.00%	0	0.00%
	Total	10	0	0.00%	0	0.00%	0	0.00%
Illinois (2021)	Groundwater	1	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	1	0	0.00%	0	0.00%	0	0.00%
Montana (2016-2021)	Groundwater	3	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	3	0	0.00%	0	0.00%	0	0.00%
Nevada (2020-2021)	Groundwater	3	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	3	0	0.00%	0	0.00%	0	0.00%
Vermont (2017-2019)	Groundwater	3	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	3	0	0.00%	0	0.00%	0	0.00%

Source: Data provided to the EPA by states and downloaded by the EPA from state websites

Exhibit 8-23: Permethrin (Mixed, Cis, Trans) State Drinking Water Occurrence Data – Summary of Systems

State (Date Range)	Source Water Type	Total Number of Systems	Systems with Detections		Detections > ½ HRL (1,500 µg/L)		Detections > HRL (3,000 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
Date Range: 1990-2011								
California (2011)	Groundwater	2	0	0.00%	0	0.00%	0	0.00%
	Surface Water	1	0	0.00%	0	0.00%	0	0.00%
	Total	3	0	0.00%	0	0.00%	0	0.00%
Louisiana (2005)	Groundwater	1	1	100.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	1	1	100.00%	0	0.00%	0	0.00%
Nevada (2002-2009)	Groundwater	14	0	0.00%	0	0.00%	0	0.00%
	Surface Water	1	0	0.00%	0	0.00%	0	0.00%
	Total	15	0	0.00%	0	0.00%	0	0.00%
Vermont (2007)	Groundwater	1	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	1	0	0.00%	0	0.00%	0	0.00%
Date Range: 2012-2022								
California (2012-2014)	Groundwater	1	0	0.00%	0	0.00%	0	0.00%
	Surface Water	2	0	0.00%	0	0.00%	0	0.00%
	Total	3	0	0.00%	0	0.00%	0	0.00%
Illinois (2021)	Groundwater	1	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	1	0	0.00%	0	0.00%	0	0.00%
Montana (2016-2021)	Groundwater	1	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	1	0	0.00%	0	0.00%	0	0.00%
Nevada (2020-2021)	Groundwater	2	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	2	0	0.00%	0	0.00%	0	0.00%

State (Date Range)	Source Water Type	Total Number of Systems	Systems with Detections		Detections > ½ HRL (1,500 µg/L)		Detections > HRL (3,000 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
Vermont (2017-2019)	Groundwater	1	0	0.00%	0	0.00%	0	0.00%
	Surface Water	0	0	0.00%	0	0.00%	0	0.00%
	Total	1	0	0.00%	0	0.00%	0	0.00%

Source: Data provided to the EPA by states and downloaded by the EPA from state websites

Exhibit 8-24: cis-Permethrin State Drinking Water Occurrence Data – Summary of Samples

State (Date Range)	Source Water Type	Total Number of Samples	All Detections		Detections > ½ HRL (1,500 µg/L)		Detections > HRL (3,000 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
Date Range: 1990-2011								
California (2011)	Groundwater	27	0	0.00%	0	0.00%	0	0.00%
	Surface Water	9	0	0.00%	0	0.00%	0	0.00%
	Total	36	0	0.00%	0	0.00%	0	0.00%
Date Range: 2012-2022								
California (2012-2014)	Groundwater	168	0	0.00%	0	0.00%	0	0.00%
	Surface Water	21	0	0.00%	0	0.00%	0	0.00%
	Unknown	23	0	0.00%	0	0.00%	0	0.00%
	Total	212	0	0.00%	0	0.00%	0	0.00%

Source: Data provided to the EPA by states and downloaded by the EPA from state websites

Exhibit 8-25: cis-Permethrin State Drinking Water Occurrence Data – Summary of Systems

State (Date Range)	Source Water Type	Total Number of Systems	Systems with Detections		Detections > ½ HRL (1,500 µg/L)		Detections > HRL (3,000 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
Date Range: 1990-2011								
California (2011)	Groundwater	11	0	0.00%	0	0.00%	0	0.00%
	Surface Water	4	0	0.00%	0	0.00%	0	0.00%
	Total	15	0	0.00%	0	0.00%	0	0.00%
Date Range: 2012-2022								
California (2012-2014)	Groundwater	22	0	0.00%	0	0.00%	0	0.00%
	Surface Water	10	0	0.00%	0	0.00%	0	0.00%

State (Date Range)	Source Water Type	Total Number of Systems	Systems with Detections		Detections > ½ HRL (1,500 µg/L)		Detections > HRL (3,000 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
	Unknown	1	0	0.00%	0	0.00%	0	0.00%
	Total	33	0	0.00%	0	0.00%	0	0.00%

Source: Data provided to the EPA by states and downloaded by the EPA from state websites

Exhibit 8-26: trans-Permethrin State Drinking Water Occurrence Data – Summary of Samples

State (Date Range)	Source Water Type	Total Number of Samples	All Detections		Detections > ½ HRL (1,500 µg/L)		Detections > HRL (3,000 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
Date Range: 1990-2011								
California (2011)	Groundwater	27	0	0.00%	0	0.00%	0	0.00%
	Surface Water	9	0	0.00%	0	0.00%	0	0.00%
	Total	36	0	0.00%	0	0.00%	0	0.00%
New Mexico (1996-2000)	Groundwater	52	0	0.00%	0	0.00%	0	0.00%
	Surface Water	170	0	0.00%	0	0.00%	0	0.00%
	Unknown	54	0	0.00%	0	0.00%	0	0.00%
	Total	276	0	0.00%	0	0.00%	0	0.00%
Date Range: 2012-2022								
California (2012-2022)	Groundwater	168	0	0.00%	0	0.00%	0	0.00%
	Surface Water	19	0	0.00%	0	0.00%	0	0.00%
	Unknown	23	0	0.00%	0	0.00%	0	0.00%
	Total	210	0	0.00%	0	0.00%	0	0.00%

Source: Data provided to the EPA by states and downloaded by the EPA from state websites

Exhibit 8-27: trans-Permethrin State Drinking Water Occurrence Data – Summary of Systems

State (Date Range)	Source Water Type	Total Number of Systems	Systems with Detections		Detections > ½ HRL (1,500 µg/L)		Detections > HRL (3,000 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
Date Range: 1990-2011								
California (2011)	Groundwater	11	0	0.00%	0	0.00%	0	0.00%
	Surface Water	4	0	0.00%	0	0.00%	0	0.00%
	Total	15	0	0.00%	0	0.00%	0	0.00%

State (Date Range)	Source Water Type	Total Number of Systems	Systems with Detections		Detections > ½ HRL (1,500 µg/L)		Detections > HRL (3,000 µg/L)	
			Number	Percent	Number	Percent	Number	Percent
New Mexico (1996-2000)	Groundwater	12	0	0.00%	0	0.00%	0	0.00%
	Surface Water	3	0	0.00%	0	0.00%	0	0.00%
	Unknown	8	0	0.00%	0	0.00%	0	0.00%
	Total	23	0	0.00%	0	0.00%	0	0.00%
Date Range: 2012-2022								
California (2012-2022)	Groundwater	22	0	0.00%	0	0.00%	0	0.00%
	Surface Water	9	0	0.00%	0	0.00%	0	0.00%
	Unknown	1	0	0.00%	0	0.00%	0	0.00%
	Total	32	0	0.00%	0	0.00%	0	0.00%

Source: Data provided to the EPA by states and downloaded by the EPA from state websites

8.4.2.2.2 *Water Systems' Consumer Confidence Reports (CCRs), 2018-2021*

CCRs are annual water quality reports that CWSs are required to provide to their customers. These reports summarize information on water sources, detected contaminants, and system compliance with EPA drinking water standards; they may also include general educational material. Under the CCR Rule (40 CFR Subpart O), CWSs with 15 or more connections or serving at least 25 year-round residents must prepare and distribute a CCR to all billing units or service connections every year. Systems serving 100,000 or more residents are also required to post their current CCRs on a publicly accessible Internet site.

The EPA reviewed CCRs published by the 25 systems that serve over one million customers (as identified in the Safe Drinking Water Information System / Federal version, or SDWIS/Fed, from the fourth quarter 2021 data) for unregulated contaminant occurrence information for the years 2018 through 2021. Data on permethrin were available from CCRs prepared by five CWSs: one system in California (Los Angeles), one system in Colorado (Denver), two systems in New York (Suffolk County and New York City), and one system in Pennsylvania (Philadelphia). Monitoring results from all five systems showed no detections of permethrin.

Los Angeles Department of Water & Power (LADWP) included data on permethrin monitoring for UCMR 4 in its 2020 and 2021 CCRs. LADWP is served by multiple surface water and groundwater sources. The sampling was conducted in 2018-2019. Permethrin was not detected.

Denver Water included data on permethrin monitoring for UCMR 4 in its 2018 CCR. Denver Water is served by the South Platte River and other surface water sources. An average permethrin concentration of “0 µg/L” was reported for treatment plant effluent.

Suffolk County, New York, included data on permethrin in its 2018-2021 CCRs. Suffolk County is served by groundwater from four major aquifers beneath Long Island. In all 4 years, permethrin was monitored for but was not detected.

New York City included data on permethrin in four CCRs covering 2018 through 2021. New York City is served by a large system of surface water networks in New York state. In all 4 years, permethrin was monitored for but was not detected.

The Philadelphia Water Department (PWD) included data on permethrin in three CCRs covering 2019 through 2021. PWD is served by surface water from the Schuylkill and Delaware rivers. In all 3 years, permethrin was monitored for but was not detected.

8.4.2.2.3 United States Department of Agriculture (USDA) Pesticide Data Program (PDP), 2001-2013

The USDA Pesticide Data Program (PDP) maintains a national pesticide residue database. PDP was initiated in 1991 to collect representative data on pesticide residues in the United States food supply, following a rigorous statistical design. Sampling and testing have been conducted on fruits and vegetables, select grains, milk, and (between 2001 and 2013) drinking water (USDA, 2022).

The PDP drinking water project was initiated at CWSs in New York and California in 2001. Since then, the drinking water sampling program has expanded, though a somewhat changing mix of states is sampled each year. At one time or another, CWSs in 29 states and the District of Columbia have contributed raw or finished water data or both to the program (USDA, 2023). The CWSs selected for sampling tend to be small and medium-sized systems (primarily CWSs serving under 50,000), systems served by surface water, and systems located in regions of heavy agriculture. Sampling of raw (“untreated”) water in addition to finished water began in 2004; sampling of raw and finished drinking water was discontinued after 2013. Note that temporal trends cannot be evaluated based on these data since the list of CWSs included in the project varied from year to year (USDA, 2022; USDA, 2023).

The two isomers of permethrin (cis- and trans-) were included in the USDA PDP (Exhibit 8-28 and Exhibit 8-29) (USDA, 2022). cis-Permethrin was not detected in any of the 1,888 raw water samples. cis-Permethrin was detected in 1 (0.04 percent) of 2,534 finished water samples, with a concentration of 0.068 µg/L. No detected concentrations exceeded one-half the HRL or the HRL. The reported limits of detection for cis-permethrin ranged from 0.0045 to 0.05 µg/L. trans-Permethrin was not detected in any of 3,711 samples (1,419 raw water and 2,292 finished water). The reported limits of detection for trans-permethrin ranged from 0.0075 to 0.05 µg/L.

Exhibit 8-28: Summary of cis-Permethrin PDP Data, 2001-2013

Year	Raw/ Finished	Total Number of Samples	Number of Detections	Percent of Detections	Minimum Value of Detections (µg/L)	Maximum Value of Detections (µg/L)
2001	Finished	No Data	No Data	No Data	No Data	No Data
2002	Finished	156	0	0.00%	N/A	N/A
2003	Finished	509	0	0.00%	N/A	N/A
2004	Finished	262	0	0.00%	N/A	N/A
	Raw	262	0	0.00%	N/A	N/A
2005	Finished	255	1	0.4%	0.068	0.068
	Raw	257	0	0.00%	N/A	N/A

Year	Raw/ Finished	Total Number of Samples	Number of Detections	Percent of Detections	Minimum Value of Detections (µg/L)	Maximum Value of Detections (µg/L)
2006	Finished	251	0	0.00%	N/A	N/A
	Raw	251	0	0.00%	N/A	N/A
2007	Finished	253	0	0.00%	N/A	N/A
	Raw	250	0	0.00%	N/A	N/A
2008	Finished	190	0	0.00%	N/A	N/A
	Raw	189	0	0.00%	N/A	N/A
2009	Finished	187	0	0.00%	N/A	N/A
	Raw	187	0	0.00%	N/A	N/A
2010	Finished	189	0	0.00%	N/A	N/A
	Raw	189	0	0.00%	N/A	N/A
2011	Finished	No Data	No Data	No Data	No Data	No Data
	Raw	No Data	No Data	No Data	No Data	No Data
2012	Finished	232	0	0.00%	N/A	N/A
	Raw	253	0	0.00%	N/A	N/A
2013	Finished	50	0	0.00%	N/A	N/A
	Raw	50	0	0.00%	N/A	N/A

Source: USDA, 2022

N/A = not applicable (no detections in this category).

Exhibit 8-29: Summary of trans-Permethrin PDP Data, 2001-2013

Year	Raw/ Finished	Total Number of Samples	Number of Detections	Percent of Detections	Minimum Value of Detections (µg/L)	Maximum Value of Detections (µg/L)
2001	Finished	134	0	0.00%	N/A	N/A
2002	Finished	375	0	0.00%	N/A	N/A
2003	Finished	381	0	0.00%	N/A	N/A
2004	Finished	142	0	0.00%	N/A	N/A
	Raw	142	0	0.00%	N/A	N/A
2005	Finished	144	0	0.00%	N/A	N/A
	Raw	144	0	0.00%	N/A	N/A
2006	Finished	133	0	0.00%	N/A	N/A
	Raw	133	0	0.00%	N/A	N/A
2007	Finished	135	0	0.00%	N/A	N/A
	Raw	132	0	0.00%	N/A	N/A
2008	Finished	190	0	0.00%	N/A	N/A
	Raw	189	0	0.00%	N/A	N/A

Year	Raw/ Finished	Total Number of Samples	Number of Detections	Percent of Detections	Minimum Value of Detections (µg/L)	Maximum Value of Detections (µg/L)
2009	Finished	187	0	0.00%	N/A	N/A
	Raw	187	0	0.00%	N/A	N/A
2010	Finished	189	0	0.00%	N/A	N/A
	Raw	189	0	0.00%	N/A	N/A
2011	Finished	No Data	No Data	No Data	No Data	No Data
	Raw	No Data	No Data	No Data	No Data	No Data
2012	Finished	232	0	0.00%	N/A	N/A
	Raw	253	0	0.00%	N/A	N/A
2013	Finished	50	0	0.00%	N/A	N/A
	Raw	50	0	0.00%	N/A	N/A

Source: USDA, 2022

N/A = not applicable (no detections in this category).

8.4.2.2.4 *National Pesticide Survey (NPS), 1988-1990*

In 1990, the EPA completed a national survey of pesticides in drinking water wells. The purpose of the NPS was to determine the national occurrence frequencies and concentrations of select pesticides in the nation's drinking water wells and to improve the EPA's understanding of how pesticide occurrence in groundwater correlates with patterns of pesticide usage and groundwater vulnerability. The survey included 566 CWS wells and 783 rural domestic wells. Sampling was conducted between 1988 and 1990. The survey targeted areas representing a variety of pesticide usage levels and groundwater vulnerability. The survey was designed to provide a statistically reliable estimate of pesticide occurrence in the nation's drinking water wells. It was not designed to provide statistically valid results at the state or local level. Wells were sampled for 101 pesticides, 25 pesticide degradates, and nitrate (USEPA, 1990). At reporting levels of 0.90 µg/L for cis-permethrin and 2.0 µg/L for trans-permethrin, neither isomer was detected in the survey (USEPA, 1990).

8.4.2.2.5 *United States Geological Survey (USGS) Pilot Monitoring Program (PMP), 1999*

In 1999, the PMP was initiated by USGS and the EPA to provide information on pesticide concentrations in drinking water. The program focused on small drinking water supply reservoirs in areas with high pesticide use in order to test the sampling approach in areas where pesticides are probably present (Blomquist et al., 2001). Sampling sites represented a variety of geographic regions as well as different cropping patterns. The ideal site candidates were mostly small reservoirs located in high pesticide-use areas with a high runoff potential. Twelve water-supply reservoirs considered vulnerable to pesticide contamination were selected from the list of candidates. These 12 sites were located in California, Indiana, Louisiana, Missouri, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, and Texas.

Samples were collected quarterly throughout the year and at weekly or biweekly intervals following the primary pesticide-application periods. Water samples were collected from the raw-

water intake and from finished drinking water taps prior to entering the distribution system. At some sites, samples were also collected at the reservoir outflow.

cis-Permethrin was an analyte in the PMP. At a method reporting level of 0.005 µg/L, cis-permethrin was not detected in any of the 323 samples from raw water sites or any of the 228 samples from finished water sites (Blomquist et al., 2001).

8.4.2.2.6 Additional Source Water and Drinking Water Studies

Note that there may be some overlap between the NAWQA data assessment presented earlier in the ambient water occurrence section and the summaries of NAWQA studies presented below.

Organic Compounds in Source Water of Selected Community Water Systems (Hopple et al., 2009 and Kingsbury et al., 2008), 2002-2005

As part of the NAWQA program, Hopple et al. (2009) and Kingsbury et al. (2008) conducted studies to characterize anthropogenic organic compounds in PWS source waters in the United States. Hopple et al. (2009) focused on groundwater, and Kingsbury et al. (2008) focused on surface water. In Phase 1 of the studies, geographically diverse source water samples were collected between October 2002 and July 2005 from surface water intakes at nine CWSs and from wells in 12 aquifers that serve as CWS sources. In Phase 2, USGS collected source and finished water samples at a subset of sites between June 2004 and September 2005. The reporting level for cis-permethrin was 0.006 µg/L.

In Phase 1 of the studies, cis-permethrin was not detected in any of the 146 stream samples or 221 groundwater samples. In Phase 2, cis-permethrin was not detected in any of the 48 source water samples or 48 finished water samples taken at groundwater systems. No data was reported in Phase 2 for surface water systems.

Water Quality in Public-Supply Wells (Toccalino et al., 2010), 1993-2007

To assess risks posed by contaminants in public-supply wells, water samples were collected from source (untreated) groundwater from 932 public-supply wells located in parts of 40 NAWQA Study Units in 41 states (Toccalino et al., 2010). Each well was sampled once between 1993 and 2007. The public wells sampled in this study represented 629 unique PWSs, constituting 0.5 percent of the approximately 140,000 groundwater-supplied PWSs, but serving nearly 25 percent of the population served by groundwater PWSs in the United States. The reporting levels used for cis-permethrin in this study ranged from 0.003 µg/L to 0.005 µg/L. cis-Permethrin was not detected in any of the 898 samples.

Water Quality in Domestic Wells (DeSimone, 2009), 1991-2004

Between 1991 and 2004, USGS assessed water quality from domestic wells across the United States using NAWQA data (DeSimone, 2009). The program included the analysis of major ions, trace elements, nutrients, radon, and organic compounds (pesticides and volatile organic compounds or VOCs) at approximately 2,100 domestic wells (private drinking water wells) across 48 states, covering 30 regional aquifers. In addition, USGS summarized data from wells sampled for NAWQA agricultural land-use assessment studies to provide an indication of the potential effects of agricultural land-use practices on the groundwater in the aquifers studied. Reporting thresholds for cis-permethrin varied; the most common thresholds were 0.003 and

0.005 µg/L. cis-Permethrin was not detected in any of the 2,115 samples from aquifer studies or any of the 424 samples from agricultural land-use studies.

Water Quality in Carbonate Aquifers (Lindsey et al., 2008), 1993-2005

As part of the NAWQA program, Lindsey et al. (2008) assessed the water quality in carbonate aquifers, which account for 22 percent of the groundwater pumped by the nation's PWSs. From 1993 to 2005, the study analyzed 1,042 wells and springs across 12 aquifer systems and 20 states for major ions, radon, nutrients, pesticides, and VOCs. Reporting levels varied. cis-Permethrin was not detected in any of the 1,027 samples.

Contaminant Occurrence in Source and Finished Water in the Sioux Falls Area, South Dakota (Hoogestraat, 2012), 2009-2010

In 2009-2010, the city of Sioux Falls and the USGS assessed the occurrence of anthropogenic organic compounds in the source waters (groundwater and surface water) and finished water in the Sioux Falls area. Two source water sites and one finished water site were sampled. The reporting level used for cis-permethrin in this study was 0.014 µg/L. cis-Permethrin was not detected in any of the 11 finished water samples, 7 groundwater samples, or 8 surface water samples (Hoogestraat, 2012).

8.5 Analytical Methods

The EPA has published four analytical methods that are available for the analysis of permethrin in drinking water (note that the structural cis- and trans- isomers of permethrin are quantitated separately in each of these methods):

- EPA Method 508, Revision 3.1, *Determination of Chlorinated Pesticides in Water by Gas Chromatography with an Electron Capture Detector*, has a Method Detection Limit (MDL) of 0.25 µg/L for cis-permethrin and 0.18 µg/L for trans-permethrin. Mean recoveries in reagent water and two synthetic waters (artesian spring water and reagent water fortified with 1 mg/L fulvic acid) range from 64.0 to 96.0 percent for cis-permethrin and 97.0 to 122 µg/L for trans-permethrin, with standard deviations and a relative standard deviation (RSD) of 9.1 to 24 µg/L and 24 percent, respectively, for cis-permethrin, and 6.7 to 9.7 µg/L and 9 percent, respectively, for trans-permethrin (USEPA, 1995a).
- EPA Method 508.1, Revision 2.0, *Determination of Chlorinated Pesticides, Herbicides, and Organohalides by Liquid-Solid Extraction and Electron Capture Gas Chromatography*, has an MDL of 0.009 µg/L for cis-permethrin and 0.007 µg/L for trans-permethrin. Mean recoveries in reagent water range from 70.0 to 102.0 percent for cis-permethrin and 85.2 to 117 µg/L for trans-permethrin, with RSDs of 11.1 to 42.9 percent for cis-permethrin and 11.1 to 20 percent for trans-permethrin (USEPA, 1995b).
- EPA Method 525.2, Revision 2.0, *Determination of Organic Compounds in Drinking Water by Liquid-Solid Extraction and Capillary Column Gas Chromatography/Mass Spectrometry*, has MDLs that range from 0.031 to 0.043 µg/L for cis-permethrin and 0.039 to 0.074 µg/L for trans-permethrin. Mean recoveries in reagent water and tap water range from 121 to 179 percent for cis-permethrin and 109.0 to 153 percent for trans-permethrin, with RSDs of 3.1 to 3.7 percent for cis-permethrin and 1.6 to 2.7 percent for trans-permethrin (USEPA, 1995c).

- EPA Method 525.3, Version 1.0, *Determination of Semivolatile Organic Chemicals in Drinking Water by Solid Phase Extraction and Capillary Column Gas Chromatography/Mass Spectrometry (GC/MS)* has detection limits (DLs) that range from 0.0026 to 0.015 µg/L for cis-permethrin and 0.012 to 0.031 µg/L for trans-permethrin in Full Scan mode and DLs of 0.0041 µg/L for cis-permethrin and 0.008 µg/L for trans-permethrin in Selected Ion Monitoring (SIM) mode. The Lowest Concentration Minimum Reporting Levels (LCMRLs) generated by the laboratories that helped develop the method range from 0.036 to 0.130 µg/L in Full Scan mode and 0.0015 to 0.012 µg/L in SIM mode for cis-permethrin and from 0.087 to 0.10 µg/L in Full Scan mode and 0.0023 to 0.020 µg/L in SIM mode for trans-permethrin. Mean recoveries in reagent water, finished water from groundwater with a hardness of 290 to ≥350 mg/L (as calcium carbonate), and finished drinking water from surface water with total organic carbon (TOC) of 2.4 to 2.8 mg/L range from 77.3 to 112 percent, with RSDs of 0.9 to 8.8 percent for cis-permethrin in Full Scan mode. Mean recoveries in the same matrices range from 79.1 to 115 percent, with RSDs of 1.5 to 9.1 percent for trans-permethrin in Full Scan mode. Mean recoveries in reagent water, finished water from groundwater with a hardness of 325 to 393 mg/L (as calcium carbonate), and finished drinking water from surface water with TOC of 2.0 to 2.52 mg/L and a hardness of 137 mg/L (as calcium carbonate) range from 81.1 to 113 percent, with RSDs of 1.4 to 9.7 percent for cis-permethrin in SIM mode. Mean recoveries in the same matrices range from 82.2 to 108 percent, with RSDs of 1.0 to 5.1 percent for trans-permethrin in SIM mode (USEPA, 2012).

Laboratories participating in UCMR 4 were required to use EPA Method 525.3 and were required to report total cis- and trans-permethrin values at or above the EPA-defined MRL of 0.04 µg/L (81 FR 92666; USEPA, 2016a). The MRL was set based on the capability of multiple laboratories at the time.

8.6 Treatment Technologies

The EPA evaluates whether suitable treatment technologies are available prior to promulgating a final NPDWR. The preliminary summary of treatment technology availability presented here represents the results of a December 2023 literature search.

Eckert (2013) investigated the removal of cis-, trans-, and total permethrin from water using powdered activated carbon (PAC). Initial total permethrin concentrations ranged from 2.0 to 4.6 µg/L and PAC doses varied from 0.0 to 10 mg/L. With one variety of PAC (WPH 650), a 0.05 mg/L dose reduced total permethrin concentrations by 38 percent and a 3 mg/L dose brought total permethrin concentrations down to undetectable levels. Another variety of PAC (WPH 1000) achieved a 35 percent reduction of total permethrin with a 0.05 mg/L dose and an 83 percent reduction with a 5 mg/L dose. Similar findings were observed for cis- and trans-permethrin.

Dehaghi et al. (2014) investigated the removal of permethrin from water using beads of chitosan loaded with zinc oxide nanoparticles as an adsorbent, at the lab scale. The bionanocomposite demonstrated high efficiency, with a dose of 0.5 grams removing 99 percent of permethrin (from an initial concentration of 0.1 mg/L in a 25 mL solution).

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Chapter 9: Profenofos

A chapter from:

Final Regulatory Determination 5 Support Document

EPA Report 815-R-26-002

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Abbreviations

AChE	Acetylcholinesterase
BMD	Benchmark Dose
BMD ₁₀	Benchmark Dose at 10 Percent Inhibition*
BMDL ₁₀	Lower Bound of 95 Percent Confidence Interval on BMD ₁₀ *
BW	Body Weight
CASRN	Chemical Abstracts Service Registry Number
CCL 5	Fifth Contaminant Candidate List
CCR	Consumer Confidence Report
CDR	Chemical Data Reporting
CWS	Community Water System
DL	Detection Limit
DWI	Drinking Water Intake
DWI-BW	Drinking Water Intake Adjusted for Body Weight
EF	Exposure Factors
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA SF	Food Quality Protection Act Safety Factor
GWUDI	Groundwater Under the Direct Influence of Surface Water
HED	Health Effects Division
HHRA	Human Health Risk Assessment
HRL	Health Reference Level
IREC	Interim Reregistration Eligibility Decision
IUR	Inventory Update Reporting
K _H	Henry's Law Constant
K _{oc}	Organic Carbon Partitioning Coefficient
K _{ow}	Octanol/Water Partitioning Coefficient
LADWP	Los Angeles Department of Water & Power
LCMRL	Lowest Concentration Minimum Reporting Level
MAC	Maximum Acceptable Concentration
MRL	Minimum Reporting Level
NAWQA	National Water-Quality Assessment
NCFAP	National Center for Food and Agricultural Policy
NIRS	National Inorganics and Radionuclides Survey
NOM	Natural Organic Matter
NPDWR	National Primary Drinking Water Regulation
NTNCWS	Non-Transient Non-Community Water Systems
NWIS	National Water Information System
OGWDW	Office of Ground Water and Drinking Water
OPP	Office of Pesticide Programs
PAD	Population-Adjusted Dose
PDP	Pesticide Data Program
PMP	Pilot Monitoring Program
POD	Point of Departure
POD/UF	Point of Departure / Uncertainty Factor
PWD	Philadelphia Water Department

PWS	Public Water System
RD 5	Regulatory Determination 5
RBC	Red Blood Cell
RfD	Reference Dose
RSC	Relative Source Contribution
RSD	Relative Standard Deviation
RUP	Restricted Use Pesticide
SDWA	Safe Drinking Water Act
SDWIS/Fed	Safe Drinking Water Information System / Federal Version
SIM	Selected Ion Monitoring
ssPAD	Steady-State Population-Adjusted Dose
STORET	Storage and Retrieval Data System
TDI	Tolerable Daily Intake
TOC	Total Organic Carbon
TRI	Toxics Release Inventory
UCM	Unregulated Contaminant Monitoring
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 1	First Unregulated Contaminant Monitoring Rule
UCMR 2	Second Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 4	Fourth Unregulated Contaminant Monitoring Rule
UF	Uncertainty Factor
UF _A	Interspecies Uncertainty Factor
UF _H	Intraspecies Uncertainty Factor
USDA	United States Department of Agriculture
USGS	United States Geological Survey
WQP	Water Quality Portal

*These definitions apply only within this chapter.

Chapter 9: Profenofos

The U.S. Environmental Protection Agency (EPA) is evaluating profenofos, a contaminant on the fifth Contaminant Candidate List (CCL 5), as a candidate for regulation under the fifth Regulatory Determination process (RD 5). Information on the CCL 5 process is found in Chapter 1. Background on data sources used to evaluate CCL 5 chemicals is found in Chapter 2.

This chapter presents information and analysis specific to profenofos, including background information on the contaminant, information on contaminant sources and environmental fate, an analysis of health effects, an analysis of occurrence in ambient and drinking water, and information about the availability of analytical methods and treatment technologies.

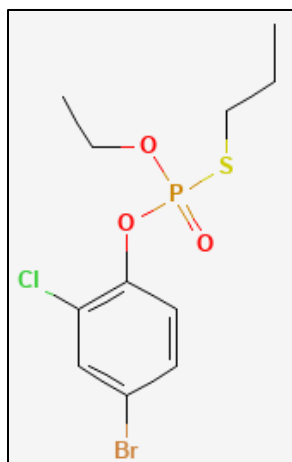
9.1 Contaminant Background and Chemical and Physical Properties

Profenofos is an organophosphate pesticide, applied as an insecticide. Synonyms for profenofos include curacron and selecron (NCBI, 2023). Profenofos was first registered in the United States in 1982 (USEPA, 2008a).

The EPA's Office of Pesticide Programs (OPP) released an Interim Reregistration Eligibility Decision (IRED) for profenofos in August of 2000, and finalized the document in July of 2006 (USEPA, 2006). Subsequent to the EPA changing from the pesticide reregistration process to the current Registration Review process, the EPA published a Summary Document for Profenofos in June of 2008 and a Final Work Plan for Profenofos in December of 2008 (USEPA, 2008a; USEPA, 2008b). Profenofos products are classified as Restricted Use Pesticides (RUP) (USEPA, 2008a). Profenofos was canceled in 2018 and no profenofos-containing products appear in the EPA's most recent RUP report (USEPA, 2022a) or in the EPA's Pesticide Product and Label System database (USEPA, 2023a).

Exhibit 9-1 presents the structural formula for profenofos. Physical and chemical properties and other reference information are listed in Exhibit 9-2.

Exhibit 9-1: Chemical Structure of Profenofos



Source: NCBI, 2023

Exhibit 9-2: Physical and Chemical Properties of Profenofos

Property	Data
Chemical Abstracts Service Registry Number (CASRN)	41198-08-7 (NCBI, 2023)
EPA Pesticide Chemical Code	111401 (NCBI, 2023)
Chemical Formula	C ₁₁ H ₁₅ BrClO ₃ PS (NCBI, 2023)
Molecular Weight	373.63 g/mol (NCBI, 2023)
Color/Physical State	Pale yellow liquid (NCBI, 2023)
Boiling Point	100 °C @ 1.35X10 ⁻² mm Hg (NCBI, 2023)
Melting Point	-- (NCBI, 2023)
Density	1.455 @ 20 °C (NCBI, 2023; reported as specific gravity)
Freundlich Adsorption Coefficient	--
Vapor Pressure	9.00X10 ⁻⁷ mm Hg @ 25 °C (NCBI, 2023)
Henry's Law Constant (K _H)	2.21X10 ⁻⁸ atm·m ³ /mole (NCBI, 2023)
Octanol/Water Partitioning Coefficient (log K _{ow})	4.68 (NCBI, 2023)
Organic Carbon Partitioning Coefficient (K _{oc})	869-3,162 L/kg (NCBI, 2023)
Solubility in Water	28 mg/L @ 25 °C (NCBI, 2023)
Other Solvents	Miscible with most organic solvents (NCBI, 2023)

Note: Many of these properties are temperature-dependent. Values are given for properties at 20-25°C unless otherwise noted. Due to varying experimental conditions, and due to the variabilities associated with modeling, standard information sources may provide a range of values. Where more than one value was available from these sources, one value was selected for this table based on best professional judgment.

9.2 Sources and Environmental Fate

9.2.1 Production, Use, and Release

No data on production of profenofos are available from the EPA's Inventory Update Reporting (IUR) and Chemical Data Reporting (CDR) programs. Data on industrial releases are available from the EPA's Toxics Release Inventory (TRI). In addition, several sources provide information about quantities of profenofos used in agriculture. Additional information about these sources is provided in Chapter 2.

Toxics Release Inventory (TRI)

The EPA established TRI in 1987 in response to Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). EPCRA Section 313 requires the reporting of annual information on toxic chemical releases from facilities that meet specific criteria. This reported information is maintained in a database accessible through TRI Explorer (USEPA, 2023b).

Although TRI can provide a general idea of release trends, it has limitations. Not all facilities are required to report all releases. Facilities are generally required to report releases if they manufacture or process more than 25,000 pounds of a chemical or use more than 10,000 pounds per year. Reporting requirements have changed over time (e.g., reporting thresholds have increased or decreased), so conclusions about temporal trends should be drawn with caution. TRI data are meant to reflect releases and should not be used to estimate general public exposure to a chemical (USEPA, 2022b).

TRI data for profenofos from the years 1995 to 2022 are summarized in Exhibit 9-3. Data for profenofos were not reported in every year. The only non-zero reported releases of profenofos were air emissions reported from Mississippi in 1998 and 1999 and from Texas in 2004; these releases were 10 pounds, 10 pounds, and 255 pounds, respectively (USEPA, 2023b).

Exhibit 9-3: Environmental Releases of Profenofos in the United States, 1995-2022 (pounds)

Year	On-Site Air Emissions	On-Site Surface Water Discharges	On-Site Underground Injection	On-site Releases to Land	Off-site Disposal or Other Releases	Total On- and Off-site Disposal or Other Releases
1995	0	0	0	0	.	0
1996	0	0	0	0	.	0
1997	.	.	.	.	.	.
1998	10	0	0	0	.	10
1999	10	0	0	0	.	10
2000	No reports	No reports	No reports	No reports	No reports	No reports
2001	.	.	.	.	.	.
2002	0	0	0	0	.	0
2003	0	0	0	0	.	0
2004	255	0	0	0	.	255
2005	0	0	0	0	.	0
2006	0	0	0	0	.	0
2007	0	0	0	0	.	0
2008	0	0	0	0	.	0
2009	No reports	No reports	No reports	No reports	No reports	No reports
2010	.	.	.	.	.	.
2011	.	.	.	.	.	.
2012	.	.	.	.	.	.
2013	.	.	.	.	.	.
2014	No reports	No reports	No reports	No reports	No reports	No reports
2015	.	.	.	.	.	.
2016	.	.	.	.	.	.
2017	.	.	.	.	.	.
2018	.	.	.	.	.	.
2019	.	.	.	.	.	.
2020	No reports	No reports	No reports	No reports	No reports	No reports
2021	No reports	No reports	No reports	No reports	No reports	No reports
2022	.	.	.	.	.	.

Source: USEPA, 2023b

Note: A decimal point indicates that one or more facilities either left an applicable field blank or certified in streamlined reporting that annual release did not exceed 500 pounds, and that otherwise no releases were reported.

National Center for Food and Agricultural Policy (NCFAP) Pesticide Use Database

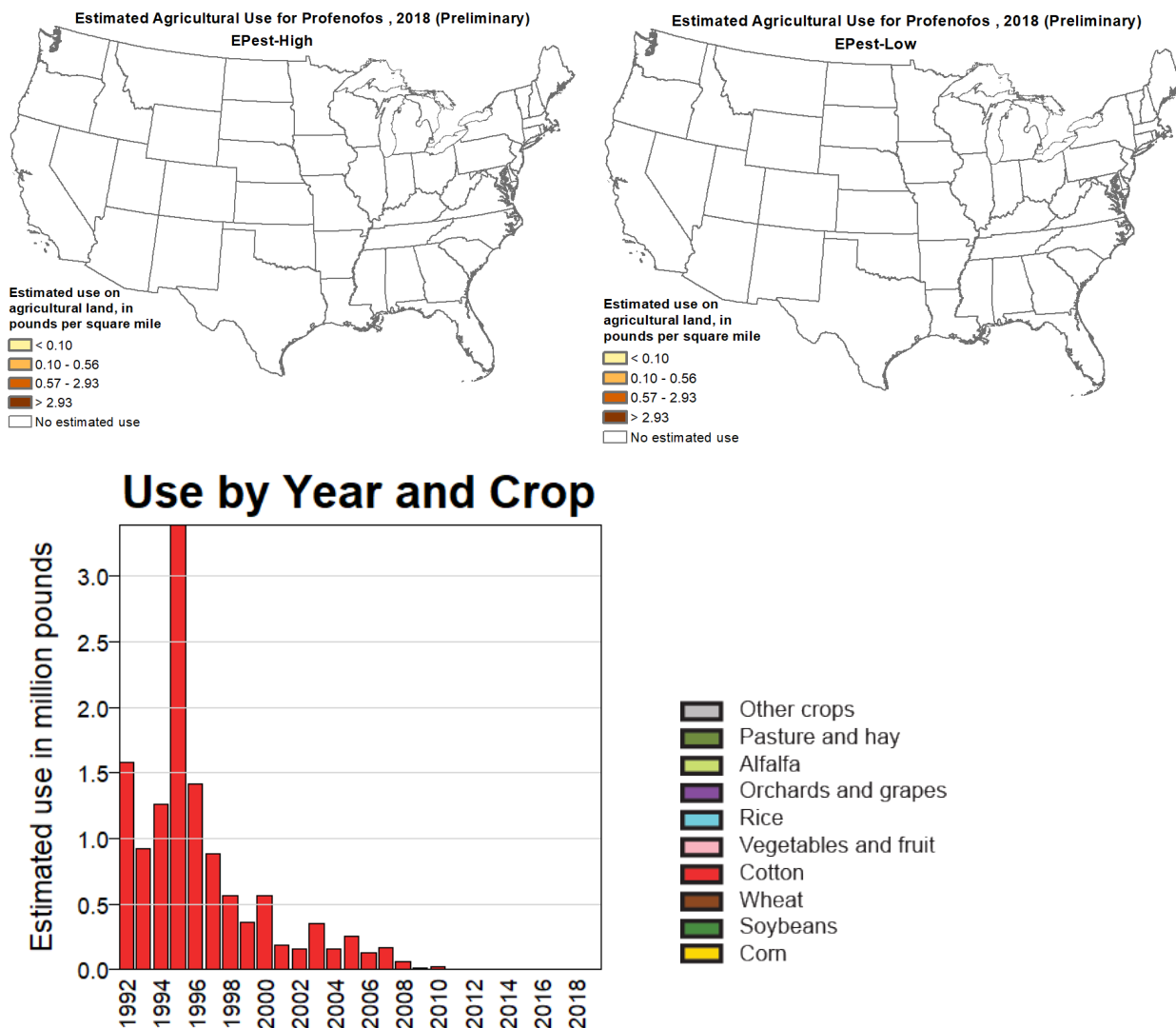
The National Center for Food and Agricultural Policy (NCFAP) maintains a national Pesticide Use Database, primarily for herbicides. Pesticide use estimates are based on state-level commercial agriculture usage patterns and state-level crop acreage. NCFAP listed uses of profenofos on one crop (cotton) totaling approximately 2.06 million pounds active ingredient per year in 15 states in 1992. In 1997, NCFAP listed uses of profenofos on one crop (cotton) totaling approximately 880,000 pounds active ingredient per year in 14 states (NCFAP, 2000).

United States Geological Survey (USGS) Pesticide Use Maps

The United States Geological Survey (USGS) produces estimates of annual national pesticide use for over 200 compounds. USGS pesticide use maps show the average annual pesticide use intensity expressed as average weight (in pounds) of a pesticide applied to each square mile of agricultural land in a county. The USGS maps are created using data from NCFAP and county-level information on harvested crop acreage from the Census of Agriculture (USGS, 2023).

Exhibit 9-4 shows the geographic distribution of estimated annual profenofos use in the United States in 2018, the most recent year with maps available for this pesticide. The differences between the “low” and “high” estimates primarily reflect assumptions made when data on usage of a pesticide were unavailable from a crop reporting district (i.e., an assumption of no pesticide usage or an assumption that usage was comparable to neighboring districts). A breakdown of use by crop from year to year is also included below, using the “high” assumption. Profenofos usage has diminished since the mid-1990s, and it appears to have ceased around 2011. Cotton is the sole crop to which profenofos has been applied during this period (USGS, 2023).

Exhibit 9-4: Estimated Annual Agricultural Use of Profenofos, 2018



Source: USGS, 2023

9.2.2 Environmental Fate

As discussed in Chapter 2, the measures used by the EPA to assess mobility include (where available) the organic carbon partitioning coefficient (K_{oc}), log octanol-water partitioning coefficient ($\log K_{ow}$), Henry's Law Constant (K_H), water solubility, and vapor pressure. A vapor pressure of 9×10^{-7} mm Hg at 25 degrees C indicates that profenofos will exist in both the vapor phase and the particulate phase if it is released to the atmosphere. Vapor phase profenofos will degrade in the atmosphere due to reaction with photochemically-produced hydroxyl radicals, with an estimated half-life of 8.6 hours. K_{oc} values of 869-3,162 L/kg suggest that profenofos will have low to slight mobility in soil. Profenofos is not expected to volatilize from dry soil surfaces and with a K_H of 2.21×10^{-8} mm Hg at 25 degrees C, volatilization from water is also not expected to occur (NCBI, 2023).

Under anaerobic, aquatic conditions, profenofos has a metabolism half-life of 3 days in pH 5.1 sediment covered by pH 7.3 water. Under aerobic conditions, biodegradation, if it occurs at all, occurs much more slowly. In pH 7.8 aerobic soil, profenofos has a hydrolysis half-life of 2 days, while in pH 7.8 anaerobic soil, profenofos has a hydrolysis half-life of 3 days. Profenofos is stable to photolysis in soil and water. Bioconcentration of profenofos in aquatic organisms is expected to be moderate to high (NCBI, 2023).

9.3 Health Effects

9.3.1 Health Assessment Identification

Profenofos is a currently registered pesticide chemical under the EPA's Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (USEPA, 2015a). For currently registered pesticide chemicals, the RD 5 Protocol provides that toxicity information from EPA OPP Health Effects Division (HED) Human Health Risk Assessments (HHRAs) are to be used as the basis for calculating health reference levels (HRLs). (See Section B.5.1.1 of the RD 5 Protocol, found in Appendix B of this document.) Therefore, the EPA reviewed the toxicity information in the HHRA for profenofos (USEPA, 2015a; USEPA, 2015b). The OPP health assessment provides a toxicity value relevant to chronic oral toxicity and was published prior to the cutoff date of January 2023.

Exhibit 9-5 provides a summary overview of the OPP health assessment data reviewed and selected for profenofos under RD 5.

Exhibit 9-5: OPP Health Assessment Supporting Current FIFRA Registration for Profenofos

Health Assessment ^a	Oral Reference Value	POD Type	Noncancer Critical Study	Oral Cancer Slope Factor	Cancer Critical Study	Cancer Descriptor
<i>EPA OPP Human Health Risk Assessment^b (USEPA 2015a; USEPA, 2015b)</i>	<i>0.00012^c</i>	<i>BMDL₁₀</i>	<i>Burdock et al. (1981)</i>	–	–	E ^d

Notes: POD = point of departure; BMDL₁₀ = lower bound of the 95 percent confidence interval on the benchmark dose associated with a 10 percent response; dash (–) = not applicable.

^a Selected health assessment and chronic toxicity value and supporting information are bolded and italicized.

^b The EPA OPP considers this health assessment “final” at the time of publication in the Federal Register.

^c The oral reference value, in units of mg/kg/day, is a steady-state population-adjusted dose (ssPAD) (USEPA, 2015b).

^d This “Evidence of non-carcinogenicity for humans” cancer descriptor was determined by following the process described in the EPA's 1986 *Guidelines for Carcinogen Risk Assessment* (USEPA, 1986).

9.3.2 Health Assessment Selection

The health assessment selected for profenofos under RD 5 is the 2015 EPA OPP HHRA (USEPA 2015a; USEPA, 2015b) because it supported the most recent FIFRA registration decision for profenofos. See Section B.5.1.2 of the RD 5 Protocol, in Appendix B of this document, for the decision logic that was applied to health assessment selection for RD 5 chemicals.

9.3.3 Health Reference Level (HRL) Development

HRLs are non-regulatory health-based toxicity values, expressed as concentrations in drinking water, that are used by the Agency to evaluate occurrence data for a contaminant when making decisions about regulatory determinations. See Section B.6.1.1 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA's approach for deriving HRLs for chemicals.

9.3.3.1 Oral Reference Value

In the 2015 EPA OPP HHRA (USEPA, 2015b), OPP selected a combined chronic toxicity and carcinogenicity study in rats (Burdock et al. 1981) as the critical study to derive the oral reference value (USEPA 2015b). In this study, doses of 0, 0.3, 10, or 100 ppm profenofos were administered to 60 male and 60 female Fischer 344 albino rats in diet for two years, resulting in ingested doses of 0, 0.015, 0.50, and 5.0 mg/kg/day. Although rat ages were not reported by the study authors, mean body weights were reported to be 175-178 grams for males and 117-120 grams for females (USEPA, 1996). Effects on erythrocyte or red blood cell (RBC) acetylcholinesterase (AChE) and plasma AChE were evaluated along with other clinical chemistry and hematological parameters, and brain AChE activity was evaluated at weeks 52 (interim sacrifice) and 105 (terminal sacrifice). Rats were necropsied and selected organs were weighed and evaluated by histopathology (USEPA, 1996).

RBC AChE inhibition was the critical effect chosen to derive the POD, as it was the most sensitive endpoint assessed (USEPA, 2015b). OPP used the EPA benchmark dose (BMD) software to calculate estimated doses associated with RBC AChE inhibition of 10 percent relative to background (BMD₁₀), as well as the lower bound of the 95 percent confidence interval on the BMD₁₀ (BMDL₁₀). Based on 13-week interim measurements of RBC AChE inhibition from the Burdock et al. (1981) study, OPP derived a BMD₁₀ of 0.14 mg/kg/day for male rats and 0.13 mg/kg/day for female rats, and for both sexes a corresponding BMDL₁₀ of 0.12 mg/kg/day. This BMDL₁₀ (0.12 mg/kg/day) was selected as the POD for profenofos (USEPA, 2015b). A total uncertainty factor (UF) of 1,000 was applied to the POD: an interspecies UF (UF_A) of 10, an intraspecies UF (UF_H) of 10, and a Food Quality Protection Act safety factor (FQPA SF) of 10 to account for uncertainty in the human dose-response relationship for neurodevelopmental effects (USEPA, 2015b). After applying the total UF, the oral reference value (a steady-state population-adjusted dose, or ssPAD) was calculated to be 0.00012 mg/kg/day (USEPA, 2015b). The EPA selected this oral reference value (0.00012 mg/kg/day) from the 2015 EPA OPP HHRA (USEPA, 2015b) to derive an HRL for profenofos.

9.3.3.2 Exposure Factor Selection

In prioritizing the contaminants of greatest public health concern for regulatory determination, Section 1412(b)(1)(C) of the Safe Drinking Water Act (SDWA) requires the Agency to consider “among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water compared to the general population.” One way that the EPA considers potentially sensitive populations or life stages (i.e., populations or life stages that may be more susceptible or sensitive to a chemical exposure) is during the selection of exposure factors (EFs) for the development of HRLs.

Drinking water intake rate adjusted for body weight (DWI-BW) is the EF used to derive HRLs for RD 5 (USEPA, 2019). EFs are input values intended to protect the general population, including sensitive populations or life stages, from adverse effects resulting from exposure to a contaminant. The Agency selects an appropriate DWI-BW for each chemical by reviewing the critical effect and study used for HRL derivation and identifying the interval of exposure (for example, see USEPA, 2022c; USEPA, 2022d). Since the critical effect represents the most sensitive adverse effect observed in the best available studies for a given chemical, it is reasonable to assume that the interval of exposure in the critical study could inform the selection of a DWI-BW protective of sensitive populations. When multiple potentially sensitive populations or life stages are identified based on the interval of exposure in the study used for HRL derivation, the EPA selects the population or life stage with the highest DWI-BW because it is the most health protective. See Section B.6.1.2 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA's EF selection process.

In the critical study (Burdock et al., 1981) selected for the 2015 EPA OPP HHRA (USEPA, 2015b), rats were orally exposed to profenofos for 13 weeks. The study does not report how old the rats were at the onset of exposure; however, it does report mean body weights of 175-178 grams for males and 117-120 grams for females (USEPA, 1996). Following the decision logic described in Section B.6.1.2 of the RD 5 Protocol, the EPA extrapolated weight to age based on conversion charts published for rats and selected the appropriate EF based on the estimated age when exposure began. For the Fischer 344 rat breed, the weight range reported by Burdock et al. (1981) at the beginning of the experiment approximates to seven to eight weeks of age (Taconic Biosciences, 2023). Rats and mice at seven to eight weeks of age are in the developmental stage between childhood and adolescence (Ghasemi et al., 2021; Wang et al., 2020). For the purpose of evaluating environmental exposures, the EPA defines childhood in humans as the period from conception through adolescence, until 21 years of age (USEPA, 2021). Therefore, the EPA used the DWI-BW representing the 90th percentile consumers-only, two-day average, direct and indirect community water consumption for children (birth to < 21 years), which equals 0.0343 L/kg/day (USEPA, 2019), to derive the HRL for profenofos.

9.3.3.3 Relative Source Contribution

Relative source contribution (RSC) is used to account for exposure via non-drinking water routes when deriving health-based drinking water concentrations for contaminants with threshold effects (noncarcinogens and nonlinear carcinogens). RSC is defined as the portion (percentage) of an individual's exposure attributed to drinking water rather than other sources (e.g., food, ambient air). A 20 percent RSC is used for all RD 5 contaminants, consistent with past practice for regulatory determinations, to derive the HRL because (1) HRLs are developed prior to completing the exposure assessment; and (2) a 20 percent RSC is the lowest RSC that can be applied for deriving health-based drinking water concentrations according to EPA guidance (USEPA, 2000), and it therefore produces the most health protective HRL. Should a contaminant proceed to a National Primary Drinking Water Regulation (NPDWR), a full exposure analysis is conducted, and an RSC is derived following the Exposure Decision Tree approach described in the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000).

9.3.3.4 HRL Calculation

Exhibit 9-6 summarizes the critical study and toxicity information from the qualifying health assessment and the EF (DWI-BW) and RSC that the EPA used to derive the HRL for profenofos.

Exhibit 9-6: Basis of HRL for Profenofos

Selected Health Assessment	Critical Study	Interval of Exposure	Critical Effect	Oral Toxicity Value	RSC	Target Population	Exposure Factor
EPA OPP Human Health Risk Assessment (USEPA, 2015a; USEPA, 2015b)	Burdock et al. 1981	13 weeks; beginning at approximately 7-8 weeks of age	RBC AChE inhibition in rats	0.00012 mg/kg/day	0.2 (20%)	Children (birth to < 21 years)	0.0343 L/kg/day

The EPA calculates HRLs for contaminants with a threshold dose-response, including profenofos, as follows:

$$HRL = \frac{RfD}{DWI-BW} * RSC$$

where:

RfD = Reference dose (mg/kg/day), an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. It is derived in the selected qualifying health assessment and is based on the critical effect and study identified in that assessment. Other values that can be used in place of an RfD in this equation can include a maximum acceptable concentration (MAC), minimal risk level, point of departure / uncertainty factor (POD/UF), population-adjusted dose (PAD), or tolerable daily intake (TDI).

DWI-BW = Drinking water intake (DWI), adjusted for body weight (BW), in units of liter per kilogram body weight per day (L/kg/day).

RSC = Relative source contribution, the percentage of the total exposure attributed to drinking water sources (USEPA, 2000), where the remainder of the exposure is allocated to other routes or sources. For HRL derivation in RD 5, an RSC of 20 percent is used for all contaminants.

Using an oral reference value of 0.00012 mg/kg/day (USEPA, 2015a; 2015b), a DWI-BW of 0.0343 L/kg/day (USEPA, 2019) and a 20 percent RSC to account for non-drinking-water sources of exposure (USEPA, 2000), the HRL for profenofos is calculated as follows:

$$HRL = \frac{0.00012 \text{ mg/kg/day}}{0.0343 \text{ L/kg/day}} * 0.2$$

$$HRL = 0.0007 \text{ mg/L}$$

or

$$HRL = 0.7\mu\text{g/L}$$

Following HRL derivation practices, the HRL for profenofos is 0.7 $\mu\text{g/L}$ after rounding to one significant figure.

9.4 Occurrence

This section presents data on the occurrence of profenofos in ambient water and drinking water in the United States. As described in Section 9.3, an HRL of 0.7 $\mu\text{g/L}$ was calculated for profenofos based on non-carcinogenic effects. HRLs are risk-derived concentrations against which the EPA evaluates the occurrence data to determine if contaminants occur at levels of potential public health concern. Occurrence data from various sources presented below are analyzed with respect to the HRL and one-half the HRL. When possible, estimates of the population exposed at concentrations above the HRL and one-half the HRL are presented.

For additional background information about data sources used to evaluate occurrence, please refer to Chapter 2.

9.4.1 Occurrence in Ambient Water

Lakes, rivers, and aquifers are the ambient sources of most drinking water. Contaminant occurrence in ambient water provides information on the potential for contaminants to adversely affect drinking water supplies. Occurrence data for profenofos in ambient water are available from the USGS National Water-Quality Assessment (NAWQA) program, the USGS National Water Information System (NWIS) database, the EPA's legacy Storage and Retrieval Data System (STORET), and several published studies. When sources of information on ambient occurrence also include limited finished water data, those finished water data are summarized here as well.

9.4.1.1 United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) Ambient Water Analyses

USGS instituted the NAWQA program in 1991 to examine ambient water quality status and trends in the United States. The NAWQA program generates high quality contaminant occurrence and other water quality parameter data for significant watersheds and aquifers across the nation. The program collects data on surface water and groundwater chemistry, hydrology, land use, stream habitat, and aquatic life in parts of nearly all 50 states. The program is designed to apply nationally consistent methods to provide a uniform basis for contaminant occurrence comparisons and assessments among study basins across the country and over time. The occurrence assessments can also serve to facilitate interpretation of natural and anthropogenic factors affecting national water quality. For more detailed information on NAWQA program design and implementation, refer to Leahy and Thompson (1994) and Hamilton et al. (2004).

The process of sampling, analysis, and data synthesis is divided into cycles of approximately ten years: Cycle 1 covered 1991-2001, Cycle 2 covered 2002-2012, and Cycle 3 covered 2013-2023. Study units are sampled and analyzed on a staggered schedule within each cycle. Each NAWQA cycle begins with a two-year startup phase for planning and retroactive analysis, followed by a three-year intensive data collection phase, and finally a five-year phase

for analyzing the data, developing reports, and continuing a low level of monitoring (NRC, 2012).

The EPA downloaded NAWQA data from the Water Quality Portal (WQP) in September 2023 (WQP, 2023). The EPA's analysis of the NAWQA data is a simple, non-parametric occurrence analysis that provides summary statistics to characterize contaminant occurrence. The EPA included in the analysis all samples that could be classified as groundwater and surface water, and also the limited number of samples labeled as finished water. Other types of samples (e.g., from soil, sediment, and wastewater) were excluded. The EPA calculated detection frequencies as the percentage of samples and the percentage of sites with at least one detection. (A detection is an analytical result equal to or greater than the reporting level.) No weighting was applied. The EPA determined the minimum and maximum detected concentrations and calculated other descriptive statistics including the median, 90th percentile, and 99th percentile concentrations (based only on samples with detections). Reporting levels varied over time during the NAWQA program.

The results of the EPA's analysis of NAWQA data downloaded from WQP are presented in Exhibit 9-7 through Exhibit 9-9. In Cycle 1, profenofos was not detected in 95 samples from 90 sites. In Cycle 2, profenofos was detected only once, in surface water (representing 0.16 percent of 632 surface water samples). In Cycle 3, profenofos was detected in 0.06 percent of both groundwater samples (1 of 1,719) and surface water samples (6 of 10,200). The highest concentration observed, 0.249 µg/L, from surface water, is less than ½ the HRL of 0.7 µg/L. The NAWQA data set for profenofos included no finished water data.

Note that there may be some overlap between the NAWQA data assessment presented here and summaries of individual NAWQA studies presented below.

Exhibit 9-7: Profenofos NAWQA Data – Summary of Detected Concentrations

Site Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90 th Percentile	99 th Percentile	Maximum
Cycle 1 (1991 - 2001)					
Groundwater	--	--	--	--	--
Surface Water	--	--	--	--	--
All Sites	--	--	--	--	--
Cycle 2 (2002 - 2012)					
Groundwater	--	--	--	--	--
Surface Water	0.0013	0.0013	0.0013	0.0013	0.0013
All Sites	0.0013	0.0013	0.0013	0.0013	0.0013
Cycle 3 (2013 - 2023)					
Groundwater	0.00072	0.00072	0.00072	0.00072	0.00072
Surface Water	0.00077	0.0262	0.212	0.245	0.249
All Sites	0.00072	0.0016	0.206	0.245	0.249

Source: WQP, 2023

-- = No detections in this category

Exhibit 9-8: Profenofos NAWQA Data – Summary of Samples

Site Type	No. of Samples	Detection Frequency (detections are results ≥ reporting level)					
		No. of Samples with Detections	Percent Samples with Detections	No. of Samples with Detections > ½ HRL	Percent Samples with Detections > ½ HRL	No. of Samples with Detections > HRL	Percent Samples with Detections > HRL
Cycle 1 (1991 - 2001)							
Groundwater	75	0	0.00%	0	0.00%	0	0.00%
Surface Water	20	0	0.00%	0	0.00%	0	0.00%
All Sites	95	0	0.00%	0	0.00%	0	0.00%
Cycle 2 (2002 - 2012)							
Groundwater	230	0	0.00%	0	0.00%	0	0.00%
Surface Water	632	1	0.16%	0	0.00%	0	0.00%
All Sites	862	1	0.12%	0	0.00%	0	0.00%
Cycle 3 (2013 - 2023)							
Groundwater	1,719	1	0.06%	0	0.00%	0	0.00%
Surface Water	10,200	6	0.06%	0	0.00%	0	0.00%
All Sites	11,919	7	0.06%	0	0.00%	0	0.00%

Source: WQP, 2023

Exhibit 9-9: Profenofos NAWQA Data – Summary of Sites

Site Type	No. of Sites	Detection Frequency (detections are results $\geq$ reporting level)					
		No. of Sites with Detections	Percent Sites with Detections	No. of Sites with Detections > ½ HRL	Percent Sites with Detections > ½ HRL	No. of Sites with Detections > HRL	Percent Sites with Detections > HRL
Cycle 1 (1991 – 2001)							
Groundwater	75	0	0.00%	0	0.00%	0	0.00%
Surface Water	15	0	0.00%	0	0.00%	0	0.00%
All Sites	90	0	0.00%	0	0.00%	0	0.00%
Cycle 2 (2002 - 2012)							
Groundwater	222	0	0.00%	0	0.00%	0	0.00%
Surface Water	81	1	1.23%	0	0.00%	0	0.00%
All Sites	303	1	0.33%	0	0.00%	0	0.00%
Cycle 3 (2013 - 2023)							
Groundwater	1,643	1	0.06%	0	0.00%	0	0.00%
Surface Water	476	5	1.05%	0	0.00%	0	0.00%
All Sites	2,119	6	0.28%	0	0.00%	0	0.00%

Source: WQP, 2023

9.4.1.2 National Water Information System (NWIS) Data

NWIS is the nation's principal repository of water resources data collected by USGS from more than 1.9 million sites in all U.S. states and territories (USGS, 2022). All USGS water

quality and flow data are stored in NWIS, including site characteristics, streamflow, groundwater level, precipitation, and chemical analyses of water, sediment, and biological media, though not all parameters are available for every site. NWIS houses the NAWQA data and includes other USGS data from a range of unspecified projects. NWIS encompasses many more samples at many more sites than are involved in the NAWQA Program. Although NWIS is comprised of primarily ambient water data, some finished drinking water data are included as well. This section presents analyses of non-NAWQA data in NWIS, downloaded from the WQP in September 2023 (WQP, 2023). These data do not overlap with the NAWQA results presented above.

The results of the non-NAWQA NWIS profenofos analysis are presented in Exhibit 9-10. Profenofos was detected in a single surface water sample, representing approximately 0.03 percent of 3,711 surface water samples from approximately 0.2 percent of 568 sites. There were no detections in 1,241 groundwater samples from 905 sites. The single surface water detection had a profenofos concentration of 0.00019 µg/L, which is less than ½ the HRL of 0.7 µg/L. The non-NAWQA NWIS data set for profenofos included a single finished water sample; profenofos was not detected in this sample.

Exhibit 9-10: Profenofos NWIS Data, 1991-2023

Sample Media Type	Detection Frequency (detections are results ≥ reporting level)				Concentration Values (of detections, in µg/L)				
	No. of Samples	No. of Samples with Detections	No. of Sites	No. of Sites with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
Finished Water	1	0	1	0	--	--	--	--	--
Groundwater	1,241	0	905	0	--	--	--	--	--
Surface Water	3,711	1	568	1	0.00019	0.00019	0.00019	0.00019	0.00019
Total	4,953	1	1,474	1	0.00019	0.00019	0.00019	0.00019	0.00019

Source: WQP, 2023

-- = No detections in this category

Note that some NWIS sites are associated with multiple sample media types, so site counts might not add up to totals.

9.4.1.3 Storage and Retrieval (STORET) Data

From its launch in 1999 until it was decommissioned in June 2018, the EPA's STORET Data Warehouse was collaboratively populated with raw biological, chemical, and physical data from surface water and groundwater sampling by federal, state and local agencies, Native American Tribes, volunteer groups, academics, and others. Legacy STORET data, as well as more current STORET data, are accessible through the WQP.

STORET data are from monitoring locations in all 50 states as well as multiple territories and jurisdictions of the United States. STORET's data quality limitations include variations in the extent of national coverage and data completeness from parameter to parameter. Data may have been collected as part of targeted, rather than randomized, monitoring. This section presents analyses of STORET data, downloaded from the WQP in September 2023 (WQP, 2023). The EPA reviewed STORET groundwater data from wells and springs and surface water data from

lakes, rivers/streams, and reservoirs. The STORET data set also included limited data from public water systems (PWSs). The database does not specify whether PWS sampling was conducted before or after treatment.

The results of the STORET analysis for profenofos are presented in Exhibit 9-11 and Exhibit 9-12. Samples were collected between 1995 and 1999. The STORET data set for profenofos includes 5 groundwater samples from 5 sites. There were no detections.

Exhibit 9-11: Profenofos STORET Data – Summary of Samples and Sites

Source Water Type	Total Number of Samples	Samples with Detections		Total Number of Sites	Sites with Detections	
		Number	Percent		Number	Percent
Groundwater	5	0	0.00%	5	0	0.00%
Surface Water	0	0	n/a	0	0	n/a
Total	5	0	0.00%	5	0	0.00%

Source: WQP, 2023

Exhibit 9-12: Profenofos STORET Data – Summary of States

Source Water Type	Total Number of States	States with Detections	
		Number	Percent
Groundwater	1	0	0%
Surface Water	0	0	n/a
Total¹	1	0	0%

Source: WQP, 2023

¹ The number of states with groundwater data plus the number of states with surface water data may not equal the “Total” number of states providing data because some states provided both groundwater and surface water data.

9.4.1.4 Additional Ambient Water Studies

Kingsbury et al. (2021) evaluated groundwater-quality samples collected from 2017 to 2019 as part of the third cycle of USGS’s NAWQA Program. Six types of well network studies were conducted: principal aquifer study networks; major aquifer study networks; land-use study networks; vertical flow-path study networks; enhanced trends networks; and modeling support studies. The reporting level used for profenofos was 0.0015 µg/L. Profenofos was not detected in any of the 468 samples at 462 sites.

9.4.2 Occurrence in Drinking Water

Data sources reviewed by the Agency for information on contaminant occurrence in drinking water included: the EPA’s first, second, third, and fourth Unregulated Contaminant Monitoring Rules (UCMR 1, UCMR 2, UCMR 3, UCMR 4); Rounds 1 and 2 of the Agency’s Unregulated Contaminant Monitoring (UCM) program that preceded the Unregulated Contaminant Monitoring Rule (UCMR); the EPA’s National Inorganics and Radionuclides

Survey (NIRS); and a range of others as discussed in Chapter 2. Among the sources reviewed, the following sources had data and information on profenofos occurrence in drinking water and are discussed in this section:

- The EPA’s Fourth Unregulated Contaminant Monitoring Rule (UCMR 4).
- Consumer Confidence Reports (CCRs) from PWSs.
- United States Department of Agriculture (USDA) Pesticide Data Program (PDP).
- USGS Pilot Monitoring Program (PMP).

Note that there may be some overlap as sources with different purposes and audiences may have reported the same underlying data. UCMR 4 is a nationally representative data source. Other data sources profiled in this section are considered “supplemental” sources. Also note that the ambient water section, above, presents some limited finished water data and miscellaneous data from PWSs found in ambient water data sources.

9.4.2.1 Primary Data Sources

9.4.2.1.1 *The EPA’s Fourth Unregulated Contaminant Monitoring Rule (UCMR 4), 2018-2020*

The UCMR program was designed to provide a national assessment of the occurrence of select unregulated contaminants in PWSs. UCMR 4 was published on December 20, 2016 (USEPA, 2016) and required monitoring for 30 chemical contaminants between 2018 and 2020. Data reporting continued into 2021.

UCMR 4 Assessment Monitoring occurrence data are available for profenofos. For UCMR 4, all large and very large community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) (serving between 10,001 and 100,000 people and serving more than 100,000 people, respectively), plus a statistically representative national sample of 800 small CWSs and NTNCWSs (serving 10,000 people or fewer), were required to conduct Assessment Monitoring during a 12-month period between January 2018 and December 2020.¹ Surface water and groundwater under the direct influence of surface water (GWUDI) sampling points were monitored four times during the applicable year of monitoring. Groundwater sampling points were monitored twice during the applicable year of monitoring. See USEPA (2016) and USEPA (2024) for more information on the UCMR 4 study design and data analysis.

The design of UCMR 4 permits estimation of national occurrence by multiplying the total number of systems (or population served) in the nation in a system size category by the percent of systems (or population served) found to exceed a specified threshold in the sample. This extrapolation methodology is applied to small systems. Because all large and very large systems were required to participate in the UCMR 4 Assessment Monitoring, national occurrence estimates in these size categories can be developed using survey census figures rather than extrapolation. Total national occurrence is estimated by summing the extrapolated figures for small systems and the census figures for the large and very large systems.

Exhibit 9-13 through Exhibit 9-17 provide an overview of profenofos occurrence results from UCMR 4 Assessment Monitoring. The minimum reporting level (MRL) used for

¹ Only 797 small systems submitted results for profenofos.

profenofos in the UCMR 4 survey was 0.3 µg/L. Exhibit 9-13 shows a statistical summary of profenofos concentrations by system size and source water type (including the minimum, median, 90th percentile, 99th percentile, and maximum).

Exhibit 9-14 presents a sample-level summary of the results. Exhibit 9-15 through Exhibit 9-17 show system-level results, including national extrapolations, at three thresholds: detections, ½ the HRL, and the HRL. Detections are evaluated on a “greater than or equal to” basis ($\geq$ the MRL), while health-based thresholds are evaluated in terms of exceedances ($> \frac{1}{2}$ HRL and $>$ HRL).

As a reminder that the figures from large and very large systems represent a census of systems in those categories, results in those categories are labeled “CENSUS” in the exhibits below. No extrapolation was necessary in these categories, as it was for the small systems, to derive national estimates of occurrence. National estimates of occurrence are reported separately in each system size and source water category, and also in the aggregate.

A total of 37,287 UCMR 4 samples for profenofos were collected from 5,028 systems. Profenofos was detected in only four samples (0.01 percent), with concentrations ranging from 0.464 µg/L to 0.848 µg/L. The detections were found at four large water systems, representing 0.08 percent of systems participating in the monitoring program. All four systems reported at least one detection of profenofos greater than ½ the HRL of 0.35 µg/L and 1 system serving nearly 15,000 people reported at least one detection of profenofos greater than the HRL of 0.7 µg/L.

Exhibit 9-13: Profenofos Occurrence Data from UCMR 4 Assessment Monitoring – Summary of Reported Concentrations

Source Water Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90th Percentile	99th Percentile	Maximum
Small Systems (serving $\leq 10,000$ people)					
Groundwater	--	--	--	--	--
Surface Water	--	--	--	--	--
All Small Systems	--	--	--	--	--
Large Systems (serving 10,001 - 100,000 people) -- CENSUS					
Groundwater	0.52	0.52	0.52	0.52	0.52
Surface Water	0.464	0.588	0.796	0.843	0.848
All Large Systems	0.464	0.554	0.770	0.840	0.848
Very Large Systems (serving $> 100,000$ people) -- CENSUS					
Groundwater	--	--	--	--	--
Surface Water	--	--	--	--	--
All Very Large Systems	--	--	--	--	--
All Systems					
All Water Systems	0.464	0.554	0.770	0.840	0.848

Source: USEPA, 2024

-- = No detections in this category

Exhibit 9-14: Profenofos National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of Samples

Source Water Type	Total # of Samples	Samples with Detections ≥ MRL (0.3 µg/L)		Samples with Detections > ½ HRL (0.35 µg/L)		Samples with Detections > HRL (0.7 µg/L)	
		Number	Percent	Number	Percent	Number	Percent
Small Systems (serving ≤ 10,000 people)							
Groundwater	1,896	0	0.00%	0	0.00%	0	0.00%
Surface Water	1,360	0	0.00%	0	0.00%	0	0.00%
All Small Systems	3,256	0	0.00%	0	0.00%	0	0.00%
Large Systems (serving 10,001 - 100,000 people) -- CENSUS							
Groundwater	10,949	1	0.01%	1	0.01%	0	0.00%
Surface Water	15,715	3	0.02%	3	0.02%	1	0.01%
All Large Systems	26,664	4	0.02%	4	0.02%	1	0.00%
Very Large Systems (serving > 100,000 people) -- CENSUS							
Groundwater	2,057	0	0.00%	0	0.00%	0	0.00%
Surface Water	5,310	0	0.00%	0	0.00%	0	0.00%
All Very Large Systems	7,367	0	0.00%	0	0.00%	0	0.00%
All Systems							
All Water Systems	37,287	4	0.01%	4	0.01%	1	0.00%

Source: USEPA, 2024

Exhibit 9-15: Profenofos National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population – All Reported Detections

Source Water Type	UCMR 4 Sample		Number With At Least One Detection $\geq$ MRL (0.3 $\mu\text{g/L}$)		Percent With At Least One Detection $\geq$ MRL (0.3 $\mu\text{g/L}$)		National Inventory ¹		National Estimate of Number With At Least One Detection $\geq$ MRL (0.3 $\mu\text{g/L}$) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving $\leq$ 10,000 people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,468	37,653,948	1	18,000	0.07%	0.05%	1,468	37,653,948	1	18,000
Surface Water	2,340	71,511,793	3	67,728	0.13%	0.09%	2,340	71,511,793	3	67,700
All Large Systems	3,808	109,165,741	4	85,728	0.11%	0.08%	3,808	109,165,741	4	85,700
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,028	249,079,866	4	85,728	0.08%	0.03%	67,732	307,144,948	4	85,700

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

**Exhibit 9-16: Profenofos National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data –
Summary of System and Population Served Data – Detections > ½ the HRL (0.35 µg/L)**

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > ½ HRL (0.35 µg/L)		Percent With At Least One Detection > ½ HRL (0.35 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > ½ HRL (0.35 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,468	37,653,948	1	18,000	0.07%	0.05%	1,468	37,653,948	1	18,000
Surface Water	2,340	71,511,793	3	67,728	0.13%	0.09%	2,340	71,511,793	3	67,700
All Large Systems	3,808	109,165,741	4	85,728	0.11%	0.08%	3,808	109,165,741	4	85,700
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,028	249,079,866	4	85,728	0.08%	0.03%	67,732	307,144,948	4	85,700

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

**Exhibit 9-17: Profenofos National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data –
Summary of System and Population Served Data – Detections > HRL (0.7 µg/L)**

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > HRL (0.7 µg/L)		Percent With At Least One Detection > HRL (0.7 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > HRL (0.7 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,468	37,653,948	0	0	0.00%	0.00%	1,468	37,653,948	0	0
Surface Water	2,340	71,511,793	1	14,999	0.04%	0.02%	2,340	71,511,793	1	15,000
All Large Systems	3,808	109,165,741	1	14,999	0.03%	0.01%	3,808	109,165,741	1	15,000
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,028	249,079,866	1	14,999	0.02%	0.01%	67,732	307,144,948	1	15,000

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

9.4.2.2 Supplemental Data Sources

9.4.2.2.1 *Water Systems' Consumer Confidence Reports (CCRs), 2018-2021*

CCRs are annual water quality reports that CWSs are required to provide to their customers. These reports summarize information on water sources, detected contaminants, and system compliance with EPA drinking water standards; they may also include general educational material. Under the CCR Rule (40 CFR Subpart O), CWSs with 15 or more connections or serving at least 25 year-round residents must prepare and distribute a CCR to all billing units or service connections every year. Systems serving 100,000 or more residents are also required to post their current CCRs on a publicly accessible Internet site.

The EPA reviewed CCRs published by the 25 systems that serve over one million customers (as identified in the Safe Drinking Water Information System / Federal version, or SDWIS/Fed, from the fourth quarter 2021 data) for unregulated contaminant occurrence information for the years 2018 through 2021. Data on profenofos were available from CCRs prepared by five CWSs: one system in California (Los Angeles), one system in Colorado (Denver), two systems in New York (Suffolk County and New York City), and one system in Pennsylvania (Philadelphia). Monitoring results from all five systems showed no detections of profenofos.

Los Angeles Department of Water & Power (LADWP) included data on profenofos monitoring for UCMR 4 in its 2020 and 2021 CCRs. LADWP is served by multiple surface water and groundwater sources. The sampling was conducted in 2018-2019. Profenofos was not detected.

Denver Water included data on profenofos monitoring for UCMR 4 in its 2018 CCR. Denver Water is served by the South Platte River and other surface water sources. An average profenofos concentration of “0 µg/L” was reported for treatment plant effluent.

Suffolk County, New York, included data on profenofos in its 2018-2021 CCRs. Suffolk County is served by groundwater from four major aquifers beneath Long Island. In all 4 years, profenofos was monitored for but was not detected.

New York City included data on profenofos in four CCRs covering 2018 through 2021. New York City is served by a large system of surface water networks in New York state. In all 4 years, profenofos was monitored for but was not detected.

The Philadelphia Water Department (PWD) included data on profenofos in three CCRs covering 2019 through 2021. PWD is served by surface water from the Schuylkill and Delaware rivers. In all 3 years, profenofos was monitored for but was not detected.

9.4.2.2.2 *United States Department of Agriculture (USDA) Pesticide Data Program (PDP), 2001-2013*

The USDA PDP maintains a national pesticide residue database. PDP was initiated in 1991 to collect representative data on pesticide residues in the United States food supply, following a rigorous statistical design. Sampling and testing have been conducted on fruits and vegetables, select grains, milk, and (between 2001 and 2013) drinking water (USDA, 2022).

The PDP drinking water project was initiated at CWSs in New York and California in 2001. Since then, the drinking water sampling program has expanded, though a somewhat

changing mix of states is sampled each year. At one time or another, CWSs in 29 states and the District of Columbia have contributed raw or finished water data or both to the program (USDA, 2023). The CWSs selected for sampling tend to be small and medium-sized systems (primarily CWSs serving under 50,000), systems served by surface water, and systems located in regions of heavy agriculture. Sampling of raw (“untreated”) water in addition to finished water began in 2004; sampling of raw and finished drinking water was discontinued after 2013. Note that temporal trends cannot be evaluated based on these data since the list of CWSs included in the project varied from year to year (USDA, 2022; USDA, 2023).

Profenofos was included in the USDA PDP (Exhibit 9-18) (USDA, 2022). Profenofos was not detected in any of 4,521 samples (1,388 raw water and 3,133 finished water). The reported limits of detection ranged from 0.0023 to 0.03 µg/L.

Exhibit 9-18: Summary of Profenofos PDP Data, 2001-2013

Year	Raw/ Finished	Total Number of Samples	Number of Detections	Percent of Detections	Minimum Value of Detections (µg/L)	Maximum Value of Detections (µg/L)
2001	Finished	283	0	0.00%	N/A	N/A
2002	Finished	669	0	0.00%	N/A	N/A
2003	Finished	794	0	0.00%	N/A	N/A
2004	Finished	239	0	0.00%	N/A	N/A
	Raw	239	0	0.00%	N/A	N/A
2005	Finished	230	0	0.00%	N/A	N/A
	Raw	232	0	0.00%	N/A	N/A
2006	Finished	235	0	0.00%	N/A	N/A
	Raw	236	0	0.00%	N/A	N/A
2007	Finished	234	0	0.00%	N/A	N/A
	Raw	232	0	0.00%	N/A	N/A
2008	Finished	120	0	0.00%	N/A	N/A
	Raw	120	0	0.00%	N/A	N/A
2009	Finished	119	0	0.00%	N/A	N/A
	Raw	119	0	0.00%	N/A	N/A
2010	Finished	91	0	0.00%	N/A	N/A
	Raw	90	0	0.00%	N/A	N/A
2011	Finished	119	0	0.00%	N/A	N/A
	Raw	120	0	0.00%	N/A	N/A
2012	Finished	No Data	No Data	No Data	No Data	No Data
	Raw	No Data	No Data	No Data	No Data	No Data

Year	Raw/ Finished	Total Number of Samples	Number of Detections	Percent of Detections	Minimum Value of Detections (µg/L)	Maximum Value of Detections (µg/L)
2013	Finished	No Data	No Data	No Data	No Data	No Data
	Raw	No Data	No Data	No Data	No Data	No Data

Source: USDA, 2022

N/A = not applicable (no detections in this category).

9.4.2.2.3 *United States Geological Survey (USGS) Pilot Monitoring Program (PMP), 1999*

In 1999, the PMP was initiated by USGS and the EPA to provide information on pesticide concentrations in drinking water. The program focused on small drinking water supply reservoirs in areas with high pesticide use in order to test the sampling approach in areas where pesticides are probably present (Blomquist et al., 2001). Sampling sites represented a variety of geographic regions as well as different cropping patterns. The ideal site candidates were mostly small reservoirs located in high pesticide-use areas with a high runoff potential. Twelve water-supply reservoirs considered vulnerable to pesticide contamination were selected from the list of candidates. These 12 sites were located in California, Indiana, Louisiana, Missouri, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, and Texas.

Samples were collected quarterly throughout the year and at weekly or biweekly intervals following the primary pesticide-application periods. Water samples were collected from the raw-water intake and from finished drinking water taps prior to entering the distribution system. At some sites, samples were also collected at the reservoir outflow.

Profenofos was an analyte in the PMP. At a method reporting level of 0.008 µg/L, profenofos was not detected in any of the 317 samples from raw water sites or any of the 221 samples from finished water sites (Blomquist et al., 2001).

9.5 Analytical Methods

The EPA has published one analytical method that is available for the analysis of profenofos in drinking water:

- EPA Method 525.3, Version 1.0, *Determination of Semivolatile Organic Chemicals in Drinking Water by Solid Phase Extraction and Capillary Column Gas Chromatography/Mass Spectrometry (GC/MS)* has detection limits (DLs) that range from 0.055 to 0.11 µg/L in Full Scan mode and a DL of 0.0081 µg/L in Selected Ion Monitoring (SIM) mode. The Lowest Concentration Minimum Reporting Levels (LCMRLs) generated by the laboratories that helped to develop the method range from 0.11 to 0.31 µg/L in Full Scan mode and 0.012 to 0.029 µg/L in SIM mode. Mean recoveries in reagent water, finished water from groundwater with a hardness of 290 to ≥350 mg/L (as calcium carbonate) and finished drinking water from surface water with total organic carbon (TOC) of 2.4 to 2.8 mg/L range from 89.9 to 125 percent, with relative standard deviations (RSDs) of 0.9 to 16.0 percent for Full Scan mode. Mean recoveries in reagent water, finished water from groundwater with a hardness of 325 to 393 mg/L (as calcium carbonate) and finished drinking water from surface water with TOC of 2.0 to 2.52 mg/L and a hardness of 137 mg/L (as calcium carbonate) range from 92.0 to 119 percent, with RSDs of 1.5 to 8.4 percent for SIM mode (USEPA, 2012).

Laboratories participating in UCMR 4 were required to use EPA Method 525.3 and were required to report profenofos values at or above the EPA-defined MRL of 0.3 µg/L (81 FR 92666; USEPA, 2016). The MRL was set based on the capability of multiple laboratories at the time.

9.6 Treatment Technologies

The EPA evaluates whether suitable treatment technologies are available prior to promulgating a final NPDWR. The preliminary summary of treatment technology availability presented here represents the results of a December 2023 literature search.

Amin et al. (2014) conducted bench-scale experiments of profenofos treatment using advanced oxidation. The tests were conducted using deionized water with initial profenofos concentrations of 10,000, 15,000, and 20,000 µg/L and varying pH (5, 6.5, and 8). The samples were exposed to a combination of UV (30, 60, and 90 minutes) and hydrogen peroxide (0.01, 0.05, and 0.10 moles). The average efficiency of removal of profenofos across nine trials under varying conditions was 86.8±/-6%. Under optimal conditions (90 minutes at pH 8, with an initial concentration of 10,000 µg/L and the highest dose of hydrogen peroxide), 98.5% removal of profenofos was achieved.

Zamy et al. (2004) examined the phototransformation of profenofos in purified water and river water when ultraviolet light is applied. Initial profenofos doses ranged from 10 to 100 µg/L. Monochromatic light (253.7 nm) and polychromatic light (>285 nm) were used. Photolysis of profenofos was slower, by factor of 0.7, in surface water than in purified water. The authors observe that whereas the presence of natural organic matter (NOM) in river water acts as a photosensitizer for some pesticides, for others, including profenofos, it acts as a filter.

9.7 References

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Chapter 10: Tebuconazole

A chapter from:

Final Regulatory Determination 5 Support Document

EPA Report 815-R-26-002

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Abbreviations

BAC	Biological Activated Carbon
BW	Body Weight
CASRN	Chemical Abstracts Service Registry Number
CCL 5	Fifth Contaminant Candidate List
CCR	Consumer Confidence Report
CDR	Chemical Data Reporting
cPAD	Chronic Population-Adjusted Dose
CWS	Community Water System
DL	Detection Limit
DWI	Drinking Water Intake
DWI-BW	Drinking Water Intake Rate Adjusted for Body Weight
EF	Exposure Factor
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GD	Gestational Days
GWUDI	Groundwater Under the Direct Influence of Surface Water
HDC	Catalytic Hydrochlorination
HED	Health Effects Division
HHRA	Human Health Risk Assessment
HRL	Health Reference Level
IUR	Inventory Update Reporting
K _H	Henry's Law Constant
K _{oc}	Organic Carbon Partitioning Coefficient
K _{ow}	Octanol/Water Partitioning Coefficient
LADWP	Los Angeles Department of Water & Power
LCMRL	Lowest Concentration Minimum Reporting Level
LOAEL	Lowest-Observed-Adverse-Effect Level
LOQ	Limit of Quantitation
MAC	Maximum Acceptable Concentration
MDL	Method Detection Limit
MRL	Minimum Reporting Level
NAWQA	National Water-Quality Assessment
NCFAP	National Center for Food and Agricultural Policy
NIRS	National Inorganics and Radionuclides Survey
NOAEL	No-Observed-Adverse-Effect Level
NPDWR	National Primary Drinking Water Regulation
NTNCWS	Non-Transient Non-Community Water Systems
NWIS	National Water Information System
OGWDW	Office of Ground Water and Drinking Water
OPP	Office of Pesticide Programs
PAD	Population-Adjusted Dose
PDP	Pesticide Data Program
POD	Point of Departure
POD/UF	Point of Departure / Uncertainty Factor

PWD	Philadelphia Water Department
PWS	Public Water System
RD 5	Fifth Regulatory Determination
RfD	Reference Dose
RSC	Relative Source Contribution
RSD	Relative Standard Deviation
RUP	Restricted Use Pesticide
SDWA	Safe Drinking Water Act
SDWIS/Fed	Safe Drinking Water Information System / Federal Version
SIM	Selected Ion Monitoring
STORET	Storage and Retrieval Data System
TDI	Tolerable Daily Intake
TOC	Total Organic Carbon
TRI	Toxics Release Inventory
UCM	Unregulated Contaminant Monitoring
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 1	First Unregulated Contaminant Monitoring Rule
UCMR 2	Second Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 4	Fourth Unregulated Contaminant Monitoring Rule
UF	Uncertainty Factor
UF _A	Interspecies Uncertainty Factor
UF _H	Intraspecies Uncertainty Factor
USDA	United States Department of Agriculture
USGS	United States Geological Survey
UVC	Ultraviolet C Radiation
VUV	Vacuum Ultraviolet
WQP	Water Quality Portal

Chapter 10: Tebuconazole

The U.S. Environmental Protection Agency (EPA) is evaluating tebuconazole, a contaminant on the fifth Contaminant Candidate List (CCL 5), as a candidate for regulation under the fifth Regulatory Determination process (RD 5). Information on the CCL 5 process is found in Chapter 1. Background on data sources used to evaluate CCL 5 chemicals is found in Chapter 2.

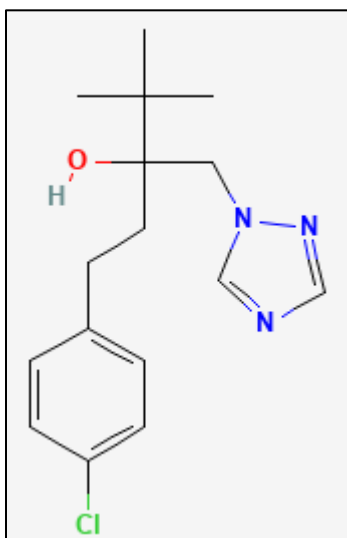
This chapter presents information and analysis specific to tebuconazole, including background information on the contaminant, information on contaminant sources and environmental fate, an analysis of health effects, an analysis of occurrence in ambient and drinking water, and information about the availability of analytical methods and treatment technologies.

10.1 Contaminant Background and Chemical and Physical Properties

Tebuconazole is a monochlorobenzene, a triazole and a tertiary alcohol and is used as a fungicide. Synonyms for tebuconazole include folicur, terbutrazole, ethyltrianol, and fenetrazole (NCBI, 2023). Tebuconazole was first registered in the United States in 1983 (USEPA, 2023a). One formulation/product, a mixture of tebuconazole and lambda-cyhalothrin, is a Restricted Use Pesticide (RUP) (USEPA, 2022a). The RUP designation is likely due to tebuconazole being co-formulated with lambda-cyhalothrin and not to the presence of tebuconazole.

Exhibit 10-1 presents the structural formula for tebuconazole. Physical and chemical properties and other reference information are listed in Exhibit 10-2.

Exhibit 10-1: Chemical Structure of Tebuconazole



Source: NCBI, 2023

Exhibit 10-2: Physical and Chemical Properties of Tebuconazole

Property	Data
Chemical Abstracts Service Registry Number (CASRN)	107534-96-3 (NCBI, 2023)
EPA Pesticide Chemical Code	128997 (NCBI, 2023)
Chemical Formula	C ₁₆ H ₂₂ ClN ₃ O (NCBI, 2023)
Molecular Weight	307.82 g/mol (NCBI, 2023)
Color/Physical State	Colorless crystals, white to beige solid (NCBI, 2023)
Boiling Point	--
Melting Point	105 °C (NCBI, 2023)
Density	--
Freundlich Adsorption Coefficient	--
Vapor Pressure	1.3 x 10 ⁻⁸ mm Hg (NCBI, 2023)
Henry's Law Constant (K _H)	1.4X10 ⁻¹⁰ atm·m ³ /mole (NCBI, 2023)
Octanol/Water Partitioning Coefficient (log K _{ow})	3.7 (NCBI, 2023)
Organic Carbon Partitioning Coefficient (K _{oc})	470-6,000 L/kg (NCBI, 2023)
Solubility in Water	36 mg/L at pH 5-9 and 20 °C (NCBI, 2023)
Other Solvents	--

Note: Many of these properties are temperature-dependent. Values are given for properties at 20-25°C unless otherwise noted. Due to varying experimental conditions, and due to the variabilities associated with modeling, standard information sources may provide a range of values. Where more than one value was available from these sources, one value was selected for this table based on best professional judgment.

10.2 Sources and Environmental Fate

10.2.1 Production, Use, and Release

No data on production of tebuconazole are available from the EPA's Inventory Update Reporting (IUR) and Chemical Data Reporting (CDR) programs, and no industrial release data are available from the EPA's Toxics Release Inventory (TRI). The list of chemicals for which TRI reporting is required has never included tebuconazole (USEPA, 2023b). However, several sources provide information about quantities of tebuconazole used in agriculture.

National Center for Food and Agricultural Policy (NCFAP) Pesticide Use Database

The National Center for Food and Agricultural Policy (NCFAP) maintains a national Pesticide Use Database, primarily for herbicides. Pesticide use estimates are based on state-level commercial agriculture usage patterns and state-level crop acreage. NCFAP lists uses of tebuconazole on seven crops totaling approximately 479,000 pounds active ingredient per year in 16 states in 1997 (NCFAP, 2000). NCFAP does not report quantities of tebuconazole used in 1992.

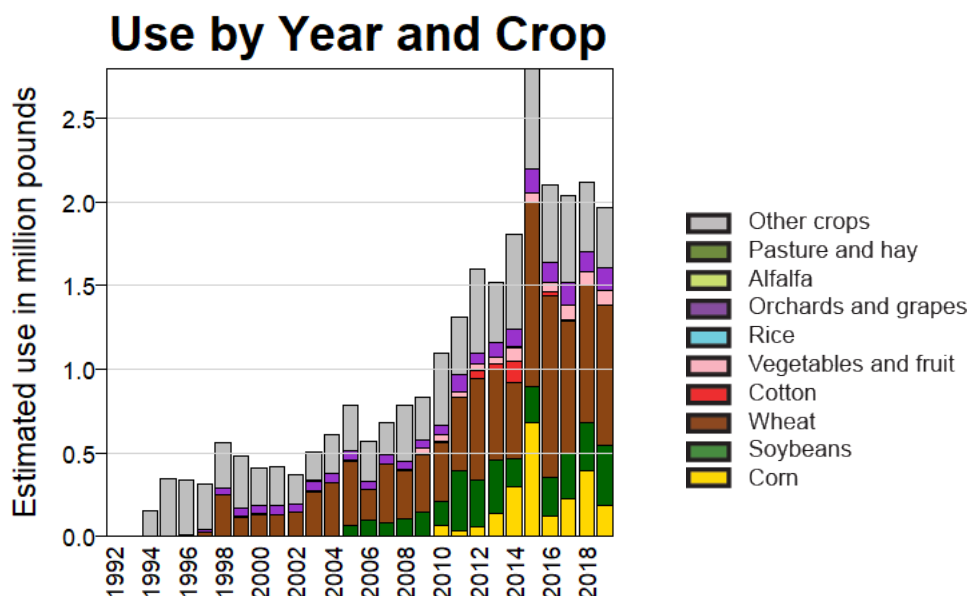
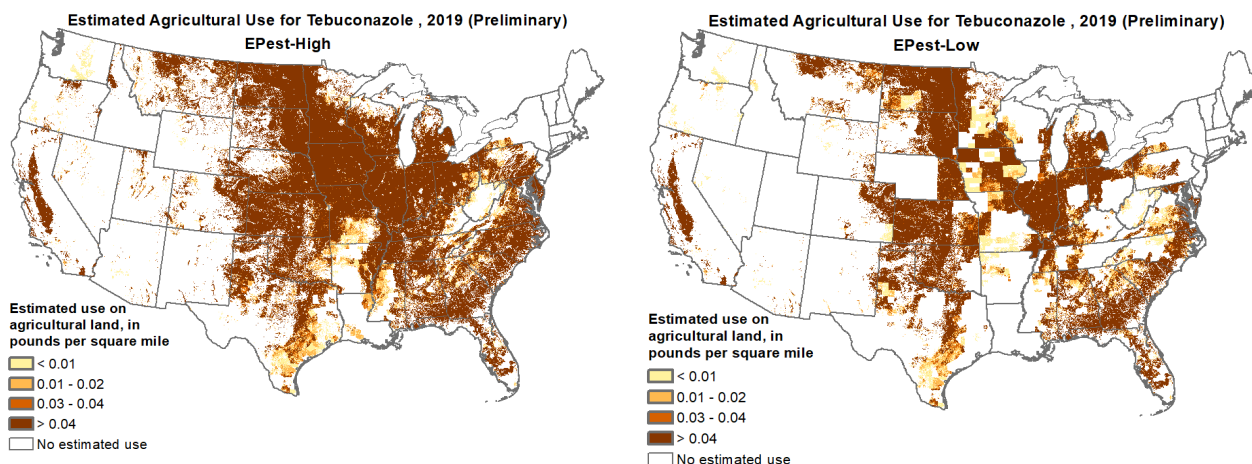
United States Geological Survey (USGS) Pesticide Use Maps

The United States Geological Survey (USGS) produces estimates of annual national pesticide use for over 200 compounds. USGS pesticide use maps show the average annual pesticide use intensity expressed as average weight (in pounds) of a pesticide applied to each

square mile of agricultural land in a county. The USGS maps are created using data from NCFAP and county-level information on harvested crop acreage from the Census of Agriculture (USGS, 2023).

Exhibit 10-3 shows the geographic distribution of estimated annual tebuconazole use in the United States in 2019. The differences between the “low” and “high” estimates primarily reflect assumptions made when data on usage of a pesticide were unavailable from a crop reporting district (i.e., an assumption of no pesticide usage or an assumption that usage was comparable to neighboring districts). A breakdown of use by crop from year to year is also included below, using the “high” assumption. Estimated usage has generally increased over the past few decades, peaking in 2015 at over 2.5 million pounds and then remaining steady at around 2.0 million pounds per year from 2016 to 2019. Wheat is the most treated crop; other important tebuconazole-treated crops have included soybeans and corn. The maps indicate that tebuconazole is widely used in the South, the Midwest, and the Great Plains states, and in California’s Central Valley (USGS, 2023).

Exhibit 10-3: Estimated Annual Agricultural Use of Tebuconazole, 2019



Source: USGS, 2023

10.2.2 Environmental Fate

As discussed in Chapter 2, the measures used by the EPA to assess mobility include (where available) the organic carbon partitioning coefficient (K_{oc}), log octanol/water partitioning coefficient ($\log K_{ow}$), Henry's Law Constant (K_H), water solubility, and vapor pressure. A vapor pressure of 1.3×10^{-8} mm Hg at 25 degrees C indicates that tebuconazole will exist only in the particulate phase if it is released to the atmosphere. K_{oc} values of 470-6,000 L/kg suggest that tebuconazole will have moderate to no mobility in soil. Tebuconazole is not expected to volatilize from dry soil surfaces and with a K_H of 1.4×10^{-10} atm-m³/mol, volatilization from water is not expected to be an important removal mechanism (NCBI, 2023).

Tebuconazole is expected to be persistent with an aerobic metabolism half-life of approximately 800 days (USEPA, 2000a). Tebuconazole is resistant/stable to hydrolysis (NCBI, 2023) with a half-life of >>>28 days (USEPA, 2000a). Tebuconazole is resistant/stable to photolysis (NCBI, 2023) with half-lives of 600 days in water (extrapolated) and 191 days in soil (USEPA, 2000a). Bioconcentration of tebuconazole in aquatic organisms is expected to be high (NCBI, 2023).

10.3 Health Effects

10.3.1 Health Assessment Identification

Tebuconazole is a currently registered pesticide chemical under the EPA’s Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (USEPA, 2021a). For currently registered pesticide chemicals, the RD 5 Protocol provides that toxicity information from EPA Office of Pesticide Programs (OPP) Health Effects Division (HED) Human Health Risk Assessments (HHRAs) are to be used as the basis of calculating health reference levels (HRL). (See Section B.5.1.1 of the RD 5 Protocol, found in Appendix B of this document.) Therefore, the EPA reviewed the toxicity information in the HHRA for tebuconazole (USEPA, 2021a; USEPA, 2021b). The OPP health assessment provides a toxicity value relevant to chronic oral toxicity and was published prior to the cutoff date of January 2023.

Exhibit 10-4 provides a summary overview of the OPP health assessment data reviewed and selected for tebuconazole under RD 5.

Exhibit 10-4: OPP Health Assessment Supporting Current FIFRA Registration for Tebuconazole

Health Assessment ^a	Oral Reference Value	POD Type	Noncancer Critical Study	Oral Cancer Slope Factor	Cancer Critical Study	Cancer Descriptor
<i>EPA OPP Human Health Risk Assessment^b (USEPA, 2021a; USEPA, 2021b)</i>	<i>0.03^c</i>	<i>NOAEL</i>	<i>Becker and Biedermann (1995)</i>	–	–	C ^d

Notes: POD = point of departure; NOAEL = no-observed-adverse-effect level; dash (–) = not applicable.

^a Selected health assessment and chronic toxicity value and supporting information are bolded and italicized.

^b The EPA OPP considers this health assessment “final” at the time of publication in the Federal Register.

^c The oral reference value, in units of mg/kg/day, is a chronic population-adjusted dose (cPAD) for females of reproductive age (USEPA, 2021b).

^d This “possible human carcinogen” cancer descriptor was determined by following the process described in the EPA’s 1986 *Guidelines for Carcinogen Risk Assessment* (USEPA, 1986).

10.3.2 Health Assessment Selection

The health assessment selected for tebuconazole under RD 5 is the 2021 EPA OPP HHRA (USEPA, 2021a; USEPA, 2021b) because it supported the most recent FIFRA registration decision for tebuconazole. See Section B.5.1.2 of the RD 5 Protocol, in Appendix B of this document, for the decision logic that was applied to health assessment selection for RD 5 chemicals.

10.3.3 Health Reference Level (HRL) Development

HRLs are non-regulatory health-based toxicity values, expressed as concentrations in drinking water, that are used by the Agency to evaluate occurrence data for a contaminant when making decisions about regulatory determinations. See Section B.6.1.1 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA's approach for deriving HRLs for chemicals.

10.3.3.1 Oral Reference Value

In the 2021 EPA OPP HHRA (USEPA, 2021b), OPP selected a developmental toxicity study in mice (Becker and Biedermann 1995) as the critical study to derive the oral reference value. In this study, tebuconazole was administered via gavage to pregnant mice on gestational days (GD) 6 through 15 at doses of 0, 10, 30, and 100 mg/kg/day ($n = 35$ per dose). Supplementary dose groups of 1 and 3 mg/kg/day were subsequently added. Shortly before the expected parturition, pregnant females were sacrificed and fetuses underwent visceral and skeletal examination. Dams were also assessed for toxicity (Becker and Biedermann 1995; USEPA, 2021b).

Evidence of liver toxicity, including increased vacuolization and dose-dependent increases in cytochrome P-450 and *N*-demethylase activity, was observed in maternal treatment groups at doses of 10 mg/kg/day and above. Relative liver weights were significantly increased in dams dosed at 30 mg/kg/day. At 30 and 100 mg/kg/day doses, increased *O*-demethylase activity, liver triglyceride content, and hepatic lipid storage were observed in a dose-dependent manner (Becker and Biedermann 1995). Significant effects seen at the highest dose group (100 mg/kg/day) in fetuses included increased post-implantation loss, decreased mean fetal body weight, and an increase in skeletal abnormalities; marginal increases in post-implantation loss and skeletal defects were observed at 30 mg/kg/day (Becker and Biedermann, 1995). The lowest-observed-adverse-effect level (LOAEL) and no-observed-adverse-effect level (NOAEL) identified for developmental toxicity were 10 and 3 mg/kg/day, respectively (USEPA, 2021b), and this NOAEL was selected for HRL derivation because it was the most sensitive point of departure (POD) derived by OPP (USEPA, 2021b). A total uncertainty factor (UF) of 100 was applied to the POD: an interspecies UF (UF_A) of 10 and an intraspecies UF (UF_H) of 10 (USEPA, 2021b). The resulting oral reference value (a chronic population-adjusted dose, or cPAD) of 0.03 mg/kg/day, based on developmental toxicity, was presented in the HHRA as applicable to females of reproductive age (USEPA, 2021b). Because it was the most sensitive chronic oral reference value derived in the HHRA, it is considered protective of all age groups and from all health effects assessed. Therefore, the EPA selected the oral reference value for females of reproductive age (0.03 mg/kg/day) from the 2021 EPA OPP HHRA (USEPA 2021b) to derive an HRL for tebuconazole.

10.3.3.2 Exposure Factor Selection

In prioritizing the contaminants of greatest public health concern for regulatory determination, Section 1412(b)(1)(C) of the Safe Drinking Water Act (SDWA) requires the Agency to consider “among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or

other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water compared to the general population.” One way that the EPA considers potentially sensitive populations or life stages (i.e., populations or life stages that may be more susceptible or sensitive to a chemical exposure) is during the selection of exposure factors (EFs) for the development of HRLs.

Drinking water intake rate adjusted for body weight (DWI-BW) is the EF used to derive HRLs for RD 5 (USEPA, 2019). EFs are input values intended to protect the general population, including sensitive populations or life stages, from adverse effects resulting from exposure to a contaminant. The Agency selects an appropriate DWI-BW for each chemical by reviewing the critical effect and study used for HRL derivation and identifying the interval of exposure (for example, see USEPA, 2022b; USEPA, 2022c). Since the critical effect represents the most sensitive adverse effect observed in the best available studies for a given chemical, it is reasonable to assume that the interval of exposure in the critical study could inform the selection of a DWI-BW protective of sensitive populations. When multiple potentially sensitive populations or life stages are identified based on the interval of exposure in the study used for HRL derivation, the EPA selects the population or life stage with the highest DWI-BW because it is the most health protective. See Section B.6.1.2 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA’s EF selection process.

In the critical study (Becker and Biedermann 1995) selected for the most sensitive chronic endpoint in the 2021 EPA OPP HHRA (USEPA, 2021b), pregnant mice were exposed to tebuconazole during GD 6 through 15. The critical effect was observed in the fetus and the exposure interval was during gestation only (Becker and Biedermann 1995). Following the decision logic described in Section B.6.1.2 of the RD 5 Protocol, the EPA selected a corresponding human life stage. The EPA determined that the critical effect corresponds with two female life stages associated with pregnancy: females of reproductive age (13 to < 50 years) who may become pregnant; and pregnant women, which includes exposure to the developing embryo and fetus. The EPA considered both of these candidate life stages, and selected the DWI-BW for females of reproductive age (0.0354 L/kg/day) because it is more health protective (i.e., greater) than the DWI-BW for pregnant women (0.0333 L/kg/day) (USEPA, 2019). Thus, the DWI-BW representing the 90th percentile consumers-only, two-day average, direct and indirect community water consumption for females of reproductive age (13 to < 50 years), which equals 0.0354 L/kg/day (USEPA, 2019), was used to derive the HRL for tebuconazole.

10.3.3.3 Relative Source Contribution

Relative source contribution (RSC) is used to account for exposure via non-drinking water routes when deriving health-based drinking water concentrations for contaminants with threshold effects (noncarcinogens and nonlinear carcinogens). RSC is defined as the portion (percentage) of an individual’s exposure attributed to drinking water rather than other sources (e.g., food, ambient air). A 20 percent RSC is used for all RD 5 contaminants, consistent with past practice for regulatory determinations, to derive the HRL because (1) HRLs are developed prior to completing the exposure assessment; and (2) a 20 percent RSC is the lowest RSC that can be applied for deriving health-based drinking water concentrations according to EPA guidance (USEPA, 2000b), and it therefore produces the most health protective HRL (USEPA, 2000b). Should a contaminant proceed to a National Primary Drinking Water Regulation

(NPDWR), a full exposure analysis is conducted, and an RSC is derived following the Exposure Decision Tree approach described in the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000b).

10.3.3.4 HRL Calculation

Exhibit 10-5 summarizes the critical study and toxicity information from the qualifying health assessment and the EF (DWI-BW) and RSC that the EPA used to derive the HRL for tebuconazole.

Exhibit 10-5: Basis of HRL for Tebuconazole

Selected Health Assessment	Critical Study	Interval of Exposure	Critical Effect	Oral Toxicity Value	RSC	Target Population	Exposure Factor
EPA OPP Human Health Risk Assessment (USEPA, 2021a; USEPA, 2021b)	Becker and Biedermann (1995)	Gestational Day 6-15	Skull/ neural tube defects in mice	0.03 mg/kg/day	0.2 (20%)	Females of reproductive age (13 < 50 years)	0.0354 L/kg/day

The EPA calculates HRLs for contaminants with a threshold dose-response, including tebuconazole, as follows:

$$HRL = \frac{RfD}{DWI-BW} * RSC$$

where:

RfD = Reference dose (mg/kg/day), an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without]t an appreciable risk of deleterious effects during a lifetime. It is derived in the selected qualifying health assessment and is based on the critical effect and study identified in that assessment. Other values that can be used in place of an RfD in this equation can include a maximum acceptable concentration (MAC), minimal risk level, point of departure / uncertainty factor (POD/UF), population-adjusted dose (PAD), or tolerable daily intake (TDI).

DWI-BW = Drinking water intake (DWI), adjusted for body weight (BW), in units of liter per kilogram body weight per day (L/kg/day).

RSC = Relative source contribution, the percentage of the total exposure attributed to drinking water sources (USEPA, 2000b), where the remainder of the exposure is allocated to other routes or sources. For HRL derivation in RD 5, an RSC of 20 percent is used for all contaminants.

Based on an oral reference value of 0.03 mg/kg/day (USEPA 2021a; USEPA, 2021b), a DWI-BW of 0.0354 L/kg/day (USEPA, 2019) and a 20 percent RSC to account for non-water sources of exposure (USEPA, 2000b), the HRL for tebuconazole is calculated as follows:

$$HRL = \frac{0.03 \text{ mg/kg/day}}{0.0354 \text{ L/kg/day}} * 0.2$$

$$HRL = 0.1695 \text{ mg/L}$$

or

$$HRL = 169.5 \text{ } \mu\text{g/L}$$

Following HRL derivation practices, the HRL for tebuconazole is 200 $\mu\text{g/L}$ after rounding to one significant figure.

10.4 Occurrence

This section presents data on the occurrence of tebuconazole in ambient water and drinking water in the United States. As described in Section 10.3, an HRL of 200 $\mu\text{g/L}$ was calculated for tebuconazole based on non-carcinogenic effects. HRLs are risk-derived concentrations against which the EPA evaluates the occurrence data to determine if contaminants occur at levels of potential public health concern. Occurrence data from various sources presented below are analyzed with respect to the HRL and one-half the HRL. When possible, estimates of the population exposed at concentrations above the HRL and one-half the HRL are presented.

For additional background information about data sources used to evaluate occurrence, please refer to Chapter 2.

10.4.1 Occurrence in Ambient Water

Lakes, rivers, and aquifers are the ambient sources of most drinking water. Contaminant occurrence in ambient water provides information on the potential for contaminants to adversely affect drinking water supplies. Occurrence data for tebuconazole in ambient water are available from the United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) program, the USGS National Water Information System (NWIS) database, the EPA's legacy Storage and Retrieval Data System (STORET), and several published studies. When sources of information on ambient occurrence also include limited finished water data, those finished water data are summarized here as well.

10.4.1.1 United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) Ambient Water Analyses

USGS instituted the NAWQA program in 1991 to examine ambient water quality status and trends in the United States. The NAWQA program generates high quality contaminant occurrence and other water quality parameter data for significant watersheds and aquifers across the nation. The program collects data on surface water and groundwater chemistry, hydrology, land use, stream habitat, and aquatic life in parts of nearly all 50 states. The program is designed to apply nationally consistent methods to provide a uniform basis for contaminant occurrence comparisons and assessments among study basins across the country and over time. The

occurrence assessments can also serve to facilitate interpretation of natural and anthropogenic factors affecting national water quality. For more detailed information on NAWQA program design and implementation, refer to Leahy and Thompson (1994) and Hamilton et al. (2004).

The process of sampling, analysis, and data synthesis is divided into cycles of approximately ten years: Cycle 1 covered 1991-2001, Cycle 2 covered 2002-2012, and Cycle 3 covered 2013-2023. Study units are sampled and analyzed on a staggered schedule within each cycle. Each NAWQA cycle begins with a two-year startup phase for planning and retroactive analysis, followed by a three-year intensive data collection phase, and finally a five-year phase for analyzing the data, developing reports, and continuing a low level of monitoring (NRC, 2012).

The EPA downloaded NAWQA data from the Water Quality Portal (WQP) in September 2023 (WQP, 2023). The EPA's analysis of the NAWQA data is a simple, non-parametric occurrence analysis that provides summary statistics to characterize contaminant occurrence. The EPA included in the analysis all samples that could be classified as groundwater and surface water, and also the limited number of samples labeled as finished water. Other types of samples (e.g., from soil, sediment, and wastewater) were excluded. The EPA calculated detection frequencies as the percentage of samples and the percentage of sites with at least one detection. (A detection is an analytical result equal to or greater than the reporting level.) No weighting was applied. The EPA determined the minimum and maximum detected concentrations and calculated other descriptive statistics including the median, 90th percentile, and 99th percentile concentrations (based only on samples with detections). Reporting levels varied over time during the NAWQA program.

The results of the EPA's analysis of NAWQA data downloaded from WQP are presented in Exhibit 10-6 through Exhibit 10-8 (WQP, 2023). Cycle 1 included no data for tebuconazole. In Cycle 2 and Cycle 3, tebuconazole was found more frequently in surface water (17.97 percent to 26.48 percent of samples) than in groundwater (0 percent to 0.11 percent of samples). The highest concentration observed, 0.93 µg/L, found in surface water, is less than ½ the HRL of 200 µg/L. No tebuconazole data were available for finished water.

Note that there may be some overlap between the NAWQA data assessment presented here and summaries of individual NAWQA studies presented below.

Exhibit 10-6: Tebuconazole NAWQA Data – Summary of Detected Concentrations

Site Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90 th Percentile	99 th Percentile	Maximum
Cycle 2 (2002 - 2012)					
Groundwater	--	--	--	--	--
Surface Water	0.00039	0.004	0.014	0.113	0.146
All Sites	0.00039	0.004	0.014	0.113	0.146

Site Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90 th Percentile	99 th Percentile	Maximum
Cycle 3 (2013 - 2023)					
Groundwater	0.00035	0.00444	0.00689	0.00837	0.00853
Surface Water	0.00024	0.00832	0.0292	0.189	0.93
All Sites	0.00024	0.00832	0.0291	0.189	0.93

Source: WQP, 2023

"--" = No detections in this category

Exhibit 10-7: Tebuconazole NAWQA Data – Summary of Samples

Site Type	No. of Samples	Detection Frequency (detections are results ≥ reporting level)					
		No. of Samples with Detections	Percent Samples with Detections	No. of Samples with Detections > ½ HRL	Percent Samples with Detections > ½ HRL	No. of Samples with Detections > HRL	Percent Samples with Detections > HRL
Cycle 2 (2002 - 2012)							
Groundwater	21	0	0.00%	0	0.00%	0	0.00%
Surface Water	287	76	26.48%	0	0.00%	0	0.00%
All Sites	308	76	24.68%	0	0.00%	0	0.00%
Cycle 3 (2013 -2023)							
Groundwater	1,881	2	0.11%	0	0.00%	0	0.00%
Surface Water	14,092	2,532	17.97%	0	0.00%	0	0.00%
All Sites	15,973	2,534	15.86%	0	0.00%	0	0.00%

Source: WQP, 2023

Exhibit 10-8: Tebuconazole NAWQA Data – Summary of Sites

Site Type	No. of Sites	Detection Frequency (detections are results $\geq$ reporting level)					
		No. of Sites with Detections	Percent Sites with Detections	No. of Sites with Detections $> \frac{1}{2}$ HRL	Percent Sites with Detections $> \frac{1}{2}$ HRL	No. of Sites with Detections $>$ HRL	Percent Sites with Detections $>$ HRL
Cycle 2 (2002 - 2012)							
Groundwater	21	0	0.00%	0	0.00%	0	0.00%
Surface Water	75	31	41.33%	0	0.00%	0	0.00%
All Sites	96	31	32.29%	0	0.00%	0	0.00%
Cycle 3 (2013 - 2023)							
Groundwater	1,764	2	0.11%	0	0.00%	0	0.00%
Surface Water	481	168	34.93	0	0.00%	0	0.00%
All Sites	2,245	170	7.57%	0	0.00%	0	0.00%

Source: WQP, 2023

10.4.1.2 National Water Information System (NWIS) Data

NWIS is the nation's principal repository of water resources data collected by USGS from more than 1.9 million sites in all U.S. states and territories (USGS, 2022). All USGS water quality and flow data are stored in NWIS, including site characteristics, streamflow, groundwater level, precipitation, and chemical analyses of water, sediment, and biological media, though not all parameters are available for every site. NWIS houses the NAWQA data and includes other USGS data from a range of unspecified projects. NWIS encompasses many more samples at many more sites than are involved in the NAWQA Program. Although NWIS is comprised of primarily ambient water data, some finished drinking water data are included as well. This section presents analyses of non-NAWQA data in NWIS, downloaded from the WQP in September 2023 (WQP, 2023). These data do not overlap with the NAWQA results presented above.

The results of the non-NAWQA NWIS tebuconazole analysis are presented in Exhibit 10-9. Tebuconazole was detected in approximately 12 percent of samples (806 of 6,984 samples) and at approximately 12 percent of sites (246 out of 2,052 sites). Tebuconazole was detected more frequently in surface water than in groundwater. The highest reported concentration, 3.24 µg/L, from surface water, was less than ½ the HRL of 200 µg/L.

Exhibit 10-9: Tebuconazole NWIS Data, 1991-2023

Sample Media Type	Detection Frequency (detections are results $\geq$ reporting level)				Concentration Values (of detections, in µg/L)				
	No. of Samples	No. of Samples with Detections	No. of Sites	No. of Sites with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
Groundwater	1,743	7	1,213	6	0.0011	0.00584	0.0468	0.091	0.0959
Surface Water	5,241	799	839	240	0.00056	0.00898	0.0385	0.189	3.24
Total	6,984	806	2,052	246	0.00056	0.00898	0.0387	0.188	3.24

Source: WQP, 2023

Note that some NWIS sites are associated with multiple sample media types, so site counts might not add up to totals.

10.4.1.3 Storage and Retrieval (STORET) Data

From its launch in 1999 until it was decommissioned in June 2018, the EPA's STORET Data Warehouse was collaboratively populated with raw biological, chemical, and physical data from surface water and groundwater sampling by federal, state and local agencies, Native American Tribes, volunteer groups, academics, and others. Legacy STORET data, as well as more current STORET data, are accessible through the WQP.

STORET data are from monitoring locations in all 50 states as well as multiple territories and jurisdictions of the United States. STORET's data quality limitations include variations in the extent of national coverage and data completeness from parameter to parameter. Data may have been collected as part of targeted, rather than randomized, monitoring. This section presents analyses of STORET data, downloaded from the WQP in September 2023 (WQP, 2023). The EPA reviewed STORET groundwater data from wells and springs and surface water data from

lakes, rivers/streams, and reservoirs. The STORET data set also included limited data from public water systems (PWSs). The database does not specify whether PWS sampling was conducted before or after treatment.

The results of the STORET analysis for tebuconazole are presented in Exhibit 10-10 and Exhibit 10-11. Samples were collected between 2003 and 2016. Of 2,021 samples taken at 484 groundwater and surface water sites, none had detectable concentrations of tebuconazole.

Exhibit 10-10: Tebuconazole STORET Data – Summary of Samples and Sites

Source Water Type	Total Number of Samples	Samples with Detections		Total Number of Sites	Sites with Detections	
		Number	Percent		Number	Percent
Groundwater	793	0	0.00%	267	0	0.00%
Surface Water	1,228	0	0.00%	217	0	0.00%
Total	2,021	0	0.00%	484	0	0.00%

Source: WQP, 2023

Exhibit 10-11: Tebuconazole STORET Data – Summary of States

Source Water Type	Total Number of States	States with Detections	
		Number	Percent
Groundwater	2	0	0%
Surface Water	2	0	0%
Total¹	3	0	0%

Source: WQP, 2023

¹ The number of states with groundwater data plus the number of states with surface water data may not equal the “Total” number of states providing data because some states provided both groundwater and surface water data.

10.4.1.4 Additional Ambient Water Studies

Kingsbury et al. (2021) evaluated groundwater-quality samples collected from 2017 to 2019 as part of the third cycle of USGS’s NAWQA Program. Six types of well network studies were conducted: principal aquifer study networks; major aquifer study networks; land-use study networks; vertical flow-path study networks; enhanced trends networks; and modeling support studies. The reporting level used for tebuconazole was 0.0025 µg/L. Tebuconazole was detected in 1 of 471 samples with a concentration of 0.00853 µg/L.

10.4.2 Occurrence in Drinking Water

Data sources reviewed by the Agency for information on contaminant occurrence in drinking water included: the EPA’s first, second, third, and fourth Unregulated Contaminant Monitoring Rules (UCMR 1, UCMR 2, UCMR 3, UCMR 4); Rounds 1 and 2 of the Agency’s

Unregulated Contaminant Monitoring (UCM) program that preceded the Unregulated Contaminant Monitoring Rule (UCMR); the EPA’s National Inorganics and Radionuclides Survey (NIRS); and a range of others as discussed in Chapter 2. Among the sources reviewed, the following sources had data and information on tebuconazole occurrence in drinking water and are discussed in this section:

- The EPA’s Fourth Unregulated Contaminant Monitoring Rule (UCMR 4).
- Consumer Confidence Reports (CCRs) from PWSs.
- United States Department of Agriculture (USDA) Pesticide Data Program (PDP).

Note that there may be some overlap as sources with different purposes and audiences may have reported the same underlying data. UCMR 4 is a nationally representative data source. Other data sources profiled in this section are considered “supplemental” sources. Also note that the ambient water section, above, presents some limited finished water data and miscellaneous data from PWSs found in ambient water data sources.

10.4.2.1 Primary Data Sources

10.4.2.1.1 The EPA’s Fourth Unregulated Contaminant Monitoring Rule (UCMR 4), 2018-2020

The UCMR program was designed to provide a national assessment of the occurrence of select unregulated contaminants in PWSs. UCMR 4 was published on December 20, 2016 (USEPA, 2016) and required monitoring for 30 chemical contaminants between 2018 and 2020. Data reporting continued into 2021.

UCMR 4 Assessment Monitoring occurrence data are available for tebuconazole. For UCMR 4, all large and very large community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) (serving between 10,001 and 100,000 people and serving more than 100,000 people, respectively), plus a statistically representative national sample of 800 small CWSs and NTNCWSs (serving 10,000 people or fewer), were required to conduct Assessment Monitoring during a 12-month period between January 2018 and December 2020.¹ Surface water and groundwater under the direct influence of surface water (GWUDI) sampling points were monitored four times during the applicable year of monitoring. Groundwater sampling points were monitored twice during the applicable year of monitoring. See USEPA (2016) and USEPA (2024) for more information on the UCMR 4 study design and data analysis.

The design of UCMR 4 permits estimation of national occurrence by multiplying the total number of systems (or population served) in the nation in a system size category by the percent of systems (or population served) found to exceed a specified threshold in the sample. This extrapolation methodology is applied to small systems. Because all large and very large systems were required to participate in the UCMR 4 Assessment Monitoring, national occurrence estimates in these size categories can be developed using survey census figures rather than

¹ Only 797 small systems submitted results for tebuconazole.

extrapolation. Total national occurrence is estimated by summing the extrapolated figures for small systems and the census figures for the large and very large systems.

Exhibit 10-12 through Exhibit 10-16 provide an overview of tebuconazole occurrence results from UCMR 4 Assessment Monitoring. The minimum reporting level (MRL) used for tebuconazole in the UCMR 4 survey was 0.2 µg/L. Exhibit 10-12 shows a statistical summary of tebuconazole concentrations by system size and source water type (including the minimum, median, 90th percentile, 99th percentile, and maximum).

Exhibit 10-13 presents a sample-level summary of the results. Exhibit 10-14 through Exhibit 10-16 show system-level results, including national extrapolations, at three thresholds: detections, ½ the HRL, and the HRL. Detections are evaluated on a “greater than or equal to” basis ($\geq$ the MRL), while health-based thresholds are evaluated in terms of exceedances ($> \frac{1}{2}$ HRL and $>$ HRL).

As a reminder that the figures from large and very large systems represent a census of systems in those categories, results in those categories are labeled “CENSUS” in the exhibits below. No extrapolation was necessary in these categories, as it was for the small systems, to derive national estimates of occurrence. National estimates of occurrence are reported separately in each system size and source water category, and also in the aggregate.

A total of 37,286 UCMR 4 samples for tebuconazole were collected from 5,028 systems. Tebuconazole was detected in only three samples (0.01 percent), with concentrations ranging from 0.21 µg/L to 1.96 µg/L. The detections were found at three large surface water systems, representing 0.06 percent of systems participating in the monitoring program. Extrapolating these findings suggests that an estimated three PWSs serving 104,000 people nationally have detectable levels of tebuconazole. There were no exceedances of the HRL or ½ the HRL.

Exhibit 10-12: Tebuconazole Occurrence Data from UCMR 4 Assessment Monitoring – Summary of Reported Concentrations

Source Water Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90th Percentile	99th Percentile	Maximum
Small Systems (serving $\leq$ 10,000 people)					
Groundwater	--	--	--	--	--
Surface Water	--	--	--	--	--
All Small Systems	--	--	--	--	--
Large Systems (serving 10,001 - 100,000 people) -- CENSUS					
Groundwater	--	--	--	--	--
Surface Water	0.21	0.233	1.61	1.93	1.96
All Large Systems	0.21	0.233	1.61	1.93	1.96
Very Large Systems (serving $>$ 100,000 people) -- CENSUS					
Groundwater	--	--	--	--	--
Surface Water	--	--	--	--	--
All Very Large Systems	--	--	--	--	--

Source Water Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90th Percentile	99th Percentile	Maximum
All Systems					
All Water Systems	0.21	0.233	1.61	1.93	1.96

Source: USEPA, 2024

"--" = No detections in this category

Exhibit 10-13: Tebuconazole National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of Samples

Source Water Type	Total # of Samples	Samples with Detections ≥ MRL (0.2 µg/L)		Samples with Detections > ½ HRL (100 µg/L)		Samples with Detections > HRL (200 µg/L)	
		Number	Percent	Number	Percent	Number	Percent
Small Systems (serving ≤ 10,000 people)							
Groundwater	1,896	0	0.00%	0	0.00%	0	0.00%
Surface Water	1,360	0	0.00%	0	0.00%	0	0.00%
All Small Systems	3,256	0	0.00%	0	0.00%	0	0.00%
Large Systems (serving 10,001 - 100,000 people) -- CENSUS							
Groundwater	10,949	0	0.00%	0	0.00%	0	0.00%
Surface Water	15,714	3	0.02%	0	0.00%	0	0.00%
All Large Systems	26,663	3	0.01%	0	0.00%	0	0.00%
Very Large Systems (serving > 100,000 people) -- CENSUS							
Groundwater	2,057	0	0.00%	0	0.00%	0	0.00%
Surface Water	5,310	0	0.00%	0	0.00%	0	0.00%
All Very Large Systems	7,367	0	0.00%	0	0.00%	0	0.00%
All Systems							
All Water Systems	37,286	3	0.01%	0	0.00%	0	0.00%

Source: USEPA, 2024

Exhibit 10-14: Tebuconazole National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population – All Reported Detections

Source Water Type	UCMR 4 Sample		Number With At Least One Detection $\geq$ MRL (0.2 $\mu\text{g/L}$)		Percent With At Least One Detection $\geq$ MRL (0.2 $\mu\text{g/L}$)		National Inventory ¹		National Estimate of Number With At Least One Detection $\geq$ MRL (0.2 $\mu\text{g/L}$) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving $\leq$ 10,000 people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,468	37,653,948	0	0	0.00%	0.00%	1,468	37,653,948	0	0
Surface Water	2,340	71,511,793	3	103,514	0.13%	0.14%	2,340	71,511,793	3	104,000
All Large Systems	3,808	109,165,741	3	103,514	0.08%	0.09%	3,808	109,165,741	3	104,000
Very Large Systems (serving $>$ 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,028	249,079,866	3	103,514	0.06%	0.04%	67,732	307,144,948	3	104,000

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

Exhibit 10-15: Tebuconazole National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population Served Data – Detections > ½ the HRL (100 µg/L)

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > ½ HRL (100 µg/L)		Percent With At Least One Detection > ½ HRL (100 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > ½ HRL (100 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) – CENSUS										
Groundwater	1,468	37,653,948	0	0	0.00%	0.00%	1,468	37,653,948	0	0
Surface Water	2,340	71,511,793	0	0	0.00%	0.00%	2,340	71,511,793	0	0
All Large Systems	3,808	109,165,741	0	0	0.00%	0.00%	3,808	109,165,741	0	0
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,028	249,079,866	0	0	0.00%	0.00%	67,732	307,144,948	0	0

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

**Exhibit 10-16: Tebuconazole National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data –
Summary of System and Population Served Data – Detections > HRL (200 µg/L)**

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > HRL (200 µg/L)		Percent With At Least One Detection > HRL (200 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > HRL (200 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,468	37,653,948	0	0	0.00%	0.00%	1,468	37,653,948	0	0
Surface Water	2,340	71,511,793	0	0	0.00%	0.00%	2,340	71,511,793	0	0
All Large Systems	3,808	109,165,741	0	0	0.00%	0.00%	3,808	109,165,741	0	0
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,028	249,079,866	0	0	0.00%	0.00%	67,732	307,144,948	0	0

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

10.4.2.2 Supplemental Data Sources

10.4.2.2.1 *Water Systems’ Consumer Confidence Reports (CCRs), 2018-2021*

CCRs are annual water quality reports that CWSs are required to provide to their customers. These reports summarize information on water sources, detected contaminants, and system compliance with the EPA drinking water standards; they may also include general educational material. Under the CCR Rule (40 CFR Subpart O), CWSs with 15 or more connections or serving at least 25 year-round residents must prepare and distribute a CCR to all billing units or service connections every year. Systems serving 100,000 or more residents are also required to post their current CCRs on a publicly accessible Internet site.

The EPA reviewed CCRs published by the 25 systems that serve over one million customers (as identified in the Safe Drinking Water Information System / Federal version, or SDWIS/Fed, from the fourth quarter 2021 data) for unregulated contaminant occurrence information for the years 2018 through 2021. Data on tebuconazole were available from CCRs prepared by five CWSs: one system in California (Los Angeles), one system in Colorado (Denver), two systems in New York (Suffolk County and New York City), and one system in Pennsylvania (Philadelphia). Monitoring results from all five systems showed no detections of tebuconazole.

Los Angeles Department of Water & Power (LADWP) included data on tebuconazole monitoring for UCMR 4 in its 2020 and 2021 CCRs. LADWP is served by multiple surface water and groundwater sources. The sampling was conducted in 2018-2019. Tebuconazole was not detected.

Denver Water included data on tebuconazole monitoring for UCMR 4 in its 2018 CCR. Denver Water is served by the South Platte River and other surface water sources. An average tebuconazole concentration of “0 µg/L” was reported for treatment plant effluent.

Suffolk County, New York, included data on tebuconazole in its 2018-2021 CCRs. Suffolk County is served by groundwater from four major aquifers beneath Long Island. In all 4 years, tebuconazole was monitored for but was not detected.

New York City included data on tebuconazole in four CCRs covering 2018 through 2021. New York City is served by a large system of surface water networks in New York state. In all 4 years, tebuconazole was monitored for but was not detected.

The Philadelphia Water Department (PWD) included data on tebuconazole in three CCRs covering 2019 through 2021. PWD is served by surface water from the Schuylkill and Delaware rivers. In all 3 years, tebuconazole was monitored for but was not detected.

10.4.2.2.2 *United States Department of Agriculture (USDA) Pesticide Data Program (PDP), 2001-2013*

The USDA PDP maintains a national pesticide residue database. PDP was initiated in 1991 to collect representative data on pesticide residues in the United States food supply, following a rigorous statistical design. Sampling and testing have been conducted on fruits and vegetables, select grains, milk, and (between 2001 and 2013) drinking water (USDA, 2022).

The PDP drinking water project was initiated at CWSs in New York and California in 2001. Since then, the drinking water sampling program has expanded, though a somewhat changing mix of states is sampled each year. At one time or another, CWSs in 29 states and the District of Columbia have contributed raw or finished water data or both to the program (USDA, 2023). The CWSs selected for sampling tend to be small and medium-sized systems (primarily CWSs serving under 50,000), systems served by surface water, and systems located in regions of heavy agriculture. Sampling of raw (“untreated”) water in addition to finished water began in 2004; sampling of raw and finished drinking water was discontinued after 2013. Note that temporal trends cannot be evaluated based on these data since the list of CWSs included in the project varied from year to year (USDA, 2022; USDA, 2023).

Tebuconazole was included in the USDA PDP (Exhibit 10-17) (USDA, 2022). Tebuconazole was detected in 56 (2.11%) of 2,656 raw water samples, with a maximum concentration of 0.150 µg/L. No detected concentrations exceeded one-half the HRL or the HRL. Tebuconazole was detected in 78 (2.18%) of 3,575 finished water samples, with a maximum concentration of 0.150 µg/L. No detected concentrations exceeded one-half the HRL or the HRL. The reported limits of detection ranged from 0.0017 to 0.299 µg/L.

Exhibit 10-17: Summary of Tebuconazole PDP Data, 2001-2013

Year	Raw/ Finished	Total Number of Samples	Number of Detections	Percent of Detections	Minimum Value of Detections (µg/L)	Maximum Value of Detections (µg/L)
2001	Finished	154	0	0.00%	N/A	N/A
2002	Finished	288	0	0.00%	N/A	N/A
2003	Finished	494	0	0.00%	N/A	N/A
2004	Finished	380	2	0.5%	0.0097	0.0097
	Raw	380	1	0.3%	0.0097	0.0097
2005	Finished	230	0	0.00%	N/A	N/A
	Raw	232	0	0.00%	N/A	N/A
2006	Finished	365	2	0.5%	0.0103	0.0103
	Raw	367	4	1.1%	0.008	0.0103
2007	Finished	365	0	0.00%	N/A	N/A
	Raw	359	0	0.00%	N/A	N/A
2008	Finished	309	2	0.6%	0.0058	0.0058
	Raw	308	4	1.3%	0.0058	0.068
2009	Finished	306	2	0.7%	0.15	0.15
	Raw	305	0	0.00%	N/A	N/A
2010	Finished	284	10	3.5%	0.0058	0.032
	Raw	282	9	3.2%	0.0058	0.15
2011	Finished	118	4	3.4%	0.007992	0.035
	Raw	120	4	3.3%	0.007992	0.056

Year	Raw/ Finished	Total Number of Samples	Number of Detections	Percent of Detections	Minimum Value of Detections (µg/L)	Maximum Value of Detections (µg/L)
2012	Finished	232	51	22%	0.0035	0.027
	Raw	253	32	12.6%	0.0035	0.069
2013	Finished	50	5	10%	0.0035	0.0035
	Raw	50	2	4%	0.0035	0.0035

Source: USDA, 2022

N/A = not applicable (no detections in this category).

10.5 Analytical Methods

The EPA has published two analytical methods that are available for the analysis of tebuconazole in drinking water. In addition, a vendor-developed method is also available for the determination of tebuconazole:

- EPA Method 525.3, Version 1.0, *Determination of Semivolatile Organic Chemicals in Drinking Water by Solid Phase Extraction and Capillary Column Gas Chromatography/Mass Spectrometry (GC/MS)* has detection limits (DLs) that range from 0.053 to 0.24 µg/L in Full Scan mode and a DL of 0.042 µg/L in Selected Ion Monitoring (SIM) mode. The Lowest Concentration Minimum Reporting Levels (LCMRLs) generated by the laboratories that helped to develop the method range from 0.18 to 2.1 µg/L in Full Scan mode and 0.037 to 0.20 µg/L in selected ion monitoring (SIM) mode. Mean recoveries in reagent water, finished water from groundwater with a hardness of 290 to ≥350 mg/L (as calcium carbonate) and finished drinking water from surface water with total organic carbon (TOC) of 2.4 to 2.8 mg/L range from 75.5 to 126 percent, with relative standard deviations (RSDs) of 0.9 to 9.9 percent for Full Scan mode. Mean recoveries in reagent water, finished water from groundwater with a hardness of 325 to 393 mg/L (as calcium carbonate) and finished drinking water from surface water with TOC of 2.0 to 2.52 mg/L and a hardness of 137 mg/L (as calcium carbonate) range from 82.6 to 138 percent, with RSDs of 0.7 to 7.4 percent for SIM mode. Note that EPA Method 525.3 indicates that tebuconazole may exhibit high bias in percent recovery due to matrix induced chromatographic response enhancement, especially at low concentrations (USEPA, 2012).
- EPA Method 543, Version 1.0, *Determination of Selected Organic Chemicals in Drinking Water by On-Line Solid Phase Extraction-Liquid Chromatography/Tandem Mass Spectrometry (On-Line SPE-LC/MS/MS)* has a method detection limit (MDL) of 0.47 ng/L. The LCMRL generated by the laboratory that developed the method is 1.3 ng/L. Mean recoveries in reagent water, finished drinking water from groundwater with a TOC of 0.71 mg/L and a hardness of 342 mg/L (as calcium carbonate) and finished drinking water from surface water with a TOC of 3.20 mg/L and a hardness of 68.5 mg/L (as calcium carbonate) range from 86.4 to 112 percent with RSDs of 2.6 to 6.9 percent (USEPA, 2015).
- Bayer Method HW-005-W17-01, *An Analytical Method for the Determination of Residues of Tebuconazole in Drinking and Surface Water Using LC/MS/MS* has a

targeted limit of quantitation (LOQ) of 0.05 µg/L. No other performance data are presented in the method (Bayer, 2017).

Laboratories participating in UCMR 4 were required to use EPA Method 525.3 and were required to report tebuconazole values at or above the EPA-defined MRL of 0.2 µg/L (81 FR 92666; USEPA, 2016). The MRL was set based on the capability of multiple laboratories at the time.

10.6 Treatment Technologies

The EPA evaluates whether suitable treatment technologies are available prior to promulgating a final NPDWR. The preliminary summary of treatment technology availability presented here represents the results of a December 2023 literature search.

Elfikrie et al. (2020) examined pesticide removal efficiency in a conventional drinking water treatment plant in Selangor, Malaysia. Plant treatment processes include coagulation with aluminum sulphate/settling, filtration, and chlorination, pH adjustment, and fluoridation. The results showed removal efficiency of 88% for tebuconazole.

Dong et al. (2021) investigated the removal of tebuconazole and other pesticides at 4 drinking water treatment plants with conventional and advanced treatment process in Shanghai, China, in 2018-2019. Treatment at three plants included coagulation/sedimentation, sand filtration, ozone, and biological activated carbon (BAC), while treatment at the fourth plant included coagulation/sedimentation, ozone, BAC, and ultrafiltration. Tebuconazole was found in raw water at an average concentration of 28.85 ng/L and in finished water at an average concentration of 9.62 ng/L. The authors evaluated the removal contribution of each treatment process. Ozone was found to have a removal rate of 18.4% for tebuconazole, BAC a removal rate of 36.7%, and ultrafiltration a removal rate of 20.7%.

Del Puerto et al. (2022) examined the effects of combined vacuum ultraviolet (VUV) (185 nm) and ultraviolet C (UVC) (254 nm) irradiation on tebuconazole. Raw water (groundwater) was spiked with a stock solution of tebuconazole. With 8 minutes of exposure to VUV/UVC irradiation, tebuconazole degradation rates of 95% (from an initial concentration of 1 µg/L) and 60% (from an initial concentration of 12 mg/L) were observed. The authors identified numerous transformation products following the irradiation treatment, many of which were found to be less toxic to aquatic organisms than the parent compound.

del Olmo et al. (2023) examined the removal of tebuconazole and other chlorinated azole pesticides at the bench scale using catalytic hydrochlorination (HDC), specifically a palladium / aluminum oxide (Pd/Al₂O₃) catalyst. Notably, complete degradation of all compounds in deionized water was achieved in a short reaction time (<15min) operating under ambient conditions and a neutral pH. The azole pesticides were quite reactive toward HDC in comparison with neonicotinoid pesticides, pharmaceuticals, and chloroacetic acids. Furthermore, the azole pesticides were completely dechlorinated by the reaction, achieving in all cases chlorine-free reaction products. The catalyst was fairly stable upon three consecutive HDC runs, maintaining its properties practically unchanged. When the researchers conducted additional tests using real aqueous matrices (tap water and surface), the results were similar. With an initial concentration of 100 µg/L tebuconazole, the application of 0.25 g/L of the catalyst resulted in complete degradation of tebuconazole within the 15 minute reaction time.

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Chapter 11: Tribufos

A chapter from:

Final Regulatory Determination 5 Support Document

EPA Report 815-R-26-002

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Abbreviations

BMD	Benchmark Dose
BMD ₁₀	Benchmark Dose at 10 Percent Response*
BMDL ₁₀	Lower Bound of 95 Percent Confidence Interval on BMD ₁₀ *
BW	Body Weight
CASRN	Chemical Abstracts Service Registry Number
CCL 5	Fifth Contaminant Candidate List
CCR	Consumer Confidence Report
CDR	Chemical Data Reporting
ChE	Plasma Cholinesterase
CWS	Community Water System
DL	Detection Limit
DWI	Drinking Water Intake
DWI-BW	Drinking Water Intake Adjusted for Body Weight
EF	Exposure Factor
EPA	U.S. Environmental Protection Agency
EPCRA	Emergency Planning And Community Right-to-Know Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FQPA SF	Food Quality Protection Act Safety Factor
GWUDI	Groundwater Under the Direct Influence of Surface Water
HED	Health Effects Division
HHRA	Human Health Risk Assessment
HRL	Health Reference Level
IREC	Interim Reregistration Eligibility Decision
IUR	Inventory Update Reporting
K _H	Henry's Law Constant
K _{oc}	Organic Carbon Partitioning Coefficient
K _{ow}	Octanol/Water Partitioning Coefficient
LADWP	Los Angeles Department of Water & Power
LCMRL	Lowest Concentration Minimum Reporting Level
LOAEL	Lowest-Observed-Adverse-Effect Level
MAC	Maximum Acceptable Concentration
MRL	Minimum Reporting Level
NAWQA	National Water-Quality Assessment
NCFAP	National Center for Food and Agricultural Policy
NIRS	National Inorganics and Radionuclides Survey
NOAEL	No-Observed-Adverse-Effect Level
NPDWR	National Primary Drinking Water Regulation
NTNCWs	Non-Transient Non-Community Water Systems
NWIS	National Water Information System
OGWDW	Office of Ground Water and Drinking Water
OPP	Office of Pesticide Programs
PAD	Population-Adjusted Dose
PDP	Pesticide Data Program
PMP	Pilot Monitoring Program
POD	Point of Departure
POD/UF	Point of Departure / Uncertainty Factor

PWD	Philadelphia Water Department
PWS	Public Water System
RBC	Red Blood Cell
RD 5	Fifth Regulatory Determination
RfD	Reference Dose
RSC	Relative Source Contribution
RSD	Relative Standard Deviation
RUP	Restricted Use Pesticide
SDWA	Safe Drinking Water Act
SDWIS	Safe Drinking Water Information System
SDWIS/Fed	Safe Drinking Water Information System / Federal Version
SIM	Selected Ion Monitoring
ssPAD	Steady-State Population Adjusted Dose
STORET	Storage and Retrieval Data System
TDI	Tolerable Daily Intake
TOC	Total Organic Carbon
TRI	Toxic Release Inventory
TSCA	Toxic Substances Control Act
UCM	Unregulated Contaminant Monitoring
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 1	First Unregulated Contaminant Monitoring Rule
UCMR 2	Second Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 4	Fourth Unregulated Contaminant Monitoring Rule
UF	Uncertainty Factor
UF _A	Interspecies Uncertainty Factor
UF _H	Intraspecies Uncertainty Factor
USDA	United States Department of Agriculture
USGS	United States Geological Survey
WQP	Water Quality Portal

*These definitions apply only within this chapter.

Chapter 11: Tribufos

The U.S. Environmental Protection Agency (EPA) is evaluating tribufos, a contaminant on the fifth Contaminant Candidate List (CCL 5), as a candidate for regulation under the fifth Regulatory Determination process (RD 5). Information on the CCL 5 process is found in Chapter 1. Background on data sources used to evaluate CCL 5 chemicals is found in Chapter 2.

This chapter presents information and analysis specific to tribufos, including background information on the contaminant, information on contaminant sources and environmental fate, an analysis of health effects, an analysis of occurrence in ambient and drinking water, and information about the availability of analytical methods and treatment technologies.

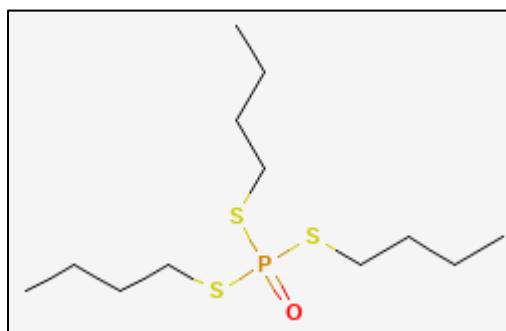
11.1 Contaminant Background and Chemical and Physical Properties

Tribufos is a thiophosphate pesticide that is used as an insecticide and as a cotton defoliant. Synonyms for tribufos include butifos, butiphos, butyl phosphorotrithioate, and tribuphos (NCBI, 2023). Tribufos was first registered in the United States in 1961 (USEPA, 2009a).

The EPA's Office of Pesticide Programs (OPP) released an Interim Reregistration Eligibility Decision (IRED) for tribufos in September of 2000 and finalized the document in July of 2006 (USEPA, 2006). Subsequent to the EPA changing from the pesticide reregistration process to the current Registration Review process, the EPA published a Summary Document for Tribufos in March of 2009 and a Final Work Plan for Tribufos in August of 2009 (USEPA, 2009a; USEPA, 2009b). Tribufos is not listed on the EPA's most recent list of Restricted Use Pesticides (RUP) (USEPA, 2022a).

Exhibit 11-1 presents the structural formula for tribufos. Physical and chemical properties and other reference information are listed in Exhibit 11-2.

Exhibit 11-1: Chemical Structure of Tribufos



Source: NCBI, 2023

Exhibit 11-2: Physical and Chemical Properties of Tribufos

Property	Data
Chemical Abstracts Service Registry Number (CASRN)	78-48-8 (ATSDR, 2020; NCBI, 2023)
EPA Pesticide Chemical Code	074801 (NCBI, 2023)
Chemical Formula	C ₁₂ H ₂₇ OPS ₃ (ATSDR, 2020; NCBI, 2023)
Molecular Weight	314.54 g/mol (ATSDR, 2020)
Color/Physical State	Colorless to pale yellow liquid (ATSDR, 2020; NCBI, 2023)
Boiling Point	210 °C at 750 mm Hg (ATSDR, 2020; NCBI, 2023)
Melting Point	<-25 °C (ATSDR, 2020; NCBI, 2023)
Density	1.057 at 20 °C (ATSDR, 2020; NCBI, 2023)
Freundlich Adsorption Coefficient	--
Vapor Pressure	5.3 x 10 ⁻⁶ mm Hg at 25 °C (ATSDR, 2020; NCBI, 2023)
Henry's Law Constant (K _H)	2.94 x 10 ⁻⁷ atm-m ³ /mole (ATSDR, 2020; NCBI, 2023)
Octanol/Water Partitioning Coefficient (log K _{ow})	5.7 (ATSDR, 2020; NCBI, 2023)
Organic Carbon Partitioning Coefficient (K _{oc})	4,870-12,684 L/kg (ATSDR, 2020; NCBI, 2023)
Solubility in Water	2.3 mg/L at 20 °C (ATSDR, 2020; NCBI, 2023)
Other Solvents	Soluble in aliphatic, aromatic, and chlorinated hydrocarbons and alcohols (ATSDR, 2020; NCBI, 2023)

Note: Many of these properties are temperature-dependent. Values are given for properties at 20-25°C unless otherwise noted. Due to varying experimental conditions, and due to the variabilities associated with modeling, standard information sources may provide a range of values. Where more than one value was available from these sources, one value was selected for this table based on best professional judgment.

11.2 Sources and Environmental Fate

11.2.1 Production, Use, and Release

Production data for tribufos are available from the EPA's Inventory Update Reporting (IUR) and Chemical Data Reporting (CDR) programs, and industrial release data are available from the EPA's Toxics Release Inventory (TRI), as described below. In addition, several sources provide information about quantities of tribufos used in agriculture. Additional information about these sources is provided in Chapter 2.

Inventory Update Reporting (IUR) and Chemical Data Reporting (CDR) Programs

Under the authority of the Toxic Substances Control Act (TSCA), the EPA gathers information on production (including both manufacture and importation) of industrial chemicals. Under IUR, producers provided information once every four years from 1986 to 2006. Since 2012, producers have continued to provide information in accordance with the CDR Rule, which superseded the IUR in 2011. Under CDR, producers collect annual production data and report it once every four years. Results are generally presented to the public in terms of production ranges. Sometimes (e.g., to protect confidential business information) the production ranges are withheld.

Until 2006, the IUR regulation required manufacturers and importers of organic chemical substances included on the TSCA Chemical Substance Inventory to report on chemicals produced (i.e., manufactured or imported) in amounts of 10,000 pounds or more at a single site. In 2006, the minimum threshold for reporting was increased to 25,000 pounds and reporting

began for inorganic chemicals (USEPA, 2008). Among changes made under CDR, a two-tier system of reporting thresholds was implemented, with 25,000 pounds as the threshold for some contaminants and 2,500 pounds as the threshold for others (USEPA, 2020). As a result of program modifications, the results from 2006 and later might not be directly comparable to results from earlier years. Under CDR, every four years manufacturers and importers are required to report annual data from each of the previous four years, provided that the thresholds of 2,500 or 25,000 pounds are met during at least one of the four years (USEPA, 2020).

Exhibit 11-3 presents the publicly available information on production of tribufos in the United States as reported under IUR. Currently, only data from the 2006 reports (representing calendar year 2005 production) are available for download; data from earlier years are not publicly available. Reported production of tribufos in 2005 was under 500,000 pounds.

Exhibit 11-4 presents the publicly available production data for tribufos in the United States from 2011 to 2019 as reported under CDR. Except in 2015, when no production was reported, annual reported production during this period exceeded one million pounds. In 2012 production came close to 4 million pounds.

Exhibit 11-3: IUR Reported Annual Production (Manufacture and Importation) of Tribufos in the United States, 2005 (pounds)

Production Year	2005
Range of Production Volume	<500,000

Source: USEPA, 2023a

Exhibit 11-4: CDR Reported Annual Production (Manufacture and Importation) of Tribufos in the United States, 2011-2019 (pounds)

Production Year	2011	2012	2013	2014	2015	2016	2017	2018	2019
Range of Production Volume	>2,089,000	3,869,965	2,822,662	1,775,834	0	1,144,619	1,666,056	2,662,387	1,876,813

Source: USEPA, 2023a

Toxics Release Inventory (TRI)

The EPA established TRI in 1987 in response to Section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA). EPCRA Section 313 requires the reporting of annual information on toxic chemical releases from facilities that meet specific criteria. This reported information is maintained in a database accessible through TRI Explorer (USEPA, 2023b).

Although TRI can provide a general idea of release trends, it has limitations. Not all facilities are required to report all releases. Facilities are generally required to report releases if they manufacture or process more than 25,000 pounds of a chemical or use more than 10,000 pounds per year. Reporting requirements have changed over time (e.g., reporting thresholds have increased or decreased), so conclusions about temporal trends should be drawn with caution. TRI

data are meant to reflect releases and should not be used to estimate general public exposure to a chemical (USEPA, 2022b).

TRI data for tribufos from the years 1995-2022 are summarized in Exhibit 11-5 (USEPA, 2023b). Most years there were on-site air emissions of tribufos, in amounts ranging from under ten pounds to nearly 1800 pounds. On site surface water discharges peaked in 1999 at 161 pounds and no discharges have been reported since 2007. There have been no reported on-site underground injections. Reported on-site releases to land and off-site releases have been rare.

Exhibit 11-5: Environmental Releases of Tribufos in the United States, 1995-2022 (pounds)

Year	On-Site Air Emissions	On-Site Surface Water Discharges	On-Site Underground Injection	On-site Releases to Land	Off-site Disposal or Other Releases	Total On- and Off-site Disposal or Other Releases
1995	1,730	2	0	0	.	1,732
1996	1,798	2	0	8	.	1,808
1997	1,611	2	0	0	.	1,613
1998	250	36	0	0	.	286
1999	250	161	0	0	.	411
2000	0	12	0	0	.	12
2001	5	14	0	0	.	19
2002	0	1	0	0	.	1
2003	3	2	0	0	.	5
2004	3	4	0	0	.	7
2005	3	4	0	0	.	7
2006	3	2	0	0	.	5
2007	3	2	0	0	.	5
2008	0	0	0	0	.	0
2009	1	0	0	0	.	1
2010	3	0	0	0	6	9
2011	110	0	0	0	.	110
2012	190	0	0	0	.	190
2013	720	0	0	0	.	720
2014	10	0	0	0	.	10
2015	0	0	0	0	.	0
2016	10	0	0	0	.	10
2017	10	0	0	0	.	10
2018	25	0	0	0	18	44
2019	10	0	0	0	.	10
2020	10	0	0	0	.	10
2021	10	0	0	0	.	10
2022	10	0	0	0	122	132

Source: USEPA, 2023b

Note: A decimal point indicates that one or more facilities either left an applicable field blank or certified in streamlined reporting that annual release did not exceed 500 pounds, and that otherwise no releases were reported.

Exhibit 11-6 presents an expanded summary of total releases and total surface water discharges that includes the count of states reporting releases (USEPA, 2023b). Note that for the purposes of TRI, “state” counts include the District of Columbia and U.S. territories in addition to the 50 states. Surface water discharges of tribufos, which ended in 2007, were reported from no more than one state in any given year. No more than two states had reported releases of any kind in any given year.

Exhibit 11-6: Summary of Total Releases and Total Surface Water Discharges of Tribufos, 1995-2022

Year	On-Site Surface Water Discharges (in pounds)	Count of States with Surface Water Discharges	Total Releases (in pounds)	Count of States with Releases
1995	2	1	1,732	1
1996	2	1	1,808	1
1997	2	1	1,613	1
1998	36	1	286	1
1999	161	1	411	1
2000	12	1	12	1
2001	14	1	19	2
2002	1	1	1	1
2003	2	1	5	1
2004	4	1	7	1
2005	4	1	7	1
2006	2	1	5	1
2007	2	1	5	1
2008	0	0	0	0
2009	0	0	1	1
2010	0	0	9	2
2011	0	0	110	2
2012	0	0	190	2
2013	0	0	720	2
2014	0	0	10	1
2015	0	0	0	0
2016	0	0	10	1
2017	0	0	10	1
2018	0	0	44	2
2019	0	0	10	2
2020	0	0	10	2
2021	0	0	10	2
2022	0	0	132	1

Source: USEPA, 2023b

National Center for Food and Agricultural Policy (NCFAP) Pesticide Use Database

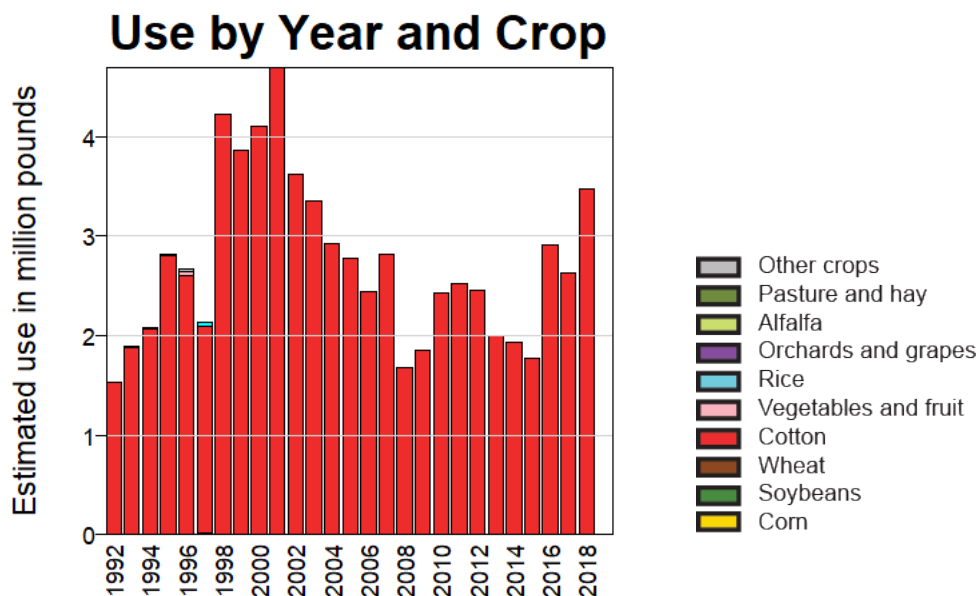
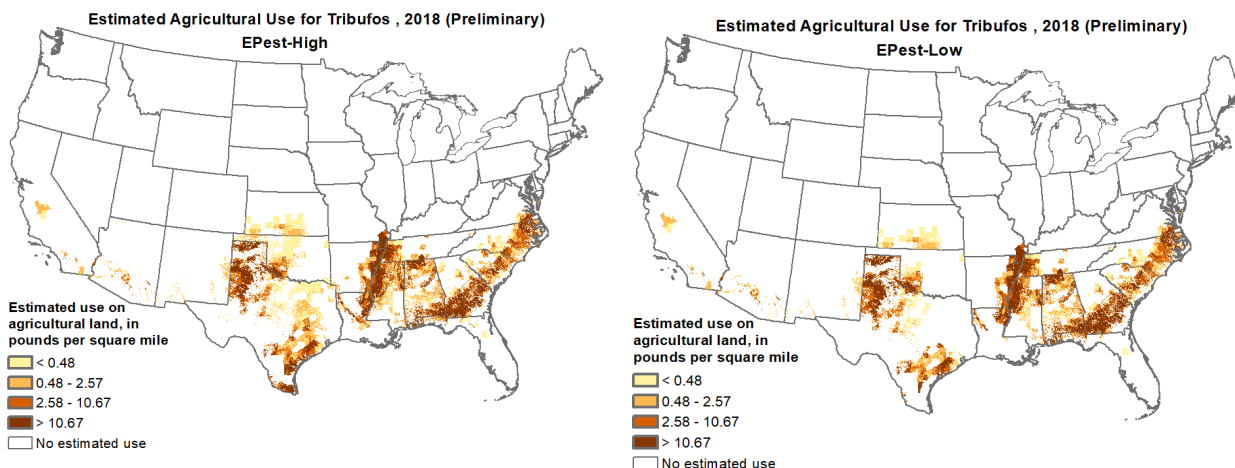
The National Center for Food and Agricultural Policy (NCFAP) maintains a national Pesticide Use Database, primarily for herbicides. Pesticide use estimates are based on state-level commercial agriculture usage patterns and state-level crop acreage. NCFAP listed uses of tribufos on one crop totaling approximately 3.96 million pounds active ingredient per year in 15 states in 1992. In 1997, NCFAP listed uses of tribufos on one crop totaling approximately 4.92 million pounds active ingredient per year in 16 states (NCFAP, 2000).

United States Geological Survey (USGS) Pesticide Use Maps

The United States Geological Survey (USGS) produces estimates of annual national pesticide use for over 200 compounds. USGS pesticide use maps show the average annual pesticide use intensity expressed as average weight (in pounds) of a pesticide applied to each square mile of agricultural land in a county. The USGS maps are created using data from NCFAP and county-level information on harvested crop acreage from the Census of Agriculture (USGS, 2023).

Exhibit 11-7 shows the geographic distribution of estimated annual tribufos use in the United States in 2018, the most recent year with maps for this pesticide. The differences between the “low” and “high” estimates primarily reflect assumptions made when data on usage of a pesticide were unavailable from a crop reporting district (i.e., an assumption of no pesticide usage or an assumption that usage was comparable to neighboring districts). A breakdown of use by crop from year to year is also included below, using the “high” assumption. From 1992 to 2018, tribufos usage has fluctuated between about 1.5 million pounds and 4.5 million pounds. Tribufos has been used almost exclusively on cotton. The maps indicate that tribufos is most intensively used in the South, in particular in the Atlantic coastal states, along the lower Mississippi River, and in Texas (USGS, 2023).

Exhibit 11-7: Estimated Annual Agricultural Use of Tribufos, 2018



Source: USGS, 2023

11.2.2 Environmental Fate

As discussed in Chapter 2, the measures used by the EPA to assess mobility include (where available) the organic carbon partitioning coefficient (K_{oc}), log octanol-water partitioning coefficient ($\log K_{ow}$), Henry's Law Constant (K_H), water solubility, and vapor pressure. A vapor pressure of 5.3×10^{-6} mm Hg at 25 degrees C indicates that tribufos will exist in both the vapor phase and the particulate phase if it is released to the atmosphere. Vapor phase tribufos will degrade in the atmosphere due to reaction with photochemically-produced hydroxyl radicals, with an estimated half-life of 5 hours. K_{oc} values of 4,870-12,684 L/kg suggest that tribufos will have little to no mobility in soil. Tribufos is not expected to volatilize from dry soil surfaces and with a K_H of 2.94×10^{-7} atm-m³/mol, volatilization from water is not expected to be an important removal mechanism (NCBI, 2023); however, volatilization may be significant from soils under hot and humid conditions (ATSDR, 2020).

Tribufos is expected to be persistent in soils with an aerobic metabolism half-life of 745 days at 25 °C (NCBI, 2023; ATSDR, 2020). The anaerobic metabolism half-life was 389 days while the anaerobic half-life in silty clay pond sediment was reported as 180 days and 120 days in replicate measurements (NCBI, 2023)

Tribufos is stable to hydrolysis at pH 5 and 7 at 24 °C but has a half-life of 124 days at pH 9 at 24 °C. Direct photolysis may be possible in the atmosphere and surface waters (NCBI, 2023). Tribufos is stable to photolysis in soil (ATSDR, 2020). Bioconcentration of tribufos in aquatic organisms is expected to be high to very high (NCBI, 2023).

11.3 Health Effects

11.3.1 Health Assessment Identification

Tribufos is a currently registered pesticide chemical under the EPA’s Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (USEPA, 2015a). For currently registered pesticide chemicals, the EPA Protocol provides that toxicity information from EPA OPP Health Effects Division (HED) Human Health Risk Assessments (HHRAs) are to be used as the basis for calculating health reference levels (HRL). (See Section B.5.1.1 of the RD 5 Protocol, found in Appendix B of this document.) Therefore, the EPA reviewed the toxicity information in the HHRA for tribufos (USEPA, 2015a; USEPA, 2015b). The OPP health assessment provides a toxicity value relevant to chronic oral toxicity and was published prior to the cutoff date of January 2023.

Exhibit 11-8 provides a summary overview of the OPP health assessment data reviewed and selected for tribufos under RD 5.

Exhibit 11-8: OPP Health Assessment Supporting Current FIFRA Registration for Tribufos

Health Assessment ^a	Oral Reference Value	POD Type	Noncancer Critical Study	Oral Cancer Slope Factor	Cancer Critical Study	Cancer Descriptor
<i>EPA OPP Human Health Risk Assessment^b (USEPA, 2015a; 2015b)</i>	<i>0.0002^c</i>	<i>BMDL₁₀</i>	<i>Sheets and Gilmore (2001)</i>	–	–	L/NL ^d

Notes: POD = point of departure; BMDL₁₀ = lower bound of the 95 percent confidence interval on the benchmark dose level associated with a 10 percent response; dash (–) = not applicable.

^a Selected health assessment and chronic toxicity value and supporting information are bolded and italicized.

^b The EPA OPP considers this health assessment “final” at the time of publication in the Federal Register.

^c The oral reference value, in units of mg/kg/day, is a steady-state population-adjusted dose (ssPAD) (USEPA, 2015b).

^d This “Likely at high doses, but unlikely to be carcinogenic to humans at low doses” cancer descriptor was determined by following the process described in the EPA’s 2005 *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005).

11.3.2 Health Assessment Selection

The health assessment selected for tribufos under RD 5 is the 2015 EPA OPP HHRA (USEPA, 2015a; USEPA, 2015b) because it supported the most recent FIFRA registration decision for tribufos. See Section B.5.1.2 of the RD 5 Protocol, in Appendix B of this document, for the decision logic that was applied to health assessment selection for RD 5 chemicals.

11.3.3 Health Reference Level (HRL) Development

HRLs are non-regulatory health-based toxicity values, expressed as concentrations in drinking water, that are used by the Agency to evaluate occurrence data for a contaminant when making decisions about regulatory determinations. See Section B.6.1.1 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA's approach for deriving HRLs for chemicals.

11.3.3.1 Oral Reference Value

In the 2015 EPA OPP HHRA (USEPA, 2015b), OPP selected a subchronic neurotoxicity study in rats (Sheets and Gilmore, 2001) as the critical study to derive the oral reference value. In this study, 18 young adult Wistar rats of each sex were fed tribufos in their diets for 13 weeks at doses of 0, 2, 40, or 500 ppm (equivalent to 0, 0.14, 2.89, or 36.8 mg/kg/day for males and 0, 0.17, 3.54, or 42.6 mg/kg/day for females), beginning at eight weeks of age. Assessments of neurobehavior, plasma cholinesterase (ChE), and erythrocyte (i.e., red blood cell, or RBC) ChE were performed throughout the experiment. At the end of the study, neuropathological examination of brain and peripheral nervous system tissues was performed (USEPA, 2015b).

Locomotor activity was significantly decreased in high-dose males and females at weeks 4, 8, and 13. Neuropathology analysis showed retinal degeneration in high-dose males and females. For systemic effects, the study authors reported a lowest-observed-adverse-effect level (LOAEL) of 40 ppm (3.53 mg/kg/day) and a no-observed-adverse-effect level (NOAEL) of 2 ppm (0.17 mg/kg/day) for females based on decreased body weight and food consumption (USEPA, 2015b); for males, the systemic LOAEL was 500 ppm (36.8 mg/kg/day) and the systemic NOAEL was 40 ppm (2.89 mg/kg/day) based on decreased body weight, food consumption, motor activity, and retinal degeneration (USEPA, 2015b). The study also identified LOAELs and NOAELs for ChE inhibition effects. RBC and plasma ChE were significantly inhibited at 40 ppm and 500 ppm in both males and females. ChE activity measured in brain tissue was decreased in females at 40 ppm and at 500 ppm in males and females. The ChE inhibition NOAEL was determined to be 2 ppm (0.14 mg/kg/day in males and 0.17 mg/kg/day in females) and the ChE inhibition LOAEL was determined to be 40 ppm (2.89 mg/kg/day in males and 3.54 mg/kg/day in females) based on ChE inhibition in plasma and RBC (for both males and females) and in the brain (females only).

ChE inhibition in rats exposed to tribufos was selected as the critical effect because it was the most sensitive endpoint assessed (USEPA, 2015b). Using benchmark dose (BMD) modeling, the EPA calculated a BMD associated with a 10 percent response (BMD₁₀) of 0.27 mg/kg/day and a BMD lower confidence limit (i.e., the lower bound of the 95 percent confidence interval on the BMD₁₀, referred to as the BMDL₁₀) of 0.19 mg/kg/day for RBC ChE inhibition. As no difference in sensitivity to RBC ChE inhibition was observed between pups and adults, OPP determined that the BMDL₁₀ would be a protective point of departure (POD) for all populations (USEPA, 2015b). A total uncertainty factor (UF) of 1000 was applied to the POD: an interspecies UF (UF_A) of 10 and an intraspecies UF (UF_H) of 10, and a Food Quality Protection Act safety factor (FQPA SF) of 10 to account for uncertainty in the human dose-response relationship for neurodevelopmental effects. After applying the total UF, the oral reference value (a steady-state population-adjusted dose, or ssPAD) was calculated to be 0.0002 mg/kg/day (USEPA, 2015b). The EPA selected this oral reference value (0.0002 mg/kg/day) from the 2015 EPA OPP HHRA to derive an HRL for tribufos.

11.3.3.2 Exposure Factor Selection

In prioritizing the contaminants of greatest public health concern for regulatory determination, Section 1412(b)(1)(C) of the Safe Drinking Water Act (SDWA) requires the Agency to consider “among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water compared to the general population.” One way that the EPA considers potentially sensitive populations or life stages (i.e., populations or life stages that may be more susceptible or sensitive to a chemical exposure) is during the selection of exposure factors (EFs) for the development of HRLs.

Drinking water intake rate adjusted for body weight (DWI-BW) is the EF used to derive HRLs for RD 5 (USEPA, 2019). EFs are input values intended to protect the general population, including sensitive populations or life stages, from adverse effects resulting from exposure to a contaminant. The Agency selects an appropriate DWI-BW for each chemical by reviewing the critical effect and study used for HRL derivation and identifying the interval of exposure (for example, see USEPA, 2022c; USEPA, 2022d). Since the critical effect represents the most sensitive adverse effect observed in the best available studies for a given chemical, it is reasonable to assume that the interval of exposure in the critical study could inform the selection of a DWI-BW protective of sensitive populations. When multiple potentially sensitive populations or life stages are identified based on the interval of exposure in the study used for HRL derivation, the EPA selects the population or life stage with the highest DWI-BW because it is the most health protective. See Section B.6.1.2 of the RD 5 Protocol, in Appendix B of this document, for more information regarding the EPA’s EF selection process.

In the critical study (Sheets and Gilmore, 2001) selected in the 2015 EPA OPP HHRA for tribufos (USEPA, 2015b), Wistar rats were orally exposed to tribufos for 13 weeks, beginning at eight weeks of age. Following the decision logic described in Section B.6.1.2 of the RD 5 Protocol, the EPA selected a corresponding human life stage. The EPA determined that rats and mice six to eight weeks of age are in the developmental stage approximately corresponding to a human life stage between juvenile or later childhood and adolescence (Ghasemi et al., 2021; Wang et al., 2020). For the purpose of evaluating environmental exposures, the EPA defines childhood in humans as the period from conception through adolescence, until 21 years of age (USEPA, 2021). Therefore, the EPA used the DWI-BW representing the 90th percentile consumers-only, two-day average, direct and indirect community water consumption for children (birth to < 21 years), which equals 0.0343 L/kg/day (USEPA, 2019), to derive the HRL for tribufos.

11.3.3.3 Relative Source Contribution

Relative source contribution (RSC) is used to account for exposure via non-drinking water routes when deriving health-based drinking water concentrations for contaminants with threshold effects (noncarcinogens and nonlinear carcinogens). RSC is defined as the portion (percentage) of an individual’s exposure attributed to drinking water rather than other sources (e.g., food, ambient air). A 20 percent RSC is used for all RD 5 contaminants, consistent with past practice for regulatory determinations, to derive the HRL because (1) HRLs are developed prior to completing the exposure assessment; and (2) a 20 percent RSC is the lowest RSC that can be applied for deriving health-based drinking water concentrations according to EPA

guidance (USEPA, 2000), and it therefore produces the most health protective HRL. Should a contaminant proceed to a National Primary Drinking Water Regulation (NPDWR), a full exposure analysis is conducted, and an RSC is derived following the Exposure Decision Tree approach described in the *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000).

11.3.3.4 HRL Calculation

Exhibit 11-9 summarizes the critical study and toxicity information from the qualifying health assessment and the EF (DWI-BW) and RSC that the EPA used to derive the HRL for tribufos.

Exhibit 11-9: Basis of HRL for Tribufos

Selected Health Assessment	Critical Study	Interval of Exposure	Critical Effect	Oral Toxicity Value	RSC	Target Population	Exposure Factor
EPA Human Health Risk Assessment (USEPA, 2015a; USEPA, 2015b)	Sheets and Gilmore (2001)	13 weeks; beginning at 8 weeks of age	Inhibition of RBC AChE in rats	0.0002 mg/kg/day	0.2 (20%)	Children (birth to < 21 years)	0.0343 L/kg/day

The EPA calculates HRLs for contaminants with a threshold dose-response, including tribufos, as follows:

$$HRL = \frac{RfD}{DWI-BW} * RSC$$

where:

RfD = Reference dose (mg/kg/day), an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. It is derived in the selected qualifying health assessment and is based on the critical effect and study identified in that assessment. Other values that can be used in place of an RfD in this equation can include a maximum acceptable concentration (MAC), minimal risk level, point of departure / uncertainty factor (POD/UF), population-adjusted dose (PAD), or tolerable daily intake (TDI).

DWI-BW = Drinking water intake (DWI), adjusted for body weight (BW), in units of liter per kilogram body weight per day (L/kg/day).

RSC = Relative source contribution, the percentage of the total exposure attributed to drinking water sources (USEPA, 2000), where the remainder of the exposure is allocated to other routes or sources. For HRL derivation in RD 5, an RSC of 20 percent is used for all contaminants.

Using an oral reference value of 0.0002 mg/kg/day (USEPA, 2015a; USEPA, 2015b), a DWI-BW of 0.0343 L/kg/day (USEPA, 2019) and a 20 percent RSC to account for non-drinking-water sources of exposure (USEPA, 2000), the HRL for tribufos is calculated as follows:

$$HRL = \frac{0.0002 \text{ mg/kg/day}}{0.0343 \text{ L/kg/day}} * 0.2$$

$$HRL = 0.00117 \text{ mg/L}$$

or

$$HRL = 1.17 \text{ } \mu\text{g/L}$$

Following HRL derivation practices, the HRL for tribufos is 1.0 $\mu\text{g/L}$ after rounding to one significant figure.

11.4 Occurrence

This section presents data on the occurrence of tribufos in ambient water and drinking water in the United States. As described in Section 11.3, an HRL of 1 $\mu\text{g/L}$ was calculated for tribufos based on non-carcinogenic effects. HRLs are risk-derived concentrations against which the EPA evaluates the occurrence data to determine if contaminants occur at levels of potential public health concern. Occurrence data from various sources presented below are analyzed with respect to the HRL and one-half the HRL. When possible, estimates of the population exposed at concentrations above the HRL and one-half the HRL are presented.

For additional background information about data sources used to evaluate occurrence, please refer to Chapter 2.

11.4.1 Occurrence in Ambient Water

Lakes, rivers, and aquifers are the ambient sources of most drinking water. Contaminant occurrence in ambient water provides information on the potential for contaminants to adversely affect drinking water supplies. Occurrence data for tribufos in ambient water are available from the USGS National Water-Quality Assessment (NAWQA) program, the USGS National Water Information System (NWIS) database, and the EPA's legacy Storage and Retrieval Data System (STORET). When sources of information on ambient occurrence also include limited finished water data, those finished water data are summarized here as well.

11.4.1.1 United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) Ambient Water Analyses

USGS instituted the NAWQA program in 1991 to examine ambient water quality status and trends in the United States. The NAWQA program generates high quality contaminant occurrence and other water quality parameter data for significant watersheds and aquifers across the nation. The program collects data on surface water and groundwater chemistry, hydrology, land use, stream habitat, and aquatic life in parts of nearly all 50 states. The program is designed to apply nationally consistent methods to provide a uniform basis for contaminant occurrence comparisons and assessments among study basins across the country and over time. The occurrence assessments can also serve to facilitate interpretation of natural and anthropogenic factors affecting national water quality. For more detailed information on NAWQA program design and implementation, refer to Leahy and Thompson (1994) and Hamilton et al. (2004).

The process of sampling, analysis, and data synthesis is divided into cycles of approximately ten years: Cycle 1 covered 1991-2001, Cycle 2 covered 2002-2012, and Cycle 3 covered 2013-2023. Study units are sampled and analyzed on a staggered schedule within each cycle. Each NAWQA cycle begins with a two-year startup phase for planning and retroactive analysis, followed by a three-year intensive data collection phase, and finally a five-year phase for analyzing the data, developing reports, and continuing a low level of monitoring (NRC, 2012).

The EPA downloaded NAWQA data from the Water Quality Portal (WQP) in September 2023 (WQP, 2023). The EPA's analysis of the NAWQA data is a simple, non-parametric occurrence analysis that provides summary statistics to characterize contaminant occurrence. The EPA included in the analysis all samples that could be classified as groundwater and surface water, and also the limited number of samples labeled as finished water. Other types of samples (e.g., from soil, sediment, and wastewater) were excluded. The EPA calculated detection frequencies as the percentage of samples and the percentage of sites with at least one detection. (A detection is an analytical result equal to or greater than the reporting level.) No weighting was applied. The EPA determined the minimum and maximum detected concentrations and calculated other descriptive statistics including the median, 90th percentile, and 99th percentile concentrations (based only on samples with detections). Reporting levels varied over time during the NAWQA program.

The results of the EPA's analysis of NAWQA data downloaded from WQP are presented in Exhibit 11-10 through Exhibit 11-12 (WQP, 2023). Tribufos was detected in groundwater only once, in a single sample in Cycle 2 (representing 0.03 percent of 3,338 Cycle 2 groundwater samples). In surface water, tribufos was detected at frequencies ranging from 0 percent (in Cycle 1) to 0.44 percent (in Cycle 2). The highest reported concentration, 0.246 µg/L, found in surface water, is less than ½ the HRL of 1 µg/L. The NAWQA data set for tribufos includes 61 finished water samples, in Cycle 2. There were no tribufos detections in finished water.

Note that there may be some overlap between the NAWQA data assessment presented here and summaries of individual NAWQA studies presented below.

Exhibit 11-10: Tribufos NAWQA Data – Summary of Detected Concentrations

Site Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90 th Percentile	99 th Percentile	Maximum
Cycle 1 (1991 - 2001)					
Groundwater	--	--	--	--	--
Surface Water	--	--	--	--	--
All Sites	--	--	--	--	--
Cycle 2 (2002 - 2012)					
Finished Water	--	--	--	--	--
Groundwater	0.009	0.009	0.009	0.009	0.009
Surface Water	0.01	0.0170	0.0601	0.109	0.117
All Sites	0.009	0.0165	0.0582	0.109	0.117

Site Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90 th Percentile	99 th Percentile	Maximum
Cycle 3 (2013 - 2023)					
Groundwater	--	--	--	--	--
Surface Water	0.00196	0.00491	0.213	0.243	0.246
All Sites	0.00196	0.00491	0.213	0.243	0.246

Source: WQP, 2023

"--" = No detections in this category

Exhibit 11-11: Tribufos NAWQA Data – Summary of Samples

Site Type	No. of Samples	Detection Frequency (detections are results ≥ reporting level)					
		No. of Samples with Detections	Percent Samples with Detections	No. of Samples with Detections > ½ HRL	Percent Samples with Detections > ½ HRL	No. of Samples with Detections > HRL	Percent Samples with Detections > HRL
Cycle 1 (1991 - 2001)							
Groundwater	81	0	0.00%	0	0.00%	0	0.00%
Surface Water	95	0	0.00%	0	0.00%	0	0.00%
All Sites	176	0	0.00%	0	0.00%	0	0.00%
Cycle 2 (2002 - 2012)							
Finished Water	61	0	0.00%	0	0.00%	0	0.00%
Groundwater	3,338	1	0.03%	0	0.00%	0	0.00%
Surface Water	4,769	21	0.44%	0	0.00%	0	0.00%
All Sites	8,168	22	0.27%	0	0.00%	0	0.00%
Cycle 3 (2013 - 2023)							
Groundwater	1,755	0	0.00%	0	0.00%	0	0.00%
Surface Water	10,415	8	0.08%	0	0.00%	0	0.00%
All Sites	12,170	8	0.07%	0	0.00%	0	0.00%

Source: WQP, 2023

Exhibit 11-12: Tribufos NAWQA Data – Summary of Sites

Site Type	No. of Sites	Detection Frequency (detections are results ≥ reporting level)					
		No. of Sites with Detections	Percent Sites with Detections	No. of Sites with Detections > ½ HRL	Percent Sites with Detections > ½ HRL	No. of Sites with Detections > HRL	Percent Sites with Detections > HRL
Cycle 1 (1991 - 2001)							
Groundwater	80	0	0.00%	0	0.00%	0	0.00%
Surface Water	44	0	0.00%	0	0.00%	0	0.00%
All Sites	124	0	0.00%	0	0.00%	0	0.00%

Site Type	No. of Sites	Detection Frequency (detections are results ≥ reporting level)					
		No. of Sites with Detections	Percent Sites with Detections	No. of Sites with Detections > ½ HRL	Percent Sites with Detections > ½ HRL	No. of Sites with Detections > HRL	Percent Sites with Detections > HRL
Cycle 2 (2002 - 2012)							
Finished Water	50	0	0.00%	0	0.00%	0	0.00%
Groundwater	2,332	1	0.04%	0	0.00%	0	0.00%
Surface Water	164	16	9.76%	0	0.00%	0	0.00%
All Sites	2,546	17	0.67%	0	0.00%	0	0.00%
Cycle 3 (2013 - 2023)							
Groundwater	1,678	0	0.00%	0	0.00%	0	0.00%
Surface Water	479	4	0.84%	0	0.00%	0	0.00%
All Sites	2,157	4	0.19%	0	0.00%	0	0.00%

Source: WQP, 2023

11.4.1.2 National Water Information System (NWIS) Data

NWIS is the nation's principal repository of water resources data collected by USGS from more than 1.9 million sites in all U.S. states and territories (USGS, 2022). All USGS water quality and flow data are stored in NWIS, including site characteristics, streamflow, groundwater level, precipitation, and chemical analyses of water, sediment, and biological media, though not all parameters are available for every site. NWIS houses the NAWQA data and includes other USGS data from a range of unspecified projects. NWIS encompasses many more samples at many more sites than are involved in the NAWQA Program. Although NWIS is comprised of primarily ambient water data, some finished drinking water data are included as well. This section presents analyses of non-NAWQA data in NWIS, downloaded from the WQP in September 2023 (WQP, 2023). These data do not overlap with the NAWQA results presented above.

The results of the non-NAWQA NWIS tribufos analysis are presented in Exhibit 11-13. Tribufos was detected in approximately 0.2 percent of samples (42 of 21,376) and at approximately 0.5 percent of sites (34 of 6,848). All of the detections were in surface water. The highest reported concentration, 0.148 $\mu\text{g/L}$, is less than ½ the HRL of 1 $\mu\text{g/L}$.

Exhibit 11-13: Tribufos NWIS Data, 1991-2023

Sample Media Type	Detection Frequency (detections are results $\geq$ reporting level)				Concentration Values (of detections, in $\mu\text{g/L}$)				
	No. of Samples	No. of Samples with Detections	No. of Sites	No. of Sites with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
Finished Water	38	0	20	0	--	--	--	--	--
Groundwater	8,279	0	5,102	0	--	--	--	--	--
Surface Water	13,059	42	1,737	34	0.005	0.020	0.085	0.132	0.148

Sample Media Type	Detection Frequency (detections are results $\geq$ reporting level)				Concentration Values (of detections, in $\mu\text{g/L}$)				
	No. of Samples	No. of Samples with Detections	No. of Sites	No. of Sites with Detections	Minimum	Median	90th Percentile	99th Percentile	Maximum
Total	21,376	42	6,848	34	0.005	0.020	0.085	0.132	0.148

Source: WQP, 2023

"--" = No detections in this category

Note that some NWIS sites are associated with multiple sample media types, so site counts might not add up to totals.

11.4.1.3 Storage and Retrieval (STORET) Data

From its launch in 1999 until it was decommissioned in June 2018, the EPA's STORET Data Warehouse was collaboratively populated with raw biological, chemical, and physical data from surface water and groundwater sampling by federal, state and local agencies, Native American Tribes, volunteer groups, academics, and others. Legacy STORET data, as well as more current STORET data, are accessible through the WQP.

STORET data are from monitoring locations in all 50 states as well as multiple territories and jurisdictions of the United States. STORET's data quality limitations include variations in the extent of national coverage and data completeness from parameter to parameter. Data may have been collected as part of targeted, rather than randomized, monitoring. This section presents analyses of STORET data, downloaded from the WQP in September 2023 (WQP, 2023). The EPA reviewed STORET groundwater data from wells and springs and surface water data from lakes, rivers/streams, and reservoirs. The STORET data set also included limited data from public water systems (PWSs). The database does not specify whether PWS sampling was conducted before or after treatment.

The results of the STORET analysis for tribufos are presented in Exhibit 11-14 through Exhibit 11-15. Samples were collected in 1994. A total of 8 groundwater samples from 7 sites were tested for tribufos. None had detections.

Exhibit 11-14: Tribufos STORET Data – Summary of Samples and Sites

Source Water Type	Total Number of Samples	Samples with Detections		Total Number of Sites	Sites with Detections	
		Number	Percent		Number	Percent
Groundwater	8	0	0.00%	7	0	0.00%
Surface Water	0	0	n/a	0	0	n/a
Total	8	0	0.00%	7	0	0.00%

Source: WQP, 2023

Exhibit 11-15: Tribufos STORET Data – Summary of States

Source Water Type	Total Number of States	States with Detections	
		Number	Percent
Groundwater	1	0	0%
Surface Water	0	0	n/a
Total¹	1	0	0%

Source: WQP, 2023

¹ The number of states with groundwater data plus the number of states with surface water data may not equal the “Total” number of states providing data because some states provided both groundwater and surface water data.

11.4.1.4 Additional Ambient Water Studies

Kingsbury et al. (2021) evaluated groundwater-quality samples collected from 2017 to 2019 as part of the third cycle of USGS’s NAWQA Program. Six types of well network studies were conducted: principal aquifer study networks; major aquifer study networks; land-use study networks; vertical flow-path study networks; enhanced trends networks; and modeling support studies. The reporting level used for tribufos was 0.001 µg/L. Tribufos was not detected in any of the 469 samples at 464 sites.

Erickson et al. (2019) conducted a study to assess groundwater quality in the United States glacial aquifer system using groundwater samples gathered from approximately 39,000 wells from 2005 to 2013. Data were derived from three sources: the USGS NWIS, the EPA’s Safe Drinking Water Information System (SDWIS), and numerous agencies and organizations at the state, regional, and local level. No detections of tribufos exceeded the “high” benchmark of 7 µg/L or the “moderate” benchmark of 0.7 µg/L in 616 analyses.

11.4.2 Occurrence in Drinking Water

Data sources reviewed by the Agency for information on contaminant occurrence in drinking water included: the EPA’s first, second, third, and fourth Unregulated Contaminant Monitoring Rules (UCMR 1, UCMR 2, UCMR 3, UCMR 4); Rounds 1 and 2 of the Agency’s Unregulated Contaminant Monitoring (UCM) program that preceded the Unregulated Contaminant Monitoring Rule (UCMR); the EPA’s National Inorganics and Radionuclides Survey (NIRS); and a range of others as discussed in Chapter 2. Among the sources reviewed, the following sources had data and information on tribufos occurrence in drinking water and are discussed in this section:

- The EPA’s Fourth Unregulated Contaminant Monitoring Rule (UCMR 4).
- Consumer Confidence Reports (CCRs) from PWSs.
- United States Department of Agriculture (USDA) Pesticide Data Program (PDP).
- USGS Pilot Monitoring Program (PMP).
- Additional source water and drinking water studies.

Note that there may be some overlap as sources with different purposes and audiences may have reported the same underlying data. UCMR 4 is a nationally representative data source.

Other data sources profiled in this section are considered “supplemental” sources. Also note that the ambient water section, above, presents some limited finished water data and miscellaneous data from PWSs found in ambient water data sources.

11.4.2.1 Primary Data Sources

11.4.2.1.1 The EPA’s Fourth Unregulated Contaminant Monitoring Rule (UCMR 4), 2018-2020

The UCMR program was designed to provide a national assessment of the occurrence of select unregulated contaminants in PWSs. UCMR 4 was published on December 20, 2016 (USEPA, 2016) and required monitoring for 30 chemical contaminants between 2018 and 2020. Data reporting continued into 2021.

UCMR 4 Assessment Monitoring occurrence data are available for tribufos. For UCMR 4, all large and very large community water systems (CWSs) and non-transient non-community water systems (NTNCWSs) (serving between 10,001 and 100,000 people and serving more than 100,000 people, respectively), plus a statistically representative national sample of 800 small CWSs and NTNCWSs (serving 10,000 people or fewer), were required to conduct Assessment Monitoring during a 12-month period between January 2018 and December 2020.¹ Surface water and groundwater under the direct influence of surface water (GWUDI) sampling points were monitored four times during the applicable year of monitoring. Groundwater sampling points were monitored twice during the applicable year of monitoring. See USEPA (2016) and USEPA (2024) for more information on the UCMR 4 study design and data analysis.

The design of UCMR 4 permits estimation of national occurrence by multiplying the total number of systems (or population served) in the nation in a system size category by the percent of systems (or population served) found to exceed a specified threshold in the sample. This extrapolation methodology is applied to small systems. Because all large and very large systems were required to participate in the UCMR 4 Assessment Monitoring, national occurrence estimates in these size categories can be developed using survey census figures rather than extrapolation. Total national occurrence is estimated by summing the extrapolated figures for small systems and the census figures for the large and very large systems.

Exhibit 11-16 through Exhibit 11-20 provide an overview of tribufos occurrence results from UCMR 4 Assessment Monitoring. The minimum reporting level (MRL) used for tribufos in the UCMR 4 survey was 0.03 µg/L. Exhibit 11-16 shows a statistical summary of tribufos concentrations by system size and source water type (including the minimum, median, 90th percentile, 99th percentile, and maximum). Exhibit 11-17 presents a sample-level summary of the results. Exhibit 11-18 through Exhibit 11-20 show system-level results, including national extrapolations, at three thresholds: detections, ½ the HRL, and the HRL. Detections are evaluated on a “greater than or equal to” basis ($\geq$ the MRL), while health-based thresholds are evaluated in terms of exceedances ($> \frac{1}{2}$ HRL and $>$ HRL).

As a reminder that the figures from large and very large systems represent a census of systems in those categories, results in those categories are labeled “CENSUS” in the exhibits below. No extrapolation was necessary in these categories, as it was for the small systems, to

¹ Only 797 small systems submitted results for tribufos.

derive national estimates of occurrence. National estimates of occurrence are reported separately in each system size and source water category, and also in the aggregate.

A total of 37,269 UCMR 4 samples for tribufos were collected from 5,027 systems. Tribufos was detected in only three samples (0.01 percent), with concentrations ranging from 0.0742 µg/L to 0.4 µg/L. The detections were found at three large systems, representing 0.06 percent of systems participating in the monitoring program. Extrapolating these findings suggests that an estimated three PWSs serving 48,700 people nationally have detectable levels of tribufos. There were no exceedances of the HRL or ½ the HRL.

Exhibit 11-16: Tribufos Occurrence Data from UCMR 4 Assessment Monitoring – Summary of Reported Concentrations

Source Water Type	Concentration Value of Detections (µg/L)				
	Minimum	Median	90th Percentile	99th Percentile	Maximum
Small Systems (serving ≤ 10,000 people)					
Groundwater	--	--	--	--	--
Surface Water	--	--	--	--	--
All Small Systems	--	--	--	--	--
Large Systems (serving 10,001 - 100,000 people) -- CENSUS					
Groundwater	0.4	0.4	0.4	0.4	0.4
Surface Water	0.0742	0.107	0.133	0.138	0.139
All Large Systems	0.0742	0.139	0.348	0.395	0.4
Very Large Systems (serving > 100,000 people) – CENSUS					
Groundwater	--	--	--	--	--
Surface Water	--	--	--	--	--
All Very Large Systems	--	--	--	--	--
All Systems					
All Water Systems	0.0742	0.139	0.348	0.395	0.4

Source: USEPA, 2024

--" = No detections in this category

Exhibit 11-17: Tribufos National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of Samples

Source Water Type	Total # of Samples	Samples with Detections ≥ MRL (0.07 µg/L)		Samples with Detections > ½ HRL (0.5 µg/L)		Samples with Detections > HRL (1 µg/L)	
		Number	Percent	Number	Percent	Number	Percent
Small Systems (serving ≤ 10,000 people)							
Groundwater	1,896	0	0.00%	0	0.00%	0	0.00%
Surface Water	1,360	0	0.00%	0	0.00%	0	0.00%
All Small Systems	3,256	0	0.00%	0	0.00%	0	0.00%
Large Systems (serving 10,001 - 100,000 people) -- CENSUS							
Groundwater	10,948	1	0.01%	0	0.00%	0	0.00%
Surface Water	15,702	2	0.01%	0	0.00%	0	0.00%
All Large Systems	26,650	3	0.01%	0	0.00%	0	0.00%

Source Water Type	Total # of Samples	Samples with Detections ≥ MRL (0.07 µg/L)		Samples with Detections > ½ HRL (0.5 µg/L)		Samples with Detections > HRL (1 µg/L)	
		Number	Percent	Number	Percent	Number	Percent
Very Large Systems (serving > 100,000 people) -- CENSUS							
Groundwater	2,057	0	0.00%	0	0.00%	0	0.00%
Surface Water	5,306	0	0.00%	0	0.00%	0	0.00%
All Very Large Systems	7,363	0	0.00%	0	0.00%	0	0.00%
All Systems							
All Water Systems	37,269	3	0.01%	0	0.00%	0	0.00%

Source: USEPA, 2024

Exhibit 11-18: Tribufos National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data – Summary of System and Population – All Reported Detections

Source Water Type	UCMR 4 Sample		Number With At Least One Detection $\geq$ MRL (0.07 $\mu\text{g/L}$)		Percent With At Least One Detection $\geq$ MRL (0.07 $\mu\text{g/L}$)		National Inventory ¹		National Estimate of Number With At Least One Detection $\geq$ MRL (0.07 $\mu\text{g/L}$) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving $\leq$ 10,000 people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,467	37,629,182	1	14,700	0.07%	0.04%	1,467	37,629,182	1	14,700
Surface Water	2,340	71,511,793	2	34,007	0.09%	0.05%	2,340	71,511,793	2	34,007
All Large Systems	3,807	109,140,975	3	48,707	0.08%	0.04%	3,807	109,140,975	3	48,707
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,027	249,055,100	3	48,707	0.06%	0.02%	67,731	307,120,182	3	48,707

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

**Exhibit 11-19: Tribufos National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data –
Summary of System and Population Served Data – Detections > ½ the HRL (0.5 µg/L)**

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > ½ HRL (0.5 µg/L)		Percent With At Least One Detection > ½ HRL (0.5 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > ½ HRL (0.5 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,467	37,629,182	0	0	0.00%	0.00%	1,467	37,629,182	0	0
Surface Water	2,340	71,511,793	0	0	0.00%	0.00%	2,340	71,511,793	0	0
All Large Systems	3,807	109,140,975	0	0	0.00%	0.00%	3,807	109,140,975	0	0
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,027	249,055,100	0	0	0.00%	0.00%	67,731	307,120,182	0	0

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

**Exhibit 11-20: Tribufos National Occurrence Measures Based on UCMR 4 Assessment Monitoring Data –
Summary of System and Population Served Data – Detections > HRL (1 µg/L)**

Source Water Type	UCMR 4 Sample		Number With At Least One Detection > HRL (1 µg/L)		Percent With At Least One Detection > HRL (1 µg/L)		National Inventory ¹		National Estimate of Number With At Least One Detection > HRL (1 µg/L) ²	
	Systems	Population	Systems	Population	Systems	Population	Systems	Population	Systems	Population
Small Systems (serving ≤ 10,000 people)										
Groundwater	518	1,540,255	0	0	0.00%	0.00%	53,877	38,056,639	0	0
Surface Water	279	1,310,370	0	0	0.00%	0.00%	9,624	22,859,068	0	0
All Small Systems	797	2,850,625	0	0	0.00%	0.00%	63,501	60,915,707	0	0
Large Systems (serving 10,001 - 100,000 people) -- CENSUS										
Groundwater	1,467	37,629,182	0	0	0.00%	0.00%	1,467	37,629,182	0	0
Surface Water	2,340	71,511,793	0	0	0.00%	0.00%	2,340	71,511,793	0	0
All Large Systems	3,807	109,140,975	0	0	0.00%	0.00%	3,807	109,140,975	0	0
Very Large Systems (serving > 100,000 people) -- CENSUS										
Groundwater	69	16,759,675	0	0	0.00%	0.00%	69	16,759,675	0	0
Surface Water	354	120,303,825	0	0	0.00%	0.00%	354	120,303,825	0	0
All Very Large Systems	423	137,063,500	0	0	0.00%	0.00%	423	137,063,500	0	0
All Systems										
All Water Systems	5,027	249,055,100	0	0	0.00%	0.00%	67,731	307,120,182	0	0

Source: USEPA, 2024

¹ The small system national inventory numbers for systems and population served by systems were derived from a freeze of the December 2015 Safe Drinking Water Information System / Federal version (SDWIS/Fed) data. These counts are based on all community and non-transient non-community water systems that served 10,000 people or fewer. All large and very large systems were required to conduct UCMR 4 Assessment Monitoring; thus, the national inventory numbers for the large and very large systems are based on the number of systems expected to complete UCMR 4 monitoring. SDWIS/Fed inventory data from 2015 were used for the UCMR 4 national extrapolations as these data were consistent with the UCMR 4 inventory data at the timeframe of the UCMR 4 sample design.

² National estimates for the small systems are generated by multiplying the UCMR 4 national statistical sample findings of system/population percentages and national system/population inventory numbers for PWSs. National estimates for the large and very large systems are based directly on the UCMR 4 results, since this was a census. Due to rounding, some calculations may appear to be slightly off.

11.4.2.2 Supplemental Data Sources

11.4.2.2.1 Water Systems' Consumer Confidence Reports (CCRs), 2018-2021

CCRs are annual water quality reports that CWSs are required to provide to their customers. These reports summarize information on water sources, detected contaminants, and system compliance with EPA drinking water standards; they may also include general educational material. Under the CCR Rule (40 CFR Subpart O), CWSs with 15 or more connections or serving at least 25 year-round residents must prepare and distribute a CCR to all billing units or service connections every year. Systems serving 100,000 or more residents are also required to post their current CCRs on a publicly accessible Internet site.

The EPA reviewed CCRs published by the 25 systems that serve over one million customers (as identified in the Safe Drinking Water Information System / Federal version, or SDWIS/Fed, from the fourth quarter 2021 data) for unregulated contaminant occurrence information for the years 2018 through 2021. Data on tribufos were available from CCRs prepared by five CWSs: one system in California (Los Angeles), one system in Colorado (Denver), two systems in New York (Suffolk County and New York City), and one system in Pennsylvania (Philadelphia). Monitoring results from all five systems showed no detections of tribufos.

Los Angeles Department of Water & Power (LADWP) included data on tribufos monitoring for UCMR 4 in its 2020 and 2021 CCRs. LADWP is served by multiple surface water and groundwater sources. The sampling was conducted in 2018-2019. Tribufos was not detected.

Denver Water included data on tribufos monitoring for UCMR 4 in its 2018 CCR. Denver Water is served by the South Platte River and other surface water sources. An average tribufos concentration of “0 µg/L” was reported for treatment plant effluent.

Suffolk County, New York, included data on tribufos in its 2018-2021 CCRs. Suffolk County is served by groundwater from four major aquifers beneath Long Island. In all 4 years, tribufos was monitored for but was not detected.

New York City included data on tribufos in four CCRs covering 2018 through 2021. New York City is served by a large system of surface water networks in New York state. In all 4 years, tribufos was monitored for but was not detected.

The Philadelphia Water Department (PWD) included data on tribufos in three CCRs covering 2019 through 2021. PWD is served by surface water from the Schuylkill and Delaware rivers. In all 3 years, tribufos was monitored for but was not detected.

11.4.2.2.2 United States Department of Agriculture (USDA) Pesticide Data Program (PDP), 2001-2013

The USDA PDP maintains a national pesticide residue database. PDP was initiated in 1991 to collect representative data on pesticide residues in the United States food supply, following a rigorous statistical design. Sampling and testing have been conducted on fruits and vegetables, select grains, milk, and (between 2001 and 2013) drinking water (USDA, 2022).

The PDP drinking water project was initiated at CWSs in New York and California in 2001. Since then, the drinking water sampling program has expanded, though a somewhat

changing mix of states is sampled each year. At one time or another, CWSs in 29 states and the District of Columbia have contributed raw or finished water data or both to the program (USDA, 2023). The CWSs selected for sampling tend to be small and medium-sized systems (primarily CWSs serving under 50,000), systems served by surface water, and systems located in regions of heavy agriculture. Sampling of raw (“untreated”) water in addition to finished water began in 2004; sampling of raw and finished drinking water was discontinued after 2013. Note that temporal trends cannot be evaluated based on these data since the list of CWSs included in the project varied from year to year (USDA, 2022; USDA, 2023).

Tribufos was included in the USDA PDP (Exhibit 11-21) (USDA, 2022). Tribufos was not detected in any of 2,744 samples (500 raw water and 2,244 finished water). The reported limits of detection ranged from 0.0038 to 0.018 µg/L.

Exhibit 11-21: Summary of Tribufos PDP Data, 2001-2013

Year	Raw/ Finished	Total Number of Samples	Number of Detections	Percent of Detections	Minimum Value of Detections (µg/L)	Maximum Value of Detections (µg/L)
2001	Finished	283	0	0.00%	N/A	N/A
2002	Finished	669	0	0.00%	N/A	N/A
2003	Finished	794	0	0.00%	N/A	N/A
2004	Finished	239	0	0.00%	N/A	N/A
	Raw	239	0	0.00%	N/A	N/A
2005	Finished	141	0	0.00%	N/A	N/A
	Raw	143	0	0.00%	N/A	N/A
2006	Finished	118	0	0.00%	N/A	N/A
	Raw	118	0	0.00%	N/A	N/A
2007	Finished	No Data	No Data	No Data	No Data	No Data
	Raw	No Data	No Data	No Data	No Data	No Data
2008	Finished	No Data	No Data	No Data	No Data	No Data
	Raw	No Data	No Data	No Data	No Data	No Data
2009	Finished	No Data	No Data	No Data	No Data	No Data
	Raw	No Data	No Data	No Data	No Data	No Data
2010	Finished	No Data	No Data	No Data	No Data	No Data
	Raw	No Data	No Data	No Data	No Data	No Data
2011	Finished	No Data	No Data	No Data	No Data	No Data
	Raw	No Data	No Data	No Data	No Data	No Data
2012	Finished	No Data	No Data	No Data	No Data	No Data
	Raw	No Data	No Data	No Data	No Data	No Data
2013	Finished	No Data	No Data	No Data	No Data	No Data
	Raw	No Data	No Data	No Data	No Data	No Data

Source: USDA, 2022

N/A = not applicable (no detections in this category).

11.4.2.2.3 *United States Geological Survey (USGS) Pilot Monitoring Program (PMP), 1999*

In 1999, the PMP was initiated by USGS and the EPA to provide information on pesticide concentrations in drinking water. The program focused on small drinking water supply reservoirs in areas with high pesticide use in order to test the sampling approach in areas where pesticides are probably present (Blomquist et al., 2001). Sampling sites represented a variety of geographic regions as well as different cropping patterns. The ideal site candidates were mostly small reservoirs located in high pesticide-use areas with a high runoff potential. Twelve water-supply reservoirs considered vulnerable to pesticide contamination were selected from the list of candidates. These 12 sites were located in California, Indiana, Louisiana, Missouri, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, and Texas.

Samples were collected quarterly throughout the year and at weekly or biweekly intervals following the primary pesticide-application periods. Water samples were collected from the raw-water intake and from finished drinking water taps prior to entering the distribution system. At some sites, samples were also collected at the reservoir outflow.

Tribufos was an analyte in the PMP. At a method reporting level of 0.016 µg/L, tribufos was not detected in any of the 317 samples from raw water sites or any of the 221 samples from finished water sites (Blomquist et al., 2001).

11.4.2.2.4 *Additional Source Water and Drinking Water Studies*

Note that there may be some overlap between the NAWQA data assessment presented earlier in the ambient water occurrence section and the summaries of NAWQA studies presented below.

Contaminant Occurrence in Source and Finished Water in the Sioux Falls Area, South Dakota (Hoogestraat, 2012), 2009-2010

In 2009-2010, the city of Sioux Falls and the USGS assessed the occurrence of anthropogenic organic compounds in the source waters (groundwater and surface water) and finished water in the Sioux Falls area. The reporting levels used for tribufos in this study ranged from 0.018-0.035. Tribufos was not detected in any of the 11 finished water samples, 7 groundwater samples, or 8 surface water samples.

11.5 Analytical Methods

The EPA has published one analytical methods for the analysis of tribufos in drinking water. Note that EPA Method 525.3 indicates that tribufos is an oxidation product of merphos and has a retention time identical to merphos (they co-elute). Many (but not all) of the performance data in the method are for tribufos + merphos:

- EPA Method 525.3, Version 1.0, *Determination of Semivolatile Organic Chemicals in Drinking Water by Solid Phase Extraction and Capillary Column Gas Chromatography/Mass Spectrometry (GC/MS)* has detection limits (DLs) that range from 0.013 to 0.12 µg/L in Full Scan mode and a DL of 0.0033 µg/L in Selected Ion Monitoring (SIM) mode. The Lowest Concentration Minimum Reporting Levels (LCMRLs) generated by the laboratories that helped to develop the method range from

0.18 to 0.53 µg/L in Full Scan mode and 0.0063 to 0.023 µg/L in SIM mode. Mean recoveries in reagent water, finished water from groundwater with a hardness of 290 to ≥350 mg/L (as calcium carbonate) and finished drinking water from surface water with total organic carbon (TOC) of 2.4 to 2.8 mg/L range from 82.0 to 126 percent, with relative standard deviations (RSDs) of 1.3 to 7.3 percent for Full Scan mode. Mean recoveries in reagent water, finished water from groundwater with a hardness of 325 to 393 mg/L (as calcium carbonate) and finished drinking water from surface water with TOC of 2.0 to 2.52 mg/L and a hardness of 137 mg/L (as calcium carbonate) range from 91.4 to 117 percent, with RSDs of 1.0 to 9.0 percent for SIM mode. (USEPA, 2012).

Laboratories participating in UCMR 4 were required to use EPA Method 525.3 and were required to report tribufos values at or above the EPA-defined MRL of 0.07 µg/L (81 FR 92666; USEPA, 2016). The MRL was set based on the capability of multiple laboratories at the time.

11.6 Treatment Technologies

The EPA evaluates whether suitable treatment technologies are available prior to promulgating a final NPDWR. A December 2023 literature search found no studies with information about treatment technologies applicable to tribufos.

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Appendix A:
Summary Information on
RD 5 Contaminants
Receiving Determinations

An appendix from:
**Final Regulatory Determination 5 Support
Document**

EPA Report 815-R-26-002

This appendix presents, in a condensed form, data and information gathered and considered by the U.S. Environmental Protection Agency (EPA) when evaluating the nine contaminants receiving determinations under the fifth round of Regulatory Determinations (RD 5). They are, in order of presentation:

1. 2-Aminotoluene
2. Cylindrospermopsin
3. Ethoprop
4. Microcystins
5. Molybdenum
6. Permethrin
7. Profenofos
8. Tebuconazole
9. Tribufos

Author-date citations used in this appendix correspond to the full references presented in the contaminants' respective chapters.

Summary Information for Phase 3 Contaminants
2-Aminotoluene (CASRN: 95-53-4)

HRL

2 µg/L

Uses / Sources

- An aminotoluene (NCBI, 2024)
- Used in the manufacture of dyes, rubber vulcanization accelerators, pharmaceuticals and pesticides (NCBI, 2024)

Quantified Production (IUR/CDR)

Annual reported production (i.e., manufacturing and importation) from the EPA's IUR and CDR programs, in pounds:

- 2005: 10M - <50M
- 2011: >23,419,290
- 2012: 50M - <100M
- 2013: 50M - <100M
- 2014: 50M - <100M
- 2015: 50M - <100M
- 2016: 50M - <100M
- 2017: 50M - <100M
- 2018: 50M - <100M
- 2019: 50M - <100M

Quantified Releases (TRI)

TRI Releases

- 2004 to surface water: 5 lbs/yr from 1 state
- 2004 total: 10,774 lbs/yr from 9 states
- 2008 to surface water: 5 lbs/yr from 1 state
- 2008 total: 13,666 lbs/yr from 10 states
- 2012 to surface water: 195 lbs/yr from 2 states
- 2012 total: 6,876 lbs/yr from 7 states
- 2016 to surface water: 195 lbs/yr from 2 states
- 2016 total: 6,838 lbs/yr from 10 states
- 2020 to surface water: 194 lbs/yr from 2 states
- 2020 total: 7,387 lbs/yr from 7 states

Quantified Usage (NCFAP, etc.)

No data available

Fate / Transport

- No info available from PubChem or ATSDR
- In soil, 2-aminotoluene will be subject to biodegradation, oxidation, and binding to soil components; in water, 2-aminotoluene will be subject to biodegradation, oxidation, and photooxidation as well as some adsorption to sediment; and in the atmosphere, 2-

aminotoluene will photodegrade with a half-life of about 3 hours (Gad, 2024)

- An equilibrium model estimates that 83.3% of o-toluidine in the environment will partition to water and much smaller amounts will partition to air, soil, sediment, biota and suspended sediments (IPCS, 1998)
- An overall removal half-life for o-toluidine in Rhine river water was estimated to be approximately 1 day (IPCS, 1998)

Health Effects

- Health assessment selected: EPA Provisional Peer-Reviewed Toxicity Value (2012)
- Critical study: Weisburger et al. (1978)
- Critical effect: Subcutaneous fibroma and fibrosarcoma in male rats
- Oral reference value: Cancer slope factor of 0.016 (mg/kg/day)⁻¹
- Life stage selected for calculating exposure factor: birth to < 21 years
- HRL: 2 µg/L (cancer)
- Cancer classification: L ("likely to be carcinogenic to humans")

Nationally Representative Drinking Water Occurrence

UCMR 4 Assessment Monitoring (2018-2020)

- MRL = 0.007 µg/L
- Occurrence in both GW and SW systems
- Samples w/ detects = 0.31% (117 of 37517); 0% > 1/2HRL; 0% > HRL
- Systems w/ detects = 1.71% (86 of 5030); 0% > 1/2HRL; 0% > HRL
- Detected Conc: Median = 0.0111 µg/L | 99%ile = 0.147 µg/L | Max = 0.38 µg/L

State Drinking Water Occurrence Data, 1990-2011

No state data identified

State Drinking Water Occurrence Data, 2012-2022

No state data identified

Additional Drinking Water Occurrence (CCRs, CWSS, PDP, NPS, etc.)

Recent CCRs from 25 CWSs that serve >1M (2018-2021)

Summary Information for Phase 3 Contaminants
2-Aminotoluene (CASRN: 95-53-4)

• Detected in 3 of 8 CWSs that reported monitoring

Water Monitoring Data from NAWQA and Other NWIS

No data from NAWQA

NWIS data, non-NAWQA, from Water Quality Portal (1991-2023)

- Samples w/ detects = 0% (0 of 145); 0% >1/2HRL; 0% >HRL
- Sites w/ detects = 0% (0 of 67); 0% >1/2HRL; 0% >HRL
- No FW data

Water Monitoring Data from STORET

STORET data from Water Quality Portal

- MRL unavailable
- Includes monitoring in GW
- Data from 1 state(s)
- No detections in 3 samples from 3 sites

Additional Water Monitoring Studies

No additional studies identified

Biomonitoring Data (CDC's Fourth National Report)

CDC Fourth National Report (2013-2014)

- LOD = 111 pg/mL
- 2013-2014: median = 468 pg/mL | 95%ile = 1,960 pg/mL in 359 urine samples in smokers
- 2013-2014: median = 290 pg/mL | 95%ile = 1,560 pg/mL in 1,794 urine samples in non-smokers
- 2013-2014: median = 485 ng/g | 95%ile = 1,330 ng/g in 359 creatinine corrected urine samples in smokers
- 2013-2014: median = 332 ng/g | 95%ile = 1,240 ng/g in 1,794 creatinine corrected urine samples in non-smokers

Applicable Analytical Methods

- EPA 530

Treatment Technologies

Results of preliminary January 2024 literature search:

• Oaikhena et al. (2023) found custom-fabricated ceramic filters to be effective as point-of-use devices for removing organic pollutants and pathogens from water. The authors consider the ceramic filters an affordable technology that could be used to provide safe drinking water in low-income countries. The filters achieved removal rates of 79.95-92.71% for 2-aminotoluene.

• No other studies were found on treatment of 2-aminotoluene in drinking water. Several studies were found on technologies for removing 2-aminotoluene from industrial water or other aqueous media. Wu et al. (2019) found that micellar enhanced ultrafiltration was effective for removing 2-aminotoluene from aqueous media. Shokri and Mahanpoor (2017) found titanium-dioxide-catalyzed ozonation effective at degrading 2-aminotoluene in petrochemical wastewater. Garcia-Segura et al. (2017) found that electro-assisted photo-Fenton technology was effective at mineralizing recalcitrant and non-biodegradable solutions of 2-aminotoluene or preparing them for biological treatment.

Summary Information for Phase 3 Contaminants
Cylindrospermopsin (CASRN: 143545-90-8)

HRL

0.6 µg/L

Uses / Sources

- A naturally occurring algal toxin
- A tricyclic alkaloid (USEPA, 2015)

Quantified Production (IUR/CDR)

No data on production from the EPA's IUR and CDR programs

Quantified Releases (TRI)

Not included in TRI

Quantified Usage (NCFAP, etc.)

Not applicable

Fate / Transport

- Highly soluble in water (WHO, 2020)
- Less subject to soil/sediment sorption than anatoxin-a (Klitzke et al., 2011)
- Based on laboratory experiments, in the presence of certain algal pigments, photodegradation can be rapid. If these pigments are not present, cylindrospermopsin is relatively stable in sunlight (Chiswell et al., 1999)

Health Effects

- Health assessment selected: EPA OW Health Effects Support Document (2015)
- Critical study: Humpage and Falconer (2002, 2003)
- Critical effect: Increased relative kidney weight in mice
- Oral reference value: RfD of 0.0001 mg/kg/day
- Life stage selected for calculating exposure factor: birth to < 21 years
- HRL: 0.6 µg/L (noncancer)
- Cancer classification: I ("inadequate information to assess carcinogenic potential")

Nationally Representative Drinking Water Occurrence

- UCMR 4 Assessment Monitoring (2018-2020)
- MRL = 0.09 µg/L
 - Occurrence in SW systems (GW systems not included in monitoring)

- Samples w/ detects = 0.04% (13 of 35425); 0.01% > 1/2HRL; 0% > HRL
- Systems w/ detects = 0.34% (12 of 3484); 0.09% > 1/2HRL; 0.03% > HRL
- Detected Conc: Median = 0.175 µg/L | 99%ile = 0.821 µg/L | Max = 0.877 µg/L

State Drinking Water Occurrence Data, 1990-2011

Ohio data from 2010 forward summarized with 2012-2022 data

State Drinking Water Occurrence Data, 2012-2022

- Systems w/ detections, by state
 - IL: 2.22% (1 of 45); 0.00% >1/2HRL; 0.00% >HRL
 - VT: 4.55% (1 of 22); 0.00% >1/2HRL; 0.00% >HRL
- States with no detections
 - OH (61 systems, date range 2010-2022); OR (15 systems)

Additional Drinking Water Occurrence (CCRs, CWSS, PDP, NPS, etc.)

Recent CCRs from 25 CWSs that serve >1M (2018-2021)

- No detections in 4 CWSs that reported monitoring

Water Monitoring Data from NAWQA and Other NWIS**NAWQA**

- MRLs unavailable
- Data only available from Cycle 3
- Cycle 3 monitoring in SW only
- Cycle 3 (2013-2023)
 - Samples w/ detects = 0% (0 of 4); 0% > 1/2HRL; 0% >HRL
 - Sites w/ detects = 0% (0 of 4); 0% > 1/2HRL; 0% >HRL

NWIS data, non-NAWQA, from Water Quality Portal (1991-2023)

- Samples w/ detects = 8.96% (18 of 201); 8.46% >1/2HRL; 5.47% >HRL

Summary Information for Phase 3 Contaminants Cylindrospermopsin (CASRN: 143545-90-8)

- Sites w/ detects = 5.41% (4 of 74); 5.41% >1/2HRL; 4.05% >HRL
- Detected conc: median = 0.895 µg/L | 99%ile = 5.76 µg/L | max = 6.1 µg/L
- No FW data

Water Monitoring Data from STORET

STORET data from Water Quality Portal

- MRL unavailable (min detect = 0.5 µg/L)
- Includes monitoring in GW, SW
- Data from 2 state(s)
- Samples w/ detects = 2% (1 of 50); 2% >1/2 HRL; 0% >HRL
- Sites w/ detects = 4% (1 of 25); 4% >1/2HRL; 0% >HRL
- Detected Conc: Median = 0.5 µg/L | 99%ile = 0.5 µg/L | Max = 0.5 µg/L

Additional Water Monitoring Studies

Cyanotoxins in US Drinking Water (AWWA, 2016)

- DL range = 0.05-5 µg/L
- Detected in 1 of 270 Ohio source water samples; conc. = 0.11 µg/L
- Detected in 0 of 179 Ohio treated drinking water samples

Cyanotoxins in New York and Lower Great Lakes, 2000-2004 (Boyer, 2008)

- Detected in 8 (2%) of 366 NY lake samples, max conc. <0.25 µg/L; RL = 0.01 µg/L
- Detected in none of 40 Lake Erie samples from one research cruise, and in 15% of 13 samples (max conc. 0.18 µg/L) from another; RL not specified

Cyanobacteria in Florida Waters, 1999-2000 (Burns, 2008; Williams et al., 2001)

- All samples collected from Florida waters in 1999 containing significant levels of Cylindrospermopsis raciborskii tested positive for cylindrospermopsin
- Nine finished drinking water samples collected from Florida waters in 2000 had concentrations ranging from 8.07-97.12 µg/L

Cyanotoxins in Oregon (Farrer et al., 2015)

- Maximum in ambient water: >6.0 µg/L (1 observation)
- Cyanotoxins in Large U.S. Rivers, 2017 (Graham et al., 2020)
- MRLs = 0.05 µg/L (Abraxis ELISA - total cylindrospermopsins); 0.1 µg/L (LC/MS/MS - cylindrospermopsin)
- 50 samples were collected from 11 large inland and coastal rivers of the US.
- Genera with cylindrospermopsin-producing strains were present in 48% of samples from 63% of rivers
- Cylindrospermopsins were not detected in any samples

Algal Bloom Disease Outbreaks at Freshwater Lakes, 2009-2010 (Hilborn et al., 2014)

- 11 HAB-associated disease outbreaks in New York, Ohio, and Washington
- Cylindrospermopsin detected in 2 of 5 outbreaks where tested
- Concentration range: 0.3 to 9.0 µg/L

U.S. HABs reporting, 2016-2018 (Roberts et al., 2020)

- Present in 4 (1%) of 421 HABs reported from 18 states

Cyanobacteria and Cyanotoxins in Five Treatment Plants, 2005 (Szlag, 2015)

- MDL = 0.25 µg/L
- Five DWTPs sampled; each in a different US state
- Raw water from one DWTP had detectable concentrations of cylindrospermopsin; single detection = 0.41 µg/L
- Not observed in finished drinking water

Biomonitoring Data (CDC's Fourth National Report)

No data

Applicable Analytical Methods

- EPA 545
- Abraxis 522011
- Beacon 20-0149

Summary Information for Phase 3 Contaminants Cylindrospermopsin (CASRN: 143545-90-8)

Treatment Technologies

Results of preliminary May 2022 literature search:

- Experiments show that chlorine is effective at oxidizing cylindrospermopsin (Senogles et al., 2000; Senogles et al., 2001; Ho et al., 2008; Rodríguez et al., 2007). For example, Senogles et al. (2000) found that a 5.0 mg/L dose of chlorine could degrade over 99% of 80 µg/L extracellular cylindrospermopsin following a contact time of 60 minutes. The effectiveness of chlorine oxidation of cylindrospermopsin is pH dependent (USEPA, 2016; Westrick et al., 2010 as cited in USEPA, 2015).
- Bench-scale experiments show that powder activated carbon (PAC) is effective for removing cylindrospermopsin (Ho et al., 2008; Ho et al., 2011). USEPA (2015) notes that the PAC doses required for cyanotoxin removal are generally in excess of 20 mg/L.
- Experiments indicate that ozonation (Alvarez et al., 2010 as cited in USEPA, 2015; Cheng et al., 2009; Yan et al., 2016) and ozonation with titanium dioxide as a catalyst (Wu et al., 2015) effectively remove cylindrospermopsin.
- Bench-scale tests also indicate that UV irradiation (Senogles et al., 2001) and UV radiation with titanium dioxide as a catalyst (Pinho et al., 2015; El-Sheikh et al., 2017) are effective against cylindrospermopsin.
- Cylindrospermopsin is susceptible to biological degradation. Smith et al. (2008) found that cylindrospermopsin concentrations between 13 to 76 µg/L could be completely degraded by aquatic organisms in 7 to 17 days in drinking water sources. The rate of biodegradation was affected by initial cylindrospermopsin concentration and temperature, among other factors. Repeated exposure to cylindrospermopsin was associated with faster onset of biodegradation. Westrick et al. (2010 as cited in USEPA, 2015) reports seasonal variability in the effectiveness of biological active slow sand filtration, with 95 percent removal of extracellular microcystins and cylindrospermopsin in the summer but less than 65 percent in the autumn.

- Nanofiltration and reverse osmosis can effectively remove cylindrospermopsin, with removal rates of 90-100 percent reported. Results are affected by membrane material, pore size and water quality (USEPA, 2015).
- Note that if intact cyanobacterial cells are ruptured during treatment, the result can be increased cyanotoxin concentrations in the water. Treatment options that are effective for removing intact cyanobacterial cells from intake water include conventional treatment (coagulation, sedimentation, and filtration), flotation (e.g., dissolved air flotation), and membrane filtration (AWWA, 2016).
- An overview of cylindrospermopsin treatment options is provided by Chorus and Welker (2021).

Summary Information for Phase 3 Contaminants
Ethoprop (CASRN: 13194-48-4)

HRL

0.09 µg/L

Uses / Sources

- An organophosphate (organothiophosphate) insecticide/nematocide (NCBI, 2023)
- First registered in U.S. in 1967 (USEPA, 2006)
- Three EPA-registered formulations (≥15% a.i.) are Restricted Use Pesticides (RUP) (USEPA, 2022)

Quantified Production (IUR/CDR)

No data on production from the EPA's IUR and CDR programs

Quantified Releases (TRI)

TRI Releases

- 2004 to surface water: 0 lbs/yr from 0 states
- 2004 total: 77,786 lbs/yr from 4 states
- 2008 to surface water: 0 lbs/yr from 0 states
- 2008 total: 44,597 lbs/yr from 2 states
- 2012 to surface water: 0 lbs/yr from 0 states
- 2012 total: 90 lbs/yr from 1 state
- 2016 to surface water: 0 lbs/yr from 0 states
- 2016 total: 0 lbs/yr from 0 states
- 2020 to surface water: 0 lbs/yr from 0 states
- 2020 total: 10 lbs/yr from 1 state

Quantified Usage (NCFAP, etc.)

Estimated pesticide usage, according to the EPA's 2017 Pesticide Industry Sales and Usage report:

- 2012: <1 million pounds

Estimated pesticide usage, according to the National Center for Food and Agricultural Policy (NCFAP):

- 1992: 1.45 million pounds
- 1997: 1.01 million pounds

Estimated pesticide usage, according to USGS's Estimated Annual Agricultural Pesticide Use portal:

- 1992: 546,000-1,650,000 kg (1.2-3.6 million pounds) in 22-27 states
- 1996: 442,000-716,000 kg (0.98-1.6 million pounds) in 25-41 states

- 2000: 232,000-372,000 kg (0.51-0.82 million pounds) in 25-37 states
- 2004: 205,000-999,000 kg (0.45-2.2 million pounds) in 24-33 states
- 2008: 187,000-420,000 kg (0.41-0.93 million pounds) in 13-24 states
- 2012: 160,000-214,000 kg (0.35-0.47 million pounds) in 21-28 states
- 2016: 108,000-421,000 kg (0.24-0.93 million pounds) in 12-14 states
- 2019: 22,300-22,800 kg (49,000-50,000 pounds) in 3 states

Fate / Transport

- Expected to have high mobility in soil and water, based on physical and chemical properties (NCBI, 2023)
- Not expected to volatilize from dry soil, moist soil or water, based on physical and chemical properties (NCBI, 2023)
- Under aerobic conditions, half-lives of ethoprop in soil, due primarily to biodegradation, in various studies are reported to be 3-4 days, 5-12 days, 3-56 days, 2-12 weeks, 12 days at 20 °C to 89 days at 2 °C, 16 days at 20 °C to 144 days at 2 °C, 73 at 20 °C to 347 days at 6 °C and 10.9-28.8 days. Temperature and the sterile/non-sterile nature of the soils were primary factors in the magnitude of observed half-lives (NCBI, 2023)
- Hydrolysis half-lives of ethoprop in distilled water, river water, brackish water and sea water range from 25-133 days (NCBI, 2023)
- Photolysis half-lives of ethoprop range from 4.7-12.3 days depending on the degree of sunlight (NCBI, 2023)

Health Effects

- Health assessment selected: EPA OPP Human Health Risk Assessment (2015)
- Critical study: Chartier et al. (2005)
- Critical effect: Inhibition of RBC AChE in male rats
- Oral reference value: BMDL10 of 0.000065 mg/kg/day
- Life stage selected for calculating exposure factor: birth to < 1 year
- HRL: 0.09 µg/L (noncancer)

Summary Information for Phase 3 Contaminants Ethoprop (CASRN: 13194-48-4)

- Cancer classification: S (“Suggestive Evidence of Carcinogenic Potential”)

Nationally Representative Drinking Water Occurrence

UCMR 4 Assessment Monitoring (2018-2020)

- MRL = 0.03 µg/L
- All but one detection occurred in SW systems.
- Samples w/ detects = 0.01% (5 of 37276); 0.01% > 1/2HRL; 0% > HRL
- Systems w/ detects = 0.1% (5 of 5028); 0.06% > 1/2HRL; 0.02% > HRL
- Detected Conc: Median = 0.047 µg/L | 99%ile = 0.204 µg/L | Max = 0.21 µg/L

State Drinking Water Occurrence Data, 1990-2011

No state data identified

State Drinking Water Occurrence Data, 2012-2022

- States with no detections
 - VT (1 system)

Additional Drinking Water Occurrence (CCRs, CWSS, PDP, NPS, etc.)

Recent CCRs from 25 CWSs that serve >1M (2018-2021)

- No detections in 5 CWSs that reported monitoring

PDP Finished Water (2001-2013)

- % Samples w/ detects = 0.02% (1 of 4,469); 0% > 1/2HRL; 0% > HRL

• Max detect = 0.027 µg/L

PDP Raw Water (2004-2013)

- No detections in 2,741 samples

National Pesticide Survey (1988-1990)

- MRL = 0.060 µg/L
- Not detected in 566 CWS wells and 783 rural domestic wells

Water Monitoring Data from NAWQA and Other NWIS

NAWQA

- MRLs unavailable (min detect = 0.00042 µg/L)
- Includes monitoring in SW, GW, and finished water

- Higher occurrence (detection percentages and concentrations) in SW than GW

- Finished water data from Cycles 1 and 2 only

- No detections of finished water (65 samples at 54 sites)

- Cycle 1 (1991-2001)

◦ Samples w/ detects = 1.14% (246 of 21626); 0.21% > 1/2HRL; 0.13% >HRL

◦ Sites w/ detects = 1.11% (82 of 7355); 0.22% > 1/2HRL; 0.12% >HRL

◦ Detected conc: median = 0.011 µg/L | 99%ile = 0.755 µg/L | max = 1.95 µg/L

- Cycle 2 (2002-2012)

◦ Samples w/ detects = 0.97% (126 of 13015); 0.29% > 1/2HRL; 0.15% >HRL

◦ Sites w/ detects = 0.4% (13 of 3256); 0.09% > 1/2HRL; 0.09% >HRL

◦ Detected conc: median = 0.023 µg/L | 99%ile = 0.584 µg/L | max = 5.75 µg/L

- Cycle 3 (2013-2023)

◦ Samples w/ detects = 1.79% (287 of 15992); 0.33% > 1/2HRL; 0.18% >HRL

◦ Sites w/ detects = 1.25% (28 of 2245); 0.27% > 1/2HRL; 0.22% >HRL

◦ Detected conc: median = 0.00762 µg/L | 99%ile = 0.539 µg/L | max = 0.861 µg/L

NWIS data, non-NAWQA, from Water Quality Portal (1991-2023)

- Samples w/ detects = 0.5% (168 of 33672); 0.17% >1/2HRL; 0.14% >HRL

• Sites w/ detects = 0.89% (98 of 10958); 0.32% >1/2HRL; 0.29% >HRL

• Detected conc: median = 0.016 µg/L | 99%ile = 2.28 µg/L | max = 7.7 µg/L

- Detected in FW in 1 of 16 samples at 1 of 8 sites; no exceedance of 1/2HRL or HRL

Water Monitoring Data from STORET

STORET data from Water Quality Portal

- MRL unavailable (min detect = 0.021 µg/L)

- Includes monitoring in GW, SW

- Data from 11 state(s)

• Samples w/ detects = 0.25% (3 of 1215); 0.08% >1/2 HRL; 0.08% >HRL

• Sites w/ detects = 0.8% (3 of 373); 0.27% >1/2HRL; 0.27% >HRL

Summary Information for Phase 3 Contaminants Ethoprop (CASRN: 13194-48-4)

- Detected Conc: Median = 0.038 µg/L | 99%ile = 0.375 µg/L | Max = 0.385 µg/L

Additional Water Monitoring Studies

PMP Raw and Finished Water, 1999-2000 (Blomquist et al., 2001)

- MRL = 0.003 µg/L
- Not detected in any water sample (0 of 323 raw water; 0 of 228 finished water)

NAWQA Domestic Well Water Quality, 1991-2004 (DeSimone, 2009)

- Common MRLs and LT-MDLs: 0.002, 0.003 µg/L
- No detections in 2,115 samples from domestic wells in primary aquifers
- No detections in 425 samples from agricultural land use wells

Monitoring of Public and Private Drinking Water Wells and Monitoring Wells in Water-Supply Interval in the Glacial Aquifer System, Northern U.S., 2005-2013 (Erickson et al., 2019)

- Analyzed against "high" benchmark of 1 µg/L and "moderate" benchmark of 0.1 µg/L; RLs not reported

- No detections above high or moderate benchmarks in wells in water-supply interval (1,449 analyses)

NAWQA Pesticides in Streams and Groundwater, 1992-2001 (Gilliom et al., 2007)

- Max LT-MDL = 0.002 µg/L
- GW: Detected in 0.07% of 1,401 agricultural wells (max = 0.009 µg/L), undetected in 2,728 mixed land-use wells, undetected in 854 urban wells, and undetected in 34 undeveloped land-use wells
- SW: Detected in 2.90% of 1,996 samples from 83 agricultural stream sites (max = 0.455 µg/L), 0.62% of 1,381 samples from 65 mixed land-use stream sites (max = 0.052 µg/L), 0.91% of 807 samples from 30 urban stream sites (max = 0.124 µg/L), and 0.7% of 144 samples of 8 undeveloped land-use stream sites (max = 0.019 µg/L)

Groundwater Quality Data from NAWQA, 2017-2019 (Kingsbury et al., 2021)

- Not Detected in 470 samples of groundwater at 464 sites
- Reporting level = 0.0025 µg/L

NAWQA Quality of Public Supply Wells, 1993-2007 (Toccalino et al., 2010)

- RL = 0.002-0.006 µg/L
- Samples w/ detections = 0.2% (1 of 647)
- Detected conc: 0.0056 µg/L

NAWQA Carbonate Aquifer Study, 1993-2005 (Lindsey et al., 2009)

- Multiple detection and reporting levels
- Samples w/ detections = 0% (0 of 992)

Biomonitoring Data (CDC's Fourth National Report)

No data

Applicable Analytical Methods

- EPA 507
- EPA 525.2
- EPA 525.3

Treatment Technologies

Results of preliminary December 2023 literature search:

- Nassar et al. (2023) investigated the effectiveness of hydrochar-loaded iron nanoparticles (HC-FeNPs) in removing ethoprop and other organophosphorus insecticides from aqueous solutions in batch experiments. The adsorption technology was found to be effective. "Almost all" ethoprop was successfully removed from environmental water samples spiked with initial concentrations of 0.5 and 1 mg/L. The removal efficiency slightly declined after treatment of samples spiked with an initial concentration of 1.5 mg/L. In a direct comparison, granular activated carbon removed <78% of ethoprop, while the prepared hydrochar removed >90%.
- Fenoll et al. (2012) studied heterogeneous photocatalysis of ethoprop and other pesticides in aqueous suspensions with a variety of semiconductor materials, such as zinc oxide

Summary Information for Phase 3 Contaminants
Ethoprop (CASRN: 13194-48-4)

(ZnO), titanium dioxide (TiO₂), tungsten (VI) oxide (WO₃), tin (IV) oxide (SnO₂), and zinc sulphide (ZnS). The experiments were carried out at pilot plant scale using compound parabolic collectors under natural sunlight. The study showed that ZnO and TiO₂ strongly enhanced photodegradation. With ZnO, it took 118.7 minutes to achieve a 90% reduction in ethoprop concentration. With TiO₂, it took 354.7 minutes.

- Abdeen & Mohammad (2014) studied the elimination of ethoprop from aqueous solutions using chitosan, a natural biosorbent. Ethoprop removals of 85.693% to 89.234% were observed at the bench scale, using chitosan doses of 0.02 to 0.1 g/100ml.

Summary Information for Phase 3 Contaminants Microcystins (no CASRN)

HRL

0.3 µg/L

Uses / Sources

- Naturally occurring algal toxins
- Monocyclic heptapeptides (USEPA, 2015)

Quantified Production (IUR/CDR)

No data on production from the EPA's IUR and CDR programs

Quantified Releases (TRI)

Not included in TRI

Quantified Usage (NCFAP, etc.)

Not applicable

Fate / Transport

- Readily soluble in water (Rivasseau et al., 1998)
- Sorption of sediment/particulate matter is low at pH values of 6-9 (de Maagd et al., 1999)
- Resistant to hydrolysis at neutral pH (USEPA, 2015)
- Photolysis occurs slowly in full sunlight (USEPA, 2015)
- Naturally occurring aquatic bacteria can metabolize/degrade microcystins (USEPA, 2015)

Health Effects

- Health assessment selected: EPA OW Health Effects Support Document (2015)
- Critical study: Heinze (1999)
- Critical effect: Hepatotoxicity in rats
- Oral reference value: Reference dose of 0.00005 mg/kg/day
- Life stage selected for calculating exposure factor: 21 years and older
- HRL: 0.3 µg/L (noncancer)
- Cancer classification: I ("inadequate information to assess carcinogenic potential")

Nationally Representative Drinking Water Occurrence

UCMR 4 Assessment Monitoring (2018-2020)

- MRL = 0.3 µg/L

- Occurrence in SW systems (GW systems not included in monitoring)
- Samples w/ detects = 0.02% (8 of 35000); 0.02% > 1/2HRL; 0.02% > HRL
- Systems w/ detects = 0.2% (7 of 3485); 0.2% > 1/2HRL; 0.2% > HRL
- Detected Conc: Median = 0.367 µg/L | 99%ile = 0.815 µg/L | Max = 0.83 µg/L

State Drinking Water Occurrence Data, 1990-2011

Ohio data from 2010 forward summarized with 2012-2022 data

State Drinking Water Occurrence Data, 2012-2022

- Systems w/ detections, by state
 - IL: 55.56% (25 of 45); 55.56% >1/2HRL; 37.78% >HRL
 - OH: 7.58% (10 of 132, date range 2010-2022); 7.58% >1/2HRL; 7.58% >HRL
 - OR: 6.67% (1 of 15); 6.67% >1/2HRL; 6.67% >HRL
- States with no detections
 - VT (22 systems)

Additional Drinking Water Occurrence (CCRs, CWSS, PDP, NPS, etc.)

Recent CCRs from 25 CWSs that serve >1M (2018-2021)

- No detections in 5 CWSs that reported monitoring

Water Monitoring Data from NAWQA and Other NWIS**NAWQA**

- MRLs unavailable (min detect = 0.1 µg/L)
- Data only available from Cycle 2 and Cycle 3
- Cycle 2 monitoring in GW only; Cycle 3 monitoring in SW only
- Cycle 2 (2002-2012)
 - Samples w/ detects = 0% (0 of 1); 0% > 1/2HRL; 0% >HRL
 - Sites w/ detects = 0% (0 of 1); 0% > 1/2HRL; 0% >HRL
- Cycle 3 (2013-2023)

Summary Information for Phase 3 Contaminants Microcystins (no CASRN)

- o Samples w/ detects = 8.7% (2 of 23);
0% > 1/2HRL; 0% >HRL
- o Sites w/ detects = 20% (1 of 5);
0% > 1/2HRL; 0% >HRL
- o Detected conc: median = 0.1 µg/L |
99%ile = 0.1 µg/L | max = 0.1 µg/L

NWIS data, non-NAWQA, from Water Quality Portal (1991-2023)

- Samples w/ detects = 19.98% (211 of 1056);
12.88% >1/2HRL; 9.47% >HRL
- Sites w/ detects = 35.91% (65 of 181);
23.2% >1/2HRL; 13.81% >HRL
- Detected conc: median = 0.3 µg/L |
99%ile = 79.7 µg/L | max = 110 µg/L
- No FW data

Water Monitoring Data from STORET

STORET data from Water Quality Portal

- MRL unavailable (min detect = 0.01252 µg/L)
- Includes monitoring in GW, SW
- Data from 48 state(s)
- Samples w/ detects = 91.44% (7319 of 8004);
67.22% >1/2 HRL; 47.18% >HRL
- Sites w/ detects = 92.49% (1331 of 1439);
50.31% >1/2HRL; 35.72% >HRL
- Detected Conc: Median = 0.33 µg/L |
99%ile = 66.6 µg/L | Max = 80000 µg/L

Additional Water Monitoring Studies

Cyanotoxins in US Drinking Water (AWWA, 2016)

- DL range = 0.01-0.6 µg/L
- Detected in 1,877 of 4,162 Ohio source water samples; mean = 25 µg/L; max = 20,000 µg/L
- Detected in 32 of 2,243 Ohio treated drinking water samples; mean = 1.33 µg/L; max = 11 µg/L

Cyanotoxins in New York and Lower Great Lakes, 2000-2004 (Boyer, 2008)

- Detected in 1,223 (53%) of 2,286 NY lake samples, max conc. <0.25 µg/L; RL = 0.01 µg/L
- Detected in 7-85% of Lake Erie samples from six research cruises (N ranging from 13 to 119), max conc. 21 µg/L; RL not specified

Cyanobacteria in Florida Waters, 1999-2000 (Burns, 2008; Williams et al., 2001)

- All 87 samples collected from Florida waters in 1999 that were tested for microcystins had microcystins present
- Of the samples collected from Florida waters in 2000, microcystins were detected in pre- and post-treated drinking water; max conc. = 12.5 µg/L

Microcystins in Raw and Finished Drinking Water, 1996-1998 (Carmichael, 2000)

- Found in 539 (80%) of 677 samples from 24 utilities (combined source and finished water)
- Found above 1 µg/L in 29 (4.3%) of the 677 samples, including 2 finished water samples

Cyanotoxins in Oregon (Farrer et al., 2015)

- Maximum in ambient water: >10.0 µg/L (14 observations)

Cyanotoxins in Large U.S. Rivers, 2017 (Graham et al., 2020)

- MRLs = 0.1 µg/L (Abraxis ELISA - total microcystins); 0.08-0.3 µg/L (LC/MS/MS - individual microcystin congeners)
- 50 samples were collected from 11 large inland and coastal rivers of the US.
- Genera with microcystin-producing strains present in 91% of rivers and in >70% of samples
- Microcystins were present in 3 samples (6%) from 2 rivers (18%)
- Microcystin concentrations ranged from 0.18 to 0.38 µg/L

Microcystins in 33 U.S. Water Supplies, 2003 (Haddix et al., 2007)

- DLs = 0.15 µg/L (m-LR); 0.24 µg/L (m-LA); 0.27 µg/L (m-RR); 0.44 µg/L (m-YR)
- Microcystins detected in 87% of 206 raw/source water samples (mean = 0.307 µg/L, max = 5.646 µg/L)
- Microcystins detected in 30% of 77 effluent/finished water samples (mean = 0.036 µg/L; max = 0.360 µg/L)

Algal Bloom Disease Outbreaks at Freshwater Lakes, 2009-2010 (Hilborn et al., 2014)

Summary Information for Phase 3 Contaminants Microcystins (no CASRN)

- 11 HAB-associated disease outbreaks in New York, Ohio, and Washington
- Microcystins detected in 8 of 8 outbreaks where tested
- Wide concentration range: 0.2 to >2,000 µg/L

Cyanotoxins in the Pacific Northwest (Jacoby and Kann, 2007)

- Lit review of sampling data from 63 lakes, reservoirs and rivers of the U.S. pacific northwest; RLs not reported
- Microcystins were the most commonly detected cyanotoxin, found at concentrations from < 1 µg/L to 30 mg/L

Microcystins in Source and Finished Water in Wisconsin, 1998-1999 (Karner et al., 2001)

- DL = 0.002 µg/L (total microcystins)
- 578 raw and finished water samples collected from five DWTPs in 1998: weekly average conc. in raw water ranged from 0.585 to 1.216 µg/L (max conc. = 6.1 µg/L); weekly average conc. in finished water at the five plants ranged from 0.0028 to 0.0054 µg/L (max conc. = 0.017 µg/L)
- 448 raw and finished water samples collected from three DWTPs in 1999: raw water concentrations ranged from 0.123 to 0.993 µg/L; finished water concentrations ranged from ND to 0.022 µg/L

Microcystin-LR in the Lake Ontario ecosystem, 2003-2006 (Makarewicz et al., 2009)

- DL = 0.003 µg/L
- Microcystin-LR detected in 91.6% of 581 samples from coastal Lake Ontario; detected in 100% of 98 samples from inland lakes in watershed
- In 66 offshore/nearshore samples, mean = 0.006 µg/L; max = 0.070 µg/L
- In 190 bay/harbor samples, mean = 0.084 µg/L; max = 7.034 µg/L
- In 213 shoreside samples, mean = 0.052 µg/L; max = 2.545 µg/L
- In 96 river/creek samples, mean = 0.020 µg/L; max = 0.435 µg/L
- In 98 inland lake samples, mean = 1.136 µg/L; max = 20.394 µg/L

Cyanobacterial Toxins in Lake Erie (Miller et al., 2017)

- RLs not reported
- Surface water on Lake Erie, 2010-2015: Microcystins detected at 16 of 25 sampling locations (N ranging from 1 to 52). Overall mean = 126.9 µg/L, max = 3144 µg/L. With two outliers removed, the mean would be 1.81 µg/L.
- Drinking water intakes in Lake Erie: Microcystins detected at 18 of 21 intakes (N ranging from 1 to 1,377). Overall mean = 1.04 µg/L, max = 340 µg/L.
- Finished drinking water in Ohio: Nine drinking water treatment plants (DWTPs) had detectable levels of microcystins. Among the six that draw from Lake Erie, max values ranged from 0.23 to 3.56 µg/L. Overall, max = 11 µg/L.

U.S. HABs reporting, 2016-2018 (Roberts et al., 2020)

- Present in 291 (94%) of 421 HABs reported from 18 states
- Present in 33 of the 35 HABs where multiple cyanotoxins were found

Drinking Water Monitoring Following HABs in Clear Lake, California, 2021 (Solomon et al., 2022)

- 17 PWSs with lake water intakes: no finished water occurrence above 0.3 µg/L
- 15 homes with private wells within 50 feet of the lake (GW): no detections in tap water
- 31 homes with lake water intakes (SW): detections in 22; occurrence ≥0.3 µg/L in 18; max conc. = 3.9 µg/L

Cyanobacteria and Cyanotoxins in Five Treatment Plants, 2005 (Szlaga, 2015)

- MDL = 0.25 µg/L (for each congener)
- Five DWTPs sampled; each in a different US state
- Raw water from four DWTPs had detectable concentrations of microcystins; frequently observed at 0.05-0.25 µg/L
- Not observed in finished drinking water

Summary Information for Phase 3 Contaminants Microcystins (no CASRN)

Microcystin Surveillance Study of Iowa's Public Water Supply Systems, 2016-2017 (Trautman, 2018)

- DL = 0.3 µg/L
- Studied 28 treatment plants at 26 systems (22 SW and 6 GWUDI)
- raw water: 15 of 26 systems, all SW, had detections (max conc. >5 µg/L)
- finished water: no detections

2007, 2012, and 2017 National Lakes Assessment

2007 NLA (USEPA 2009)

- Detected in 30.6% of natural lakes (8,955 out of 29,308 lakes)
- Detected in 29.5% of man-made lakes (5,975 out of 20,238 lakes)
- Regional detection rates varied from 5% (Western Mountains) to 75% (Northern Plains)
- Found at "levels of concern" in 1% of the nation's lakes

2012 NLA (USEPA 2016)

- Detected in 39% of lakes
- <1% of lakes are in the "most disturbed" or "moderately disturbed" condition

2017 NLA (USEPA 2022)

- Detected in 21% of lakes (MDL = 0.1 µg/L)
- Regional detection rates varied from 2% (Northern Appalachians) to 58% (Northern Plains)
- The EPA's recreational criterion exceeded in 2% of lakes (4,400 lakes)

Cyanobacteria in Kabetogama Lake, 2008-09 (USGS, 2012)

- Detected in 11 (78%) of 14 algal bloom samples
- Exceeded WHO benchmark of 1 µg/L in 7 (50%) of the samples
- Exceeded 20 µg/L in 2 samples

Cyanobacteria and Cyanotoxins in Lakes and Drinking Water (Weirich, 2017)

- Collected water samples from 39 lakes across North America, South America, Europe, and Africa
- 2 to 68 samples were taken from each lake

- Microcystin-LR and microcystin-RR were the most frequently detected microcystins, found in 19.8 percent and 12.1 percent of samples, respectively

Biomonitoring Data (CDC's Fourth National Report)

No data

Applicable Analytical Methods

- EPA 544
- EPA 546
- OH EPA 701.0 and 701.0-A, version 2.4
- Abraxis 520011
- Abraxis 520011SAES
- Abraxis 520012
- Abraxis 520016/520017
- Abraxis 522015
- Beacon 20-0068
- Beacon 20-0098

Treatment Technologies

Results of preliminary May 2022 literature search:

- Adsorption by GAC and PAC has been shown to be effective at removing microcystins (AWWA, 2016; USEPA, 2016). Newcombe and Nicholson (2004) report that some microcystin congeners may be more readily removed than others. Wood-based activated carbon media may be most effective at removing microcystins (USEPA, 2015; Walker, 2015 as cited in USEPA, 2016). USEPA (2015) notes that the PAC doses required for cyanotoxin removal are generally in excess of 20 mg/L. Alvarez et al. (2010 as cited in USEPA, 2015) reports that removal of microcystin-LR by GAC may require an empty bed contact time of at least 10 minutes.
- Conventional treatment with post-filtration GAC has been shown effective at reducing microcystin concentrations (Bogialli et al., 2013). High total organic carbon (TOC) levels (25-30 mg/L) in the raw water may compromise microcystin removal in full-scale treatment (Lambert et al., 1996).
- Chlorine and ozone have both been shown to be effective oxidants for the destruction of microcystins. The efficiency of chlorination and

Summary Information for Phase 3 Contaminants Microcystins (no CASRN)

ozonation is dependent on the chemical characteristics of the water, including pH and dissolved organic carbon (DOC) (Chorus and Welker, 2021; Rositano et al., 2001). For microcystin-LR, the desirable pH range for the most efficient oxidation with free chlorine is between 6 and 8 (USEPA, 2016). Ho et al. (2006) find chlorination contact times to be dependent on dosage, microcystin variant, pH, and presence of natural organic material (NOM). Alvarez et al. (2010 as cited in USEPA, 2015) found that ozone is effective at doses of 0.5 – 1.1 mg/L under most water quality conditions and contact times.

- Potassium permanganate can effectively destroy microcystins, independent of pH (USEPA, 2016). Several studies report that doses of 1-2 mg/L can be effective for microcystins (Walker, 2015 as cited in USEPA, 2016; Chorus and Welker, 2021; Rodríguez et al., 2007).

- Biological degradation is an effective method for removing and inactivating microcystins (Chorus and Welker, 2021). Ho et al. (2012 as cited in USEPA, 2016) notes that efficiency of biological degradation is dependent on water temperature, the abundance of specific bacteria capable of degrading the cyanotoxins present, the concentration of the target cyanotoxins, and the presence of organic matter and metals in the source water. Full-scale testing of slow sand filtration yielded extracellular microcystin elimination rates of up to >95 percent, corresponding to a half-life of approximately 1 hour; elimination was slower at lower temperatures (Grützmacher et al., 2002).

Westrick et al. (2010 as cited in USEPA, 2015) reports seasonal variability in the effectiveness of biological active slow sand filtration, with 95 percent removal of extracellular microcystins and cylindrospermopsin in the summer but less than 65 percent in the autumn. Newcombe et al., (2003) reports effective biodegradation of microcystin-LR and microcystin-LA (100% after nine days in a batch bioreactor) by microorganisms removed from a GAC pilot filter sample. The efficacy of conventional GAC

filters may be enhanced by biodegradation after an initial lag period (Wang et al. 2007).

- Nanofiltration and reverse osmosis can effectively remove microcystins, with removal rates of 82-100 percent reported (Westrick et al., 2010 as cited in USEPA, 2015). Results are affected by membrane material, pore size and water quality (USEPA, 2015).
- Note that if intact cyanobacterial cells are ruptured during treatment, the result can be increased cyanotoxin concentrations in the water. Treatment options that are effective for removing intact cyanobacterial cells from intake water include conventional treatment (coagulation, sedimentation, and filtration), flotation (e.g., dissolved air flotation), and membrane filtration (AWWA, 2016).

Summary Information for Phase 3 Contaminants

Molybdenum (CASRN: 7439-98-7)

HRL

100 µg/L

Uses / Sources

- A naturally occurring element
- Commonly used in alloys with cast iron, steel, and superalloys (USGS, 2021)
- Molybdenum compounds are also commonly used in catalysts, lubricants, and pigments (USGS, 2021)

Quantified Production (IUR/CDR)

Annual reported production (i.e., manufacturing and importation) from the EPA's IUR and CDR programs, in pounds:

- 2005: 1B and greater
- 2011: >8,478,869
- 2012: 10M - <50M
- 2013: 10M - <50M
- 2014: 10M - <50M
- 2015: 10M - <50M
- 2016: 1M - <10M
- 2017: 10M - <50M
- 2018: 10M - <50M
- 2019: 10M - <50M

EPA's CDR program reports production of over 70 additional manganese-containing compounds. Those with multiple years of production in ranges higher than 10 million pounds include:

- Ammonium molybdenum oxide ((NH₄)₂Mo₂O₇) [27546-07-2]
- Molybdenum oxide (MoO₃) [1313-27-5]
- Molybdenum sulfide (MoS₂) [1317-33-5]

Quantified Releases (TRI)

TRI Releases

- 2004 to surface water: 36,162 lbs/yr from 17 states
- 2004 total: 1,837,916 lbs/yr from 35 states
- 2008 to surface water: 45,848 lbs/yr from 17 states
- 2008 total: 1,709,743 lbs/yr from 30 states
- 2012 to surface water: 39,548 lbs/yr from 18 states
- 2012 total: 1,338,701 lbs/yr from 30 states
- 2016 to surface water: 37,956 lbs/yr from 14 states

- 2016 total: 1,914,770 lbs/yr from 30 states
- 2020 to surface water: 28,439 lbs/yr from 16 states
- 2020 total: 2,302,772 lbs/yr from 33 states

This is for molybdenum trioxide, the only molybdenum compound with information available

Quantified Usage (NCFAP, etc.)

No data available

Fate / Transport

- At pH >6.5, molybdenum may exist solely as molybdate (MoO₄²⁻) in water, although under low REDOX conditions, molybdate can be reduced to MoS₂ (ATSDR, 2020)
- Molybdenum is generally more mobile in water under alkaline conditions; adsorptive processes become more important as pH decreases (ATSDR, 2020)
- As an element, non-radioactive forms are considered to be persistent in the environment

Health Effects

- Health assessment selected: ATSDR Toxicological Profile (2020)
- Critical study: Murray et al. (2014)
- Critical effect: Renal proximal tubule hyperplasia in female rats
- Oral reference value: Intermediate-duration minimal risk level of 0.06 mg/kg/day
- Life stage selected for calculating exposure factor: birth to < 21 years
- HRL: 100 µg/L (noncancer)
- Cancer classification: none

Nationally Representative Drinking Water Occurrence

UCMR 3 Assessment Monitoring (2013-2015)

- MRL = 1 µg/L
- Occurrence in both GW and SW systems
- Samples w/ detects = 40.29% (25377 of 62986); 0.16% > 1/2HRL; 0.04% > HRL
- Systems w/ detects = 51.73% (2546 of 4922); 0.59% > 1/2HRL; 0.14% > HRL
- Detected Conc: Median = 2.4 µg/L | 99%ile = 29 µg/L | Max = 196 µg/L

Summary Information for Phase 3 Contaminants Molybdenum (CASRN: 7439-98-7)

NIRS (1984-1986)

- MRL = 6 µg/L
- One sample per system, GW only
- Systems w/ detects = 7.79% (77 of 989); 0.40% > 1/2HRL; 0.10% >HRL
- Detected Conc: Median = 10 µg/L | 99%ile = 106 µg/L | Max = 180.7 µg/L

- o WI: 60.00% (3 of 5); 20.00% > 1/2HRL; 20.00% >HRL
- o WV: 12.50% (2 of 16); 0.00% > 1/2HRL; 0.00% >HRL
- States with no detections
 - o MD (1 system)

State Drinking Water Occurrence Data, 1990-2011

- Systems w/ detections, by state
 - o AK: 20.00% (1 of 5); 0.00% > 1/2HRL; 0.00% >HRL
 - o CA: 65.70% (136 of 207); 3.38% > 1/2HRL; 0.00% >HRL
 - o IL: 25.84% (316 of 1,223); 2.13% > 1/2HRL; 0.49% >HRL
 - o MT: 28.57% (2 of 7); 0.00% > 1/2HRL; 0.00% >HRL
 - o NM: 100.00% (1 of 1); 0.00% > 1/2HRL; 0.00% >HRL
 - o NV: 71.43% (15 of 21); 0.00% > 1/2HRL; 0.00% >HRL
 - o OH: 51.85% (14 of 27); 7.41% > 1/2HRL; 0.00% >HRL
 - o WI: 33.33% (1 of 3); 0.00% > 1/2HRL; 0.00% >HRL
 - o WV: 6.25% (1 of 16); 0.00% > 1/2HRL; 0.00% >HRL
- States with no detections
 - o DE (2 systems)

State Drinking Water Occurrence Data, 2012-2022

- Systems w/ detections, by state
 - o CA: 68.53% (98 of 143); 3.50% > 1/2HRL; 1.40% >HRL
 - o IA: 66.67% (2 of 3); 0.00% > 1/2HRL; 0.00% >HRL
 - o ID: 100.00% (1 of 1); 100.00% > 1/2HRL; 100.00% >HRL
 - o IL: 5.15% (30 of 583); 0.34% > 1/2HRL; 0.00% >HRL
 - o NV: 50.00% (9 of 18); 0.00% > 1/2HRL; 0.00% >HRL
 - o OH: 20.00% (1 of 5); 0.00% > 1/2HRL; 0.00% >HRL

Additional Drinking Water Occurrence (CCRs, CWSS, PDP, NPS, etc.)

Recent CCRs from 25 CWSs that serve >1M (2018-2021)

- Detected in 4 of 7 CWSs that reported monitoring

2006 Community Water System Survey (CWSS), findings from systems serving >500K

- Data from 2 systems
- Detected in 2 of 2 finished water samples; 90%ile detect = 31.000 µg/L

Water Monitoring Data from NAWQA and Other NWIS

NAWQA

- MRLs unavailable (min detect = 0.01 µg/L)
- Includes monitoring in SW, GW, and finished water
- Higher occurrence (detection percentages and concentrations) in GW than SW
- Finished water data from Cycle 2 only
- Detected in 2 of 2 finished water samples, max conc. 0.687 µg/L
- Cycle 1 (1991-2001)
 - o Samples w/ detects = 48.53% (3403 of 7012); 0.53% > 1/2HRL; 0.14% >HRL
 - o Sites w/ detects = 54.5% (1937 of 3554); 0.96% > 1/2HRL; 0.28% >HRL
 - o Detected conc: median = 2.67 µg/L | 99%ile = 51 µg/L | max = 4730 µg/L
- Cycle 2 (2002-2012)
 - o Samples w/ detects = 82.68% (4339 of 5248); 0.38% > 1/2HRL; 0.15% >HRL
 - o Sites w/ detects = 83.61% (2648 of 3167); 0.47% > 1/2HRL; 0.16% >HRL
 - o Detected conc: median = 1.14 µg/L | 99%ile = 31 µg/L | max = 208 µg/L
- Cycle 3 (2013-2023)

Summary Information for Phase 3 Contaminants Molybdenum (CASRN: 7439-98-7)

- o Samples w/ detects = 83.75% (2835 of 3385); 0.27% > 1/2HRL; 0.12% >HRL
- o Sites w/ detects = 84.19% (2641 of 3137); 0.29% > 1/2HRL; 0.13% >HRL
- o Detected conc: median = 0.839 µg/L | 99%ile = 29 µg/L | max = 226 µg/L

NWIS data, non-NAWQA, from Water Quality Portal (1991-2023)

- Samples w/ detects = 61.07% (51874 of 84943); 0.94% >1/2HRL; 0.48% >HRL
- Sites w/ detects = 71.3% (15728 of 22058); 2.2% >1/2HRL; 1.12% >HRL
- Detected conc: median = 1.64 µg/L | 99%ile = 80 µg/L | max = 42000 µg/L
- Detected in FW in 38 of 47 samples at 28 of 29 sites; 1 sample exceeded 1/2 HRL, 0 samples exceeded HRL

Water Monitoring Data from STORET

STORET data from Water Quality Portal

- MRL unavailable (min detect = 0.00053 µg/L)
- Includes monitoring in GW, SW
- Data from 33 state(s)
- Samples w/ detects = 52.11% (9208 of 17671); 5.31% >1/2 HRL; 5.13% >HRL
- Sites w/ detects = 34.41% (1107 of 3217); 2.61% >1/2HRL; 2.33% >HRL
- Detected Conc: Median = 5.54 µg/L | 99%ile = 25000 µg/L | Max = 50000 µg/L

Additional Water Monitoring Studies

NAWQA Trace Elements in Groundwater, 1992-2003 (Ayotte et al., 2011)

- RL = 1 µg/L
- Samples w/ detections = 57.6% of 3,063 samples, max conc. = 4,700 µg/L

NAWQA Domestic Well Water Quality, 1991-2004 (DeSimone, 2009)

- Range of common MRLs and LT-MDLs: 0.03-1 µg/L
- Samples w/ detections from domestic wells in primary aquifers = 921 of 1,572; 90%ile = 6.00 µg/L
- Samples w/ detections from agricultural land use wells = 49 of 78; 90%ile = 3.00 µg/L

Monitoring of Public and Private Drinking Water Wells and Monitoring Wells in Water-Supply Interval in the Glacial Aquifer System, Northern U.S., 2005-2013 (Erickson et al., 2019)

- Analyzed against "high" benchmark of 40 µg/L and "moderate" benchmark of 20 µg/L; RLs not reported

- High benchmark exceeded in 0.7% (area weighted) and 1.5% (population weighted) of 2,262 analyses from wells in water-supply interval
- Concentrations between moderate and high benchmarks found in 2.9% (area weighted) and 4.2% (population weighted) of 2,262 analyses from wells in water-supply interval

NAWQA Glacial Aquifer Study of Northern U.S., 1991-2003 (Groschen et al., 2009)

- Multiple detection and reporting Levels
- Samples w/ detections = 71.8% (608 of 847), max conc. = 304 µg/L

Groundwater Quality Data from NAWQA, 2017-2019 (Kingsbury et al., 2021)

- Detected in 841 (80.7%) of 1,042 samples of groundwater
- Detected at 791 (80.9%) of 978 sites
- Conc (µg/L): Min = 0.05 | Median = 0.724 | 99%ile = 21.1 | Max = 92.6
- Reporting level = 0.05 µg/L

NAWQA Quality of Public Supply Wells, 1993-2007 (Toccalino et al., 2010)

- RL = 0.06-1 µg/L
- Samples w/ detections = 77.2% (485 of 628)
- Detected conc: median = 2 µg/L | 99%ile = 30.3 µg/L | max = 89 µg/L

Biomonitoring Data (CDC's Fourth National Report)

CDC Fourth National Report (1999-2018)

- LOD from 1999-2018 ranged from 0.8 to 1.5 µg/L in urine
- 1999-2000: median = 50.7 µg/L | 95%ile = 180 µg/L in 2257 urine samples
- 2001-2002: median = 52.4 µg/L | 95%ile = 165 µg/L in 2690 urine samples

Summary Information for Phase 3 Contaminants Molybdenum (CASRN: 7439-98-7)

- 2003-2004: median = 44.5 µg/L | 95%ile = 138 µg/L in 2558 urine samples
- 2005-2006: median = 51.0 µg/L | 95%ile = 158 µg/L in 2576 urine samples
- 2007-2008: median = 49.7 µg/L | 95%ile = 163 µg/L in 2627 urine samples
- 2009-2010: median = 45.2 µg/L | 95%ile = 160 µg/L in 2848 urine samples
- 2011-2012: median = 40.0 µg/L | 95%ile = 146 µg/L in 2504 urine samples
- 2013-2014: median = 36.0 µg/L | 95%ile = 139 µg/L in 2664 urine samples
- 2015-2016: median = 38.6 µg/L | 95%ile = 137 µg/L in 3060 urine samples
- 2017-2018: median = 37.9 µg/L | 95%ile = 140 µg/L in 2808 urine samples
- 1999-2000: median = 41.6 µg/g | 95%ile = 144 µg/g in 2257 creatinine corrected urine samples
- 2001-2002: median = 42.2 µg/g | 95%ile = 130 µg/g in 2689 creatinine corrected urine samples
- 2003-2004: median = 39.2 µg/g | 95%ile = 120 µg/g in 2558 creatinine corrected urine samples
- 2005-2006: median = 43.9 µg/g | 95%ile = 132 µg/g in 2576 creatinine corrected urine samples
- 2007-2008: median = 46.3 µg/g | 95%ile = 137 µg/g in 2627 creatinine corrected urine samples
- 2009-2010: median = 44.4 µg/g | 95%ile = 143 µg/g in 2848 creatinine corrected urine samples
- 2011-2012: median = 41.0 µg/g | 95%ile = 130 µg/g in 2502 creatinine corrected urine samples
- 2013-2014: median = 39.4 µg/g | 95%ile = 117 µg/g in 2663 creatinine corrected urine samples
- 2015-2016: median = 40.0 µg/g | 95%ile = 123 µg/g in 3057 creatinine corrected urine samples
- 2017-2018: median = 38.5 µg/g | 95%ile = 122 µg/g in 2806 creatinine corrected urine samples

Applicable Analytical Methods

- EPA 200.7
- EPA 200.8
- SM 3111 D
- SM 3111 E
- SM 3113 B
- SM 3120 B (total)
- SM 3125 B

Treatment Technologies

Results of preliminary January 2024 literature search:

- Chen et al. (2020) evaluated simultaneous removal of arsenic and several co-contaminants, including molybdenum, from groundwater high in nitrate using full-scale ion exchange at a community water system in Idaho. The ion exchange system, using a strong base anionic resin, successfully reduced molybdenum concentrations to <0.1 µg/L in all but a few samples at the baseline regeneration setpoint of 422 bed volumes, indicating that molybdenum was highly preferred by this resin. At 714 bed volumes, molybdenum was still preferentially removed by the resin, with initial concentrations of 12.2 µg/L reduced to 0.7 µg/L.
- Zhang et al. (2015) conducted bench-scale jar testing of coagulation-filtration for removal of molybdenum (as Mo(VI)) from lab-prepared water. The coagulants tested were ferric chloride and ferric sulfate. Ferric sulfate performed better than ferric chloride under acidic conditions (pH of 4-5), and about as well at higher pH values. Optimum removal efficiency by ferric sulfate, 94%, was achieved at pH of 5. The presence of calcium reduced Mo(VI) removal across all pH ranges. The mechanisms of interference by natural organic matter (represented in the study by dosed humic acids) were also investigated.
- In China, Zhu et al. (2020) conducted experiments on the application of nanoscale zero-valent iron, supported by activated carbon, to raw water from a reservoir in Songxian County, Henan Province, that was contaminated with molybdenum from upstream mining operations. At a pH of 8.1, the predominant form of molybdenum in the raw water was Mo(VI). In bench-scale experiments of a fixed-bed column system containing nanoscale zero-valent iron and activated carbon, 74% of the original Mo(VI) was removed within the first 14 hours of operation. The raw water concentration of Mo(VI) was 1,603 µg/L, with a target effluent concentration of 70 µg/L (based on WHO provisional guidelines). The breakthrough empty-bed volumes were between 800 and 1,110

Summary Information for Phase 3 Contaminants
Molybdenum (CASRN: 7439-98-7)

and the empty-bed contact time was between 3
and 6 minutes.

Summary Information for Phase 3 Contaminants
Permethrin (CASRN: 52645-53-1)

HRL

3000 µg/L

Uses / Sources

- A pyrethroid insecticide (USEPA, 2011)
- First registered in U.S. in 1979 (USEPA, 2011)
- 22 EPA-registered formulations ($\geq 0.5\%$ a.i.) are Restricted Use Pesticides (RUP) (USEPA, 2022)

Quantified Production (IUR/CDR)

No data on production from the EPA's IUR and CDR programs

Quantified Releases (TRI)

TRI Releases

- 2004 to surface water: 0 lbs/yr from 0 states
- 2004 total: 17,888 lbs/yr from 7 states
- 2008 to surface water: 0 lbs/yr from 0 states
- 2008 total: 4,842 lbs/yr from 4 states
- 2012 to surface water: 0 lbs/yr from 0 states
- 2012 total: 5,552 lbs/yr from 4 states
- 2016 to surface water: 0 lbs/yr from 0 states
- 2016 total: 20,108 lbs/yr from 4 states
- 2020 to surface water: 0 lbs/yr from 0 states
- 2020 total: 11,428 lbs/yr from 7 states

Quantified Usage (NCFAP, etc.)

Estimated pesticide usage, according to the EPA's 2017 Pesticide Industry Sales and Usage report: (for "permethrin and other pyrethroids")

- 2009: 2-4 million pounds
- 2012: 1-3 million pounds

Estimated pesticide usage, according to the National Center for Food and Agricultural Policy (NCFAP):

- 1992: 1.07 million pounds
- 1997: 1.07 million pounds

Estimated pesticide usage, according to USGS's Estimated Annual Agricultural Pesticide Use portal:

- 1992: 310,000-532,000 kg (0.68-1.1 million pounds) in 48 states
- 1996: 398,000-588,000 kg (0.88-1.3 million pounds) in 47-48 states

- 2000: 251,000-415,000 kg (0.55-0.91 million pounds) in 48 states
- 2004: 162,000-324,000 kg (0.36-0.71 million pounds) in 47-48 states
- 2008: 117,000-291,000 kg (0.26-0.64 million pounds) in 47-48 states
- 2012: 122,000-346,000 kg (0.27-0.76 million pounds) in 46-47 states
- 2016: 122,000-274,000 kg (0.27-0.60 million pounds) in 38-45 states
- 2019: 102,000-308,000 kg (0.23-0.68 million pounds) in 28-35 states

Fate / Transport

- Expected to have low mobility in soil, based on physical and chemical properties (ATSDR, 2003)
- Expected to volatilize slowly from soil and water, based on physical and chemical properties (ATSDR, 2003)
- Expected to be readily biodegradable (ATSDR, 2003)
- Half-life of permethrin in sediment/seawater is < 2.5 days, with no change in permethrin concentration for 4 weeks under sterilized conditions (ATSDR, 2003)
- Half-life of permethrin in a model ecosystem at 15-19 °C and a pH of 7.7 was 1.1-3.6 days (ATSDR, 2003)
- The USDA Pesticide Database reports an aerobic soil half-life of permethrin of 4-40 days (ATSDR, 2003)
- The cis- and trans- isomers of permethrin have photolysis half-lives of 27.1 and 19.6 hours, respectively (ATSDR, 2003)
- At pH 5 and 7, permethrin is stable to hydrolysis but at pH 9, the hydrolysis half-life is approximately 50 days (ATSDR, 2003)

Health Effects

- Health assessment selected: EPA OPP Human Health Risk Assessment (2020)
- Critical study: Wolansky et al. (2006)
- Critical effect: Decreased motor activity
- Oral reference value: BMDL1SD of 0.44 mg/kg/day
- Life stage selected for calculating exposure factor: birth to < 21 years

Summary Information for Phase 3 Contaminants Permethrin (CASRN: 52645-53-1)

- HRL: 3,000 µg/L (noncancer)
- Cancer classification: S (“Sufficient evidence of carcinogenic potential”)
- Note: the reference value, an acute oral toxicity value, is considered protective of chronic oral exposure as well.

Nationally Representative Drinking Water Occurrence

UCMR 4 Assessment Monitoring (2018-2020)

- MRL = 0.04 µg/L
- Occurrence in both GW and SW systems
- Samples w/ detects = 0.04% (16 of 37291); 0% > 1/2HRL; 0% > HRL
- Systems w/ detects = 0.26% (13 of 5028); 0% > 1/2HRL; 0% > HRL
- Detected Conc: Median = 0.0496 µg/L | 99%ile = 0.205 µg/L | Max = 0.212 µg/L

State Drinking Water Occurrence Data, 1990-2011

- States with no detections of permethrin (mixed, cis, trans)
 - CA (3 system)
 - LA (1 system)
 - NV (15 systems)
 - VT (1 system)
- States with no detections of cis-permethrin
 - CA (15 system)
- States with no detections of trans-permethrin
 - CA (15 system)

State Drinking Water Occurrence Data, 2012-2022

- States with no detections of permethrin (mixed, cis, trans)
 - CA (3 system)
 - IL (1 system)
 - MT (1 system)
 - NV (2 systems)
 - VT (1 system)
- States with no detections of cis-permethrin
 - CA (33 system)
- States with no detections of trans-permethrin

- CA (32 system)

Additional Drinking Water Occurrence (CCRs, CWSS, PDP, NPS, etc.)

Recent CCRs from 25 CWSs that serve >1M (2018-2021)

- No detections in 5 CWSs that reported monitoring

PDP Finished Water (2001-2013) for trans-Permethrin

- No detections in 2,292 samples

PDP Raw Water (2004-2013) for trans-Permethrin

- No detections in 1,419 samples

PDP Finished Water (2001-2013) for cis-Permethrin

- % Samples w/ detects = 0.04% (1 of 2,534); 0% > 1/2HRL; 0% > HRL
- Max detect = 0.068 µg/L

PDP Raw Water (2004-2013) for cis-Permethrin

- No detections in 1,888 samples

National Pesticide Survey (1988-1990)

- MRL = 0.90 µg/L for cis-permethrin, 2.0 µg/L for trans-permethrin
- Neither isomer detected in 566 CWS wells and 783 rural domestic wells

Water Monitoring Data from NAWQA and Other NWIS

NAWQA

- MRLs unavailable (min detect = 0.0077 µg/L)
- Includes only surface water monitoring
- Data only available from Cycle 2 and Cycle 3

- Cycle 2 (2002-2012)

- Samples w/ detects = 0% (0 of 2); 0% > 1/2HRL; 0% > HRL

- Sites w/ detects = 0% (0 of 2); 0% > 1/2HRL; 0% > HRL

- Cycle 3 (2013-2023)

- Samples w/ detects = 3.33% (2 of 60); 0% > 1/2HRL; 0% > HRL

- Sites w/ detects = 18.18% (2 of 11); 0% > 1/2HRL; 0% > HRL

Summary Information for Phase 3 Contaminants Permethrin (CASRN: 52645-53-1)

o Detected conc: median = 0.00885 µg/L |
99%ile = 0.00995 µg/L | max = 0.01 µg/L

NWIS data, non-NAWQA, from Water Quality Portal (1991-2023)

- Samples w/ detects = 0.46% (6 of 1312);
0% >1/2HRL; 0% >HRL
- Sites w/ detects = 1.4% (5 of 357);
0% >1/2HRL; 0% >HRL
- Detected conc: median = 0.0053 µg/L |
99%ile = 0.0142 µg/L | max = 0.0146 µg/L
- No FW data

Water Monitoring Data from STORET

STORET data from Water Quality Portal

- MRL unavailable (min detect = 0.348 µg/L)
- Includes monitoring in GW, SW
- Data from 9 state(s)
- Samples w/ detects = 0.13% (1 of 772);
0% >1/2 HRL; 0% >HRL
- Sites w/ detects = 0.34% (1 of 295);
0% >1/2HRL; 0% >HRL
- Detected Conc: Median = 0.348 µg/L |
99%ile = 0.348 µg/L | Max = 0.348 µg/L

Additional Water Monitoring Studies

PMP Raw and Finished Water, 1999-2000
(Blomquist et al., 2001)

- MRL = 0.005 µg/L
- Not detected in any water sample (0 of 323 raw water; 0 of 228 finished water)

NAWQA Domestic Well Water Quality, 1991-2004 (DeSimone, 2009)

- Common MRLs and LT-MDLs: 0.003, 0.005 µg/L (for cis-Permethrin)
- No samples w/ detections in 2,115 samples from domestic wells in primary aquifers (for cis-Permethrin)
- No samples w/ detections in 424 samples from agricultural land-use wells (for cis-Permethrin)

Monitoring of Public and Private Drinking Water Wells and Monitoring Wells in Water-Supply Interval in the Glacial Aquifer System, Northern U.S., 2005-2013 (Erickson et al., 2019)

- Cis-permethrin analyzed against "high" benchmark of 4 µg/L and "moderate" benchmark of 0.4 µg/L; RLs not reported
- No detections of cis-permethrin above high or moderate benchmarks in wells in water-supply interval (1,532 analyses)
- Trans-permethrin also included in study, but results not presented due to insufficient data

NAWQA Pesticides in Streams and Groundwater, 1992-2001 (Gilliom et al., 2007)

- Max LT-MDL = 0.003 µg/L (for cis-permethrin)
- GW: Detected in 0.14% of 1,402 agricultural wells (max = 0.007 µg/L), undetected in 2,728 mixed land-use wells, undetected in 855 urban wells, and undetected in 34 undeveloped land-use wells (for cis-permethrin)
- SW: Detected in 0.18% of 2,003 samples from 83 agricultural stream sites (max = 0.019 µg/L), 0.53% of 1,385 samples from 65 mixed land-use stream sites (max = 0.013 µg/L), undetected in 813 samples from 30 urban stream sites, and undetected in 144 samples of 8 undeveloped land-use stream sites (for cis-permethrin)

USGS Sioux Falls Report, 2009-2010
(Hoogestraat, 2012)

- RL = 0.014 µg/L (for cis-permethrin only)
- No detections in 11 finished water samples, 7 groundwater samples, and 8 surface water samples (for cis-permethrin only)

USGS CWSs Drawing from Streams and Groundwater, 2002-2005 (Hipple et al., 2009 and Kingsbury et al., 2008)

- Study investigated cis-permethrin only
- Laboratory reporting level = 0.006 µg/L
- Phase 1 GW: no detections in 221 samples
- Phase 1 SW: no detections in 146 stream samples
- Phase 2 GW: no detections in 48 source water samples and no detections in 48 finished water samples
- Phase 2 SW: no results reported

Groundwater Quality Data from NAWQA, 2017-2019 (Kingsbury et al., 2021)

Summary Information for Phase 3 Contaminants Permethrin (CASRN: 52645-53-1)

cis-permethrin

- Detected in 1 (0.2%) of 462 GW samples at 1 (0.2%) of 456 sites
- Conc (µg/L): Min = 0.163 | Median = 0.163 | 99%ile = 0.163 | Max = 0.163
- Reporting level = 0.0021 µg/L

trans-permethrin

- Detected in 3 (0.6%) of 463 GW samples at 3 (0.7%) of 457 sites
- Conc (µg/L): Min = 0.00564 | Median = 0.00744 | 99%ile = 0.179 | Max = 0.183
- Reporting level = 0.0019 µg/L

NAWQA Quality of Public Supply Wells, 1993-2007 (Toccalino et al., 2010)

- Study investigated cis-permethrin only
- RL = 0.003-0.005 µg/L
- Samples w/ detections = 0% (0 of 898)

NAWQA Carbonate Aquifer Study, 1993-2005 (Lindsey et al., 2009)

- Study investigated cis-permethrin only
- Multiple detection and reporting levels
- Samples w/ detections = 0% (0 of 1,027)

Biomonitoring Data (CDC's Fourth National Report)

No data

Applicable Analytical Methods

- EPA 508
- EPA 508.1
- EPA 525.2
- EPA 525.3

Treatment Technologies

Results of preliminary December 2023 literature search:

- Eckert (2013) investigated the removal of cis-, trans-, and total permethrin from water using powdered activated carbon (PAC). Initial total permethrin concentrations ranged from 2.0 to 4.6 µg/L and PAC doses varied from 0.0 to 10 mg/L. With one variety of PAC (WPH 650), a 0.05 mg/L dose reduced total permethrin concentrations by 38% and a 3 mg/L dose brought total permethrin concentrations down to

undetectable levels. Another variety of PAC (WPH 1000) achieved 35% reduction of total permethrin with a 0.05 mg/L dose and 83% reduction with a 5 mg/L dose. Similar findings were observed for cis- and trans-permethrin.

- Dehaghi et al. (2014) investigated the removal of permethrin from water using beads of chitosan loaded with zinc oxide nanoparticles (CS-ZnONPs) as an adsorbent, at the lab scale. The bionanocomposite demonstrated high efficiency, with a dose of 0.5 grams removing 99% of permethrin (from an initial concentration of 0.1 mg/L in a 25 mL solution).

Summary Information for Phase 3 Contaminants

Profenofos (CASRN: 41198-08-7)

HRL

0.7 µg/L

Uses / Sources

- An organophosphate insecticide (USEPA, 2008)
- First registered in U.S. in 1982 (USEPA, 2008)
- Profenofos products are classified as Restricted Use Pesticides (RUP) (USEPA, 2008)

Quantified Production (IUR/CDR)

No data on production from the EPA's IUR and CDR programs

Quantified Releases (TRI)

TRI Releases

- 2004 to surface water: 0 lbs/yr from 0 states
- 2004 total: 255 lbs/yr from 1 state
- 2008 to surface water: 0 lbs/yr from 0 states
- 2008 total: 0 lbs/yr from 0 states
- 2012 to surface water: 0 lbs/yr from 0 states
- 2012 total: 0 lbs/yr from 0 states
- 2016 to surface water: 0 lbs/yr from 0 states
- 2016 total: 0 lbs/yr from 0 states
- 2020 to surface water: 0 lbs/yr from 0 states
- 2020 total: 0 lbs/yr from 0 states

Quantified Usage (NCFAP, etc.)

Estimated pesticide usage, according to the National Center for Food and Agricultural Policy (NCFAP):

- 1992: 2.06 million pounds
- 1997: 880,000 pounds

Estimated pesticide usage, according to USGS's Estimated Annual Agricultural Pesticide Use portal:

- 1992: 662,000-718,000 kg (1.5-1.6 million pounds) in 11-13 states
- 1996: 597,000-642,000 kg (1.3-1.4 million pounds) in 14-15 states
- 2000: 195,000-255,000 kg (430,000-560,000 pounds) in 10-13 states
- 2004: 13,800-72,000 kg (30,000-160,000 pounds) in 5-9 states
- 2008: 9,030-28,900 kg (20,000-64,000 pounds) in 4-6 states
- 2012: 26.4-26.4 kg (58 pounds) in 1 state

Fate / Transport

- Expected to have low to slight mobility in soil and water, based on physical and chemical properties (NCBI, 2003)
- Not expected to volatilize from dry soil, moist soil or water, based on physical and chemical properties (NCBI, 2023)
- Under anaerobic, aquatic conditions, profenofos has a metabolism half-life of 3 days in pH 5.1 sediment covered by pH 7.3 water (NCBI, 2023)
- Under aerobic conditions, biodegradation, if it occurs at all, occurs much more slowly (NCBI, 2023)
- In pH 7.8 aerobic soil, profenofos has a hydrolysis half-life of 2 days (NCBI, 2023)
- In pH 7.8 anaerobic soil, profenofos has a hydrolysis half-life of 3 days (NCBI, 2023)
- Profenofos is stable to photolysis in soil and water (NCBI, 2023)

Health Effects

- Health assessment selected: EPA OPP Human Health Risk Assessment (2015)
- Critical study: Burdock et al. (1981)
- Critical effect: RBC AChE inhibition in rats
- Oral reference value: BMDL10 of 0.00012 mg/kg/day
- Life stage selected for calculating exposure factor: birth to < 21 years
- HRL: 0.7 µg/L (noncancer)
- Cancer classification: E (“Evidence of non-carcinogenicity for humans”)

Nationally Representative Drinking Water Occurrence

UCMR 4 Assessment Monitoring (2018-2020)

- MRL = 0.3 µg/L
- Occurrence observed in large GW and SW systems only
- Samples w/ detects = 0.01% (4 of 37287); 0.01% > 1/2HRL; 0% > HRL
- Systems w/ detects = 0.08% (4 of 5028); 0.08% > 1/2HRL; 0.02% > HRL
- Detected Conc: Median = 0.554 µg/L | 99%ile = 0.84 µg/L | Max = 0.848 µg/L

Summary Information for Phase 3 Contaminants
Profenofos (CASRN: 41198-08-7)

**State Drinking Water Occurrence Data,
1990-2011**

No state data identified

**State Drinking Water Occurrence Data,
2012-2022**

No state data identified

**Additional Drinking Water Occurrence
(CCRs, CWSS, PDP, NPS, etc.)**

Recent CCRs from 25 CWSs that serve >1M
(2018-2021)

- No detections in 5 CWSs that reported monitoring

PDP Finished Water (2001-2013)

- No detections in 3,133 samples

PDP Raw Water (2004-2013)

- No detections in 1,388 samples

**Water Monitoring Data from NAWQA and
Other NWIS**

NAWQA

- MRLs unavailable (min detect = 0.00072 µg/L)
- Includes monitoring in SW and GW
- Higher concentrations in SW than in GW
- Cycle 1 (1991-2001)

o Samples w/ detects = 0% (0 of 95);

0% > 1/2HRL; 0% >HRL

o Sites w/ detects = 0% (0 of 90);

0% > 1/2HRL; 0% >HRL

- Cycle 2 (2002-2012)

o Samples w/ detects = 0.12% (1 of 862);

0% > 1/2HRL; 0% >HRL

o Sites w/ detects = 0.33% (1 of 303);

0% > 1/2HRL; 0% >HRL

o Detected conc: median = 0.0013 µg/L |

99%ile = 0.0013 µg/L | max = 0.0013 µg/L

- Cycle 3 (2013-2023)

o Samples w/ detects = 0.06% (7 of 11919);

0% > 1/2HRL; 0% >HRL

o Sites w/ detects = 0.28% (6 of 2119);

0% > 1/2HRL; 0% >HRL

o Detected conc: median = 0.0016 µg/L |

99%ile = 0.245 µg/L | max = 0.249 µg/L

NWIS data, non-NAWQA, from Water Quality
Portal (1991-2023)

- Samples w/ detects = 0.02% (1 of 4953);
0% >1/2HRL; 0% >HRL

- Sites w/ detects = 0.07% (1 of 1474);

0% >1/2HRL; 0% >HRL

- Detected conc: median = 0.00019 µg/L |
99%ile = 0.00019 µg/L | max = 0.00019 µg/L

- No FW detections in 1 sample at 1 site

Water Monitoring Data from STORET

STORET data from Water Quality Portal

- MRL unavailable
- Includes monitoring in GW
- Data from 1 state(s)
- No detections in 5 samples from 5 sites

Additional Water Monitoring Studies

PMP Raw and Finished Water, 1999-2000
(Blomquist et al., 2001)

- MRL = 0.008 µg/L

- Not detected in any water sample (0 of 317 raw
water; 0 of 221 finished water)

Monitoring of Public and Private Drinking
Water Wells and Monitoring Wells in Water-
Supply Interval in the Glacial Aquifer System,
Northern U.S., 2005-2013 (Erickson et al., 2019)

- Included in study, but results not presented due
to insufficient data

Groundwater Quality Data from NAWQA,
2017-2019 (Kingsbury et al., 2021)

- Not detected in 468 samples of groundwater at
462 sites

- Reporting level = 0.0015 µg/L

**Biomonitoring Data (CDC's Fourth National
Report)**

No data

Applicable Analytical Methods

- EPA 525.3

Treatment Technologies

Results of preliminary December 2023 literature
search:

- Amin et al. (2014) conducted bench-scale
experiments of profenofos treatment using
advanced oxidation. The tests were conducted

Summary Information for Phase 3 Contaminants
Profenofos (CASRN: 41198-08-7)

using deionized water with initial profenofos concentrations of (10,000, 15,000, and 20,000 µg/L) and varying pH (5, 6.5, and 8). The samples were exposed to a combination of UV (30, 60, and 90 minutes) and hydrogen peroxide (0.01, 0.05, and 0.10 moles). The average efficiency of removal of profenofos across nine trials under varying conditions was 86.8+/-6%. Under optimal conditions (90 minutes at pH 8, with an initial concentration of 10,000 µg/L and the highest dose of hydrogen peroxide), 98.5% removal of profenofos was achieved.

- Zamy et al. (2004) examined the phototransformation of profenofos in purified water and river water when ultraviolet light is applied. Initial profenofos doses ranged from 10 to 100 µg/L. Monochromatic light (253.7 nm) and polychromatic light (>285 nm) were used. Photolysis of profenofos was slower, by factor of 0.7, in surface water than in purified water. The authors observe that whereas the presence of natural organic matter (NOM) in river water acts as a photosensitizer for some pesticides, for others, including profenofos, it acts as a filter.

Summary Information for Phase 3 Contaminants Tebuconazole (CASRN: 107534-96-3)

HRL

200 µg/L

Uses / Sources

- Typical EPA supporting documents (e.g., RED, IRED, TRED, Summary Document or Work Plan) are not available for tebuconazole
- A monochlorobenzene, triazole and tertiary alcohol (NCBI, 2023)
- First registered in U.S. in 1983 (USEPA, 2023)
- One formulation/product, a mixture of tebuconazole and lambda-cyhalothrin, is a Restricted Use Pesticide (RUP) (USEPA, 2022). The RUP designation is likely due to tebuconazole being co-formulated with lambda-cyhalothrin and not to the presence of tebuconazole

Quantified Production (IUR/CDR)

No data on production from the EPA's IUR and CDR programs

Quantified Releases (TRI)

Not included in TRI

Quantified Usage (NCFAP, etc.)

Estimated pesticide usage, according to the National Center for Food and Agricultural Policy (NCFAP):

- 1992: not reported
- 1997: 479,000 pounds

Estimated pesticide usage, according to USGS's Estimated Annual Agricultural Pesticide Use portal:

- 1994: 65,800-70,800 kg (0.15-0.16 million pounds) in 8-10 states
- 1998: 176,000-255,000 kg (0.39-0.56 million pounds) in 22-25 states
- 2002: 151,000-169,000 kg (0.33-0.37 million pounds) in 30-35 states
- 2006: 176,000-258,000 kg (0.39-0.57 million pounds) in 36-37 states
- 2010: 396,000-495,000 kg (0.87-1.1 million pounds) in 40-41 states
- 2014: 549,000-818,000 kg (1.2-1.8 million pounds) in 40-41 states

- 2018: 638,000-958,000 kg (1.4-2.1 million pounds) in 40-41 states

Fate / Transport

- Expected to have moderate to no mobility in soil and water, based on physical and chemical properties (USEPA, 2000; NCBI, 2023)
- Not expected to volatilize from dry soil, moist soil or water, based on physical and chemical properties (NCBI, 2023)
- Expected to be persistent with an aerobic metabolism half-life of approximately 800 days (USEPA, 2000)
- Resistant/stable to hydrolysis (NCBI, 2023) with a half-life of >>28 days (USEPA, 2000)
- Resistant/stable to photolysis (NCBI, 2023) with half-lives of 600 days in water (extrapolated) and 191 days in soil (USEPA, 2000)

Health Effects

- Health assessment selected: EPA OPP Human Health Risk Assessment (2021)
- Critical study: Becker and Biedermann (1995)
- Critical effect: Skull/neural tube defects in mice
- Oral reference value: Reference dose of 0.03 mg/kg/day
- Life stage selected for calculating exposure factor: Females 13 < 50 years
- HRL: 200 µg/L (noncancer)
- Cancer classification: C ("possible human carcinogen")

Nationally Representative Drinking Water Occurrence

UCMR 4 Assessment Monitoring (2018-2020)

- MRL = 0.2 µg/L
- Occurrence observed in large SW systems only
- Samples w/ detects = 0.01% (3 of 37286); 0% > 1/2HRL; 0% > HRL
- Systems w/ detects = 0.06% (3 of 5028); 0% > 1/2HRL; 0% > HRL
- Detected Conc: Median = 0.233 µg/L | 99%ile = 1.93 µg/L | Max = 1.96 µg/L

Summary Information for Phase 3 Contaminants
Tebuconazole (CASRN: 107534-96-3)

**State Drinking Water Occurrence Data,
1990-2011**

No state data identified

**State Drinking Water Occurrence Data,
2012-2022**

No state data identified

**Additional Drinking Water Occurrence
(CCRs, CWSS, PDP, NPS, etc.)**

Recent CCRs from 25 CWSs that serve >1M
(2018-2021)

- No detections in 5 CWSs that reported monitoring

PDP Finished Water (2001-2013)

- % Samples w/ detects = 2.18% (78 of 3,575);
0% > 1/2HRL; 0% > HRL

- Max detect = 0.150 µg/L

PDP Raw Water (2004-2013)

- % Samples w/ detects = 2.11% (56 of 2,656);
0% > 1/2HRL; 0% > HRL

- Max detect = 0.150 µg/L

**Water Monitoring Data from NAWQA and
Other NWIS**

NAWQA

- MRLs unavailable (min detect = 0.00024 µg/L)
- Includes SW and GW monitoring
- Data only available from Cycle 2 and Cycle 3
- Higher occurrence (detection percentages and concentrations) in SW than GW

- Cycle 2 (2002-2012)

o Samples w/ detects = 24.68% (76 of 308);
0% > 1/2HRL; 0% > HRL

o Sites w/ detects = 32.29% (31 of 96);
0% > 1/2HRL; 0% > HRL

o Detected conc: median = 0.004 µg/L |
99%ile = 0.113 µg/L | max = 0.146 µg/L

- Cycle 3 (2013-2023)

o Samples w/ detects = 15.86% (2534 of
15973); 0% > 1/2HRL; 0% > HRL

o Sites w/ detects = 7.57% (170 of 2245);
0% > 1/2HRL; 0% > HRL

o Detected conc: median = 0.00832 µg/L |
99%ile = 0.189 µg/L | max = 0.93 µg/L

NWIS data, non-NAWQA, from Water Quality
Portal (1991-2023)

- Samples w/ detects = 11.54% (806 of 6984);
0% > 1/2HRL; 0% > HRL
- Sites w/ detects = 11.99% (246 of 2052);
0% > 1/2HRL; 0% > HRL
- Detected conc: median = 0.00898 µg/L |
99%ile = 0.188 µg/L | max = 3.24 µg/L
- No FW data

Water Monitoring Data from STORET
STORET data from Water Quality Portal

- MRL unavailable
- Includes monitoring in GW, SW
- Data from 3 state(s)
- No detections in 2021 samples from 484 sites

Additional Water Monitoring Studies

Monitoring of Public and Private Drinking
Water Wells and Monitoring Wells in Water-
Supply Interval in the Glacial Aquifer System,
Northern U.S., 2005-2013 (Erickson et al., 2019)

- Included in study, but results not presented due to insufficient data

Groundwater Quality Data from NAWQA,
2017-2019 (Kingsbury et al., 2021)

- Detected in 1 (0.2%) of 471 samples of
groundwater
- Detected at 1 (0.2%) of 465 sites
- Conc (µg/L): Min = 0.00853 |
Median = 0.00853 | 99%ile = 0.00853 |
Max = 0.00853
- Reporting level = 0.0025 µg/L

**Biomonitoring Data (CDC's Fourth National
Report)**

No data

Applicable Analytical Methods

- EPA 525.3 (but subject to matrix-induced
response enhancement)
- EPA 543
- Bayer Method HW-005-W17-01

Treatment Technologies

Results of preliminary December 2023 literature
search:

Summary Information for Phase 3 Contaminants
Tebuconazole (CASRN: 107534-96-3)

- Elfikrie et al. (2020) examined pesticide removal efficiency in a conventional drinking water treatment plant in Selangor, Malaysia. Plant treatment processes include coagulation with aluminum sulphate/settling, filtration, and chlorination, pH adjustment, and fluoridation. The results showed removal efficiency of 88% for tebuconazole.
- Dong et al. (2021) investigated the removal of tebuconazole and other pesticides at 4 drinking water treatment plants with conventional and advanced treatment process in Shanghai, China, in 2018-2019. Treatment at three plants included coagulation/sedimentation, sand filtration, ozone, and biological activated carbon (BAC), while treatment at the fourth plant included coagulation/sedimentation, ozone, BAC, and ultrafiltration. Tebuconazole was found in raw water at an average concentration of 28.85 ng/L and in finished water at an average concentration of 9.62 ng/L. The authors evaluated the removal contribution of each treatment process. Ozone was found to have a removal rate of 18.4% for tebuconazole, BAC a removal rate of 36.7%, and ultrafiltration a removal rate of 20.7%.
- Del Puerto et al. (2022) examined the effects of combined vacuum UV (185 nm) and UVC (254 nm) irradiation (VUV/UVC) on tebuconazole. Raw water (groundwater) was spiked with a stock solution of tebuconazole. With 8 minutes of exposure to VUV/UVC irradiation, tebuconazole degradation rates of 95% (from an initial concentration of 1 µg/L) and 60% (from an initial concentration of 12 mg/L) were observed. The authors identified numerous transformation products following the irradiation treatment, many of which were found to be less toxic to aquatic organisms than the parent compound.
- del Olmo et al. (2023) studied removal of tebuconazole and other chlorinated azole pesticides at the bench scale using catalytic hydrochlorination (HDC), specifically a palladium/aluminum oxide (Pd/Al₂O₃) catalyst. Notably, complete degradation of all compounds in deionized water was achieved in a short reaction time (<15min) operating under ambient conditions and a neutral pH. The azole

pesticides were quite reactive toward HDC in comparison with neonicotinoid pesticides, pharmaceuticals, and chloroacetic acids. Furthermore, the azole pesticides were completely dechlorinated by the reaction, achieving in all cases chlorine-free reaction products. The catalyst was fairly stable upon three consecutive HDC runs, maintaining its properties practically unchanged. When the researchers conducted additional tests using real aqueous matrices (tap water and surface), the results were similar. With an initial concentration of 100 µg/L tebuconazole, the application of 0.25 g/L of the catalyst resulted in complete degradation of tebuconazole within the 15 minute reaction time.

Summary Information for Phase 3 Contaminants Tribufos (CASRN: 78-48-8)

HRL

1 µg/L

Uses / Sources

- An organophosphate defoliant (USEPA, 2009)
- First registered in U.S. in 1961 (USEPA, 2009)
- Not a Restricted Use Pesticide (RUP) (USEPA, 2022)

Quantified Production (IUR/CDR)

Annual reported production (i.e., manufacturing and importation) of tribufos from the EPA's IUR and CDR programs, in pounds:

- 2005: <500,000
- 2011: >2,089,000
- 2012: 3,869,965
- 2013: 2,822,662
- 2014: 1,775,834
- 2015: 0
- 2016: 1,144,619
- 2017: 1,666,056
- 2018: 2,662,387
- 2019: 1,876,813

Quantified Releases (TRI)

TRI Releases

- 2004 to surface water: 4 lbs/yr from 1 state
- 2004 total: 7 lbs/yr from 1 state
- 2008 to surface water: 0 lbs/yr from 0 states
- 2008 total: 0 lbs/yr from 0 states
- 2012 to surface water: 0 lbs/yr from 0 states
- 2012 total: 190 lbs/yr from 2 states
- 2016 to surface water: 0 lbs/yr from 0 states
- 2016 total: 10 lbs/yr from 1 state
- 2020 to surface water: 0 lbs/yr from 0 states
- 2020 total: 10 lbs/yr from 2 states

Quantified Usage (NCFAP, etc.)

Estimated pesticide usage, according to the National Center for Food and Agricultural Policy (NCFAP):

- 1992: 3.96 million pounds
- 1997: 4.92 million pounds

Estimated pesticide usage, according to USGS's Estimated Annual Agricultural Pesticide Use portal:

- 1992: 668,000-698,000 kg (1.5 million pounds) in 17-20 states
- 1996: 1.12-1.21 million kg (2.5-2.7 million pounds) in 18 states
- 2000: 1.84-1.86 million kg (4.1 million pounds) in 17 states
- 2004: 1.30-1.32 million kg (2.9 million pounds) in 17 states
- 2008: 741,000-759,000 kg (1.6-1.7 million pounds) in 16-17 states
- 2012: 1.01-1.12 million kg (2.2-2.5 million pounds) in 17 states
- 2016: 1.23-1.32 million kg (2.7-2.9 million pounds) in 17 states

Fate / Transport

- Expected to have little to no mobility in soil, based on physical and chemical properties (NCBI, 2023; ATSDR, 2020)
- Not expected to volatilize from dry soil, moist soil or water, based on physical and chemical properties (NCBI, 2023); however, volatilization may be significant from soils under hot and humid conditions (ATSDR, 2020)
- Expected to be persistent in soils with an aerobic metabolism half-life of 745 days at 25 °C (NCBI, 2023; ATSDR, 2020). The anaerobic metabolism half-life was 389 days (NCBI, 2023)
- The anaerobic half-life in silty clay pond sediment was reported as 180 days and 120 days in replicate measurements (NCBI, 2023)
- Stable to hydrolysis at pH 5 and 7 at 24 °C, but has a half-life of 124 days at pH 9 at 24 °C (NCBI, 2023)
- Direct photolysis may be possible in the atmosphere and surface waters (NCBI, 2023)
- Tribufos is stable to photolysis in soil (ATSDR, 2020)

Health Effects

- Health assessment selected: EPA OPP Human Health Risk Assessment (2015)
- Critical study: Sheets and Gilmore (2001)
- Critical effect: Inhibition of RBC AChE in rats
- Oral reference value: BMDL10 of 0.0002 mg/kg/day
- Life stage selected for calculating exposure factor: birth to < 21 years

Summary Information for Phase 3 Contaminants Tribufos (CASRN: 78-48-8)

- HRL: 1.0 µg/L (noncancer)
- Cancer classification: L/NL ("Likely at high doses, but unlikely to be carcinogenic to humans at low doses")

Nationally Representative Drinking Water Occurrence

UCMR 4 Assessment Monitoring (2018-2020)

- MRL = 0.07 µg/L
- Occurrence observed in large GW and SW systems only
- Samples w/ detects = 0.01% (3 of 37269); 0% > 1/2HRL; 0% > HRL
- Systems w/ detects = 0.06% (3 of 5027); 0% > 1/2HRL; 0% > HRL
- Detected Conc: Median = 0.139 µg/L | 99%ile = 0.395 µg/L | Max = 0.4 µg/L

State Drinking Water Occurrence Data, 1990-2011

No state data identified

State Drinking Water Occurrence Data, 2012-2022

No state data identified

Additional Drinking Water Occurrence (CCRs, CWSS, PDP, NPS, etc.)

Recent CCRs from 25 CWSs that serve >1M (2018-2021)

- No detections in 5 CWSs that reported monitoring

PDP Finished Water (2001-2013)

- No detections in 2,244 samples

PDP Raw Water (2004-2013)

- No detections in 500 samples

Water Monitoring Data from NAWQA and Other NWIS

NAWQA

- MRLs unavailable (min detect = 0.00196 µg/L)
- Includes monitoring in SW, GW, and finished water
- Higher occurrence (detection percentages and concentrations) in SW than GW
- Finished water data from Cycle 2 only

- No detections in finished water (61 samples at 50 sites)

• Cycle 1 (1991-2001)

- o Samples w/ detects = 0% (0 of 176); 0% > 1/2HRL; 0% > HRL

- o Sites w/ detects = 0% (0 of 124);

- 0% > 1/2HRL; 0% > HRL

• Cycle 2 (2002-2012)

- o Samples w/ detects = 0.27% (22 of 8168); 0% > 1/2HRL; 0% > HRL

- o Sites w/ detects = 0.67% (17 of 2546);

- 0% > 1/2HRL; 0% > HRL

- o Detected conc: median = 0.0165 µg/L |

- 99%ile = 0.109 µg/L | max = 0.117 µg/L

• Cycle 3 (2013-2023)

- o Samples w/ detects = 0.07% (8 of 12170); 0% > 1/2HRL; 0% > HRL

- o Sites w/ detects = 0.19% (4 of 2157);

- 0% > 1/2HRL; 0% > HRL

- o Detected conc: median = 0.00491 µg/L |

- 99%ile = 0.243 µg/L | max = 0.246 µg/L

NWIS data, non-NAWQA, from Water Quality Portal (1991-2023)

- Samples w/ detects = 0.2% (42 of 21376); 0% > 1/2HRL; 0% > HRL

- Sites w/ detects = 0.5% (34 of 6848); 0% > 1/2HRL; 0% > HRL

- Detected conc: median = 0.02 µg/L | 99%ile = 0.132 µg/L | max = 0.148 µg/L

- No FW detections in 38 samples at 20 sites

Water Monitoring Data from STORET

STORET data from Water Quality Portal

- MRL unavailable

- Includes monitoring in GW

- Data from 1 state(s)

- No detections in 8 samples from 7 sites

Additional Water Monitoring Studies

PMP Raw and Finished Water, 1999-2000 (Blomquist et al., 2001)

- MRL = 0.016 µg/L

- not detected in any water sample (0 of 317 raw water; 0 of 221 finished water)

Monitoring of Public and Private Drinking Water Wells and Monitoring Wells in Water-

Summary Information for Phase 3 Contaminants
Tribufos (CASRN: 78-48-8)

Supply Interval in the Glacial Aquifer System,
Northern U.S., 2005-2013 (Erickson et al., 2019)

- Analyzed against "high" benchmark of 7 µg/L and "moderate" benchmark of 0.7 µg/L; RLs not reported
- No detections above high or moderate benchmarks in wells in water-supply interval (616 analyses)

USGS Sioux Falls Report, 2009-2010
(Hoogestraat, 2012)

- RL = 0.018-0.035 µg/L
- No detections in 11 finished water samples, 7 groundwater samples, and 8 surface water samples

Groundwater Quality Data from NAWQA,
2017-2019 (Kingsbury et al., 2021)

- Not detected in 469 samples of groundwater at 464 sites
- Reporting level = 0.001 µg/L

Biomonitoring Data (CDC's Fourth National Report)

No data

Applicable Analytical Methods

- EPA 525.3

Treatment Technologies

Results of preliminary December 2023 literature search:

- No relevant literature identified.

Appendix B: Regulatory Determination 5 Protocol

An appendix from:

Final Regulatory Determination 5 Support Document

EPA Report 815-R-26-002

Executive Summary

The Safe Drinking Water Act (SDWA), as amended in 1996, requires the U.S. Environmental Protection Agency (EPA) to make regulatory determinations every five years on at least five unregulated contaminants from the Contaminant Candidate List (CCL). The CCL itself is updated on a five year cycle. A regulatory determination is a decision about whether or not to begin the process to propose and promulgate a national primary drinking water regulation (NPDWR) for an unregulated contaminant.

The EPA published the final fifth contaminant candidate list (CCL 5), which listed 66 chemicals, 3 chemical groups, and 12 microbiological contaminants, in the *Federal Register* on November 14, 2022. The contaminants on CCL 5 were evaluated for the fifth round of Regulatory Determination (Regulatory Determination 5 or RD 5).

This document is structured as follows: Section B.1 is an introduction that provides an overview of the EPA’s drinking water program risk management processes. Section B.2 presents the statutory background of the CCL and Regulatory Determination processes and the Unregulated Contaminant Monitoring Rule (UCMR) established under the 1996 SDWA Amendments. Section B.3 provides background on the CCLs and Regulatory Determinations that preceded this round. Section B.4 provides an overview of the Regulatory Determination process. Sections B.5 through B.7 explain in detail the RD 5 protocol.

RD 5 is a three-phase process. In the Data Availability Phase, described in Section B.5, the EPA conducts an assessment of the availability, for each CCL 5 contaminant, of (a) a suitable published health assessment from the EPA or other sources, (b) finished water occurrence data, with a preference for nationally representative sources, and (c) analytical methods in widespread use. Those contaminants with suitable health assessments, occurrence data and analytical methods available proceed to the second phase.

In the Data Evaluation Phase, described in Section B.6, the EPA gathers available data on occurrence and exposure and evaluates occurrence data relative to a health-based threshold, the health reference level (HRL). Based on this evaluation, the EPA identifies contaminants that appear to occur at levels and frequencies of public health concern (potential positive determinations), those that have no or low occurrence at levels of health concern (potential negative determinations), and those that have data gaps. Contaminants that are candidates for positive and negative determinations proceed to the third phase.

In the Regulatory Determination Assessment Phase, described in Section B.7, the EPA formally evaluates candidates for positive and negative determinations against the three statutory criteria by asking the following questions:

- Might the contaminant have an adverse effect on the health of persons?
- Is the contaminant known to occur or is there a substantial likelihood that the contaminant will occur in public water systems (PWSs) with a frequency and at levels of public health concern?
- In the sole judgment of the Administrator, does regulation of the contaminant present a meaningful opportunity for health risk reduction for persons served by PWSs?

If the Agency answers “yes” to all three statutory criteria, then the Agency makes a positive preliminary determination. After a positive determination is finalized, the Agency has 24 months to publish a proposed Maximum Contaminant Level Goal (MCLG) and NPDWR and

then 18 months to publish a final MCLG and promulgate a final NPDWR (SDWA Section 1412(b)(1)(E)). (SDWA permits the Agency to extend the promulgation date by an additional nine months if needed.)

If the Agency answers “no” to one or more of the three statutory criteria, then the Agency considers making a “negative” determination that an NPDWR is not necessary for the contaminant at this time. The Agency may also elect to issue no determination for a contaminant in Phase 3. If a negative determination or no determination is made for a contaminant, the Agency may decide to develop a Health Advisory (HA), which is a non-regulatory action. While a negative determination is considered a final Agency action for this round of regulatory determination, the contaminant may be relisted on a future CCL based on newly available health or occurrence information.

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Abbreviations

ADAF	Age Dependent Adjustment Factor
ATSDR	Agency for Toxic Substances and Disease Registry
BAT	Best Available Technology
BMD	Benchmark Dose
BW	Body Weight
CalEPA	California Environmental Protection Agency
CCL	Contaminant Candidate List
CCL 1	First CCL
CCL 2	Second CCL
CCL 3	Third CCL
CCL 4	Fourth CCL
CCL 5	Fifth CCL
CDC	Centers for Disease Control and Prevention
CRL	Cancer Risk Level
CSF	Cancer Slope Factor
CSFII	Continuing Survey of Food Intakes by Individuals
DALY	Disability-Adjusted Life Year
DDE	1,1-Dichloro-2,2-bis(p-chlorophenyl)ethylene
DL	Detection Limit
DWI	Drinking Water Intake
DWI-BW	Body-Weight-Adjusted Drinking Water Intake
EF	Exposure Factor
EFH	Exposure Factors Handbook
EFSA	European Food Safety Authority
EPA	U.S. Environmental Protection Agency
EPTC	S-Ethyl Dipropylthiocarbamate
F	Fraction of Life
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
GDWQ	Guidelines for Drinking Water Quality
HA	Health Advisory
HED	Health Effects Division
HESD	Health Effects Support Document
HFPO-DA	Hexafluoropropylene Oxide Dimer Acid
HHRA	Human Health Risk Assessment
HRL	Health Reference Level
HRRCA	Health Risk Reduction Cost Analysis
IRIS	Integrated Risk Information System
LOAEL	Lowest-Observed-Adverse-Effect Level
MAC	Maximum Acceptable Concentration
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
MOA	Mode of Action
MRL	Minimum Reporting Level
NCOD	National Contaminant Occurrence Database
NDWAC	National Drinking Water Advisory Council
NHANES	National Health and Nutrition Examination Survey

NIRS	National Inorganics and Radionuclides Survey
NOAEL	No-Observed-Adverse-Effect Level
NPDWR	National Primary Drinking Water Regulation
NRC	National Research Council
OGWDW	Office of Ground Water and Drinking Water
OPP	Office of Pesticide Programs
OPPT	Office of Pollution Prevention and Toxics
ORD	Office of Research and Development
OW	Office of Water
PAD	Population-Adjusted Dose
PFAS	Per-and-Polyfluoroalkyl Substances
PFBS	Perfluorobutane Sulfonic Acid
PFHxS	Perfluorohexane Sulfonic Acid
PFNA	Perfluorononanoic Acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctanesulfonic Acid
PHG	Public Health Goal
PMP	Pesticide Monitoring Program
POD/UF	Point of Departure / Uncertainty Factor
PPRTV	Provisional Peer-Reviewed Toxicity Values
PWS	Public Water System
QMRA	Quantitative Microbial Risk Assessment
RD 1	First Regulatory Determination
RD 3	Third Regulatory Determination
RD 4	Fourth Regulatory Determination
RD 5	Fifth Regulatory Determination
RDX	Royal Demolition eXplosive
RED	Reregistration Eligibility Decision
RfD	Reference Dose
RL	Reporting Level
RSC	Relative Source Contribution
SAB	Science Advisory Board
SDWA	Safe Drinking Water Act
SSCT	Small System Compliance Technology
TDI	Tolerable Daily Intake
TSCA	Toxic Substances Control Act
TT	Treatment Technique
UA	Unit Adjustment Factor
UCM	Unregulated Contaminant Monitoring
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 1	First Unregulated Contaminant Monitoring Rule
UCMR 2	Second Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 4	Fourth Unregulated Contaminant Monitoring Rule
UCMR 5	Fifth Unregulated Contaminant Monitoring Rule
WHO	World Health Organization

Appendix B: Regulatory Determination 5 Protocol

B.1 Introduction

Section 1412(b)(1)(B) of the Safe Drinking Water Act (SDWA), as amended in 1996, requires the U.S. Environmental Protection Agency (EPA) to periodically develop or update a list of substances of public health concern not currently regulated as drinking water contaminants (the contaminant candidate list, or CCL), and to periodically determine whether regulation is warranted for contaminants from that list (Regulatory Determination). The statute directs the EPA to determine whether to regulate at least five contaminants from the most recent CCL every five years and allow an opportunity for public notice and comment.

The fifth CCL (CCL 5) was published on November 24, 2022 (87 FR 68060; USEPA, 2022a). This document presents the Protocol that the EPA will follow as the Agency conducts the fifth round of Regulatory Determination (Regulatory Determination 5 or RD 5). The document provides an overview of the Regulatory Determination program and describes the three-phase procedure that the EPA will use to screen CCL 5 contaminants for data availability, select a limited number of CCL 5 contaminants for Regulatory Determination, and make those determinations.

Final decisions of the RD 5 process will be presented in the *Federal Register* and supporting information will be presented in the Regulatory Determination 5 Support Document and other documentation.

B.2 Statutory Background

The 1996 SDWA Amendments required the EPA to develop a revised risk management and regulatory development approach for drinking water to protect public health. To meet these requirements the EPA developed an integrated framework to:

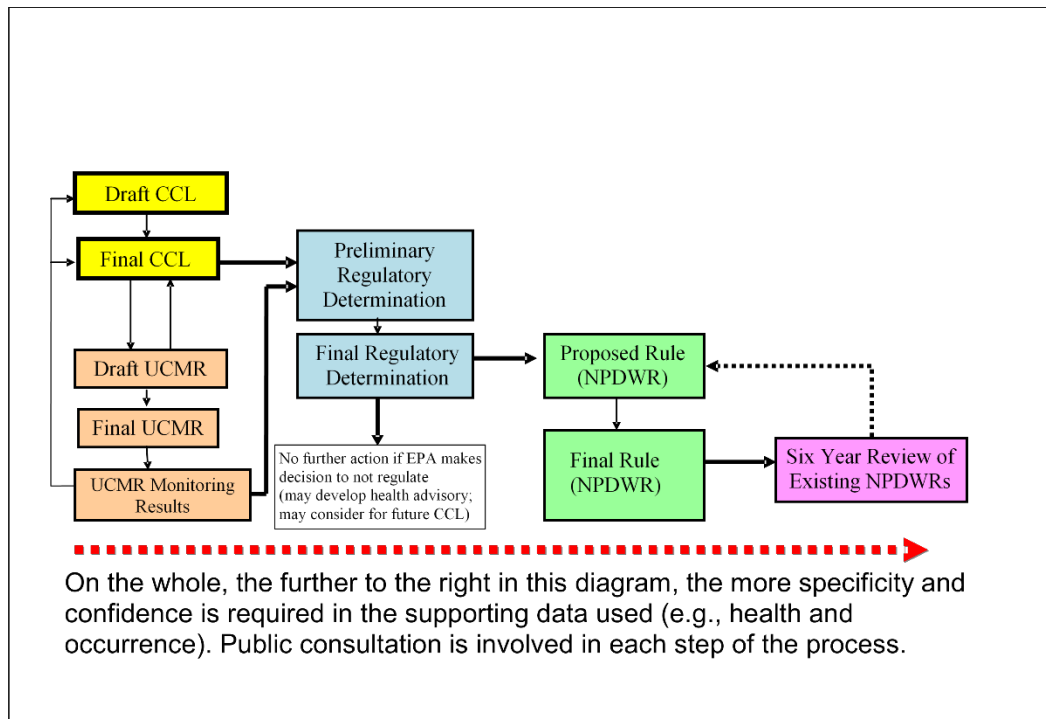
- (1) List currently unregulated contaminants of public health concern, called the Contaminant Candidate List (CCL);
- (2) Collect drinking water monitoring data for unregulated contaminants under the Unregulated Contaminant Monitoring Rule (UCMR);
- (3) Evaluate CCL contaminants and determine whether or not they warrant a national primary drinking water regulation (NPDWR), a process called Regulatory Determination; and
- (4) Periodically review existing regulations and assess whether revisions are needed to maintain or improve public health protection for drinking water consumers (called the Six-Year Review).

The specific statutory requirements for the CCL and Regulatory Determination programs can be found in SDWA Section 1412(b)(1). The statutory requirements for the UCMR can be found in SDWA Section 1445(a)(2). The statutory requirements for the Six-Year Review program can be found in SDWA 1412(b)(9).

Relationships among the programs are depicted in Exhibit B-1. As the diagram shows, the Regulatory Determination program is an integral part of a larger framework of programs intended to manage public health risks posed by drinking water contaminants. The EPA has relied on considerable stakeholder and expert input in developing and implementing each of these programs. The Regulatory Determination program interacts directly with the CCL and the

UCMR programs. The CCL, Regulatory Determination, and UCMR programs are briefly described below.

Exhibit B-1: Drinking Water Program Risk Management Processes



B.2.1 The Contaminant Candidate List (CCL)

The 1996 SDWA Amendments required the EPA to publish the first CCL (CCL 1) 18 months after the date of their enactment, and to publish a new CCL every five years after publication of the previous CCL. The CCL is a list of contaminants that are not subject to any proposed or promulgated NPDWRs, are known or anticipated to occur in public water systems (PWSs) and may require regulation under SDWA to protect public health. SDWA also specifies that the CCL must consider substances identified in Section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) and substances registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and must consider data and information from the National Contaminant Occurrence Database (NCOD), which the EPA established as required under SDWA Section 1445(g). For the CCL, SDWA requires consultation with the scientific community, including the EPA's Science Advisory Board (SAB), and opportunity for public comment. The CCL is the starting point for the Regulatory Determination process and is the list of priority contaminants that are evaluated for potential drinking water regulations. Additional information about the CCL process and CCL outcomes, including references, is provided below in Section B.3.

B.2.2 The Unregulated Contaminant Monitoring Rule (UCMR)

The 1996 SDWA Amendments (Section 1445(a)(2)) also required that once every five years the EPA issue a new list of no more than 30 unregulated contaminants to be monitored by PWSs. The UCMR occurrence data are designed to help determine if the contaminant occurs “with a frequency and at levels of public health concern” (per the second statutory criterion for regulatory determinations, below) to support the Administrator’s determination under the Regulatory Determination process of whether or not to regulate a contaminant. The 1996 SDWA Amendments require the EPA to enter the monitoring data into a national drinking water contaminant occurrence database (implemented as NCOD).

B.2.3 Regulatory Determination

The SDWA, as amended in 1996, Section 1412(b)(1)(B), directs the EPA to determine whether or not to regulate at least five contaminants from the most recent CCL every five years and allow an opportunity for public notice and comment. The first Regulatory Determination (RD 1) was due within three and one-half years after the publication of CCL 1, and then once every five years. When making a regulatory determination, the 1996 SDWA Amendments require that the EPA assess three criteria and decide whether:

- (1) The contaminant may have an adverse effect on the health of persons.
- (2) The contaminant is known to occur or there is substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern.
- (3) In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

If the EPA finds that all three of these statutory criteria are met, the Agency makes a determination to regulate the contaminant (i.e., a positive determination). Following a positive regulatory determination, SDWA Section 1412(b)(1) directs the Agency to publish a proposed Maximum Contaminant Level Goal (MCLG)¹ and NPDWR² in 24 months. After the proposal, SDWA directs the Agency to publish a final MCLG and promulgate a final NPDWR within 18 months. The EPA may extend the deadline for such promulgation for up to nine additional months. If the EPA finds that one or more of the statutory criteria are not met, it may make a determination not to regulate the contaminant (i.e., a negative determination). A determination not to regulate a contaminant is considered a final Agency action and is subject to judicial review. A third outcome is for the EPA to make no determination for a contaminant. In some cases, a contaminant may receive no determination due to lack of adequate health effects or occurrence data. In other cases, a decision may have been made to evaluate the contaminant outside the Regulatory Determination process (e.g., alongside regulated contaminants as part of the Six-Year Review process). Generally, only a fraction of CCL contaminants receive a positive or negative determination in any given round of Regulatory Determination. CCL contaminants

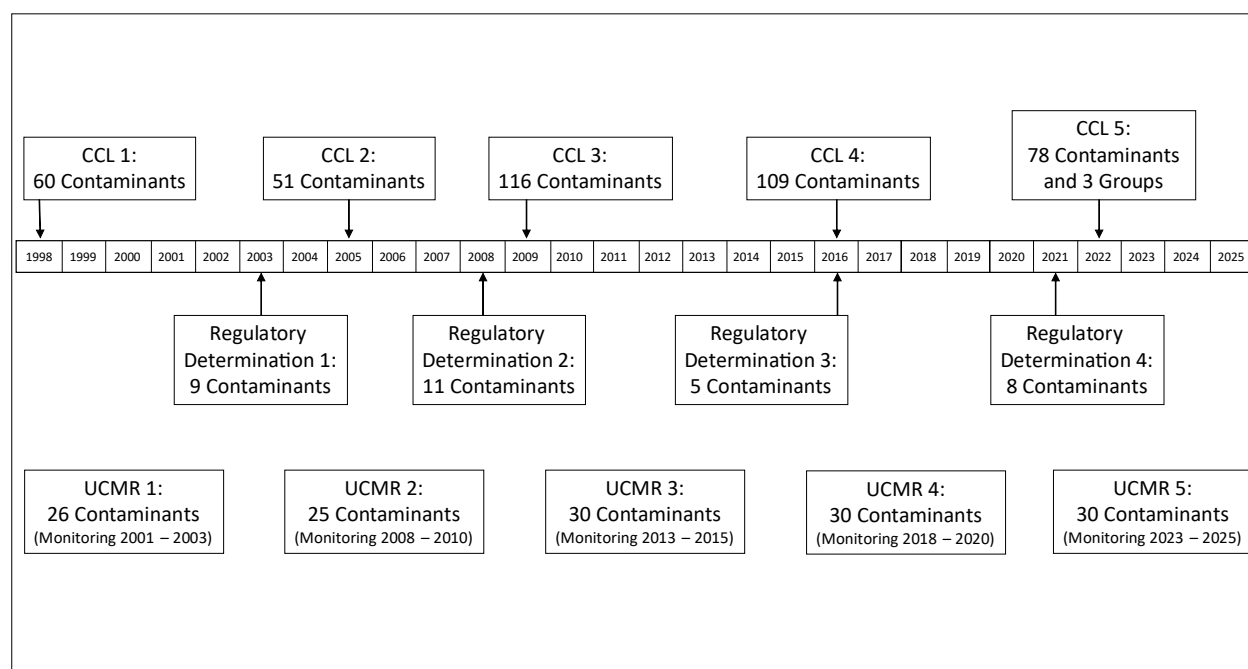
¹ An MCLG is the maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. MCLGs are non-enforceable health goals.

² An NPDWR is a legally enforceable standard that applies to PWSs. An NPDWR sets a legal limit (called a maximum contaminant level or MCL) or specifies a certain treatment technique (TT) for PWSs for a specific contaminant or group of contaminants.

that receive no determination in one round of Regulatory Determination may be relisted on the next CCL and evaluated again in the next round of Regulatory Determination.

The CCL and UCMR are integral components of the coordinated risk management process that inform and support Regulatory Determination (Exhibit B-2 illustrates the time-line relationship among the programs). The list of contaminants for each UCMR monitoring cycle are developed in coordination with the CCL process and other Agency priorities. The programs continually support and inform each other. The UCMR is designed to inform the Regulatory Determination process, and in some cases may also collect data that would support regulation development and help determine whether new or emerging contaminants should be listed on future CCLs.

Exhibit B-2: CCL, Regulatory Determination, and UCMR Timeline



B.3 Past CCL and Regulatory Determination Cycles

As noted above, the EPA is conducting the fifth round of Regulatory Determination based on CCL 5. The following table (Exhibit B-3) summarizes the process and outcomes of the three previous rounds of CCL and the associated regulatory determinations.

Exhibit B-3: Summary of Past CCL and Regulatory Determination Cycles

First CCL and Regulatory Determination Cycle	Second CCL and Regulatory Determination Cycle	Third CCL and Regulatory Determination Cycle	Fourth CCL and Regulatory Determination Cycle
CCL 1 was assembled based on expert	The remaining 51 CCL 1 contaminants were	The third CCL (CCL 3) was developed using a	The remaining CCL 3 contaminants were

First CCL and Regulatory Determination Cycle	Second CCL and Regulatory Determination Cycle	Third CCL and Regulatory Determination Cycle	Fourth CCL and Regulatory Determination Cycle
knowledge and the evaluation of readily available information, with input from the National Drinking Water Advisory Council (NDWAC), the scientific community, and the public (through stakeholder meetings and the public comments). Draft CCL 1 published October 6, 1997 (62 FR 52193; USEPA, 1997). Final CCL 1 published March 2, 1998 (63 FR 10273; USEPA, 1998a) The final CCL 1 contained 50 chemical and 10 microbiological contaminants. Preliminary Regulatory Determination published June 3, 2002 (67 FR 38222; USEPA, 2002a). Final Regulatory Determination published July 18, 2003 (68 FR 42898; USEPA, 2003).	carried forward onto the second CCL (CCL 2). Draft CCL 2 published on April 2, 2004 (69 FR 17406; USEPA, 2004). Final CCL 2 published on February 24, 2005 (70 FR 9071; USEPA, 2005a). Preliminary Regulatory Determination published on May 1, 2007 (72 FR 24106; USEPA, 2007). Final Regulatory Determination published on July 30, 2008 (73 FR 44251; USEPA, 2008a).	systematic process based on input and recommendations from the National Research Council (NRC), NDWAC and the public, involving the use of algorithms to screen and evaluate contaminants based on properties (prevalence, magnitude, persistence/mobility, severity and potency) using data from a wide range of sources. Draft CCL 3 published on February 21, 2008 (73 FR 9628; USEPA, 2008b). Final CCL 3 published on October 8, 2009 (74 FR 51850; USEPA, 2009a). The final CCL 3 consists of 104 chemicals or chemical groups and 12 microbiological contaminants. Preliminary Regulatory Determination published on October 20, 2014 (79 FR 62715; USEPA, 2014a). Final Regulatory Determination published on January 4, 2016 (81 FR 13; USEPA, 2016b).	carried forward onto the fourth CCL (CCL 4), except three pesticides with cancelled registrations (disulfoton, fenamiphos, molinate). Two more contaminants were added based on nominations (manganese and nonylphenol). Draft CCL 4 published on February 4, 2015 (80 FR 6076; USEPA, 2015a). Final CCL 4 published on November 17, 2016 (81 FR 81099; USEPA, 2016a). The final CCL 4 consists of 97 chemicals or chemical groups and 12 microbiological contaminants. Preliminary Regulatory Determination published on March 10, 2020 (85 FR 14098; USEPA, 2020a). Final Regulatory Determination published on March 3, 2021 (86 FR 12272; USEPA, 2021a).
Outcomes: <i>Acanthamoeba</i>: negative determination (information about microbe posted on the EPA's website)	Outcomes: Boron: negative determination (health advisory issued) Dacthal mono- and di-acid degradates: negative determination	Outcomes: Dimethoate: negative determination 1,3-Dinitrobenzene: negative determination Perchlorate: positive determination (made	Outcomes: Acetochlor: negative determination 1,1-Dichloroethane: negative determination

First CCL and Regulatory Determination Cycle	Second CCL and Regulatory Determination Cycle	Third CCL and Regulatory Determination Cycle	Fourth CCL and Regulatory Determination Cycle
Aldrin: negative determination Dieldrin: negative determination Hexachlorobutadiene: negative determination Manganese: negative determination (health advisory issued) Metribuzin: negative determination Naphthalene: negative determination Sodium: negative determination (health advisory issued) Sulfate: negative determination (health advisory issued)	(health advisory issued) 1,1-Dichloro-2,2-bis(p-chlorophenyl)ethylene (DDE): negative determination 1,3-Dichloropropene (Telone): negative determination 2,4-Dinitrotoluene: negative determination (health advisory issued) 2,6-Dinitrotoluene: negative determination (health advisory issued) S-Ethyl dipropylthiocarbamate (EPTC): negative determination Fonofos: negative determination Terbacil: negative determination 1,1,2,2-Tetrachloroethane: negative determination (health advisory issued)	off-cycle, but counted for purposes of Regulatory Determination 3) Strontium: preliminary positive determination (final determination pending) Terbufos: negative determination Terbufos sulfone: negative determination	Methyl bromide (bromomethane) : negative determination Metolachlor: negative determination Nitrobenzene: negative determination Perfluorooctanesulfonic acid (PFOS): positive determination Perfluorooctanoic acid (PFOA): positive determination RDX (also known as hexahydro-1,3,5-trinitro-1,3,5-triazine and Royal Demolition eXplosive): negative determination

Perchlorate is an example of a contaminant handled off-cycle. The final determination for perchlorate is considered part of the third Regulatory Determination cycle (RD 3). The EPA published a preliminary determination not to regulate perchlorate with an NPDWR in October 2008 (73 FR 60262; USEPA, 2008c). In 2009, the EPA solicited input from the public on approaches for analyzing and evaluating perchlorate data (74 FR 41883; USEPA, 2009b and 74 FR 48541; USEPA, 2009c), and in February 2011, the EPA issued a final determination to regulate perchlorate (76 FR 7762; USEPA, 2011a). This decision was the first time the EPA decided to regulate a substance from the CCL. On May 23, 2019, the EPA released a pre-publication notice of proposed rulemaking that seeks public input on a range of options regarding the regulation of perchlorate in PWSs. On July 21, 2020 (85 FR 43990; USEPA, 2020b), the EPA announced its withdrawal of the 2011 determination to regulate perchlorate, citing more recent health effects and occurrence analyses that support a new final determination that perchlorate does not satisfy the three statutory criteria. (USEPA, 2022b). Since then, the Agency's decision regarding perchlorate was the subject of a lawsuit. Pursuant with a court

order, the EPA is planning to issue a final NPDWR for perchlorate by 2027. More details are available on the EPA website (<https://www.epa.gov/sdwa/perchlorate-drinking-water>).

Since CCL 4, the EPA has made four regulatory determinations. The Agency issued preliminary regulatory determinations for perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), perfluorobutane sulfonic acid (PFBS), and mixtures of two or more of these four per- and polyfluoroalkyl substances (PFAS) concurrently with the proposed PFAS NPDWR (88 FR 18638; USEPA 2023a). Along with the final PFAS NPDWR, the EPA issued final determinations to regulate PFHxS, PFNA and HFPO-DA as individual contaminants and to regulate mixtures of two or more of the four PFAS; a final determination about regulation of PFBS as an individual contaminant was deferred (89 FR 32532; USEPA 2024).³

The draft CCL 5 was published on July 19, 2021 (86 FR 37948; USEPA, 2021b). The final CCL 5 was published on November 24, 2022 (87 FR 68060; USEPA, 2022a). The final CCL 5 consists of 66 chemicals, 3 chemical groups, and 12 microbiological contaminants.

B.4 Overview of the Regulatory Determination 5 Process

RD 5 follows a three-phase process. The three phases of the RD 5 Process are (1) the *Data Availability Phase*, (2) the *Data Evaluation Phase*, and (3) the *Regulatory Determination Assessment Phase*. The overall RD 5 Process is displayed in Exhibit B-4.

The purpose of the first phase, the *Data Availability Phase*, is to determine if the EPA “may have” sufficient data to characterize the potential health effects and known or likely occurrence in drinking water. Although contaminants must have sufficient data to evaluate the statutory criteria in Phase 3, the EPA does not want to rule out any contaminants prematurely. Therefore, if sufficient health and occurrence data “are likely” to be available, the contaminants may be placed on a “short list” for the *Data Evaluation Phase*, the second phase of the Regulatory Determination process.

During the second phase, the EPA will further evaluate each contaminant on the short list to identify those that have sufficient data for the EPA to assess the three statutory criteria. As part of the second phase, the EPA will specifically focus its efforts to identify those contaminants or contaminant groups that are occurring or have substantial likelihood to occur at levels and frequencies of public health concern, based on the best available data.

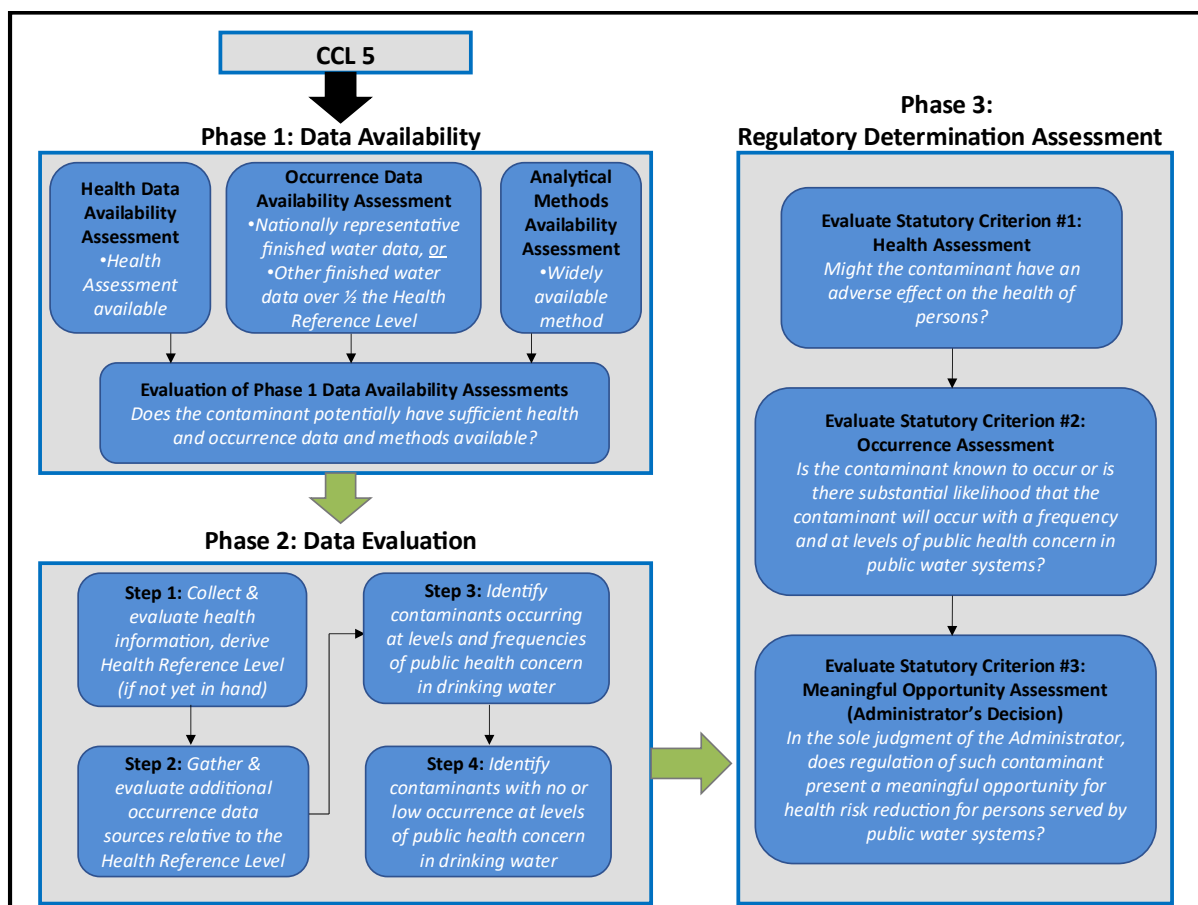
If sufficient data are available for a contaminant to characterize the potential health effects and known or likely occurrence in drinking water, the contaminant will be evaluated against the three statutory criteria in the *Regulatory Determination Assessment Phase*, which is the third phase of the approach. Results will be published in the *Federal Register* as preliminary regulatory determinations for public comment. The EPA will analyze and respond to the comments and issue the final determinations in the *Federal Register*.

Contaminants that do not advance from one phase to the next or do not receive a regulatory determination due to insufficient data are recognized as having information gaps by

³ Further developments re: PFAS since the Protocol was written, including an announcement of the Agency’s intention to reconsider the regulatory determinations for PFHxS, PFNA, HFPO-DA, and mixtures of two or more of those PFAS and PFBS, are presented on the EPA’s website (<https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas>) and summarized in chapter 1 of this support document.

the EPA. The EPA can work towards filling information gaps: e.g., by including a contaminant on the next round of UCMR, developing an analytical method, or conducting a health assessment.

Exhibit B-4: The Three Primary Phases of the Regulatory Determination 5 Process



In addition to considering CCL 5 contaminants individually, the EPA also may consider some of them collectively as groups or mixtures. The EPA considers grouping contaminants for purposes of regulation when it may strengthen public health protection from contaminants in drinking water. When deciding whether to consider two or more contaminants as a group, the EPA will evaluate whether the contaminants have some or all of the following characteristics:

- (a) have a similar health endpoint,
- (b) can be measured by the same analytical methods,
- (c) can be treated using the same technologies or treatment techniques, and
- (d) have been shown to occur together.

The purpose of grouping contaminants by a similar health endpoint is to better protect public health from the potential risk of co-occurring contaminants with common additive or synergistic (i.e., greater than additive) adverse health effects. The affected target organ(s), specific endpoint(s), mechanism(s)/mode(s) of action, functional molecular group(s) and the

potential for additive risk based on available data are considered in the selection of endpoints that are used to group contaminants for regulatory consideration. The ability to measure a group of contaminants by the same analytical method and to treat the contaminants using the same technology or treatment technique approach improves cost effectiveness and efficiency of regulating the group of contaminants because there is likely only a marginal additional cost for monitoring and treating additional contaminants in the group if they co-occur.

When grouping contaminants for consideration under the RD 5 Protocol using the evaluation criteria listed above, the EPA may also choose to include non-CCL contaminants in a group with one or more CCL contaminants.

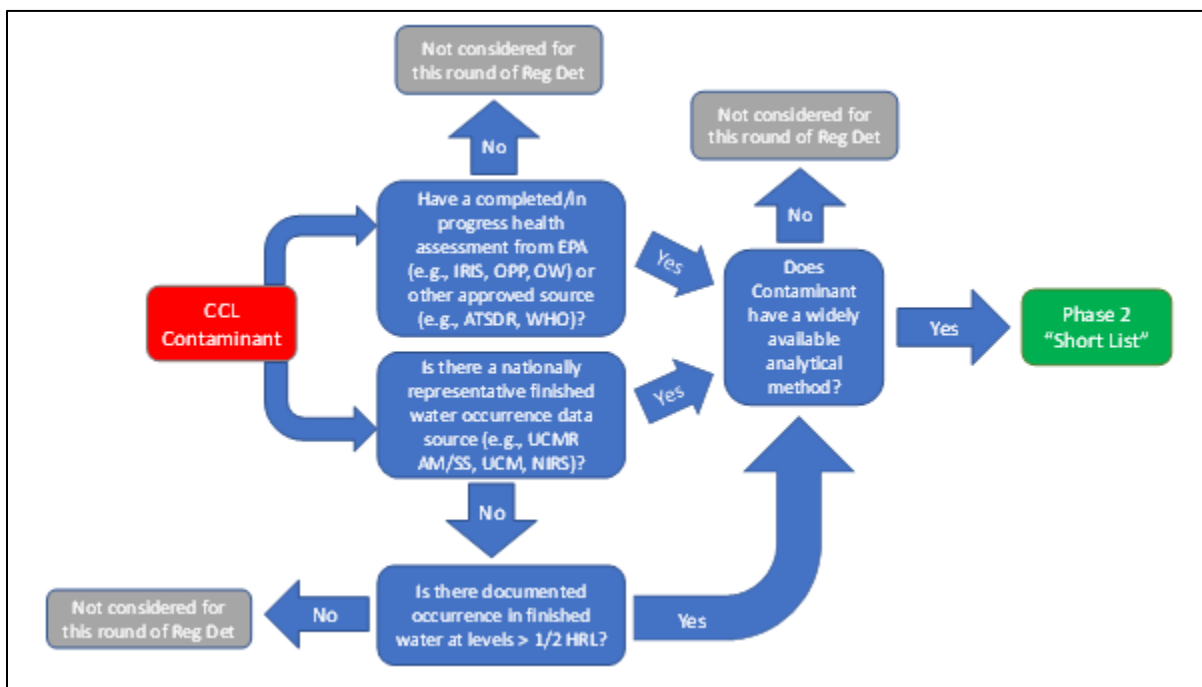
When working with groups, the Agency will gather data (where available) on both the individual contaminants and the group. The Agency may determine that a group satisfies a particular criterion in the RD 5 Protocol even if one or more individual component contaminants do not.

The following sections describe in more detail the steps involved in the three primary phases of the RD 5 process.

B.5 Phase 1: Data Availability

Within the *Data Availability Phase*, three assessments will be conducted: the Health Data Availability Assessment, the Occurrence Data Availability Assessment, and the Analytical Methods Availability Assessment. Contaminants and groups that pass all three assessments will be placed on the “short list” for further evaluation in the *Data Evaluation Phase* (see Exhibit B-5).

Exhibit B-5: Regulatory Determination 5 Phase 1 Flowchart



B.5.1 Health Data Availability Assessment

Qualifying health assessments will be identified from the available sources and then one will be selected according to the criteria described below for cancer and noncancer health reference level (HRL) derivation (See B.6.1.1 for additional information on HRLs).

B.5.1.1 Health Assessment Identification for Chemicals

In making a regulatory determination for a contaminant, SDWA requires that the Agency assess whether the contaminant “may have an adverse effect on the health of persons.” The Agency relies on EPA health assessments and externally peer-reviewed health assessments from other authoritative sources to determine if, how, and at what level a contaminant “may have an adverse effect on the health of persons.”

In order to identify qualifying health effects assessments, the EPA conducts a systematic search for EPA and other authoritative sources of human health effects assessments for each drinking water chemical contaminant on CCL 5. For RD 5, the timeframe of the search was January 2023. Section 2.4 in Chapter 2 of this support document describes the EPA’s approach for identifying health effects assessments from each of the sources described below. Health effects assessments are considered qualifying if they (1) derived one or more toxicity values (e.g., oral reference value or cancer slope factor (CSF)) based on the best available science; (2) underwent a documented peer-review process; (3) are publicly available and final; (4) were developed using human health risk assessments methods that are comparable to current EPA human health risk assessment principles and approaches (e.g., a weight of evidence approach); and (5) are produced from an authoritative body that routinely develops health effects assessments (e.g., the Agency for Toxic Substances and Disease Registry (ATSDR)). Recognizing that health assessment methodologies vary across sources, Section 2.4 in Chapter 2 transparently describes the differences that were identified.

For currently registered pesticide chemicals, the EPA will use the following source of assessments under RD 5:

- EPA Office of Pesticide Programs (OPP) Reregistration Eligibility Decisions (REDs), Health Effects Division Human Health Risk Assessments (HED HHRAs) (available at: <https://ordspub.epa.gov/ords/pesticides/f?p=chemicalsearch:1>)

For all other chemicals, sources of qualifying assessments include the following EPA program offices and other authoritative national, international and state programs:

- EPA Office of Pesticide Programs (OPP) Reregistration Eligibility Decisions (REDs), Health Effects Division (HED) Human Health Risk Assessments (HHRAs) (available at: <https://ordspub.epa.gov/ords/pesticides/f?p=chemicalsearch:1>)
- EPA Office of Pollution Prevention and Toxics (OPPT) Toxic Substances Control Act (TSCA) Risk Evaluations (available at: <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under>)
- EPA Office of Research and Development (ORD) Integrated Risk Information System (IRIS) Assessments (available at: <http://www.epa.gov/iris/>)
- EPA ORD Provisional Peer-Reviewed Toxicity Values (PPRTVs) (available at: <https://www.epa.gov/pprtv/provisional-peer-reviewed-toxicity-values-pprtvs-assessments>)

- EPA Office of Water (OW) Health Assessments: Drinking Water Standards and Health Advisory Documents, Health Effects Support Documents (HESDs) (available at: <https://www.epa.gov/sdwa/drinking-water-contaminant-human-health-effects-information#hh1>)
- Centers for Disease Control and Prevention’s (CDC) Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profiles (available at: <https://www.atsdr.cdc.gov/toxprofiledocs/index.html>)
- World Health Organization (WHO) Guidelines for Drinking Water Quality (GDWQ) (available at: <https://www.who.int/teams/environment-climate-change-and-health/water-sanitation-and-health/chemical-hazards-in-drinking-water>)
- Health Canada Guidelines for Canadian Drinking Water Quality (available at: https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/water-quality.html#tech_doc)
- European Food Safety Authority (EFSA) publications peer-reviewed by a scientific panel (available at: https://www.efsa.europa.eu/en/publications?sort=computed_sort_date&order=desc)
- California Environmental Protection Agency (CalEPA) Public Health Goals (PHGs) (available at: <https://oehha.ca.gov/water/public-health-goals-phgs>)

B.5.1.2 Health Assessment Selection for Chemicals

After identifying all of the qualifying peer-reviewed health effects assessments for a chemical, the EPA follows a structured and transparent process to select the assessment(s) for both cancer and noncancer HRL derivation. The systematic approach described herein builds in transparency and flexibility to select a drinking water relevant assessment based on the best available science.

For currently registered pesticide chemicals, toxicity information from HED HHRAs are used as the basis of HRL derivation. These HED HHRAs are a component of EPA OPP risk assessments, which are used to make safety determinations for pesticides. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires all pesticides sold or distributed in the United States (including imported pesticides) to be registered by the EPA (for more information about EPA pesticide registration see USEPA, 2023b). Pesticide registrations, reregistration decisions, and registration review decisions are based on final OPP risk assessments, which evaluate the most current and best available scientific data and assess the current risks (USEPA, 2023b). As a component of the OPP risk assessment, an HED HHRA may be a stand-alone document or part of a larger, more encompassing document referred to as Reregistration Eligibility Decision (RED). In either case, HED HHRAs undergo peer review by scientific experts prior to publication in the *Federal Register* (USEPA, 2023b). It is important to note that although some HED HHRAs are labeled “draft,” these assessments are considered final at the time of publication in the *Federal Register*. HED HHRAs can be updated at any time based on the availability of new scientific information. For RD 5, OW coordinates with OPP to ensure the most recent HED HHRA that is the basis of the current pesticide registration decision is selected.

For industrial contaminants regulated under TSCA, a final EPA OPPT Risk Evaluation is selected as the health assessment source for HRL derivation when the assessment is relevant to the drinking water pathway and is based on the best available science.

For all other chemical contaminants, including industrial chemicals without a recent final TSCA risk evaluation and pesticide chemicals with uses no longer registered under FIFRA, the

EPA follows a systematic process to select a health assessment for HRL derivation from among the qualifying assessments identified. The EPA considers a number of factors when evaluating qualifying health assessments. First, the publication date is used to identify the most recently published health assessment for a chemical, as the recency of an assessment is an indication that it may incorporate the best available science. Second, the EPA considers whether the health assessments were developed using human health risk assessment methods that are consistent with current EPA practice (e.g., use of benchmark dose modeling and application of systematic review methods (USEPA, 2022c)). Finally, the EPA uses professional judgment to evaluate whether assessments use the best available science (e.g., a most recent critical study) and to evaluate their relevance to the drinking water pathway. The EPA applies expert judgement when evaluating a set of assessments for a given contaminant because certain health assessments and chemicals can present unique challenges.

The EPA uses the following decision logic when selecting a health assessment among all qualifying assessments to derive an HRL.

The EPA selects an EPA health assessment if *any* of the following conditions are met:

- 1) An EPA assessment is the only available source of a toxicity value.
- 2) An EPA assessment is the most current source of a toxicity value.
- 3) The toxicity value from a more current toxicological assessment from a source other than EPA is based on the same critical study and is numerically the same as an older EPA toxicity value (i.e., both assessments use the best available science).
- 4) A more current toxicological assessment from a source other than the EPA is available, but it does *not* derive a toxicity value relevant to the drinking water pathway (subchronic or chronic-duration oral reference dose (RfD) or CSF).
- 5) A more current toxicological assessment from a source other than the EPA is available, but it does *not* introduce newer, better science (e.g., the toxicity value is not based on a newer critical study) or use a modeling approach based on the best available science compared to an older EPA toxicological assessment (e.g., used a no-observed-adverse-effect level (NOAEL) / lowest-observed-adverse-effect level (LOAEL) approach when the EPA assessment used benchmark dose (BMD) modeling).

The EPA selects the toxicity value from a qualifying available source other than the EPA (see Section B.5.1.1) if *any* of the following conditions are met:

- 1) A toxicological assessment from a source other than the EPA is the only available one.
- 2) A more recent toxicological assessment from a source other than the EPA introduces the best available science (e.g., the toxicity value was based on a newer, better critical study) or uses a more current modeling approach compared to an older EPA toxicological assessment.

In summary, the EPA selects the health effects assessment for HRL derivation for a chemical based on expert evaluation of a number of factors, described above. These factors are designed to identify the drinking water relevant assessment that was developed using comparable approaches to EPA human health risk assessment methods and based on the best available science.

B.5.1.3 Health Assessment Identification and Selection for Microbes

The procedure for identifying and selecting health assessments for microbes is largely the same as that described above for chemicals. There are two key differences.

First, HRLs are not calculated for microbes, so microbial health assessments are evaluated not for their suitability to derive HRLs (via the presence of appropriate RfDs or CSFs) but more generally for their suitability to support qualitative and quantitative health risk assessment associated with drinking water exposure. Sources of qualifying health assessments for microbial contaminants include EPA program offices, national and international programs, and state programs.

Second, a different set of EPA reports is used to evaluate candidate health assessments for their conformity to current Agency practices. Current EPA guidelines for microbial health assessment are laid out in the following documents:

- *Microbial Risk Assessment Guideline: Pathogenic Microorganisms with Focus on Food and Water* (USEPA 2012b)
- *Microbiological Risk Assessment (MRA) Tools, Methods, and Approaches for Water Media* (USEPA 2014d)

Qualifying health assessments for microbes must still be produced from an authoritative body and meet the other standards laid out above for chemicals. If more than one qualifying health assessment is available for a microbe, the same general principles described above are used to select one EPA or non-EPA assessment.

The following sources will be examined for qualifying assessments of microbial health risks under RD 5:

- EPA Assessments:
 - Office of Water (OW) Health Advisories (<https://www.epa.gov/sdwa/drinking-water-health-advisories-has>)
 - OW human health criteria documents
- Health Canada Guidelines for Canadian Drinking Water Quality
- WHO Guidelines for Drinking Water-Quality (GDWQ)
- State assessments

EPA Health Advisories (HAs) provide information on the occurrence and exposure, health effects, analytical methods, and treatment technology for particular drinking water contaminants. While for chemical contaminants, HAs identify the concentration thresholds in drinking water below which adverse health effects are not anticipated to occur over specific exposure durations (e.g., one-day, ten-days, and a lifetime), this is not the case for microbial contaminants.

EPA human health criteria documents for microbial contaminants provide the state of science at the time written, addressing such things as the microbial contaminant's health effects, occurrence, exposure route, disease transmission, outbreaks, water treatment options.

Health Canada's Water Bureau develops non-regulatory Guideline documents for drinking water quality in partnership with their provinces, territories and other federal departments. Health Canada's Guidelines are comparable to the EPA's Health Advisories, in that they are based on a comprehensive review of the known health effects associated with each

contaminant, plus exposure levels and the availability of treatment and analytical technologies. In some cases, Health Canada's Guidelines for pathogenic microbes include quantitative microbial risk assessment (QMRA), with results expressed in terms of concentration (or log removal) associated with an acceptable risk threshold expressed in units of disability-adjusted life years (DALYs) per person per year of exposure.

The WHO issues Guidelines for Drinking Water Quality (GDWQ) that are intended to be used as a basis for the development of national and regional standards. For microbes, WHO typically provides a synthesis of available information on topics such as taxonomy and life cycle, health significance, sources, occurrence, and prevention and management, but does not provide a numerical guideline value. WHO's current edition of the Guidelines (WHO, 2022) discusses QMRA methodology and offers a few cursory examples for illustration, but does not apply this methodology systematically to all reviewed microbial pathogens.

B.5.2 Occurrence Data Availability Assessment

In making a regulatory determination, SDWA requires that the Agency assess whether the contaminant "is known to occur or there is substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern." When addressing this criterion, the Agency gives preference to nationally representative finished drinking water occurrence data, and also evaluates other sources of finished water data. Finished water is water that has undergone any applicable treatment and is ready for distribution to customers. Nationally representative finished water occurrence data are data that can be used to infer the extent of occurrence of a contaminant in PWSs across the nation with reasonable confidence. Factors that contribute to determining whether a finished water occurrence data source is nationally representative include: the number of PWSs represented in the data set, the geographic or spatial distribution of those PWSs and distribution of those PWSs among PWS sizes and types, and the selection of PWSs for inclusion using a statistically representative approach.

The steps for this assessment will involve answering the following two questions:

- Are nationally representative finished water occurrence data available?
- Are non-nationally-representative finished water occurrence data available that show occurrence at levels of potential public health concern?

If the answer to either question is "yes," the contaminant passes the Occurrence Data Availability Assessment.

B.5.2.1 Nationally Representative Finished Water Occurrence Data

Nationally representative data sets will be the primary source of the drinking water occurrence data used by the Agency to evaluate whether or not a contaminant is "known to occur" in PWSs with a frequency and at levels of public health concern. If a contaminant has data available from at least one of the following data sources, which are administered or overseen by the EPA, then it has nationally representative drinking water occurrence data:

- Fourth Unregulated Contaminant Monitoring Rule (UCMR 4) – Assessment Monitoring or Screening Survey.
- Third Unregulated Contaminant Monitoring Rule (UCMR 3) – Assessment Monitoring or Screening Survey.

- Second Unregulated Contaminant Monitoring Rule (UCMR 2) – Assessment Monitoring or Screening Survey.
- First Unregulated Contaminant Monitoring Rule (UCMR 1) – Assessment Monitoring.
- Unregulated Contaminant Monitoring (UCM) program.
- National Inorganics and Radionuclides Survey (NIRS).

These data sources will be described in the Regulatory Determination 5 Support Document.

If a contaminant has nationally representative data, it passes the Occurrence Data Availability Assessment. If it does not, the EPA will evaluate whether pertinent non-nationally-representative data are available, as described below.

B.5.2.2 Non-Nationally-Representative Finished Water Occurrence Data that Show Occurrence at Levels of Public Health Concern

If nationally representative occurrence data are not available, the EPA will evaluate additional sources of finished water data. Source of non-nationally-representative finished water data may include:

- Finished water assessments by federal agencies (e.g., the EPA and the United States Geological Survey). These may be assessments that are geographically distributed across the nation but not intended to be statistically representative of the nation. Examples include the UCMR 1 Screening Survey and the 1996 Monitoring Requirements for Public Drinking Water Supplies, also known as the Information Collection Rule. Finished water monitoring data reported under the in-progress fifth Unregulated Contaminant Monitoring Rule (UCMR 5) may also be considered.
- State-level finished water monitoring data.
- Research performed by institutions, universities, and government scientists (e.g., information published in the scientific literature).
- Other supplemental finished water monitoring surveys (e.g., Pesticide Monitoring Program (PMP) and other targeted surveys or localized state/federal monitoring surveys).

Non-nationally-representative data may be sufficient to evaluate the statutory criteria and support regulatory determination in some cases. It is difficult to determine that a contaminant is *not occurring or not likely to occur* based on single studies or evaluations containing non-nationally-representative data because the data are limited in scope and the contaminant could be occurring at water systems of other types or in other locations. However, a compilation of non-nationally-representative data sources can support a determination that there *is* a “substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern.” Therefore, a contaminant without nationally representative finished water occurrence data will be evaluated further to determine whether there is documented occurrence in finished water at a level of public health concern. The purpose of this step is to avoid ruling out any contaminants too early in the process that may have occurrence at levels of public health concern in finished water.

The Agency will assess whether non-nationally-representative finished water occurrence data show at least one detection in finished water at levels $> \frac{1}{2}$ the HRL for the critical

endpoint.⁴ If a contaminant has such finished water occurrence data showing at least one detection $> \frac{1}{2}$ HRL, the contaminant passes the Occurrence Data Availability Assessment. Note that only chemical contaminants have HRLs, so this assessment of non-nationally-representative finished water occurrence data in Phase 1 is only undertaken for RD 5 chemical contaminants, not RD 5 microbial contaminants.

B.5.3 Analytical Methods Availability Assessment

In certain limited cases, a contaminant's occurrence data may have been gathered using a specialized or experimental method that is not in general use. If a widely available analytical method does not exist, the contaminant will not be a viable candidate for regulation with a Maximum Contaminant Level (MCL). With that in mind, in the Analytical Methods Availability Assessment the EPA will determine for each contaminant whether a widely available analytical method for drinking water monitoring exists. (A widely available analytical method is a method employing technology that is commonly in use at numerous drinking water laboratories.) If a widely available analytical method exists, the contaminant passes the Analytical Methods Availability Assessment. If a widely available analytical method does not exist, the EPA may advance the contaminant to Phase 2 if the Agency determines that indicator or surrogate monitoring, or use of a treatment technique (TT), could allow for effective regulation and there is compelling evidence of occurrence.

B.5.4 Evaluation of Outcomes of Health Data, Occurrence Data, and Analytical Methods Availability Assessments

Based on the three outcomes of the three assessments, the contaminants will be binned as shown in Exhibit B-6:

⁴ Use of the $\frac{1}{2}$ HRL threshold in RD efforts is based on a recommendation from the National Drinking Water Advisory Council (NDWAC) working grouping that provided recommendations on the RD 1 effort (USEPA, 2000). An explanation of HRL derivation is provided in the description of Phase 2, below. Although HRL derivation formally belongs to Phase 2 of the protocol, the evaluation of Group B chemical contaminants under in this step of Phase 1 cannot be completed until HRLs have been established for the affected contaminants. In practice, work performed on different Phases sometimes overlaps.

Exhibit B-6: Binning Scheme for the Fifth Contaminant Candidate List (CCL 5) Contaminants Based on Phase 1 Data Availability Assessments

Analytical Methods Availability Assessment: <i>Does a widely available analytical method for drinking water monitoring exist?</i>	Occurrence Data Availability Assessment: <i>Are nationally representative finished water occurrence data available?</i>	Health Data Availability Assessment: <i>Is a qualifying health assessment available?</i>	
		Yes	No
Yes	Yes	Group A	Group C
	No, but other finished water occurrence data are available	Group B	Group D
	No finished water data are available	Group E	Group F
No		Group G	

The alphabetical ordering and color-coding give a sense of the relative priority of the seven groups into which the contaminants are binned. Contaminants in Group A, receiving a “yes” to all three assessments, are in the best position for a possible regulatory determination. Contaminants in Group B, though they lack nationally representative occurrence data, could still be evaluated for suitability as candidates for possible positive determinations using other data sources demonstrating occurrence in finished water. Contaminants in Groups C and D need only a qualifying health assessment to be shifted to Group A or B in a future cycle; these contaminants can be prioritized for health effects research. Contaminants in Groups E and F (lacking finished water data of any kind) and Group G (lacking a widely available analytical method) have other kinds of research needs; they could be prioritized for methods development, occurrence monitoring, etc., for higher prioritization in future cycles.

Based on the binning, the EPA will identify a “short list” of contaminants to proceed to Phase 2, the *Data Evaluation Phase*. The short list will include all the contaminants in Group A, plus those chemical contaminants from Group B that have at least one documented instance of occurrence at levels $> \frac{1}{2}$ HRL in finished water. Evaluating the Group B chemical contaminants to determine whether they belong on the short list will require a comprehensive review of available (non-nationally-representative) sources of finished water occurrence data for those contaminants. See Exhibit B-7.

Exhibit B-7: Determining Phase 1 Outcomes

Bin		Phase 1 Outcome
Group A		Include on “short list”
Group B	Having documented occurrence > ½ HRL (applicable to chemicals only)	
	Having no documented occurrence > ½ HRL	
Groups C-G		Do not include on “short list”

Contaminants that do not proceed to Phase 2 will be recognized as having information gaps by the EPA. Actions that the EPA and partners can take towards filling information gaps include listing contaminants on the next round of UCMR, developing analytical methods, and conducting health assessments. The binning of contaminants into groups, as outlined above, can help with organizing and prioritizing efforts to fill data gaps.

B.6 Phase 2: Data Evaluation

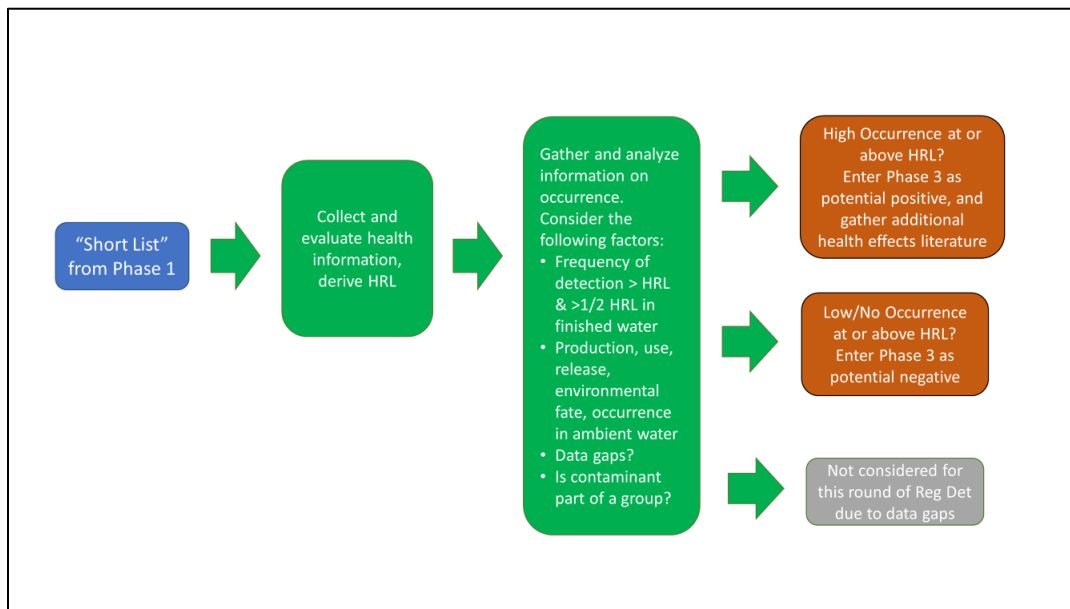
The Regulatory Determination “short list” is a list of contaminants that have been identified in Phase 1 as having sufficient data to warrant an expanded assessment. The purpose of Phase 2 is to undertake the following for the “short list” contaminants:

- (1) Collect and evaluate health information and derive an HRL.
- (2) Gather additional data on occurrence in finished and ambient water and related data (e.g., on production, use, release, and environmental fate and transport) and evaluate occurrence data relative to the HRL.
- (3) Identify contaminants occurring with levels and frequencies of public health concern. These will become “potential positive regulatory determinations.”
- (4) Identify contaminants that are occurring with levels and frequencies with no or low potential for public health concern. These will become “potential negative regulatory determinations.”
- (5) Identify contaminants that do not proceed to Phase 3 because they have data gaps to be addressed.

The steps involved in the *Data Evaluation Phase* are described in the sections that follow. Note that the Agency does not have a rigid threshold for health or occurrence values that trigger a finding that a contaminant or group is or is not of public health concern. There are a number of factors to consider in evaluating a potential public health concern, including the critical health effect(s), the potency of a contaminant, the concentrations at which the contaminant is occurring in finished water and ambient or source water, how frequently the contaminant is found, the geographic distribution (national, regional, or local occurrence), patterns of industrial or agricultural usage and release, other possible sources of exposure, and potential impacts on sensitive populations or life stages. Given the many possible combinations of factors and the constantly evolving science, the EPA believes it is best to study contaminants in depth and present the best available information that helps determine whether the occurrence

of a contaminant or group is of public health concern. See Exhibit B-8 for an overview of Phase 2.

Exhibit B-8: Regulatory Determination 5 Phase 2 Flowchart



B.6.1 Phase 2--Step 1: Collect and Evaluate Health Information, Derive Health Reference Level (HRL)

B.6.1.1 Approach For Deriving HRLs

Health reference levels (HRLs) are non-regulatory health-based toxicity values expressed as concentrations of a chemical in drinking water that are used by the Agency to evaluate occurrence data for a chemical when making decisions about regulatory determinations. The HRL is not equivalent to an MCLG derived during the development of NPDWRs. Unlike an MCLG, an HRL is derived prior to development of a complete health and exposure assessment for a drinking water chemical contaminant and can be considered a screening value. Additionally, for HRL derivation, the one-in-a-million (10^{-6}) cancer risk level (CRL) is calculated for carcinogens.

HRLs are typically derived from chronic oral toxicity values (e.g., RfD, population-adjusted dose or PAD, CSF) extracted from qualifying final health assessments (see Section B.5.1.2 for more information on assessment selection). In certain instances, the EPA considers toxicity values derived for shorter exposure durations (e.g., acute, subchronic) for HRL derivation. For example, a short duration exposure critical study can be the basis of a chronic toxicity value if the exposure occurred only during development because short term exposures during development can lead to life-long impacts (USEPA, 1991).

There are two general approaches to the derivation of an HRL. One approach is used for chemicals with a threshold dose-response. For noncancer effects and non-linear carcinogens, HRLs are obtained by dividing the RfD (or equivalent, such as an ATSDR Minimal Risk Level)

by an exposure factor, or EF (i.e., drinking water intake rate adjusted for body weight, or DWI-BW) relevant to the target population and critical effect (USEPA, 2019) and multiplying by a 20 percent relative source contribution (RSC) to account for non-water sources of exposure (USEPA, 2000). To inform Regulatory Determination, a 20 percent RSC is used for HRL derivation because (1) HRLs are developed prior to a complete exposure assessment, and (2) 20 percent is the lowest and most health protective RSC used according to Agency guidance (USEPA, 2000).

HRLs for contaminants with a threshold dose-response (typically non-cancer endpoints) are calculated as follows:

$$HRL = \frac{RfD}{DWI-BW} * RSC$$

The second general approach is used for chemicals that exhibit a linear, non-threshold response to dose as is typical of carcinogens. For this approach, the HRL is calculated for one-in-a-million (10^{-6}) cancer risk expressed as a drinking water concentration.

HRLs for contaminants with a linear dose-response (typically cancer endpoints) are calculated as follows:

$$HRL = \frac{CRL}{CSF * DWI-BW}$$

In this second approach, when a carcinogen with a linear dose-response has a known mutagenic mode of action (MOA), the EPA follows the Cancer Guidelines (USEPA, 2005b) when deriving HRLs. For carcinogens with a mutagenic MOA, the 2005 Cancer Guidelines require consideration of increased risk due to early-life exposure. When chemical-specific data to quantify the increased risk from developmental exposure are lacking, Age Dependent Adjustment Factors (ADAFs) are applied. The recommended ADAFs are a 10-fold adjustment for exposure during the interval from birth to <2 years (infant and toddler); a 3-fold adjustment for exposure from 2 to < 16 years (childhood and adolescence); and no additional adjustment for exposures for 16 years to 70 years of age. In cases where the MOA cannot be determined, the default low-dose linear extrapolation approach without ADAFs (described above) is used.

Using a calculator that the EPA developed in Excel, HRLs for carcinogenic contaminants with a known mutagenic mode of action are calculated as follows:

$$HRL = \frac{CRL}{\sum_i (CSF * ADAF_i * DWI-BW_i * UA * F_i)}$$

The following terms are used in these equations:

HRL = Health reference level (mg/L), a non-regulatory health-based drinking water concentration level of a specific contaminant at or below which is not anticipated to lead

to adverse human health effects. Consistent with HRL development for previous regulatory determinations, HRLs derived for RD 5 are rounded to one significant figure.

RfD = Reference dose (mg/kg/day), an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure of the human population to a substance that is likely to be without an appreciable risk of deleterious effects during a lifetime. The value of this parameter is derived in the selected qualifying health assessment and is based on the critical effect and study identified in that assessment. An RfD is considered an oral reference value for RD 5. Other values that can be used in place of an RfD in this equation can include a maximum acceptable concentration (MAC), minimal risk level, point of departure / uncertainty factor (POD/UF), population-adjusted dose (PAD), or tolerable daily intake (TDI).

DWI-BW_i = Drinking water intake (DWI), adjusted for body weight (BW), in units of liter per kilogram body weight per day (L/kg/day) for each age group (i).

RSC = Relative source contribution, the percentage of the total exposure attributed to drinking water sources (USEPA, 2000), where the remainder of the exposure is allocated to other routes or sources.

CSF = Cancer slope factor (mg/kg/day)⁻¹, an upper-bound estimate of risk per increment of dose that can be used to estimate cancer risk probabilities for different exposure levels (USEPA, 2005b).

CRL = Cancer risk level, one excess cancer case in a population of one million (1 x 10⁻⁶).

ADAF_i = the age-dependent adjustment factor for each age group (i), used when calculating cancer risk concentrations for carcinogens that act via a mutagenic mode of action; by default, ADAF = 10 from birth to two years of age, ADAF = 3 from two to sixteen years of age, and ADAF = 1 from 16 to 70 years of age (USEPA, 2005b).

UA = Unit adjustment factor, needed to convert the dose (i.e., the CSF) from mg of a chemical to µg of the chemical. This ensures the ADAF-adjusted Unit Risk is in µg/L. The UA is not needed if the CSF is presented in (µg/kg/day)⁻¹ or if the desired units of the ADAF-adjusted concentration (i.e., the HRL) is mg/L. A different adjustment factor is needed for other units.

F_i = the fraction of life spent in each age group (i), used when calculating cancer risk concentrations for mutagens (USEPA, 2005b).

In some cases, the health assessments identified for HRL derivation provide both cancer and non-cancer toxicity values (e.g., an oral reference value and oral CSF). When this situation occurs, the EPA selects two health assessments according to the criteria above and derives both a noncancer HRL and a cancer HRL based on noncancer and cancer health effects information,

respectively, and then selects the more health protective of the two (i.e., the lower value) to serve as the final HRL (USEPA, 2000).

B.6.1.2 Exposure Factor Selection Process for HRL Derivation

In prioritizing the contaminants of greatest public health concern for regulatory determination, Section 1412(b)(1)(C) of SDWA requires the Agency to consider “among other factors of public health concern, the effect of such contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water compared to the general population.” It is also the EPA’s policy to “protect children from environmental exposures by consistently and explicitly considering early life exposures and lifelong health in human health decisions” (USEPA, 2021c). One way that the EPA considers potentially sensitive populations or life stages (i.e., populations or life stages that may be more susceptible or sensitive to a chemical exposure) is through the selection of exposure factors (EFs) for HRL derivation.

EFs are factors related to human activity patterns, behavior, and characteristics that help determine an individual’s exposure to a contaminant. An example of an EF is the body-weight-adjusted drinking water intake (DWI-BW), which is, as mentioned above, used for deriving an HRL. The EPA’s *Exposure Factors Handbook* (EFH)⁵ is the primary resource used for conducting exposure assessments for HRL development as part of Regulatory Determinations. The EFH provides EFs based on information from publicly available, peer-reviewed studies. The most recently updated EFs for drinking water intake for various populations or life stages within the general population are in the 2019 Chapter 3 of the EFH (USEPA, 2019). The inclusion of the DWI-BW in the HRL calculation is intended to protect sensitive populations within the general population from adverse effects resulting from exposure to contaminants. The greater the DWI-BW, the lower the HRL. The following sections describe EF selection approaches for deriving HRLs as part of RD 5 for: (1) non-mutagenic carcinogens and chemicals exhibiting a threshold response; and (2) mutagenic carcinogens.

B.6.1.2.1 Exposure Factor Selection for Non-Mutagenic Carcinogens and Chemicals Exhibiting a Threshold Response

The Agency selects an appropriate DWI-BW for each chemical by reviewing the critical effect and study used for HRL derivation and identifying the interval of exposure (for examples, see USEPA, 2022d; USEPA 2022e). The critical effect used as the basis for the RfD or CSF typically represents the health outcome at the lowest dose associated with an adverse outcome from the critical study among the best available studies. Since the critical effect typically represents the most sensitive adverse effect observed based on the available published data for a given chemical, it is reasonable to assume that the interval of exposure in the critical study could inform the selection of a DWI-BW protective of sensitive populations. Therefore, the EPA uses the interval of exposure in the critical study to identify potentially sensitive life stages as the basis for EF selection. When multiple potentially sensitive populations or life stages are identified based on the interval of exposure in the study used for HRL derivation, the EPA

⁵ The EFH is available at <https://www.epa.gov/expobox/about-exposure-factors-handbook>. The latest edition of the EFH was released in 2011, but since October 2017 the EPA has begun to release chapter updates individually.

selects the population or life stage with the highest DWI-BW because it is the most health protective. Different procedures are followed depending on whether the critical study is an epidemiological study or an animal study.

a) Critical study is an epidemiological study:

For human epidemiological data, the steps for selecting EFs include: (1) reviewing the critical study to identify the exposure interval; (2) selecting candidate EFs that correspond to or overlap with the interval of exposure; and (3) selecting the most health protective EF among the candidates. In most cases, the EPA selects the corresponding EFs for each sensitive population or life stage from Chapter 3 of the EFH for use in HRL derivation (USEPA, 2019). Sometimes the EPA uses values found in the Joint Institute for Food Safety and Applied Nutrition's Food Commodity Intake Database (FCID) Consumption Calculator tool, which utilizes the same underlying data as the EPA's EFH but offers information for specific populations, life stages, or age ranges beyond those reported in the EFH (JIFSAN, 2023). The EPA uses the 90th percentile two-day average, consumer-only DWI-BW to ensure that the HRL is protective of the general population as well as sensitive populations or life stages (USEPA, 2000; USEPA, 2019).

For example, for methomyl, the critical effect described in the critical study (McFarlane et al. 1998) is increased peak red blood cell acetylcholinesterase inhibition in five healthy male volunteers ages 18–40 years (USEPA, 2018). In this case, only one sensitive population is identified; therefore, the EPA uses the FCID Consumption Calculator Tool to select the DWI-BW for adult males ages 18 to <41 years (viz., 0.0312 L/kg_{bw}/day).

b) Critical effect is from an animal study:

The majority of the critical studies used to derive HRLs under RD 5 were conducted in animals, specifically rodents (i.e., mice or rats). The EPA recognizes that extrapolating exposure intervals from animals to humans is not a direct comparison and is dependent on factors like the species, strain, and affected organ system, which introduces uncertainty (Ghasemi et al., 2021). EPA's approach for selecting an exposure factor for chemical contaminants where the toxicity endpoint was based on rodent studies requires approximating the corresponding human age ranges from rodent study exposure intervals based on the available information on rodent to human life stages (Ghasemi et al., 2021; Wang et al., 2020). While the available data provides some information to identify the corresponding ages and life stages across rodents and humans, there is uncertainty in extrapolating from rodent ages. Further, the estimate will be more imprecise when the interval of exposure in rodents is short in duration.

Due to the uncertainties and limitations on available data on postnatal developmental life stage comparisons between rodents and humans, the EPA has made the decision to select one of two postnatal developmental intervals, either birth to <1 year (infancy) or birth to <21 years (all of postnatal childhood), as reasonable EF options (see Exhibit B-9 and examples below) (USEPA, 2019).

- Based on the available data, the interval of exposure from birth through 3 weeks in rodent (rat or mouse) studies corresponds approximately to birth to <1 year in

humans. The EPA selected the 0–3-week cutoff for this exposure interval because two recent publications both conclude that rats and mice from birth through 3 weeks old are in the growth stage between birth and weaning and likely represents neonatal and infancy life stages in humans (Ghasemi et al., 2021; Wang et al., 2020). For critical studies with rodent exposure between birth and 3 weeks, the EPA selected the DWI-BW for infants from birth to <1 year from Chapter 3 of the EFH (viz., 0.143 L/kg_{bw}/day, found in Table 3-21), representing the consumers-only two-day average of direct and indirect community water consumption at the 90th percentile, based on the EPA's analysis of 2005-2010 (National Health and Nutrition Examination Survey (NHANES) data (USEPA 2019).

The EPA recognizes that formula-fed infants in the age range of 1 to <3 months ingest more drinking water (via reconstituted infant formula) and that their DWI-BW is greater (viz, 0.249 L/kg_{bw}/day) (Kahn, 2013) compared to the more general category of infants from birth to <1 year (USEPA, 2019). However, EPA selected infants from birth to <1 year because results for this category are based on more statistically robust data, as indicated by the EFH (USEPA, 2019). Specifically, the DWI-BW for infants from birth to <1 year is based on a greater sample size (n = 374) than that for the formula fed infants (n = 90), and it is also based on more recent NHANES data (2005-2010) than the data used for formula-fed infants (viz., 1994–1996 and 1998 Continuing Survey of Food Intakes by Individuals (CSFII)). For these reasons, the EPA selected infants from birth to <1 year for the infant EF.

- EPA considers a critical effect observed in the rodent fetus, when the exposure interval from a rodent study was during gestation only, to correspond approximately with two female life stages associated with pregnancy:
 - females of reproductive age (13 to < 50 years) who may be or become pregnant; and
 - pregnant women, which includes exposure to the developing embryo and fetus.

For critical studies exposed during gestation, EPA considers these candidate lifestages and then selects the most health protective (or greater) DWI-BW. In this case, the DWI-BW for females of reproductive age (0.0354 L/kg_{bw}/day) is more health protective (i.e., greater) than that for pregnant women (0.0333 L/kg_{bw}-day) (USEPA, 2019). Therefore, for rodent studies with a critical effect involving gestational exposure, the EPA uses the DWI-BW for females of reproductive age.

- The EPA considers a critical effect observed in rodent offspring after exposure of the dam to the chemical from the time of pregnancy/gestation through to lactation or early post-natal development (i.e., through three weeks of age; see above for rationale) to correspond with the following human life stages:
 - females of reproductive age (13 to < 50 years) who may be or become pregnant;
 - pregnant women, which includes exposure to the embryo and fetus; and
 - infants (birth to <1 year).

In this case, the EPA selects infants (birth to <1 year) as the sensitive life stage for HRL derivation because the DWI-BW for this life stage (0.143 L/kg_{bw}/day) is

more health protective than that for females of reproductive age (0.0354 L/kg_{bw}/day) or pregnant women (0.0333 L/kg_{bw}/day) (USEPA, 2019), and also because the critical effect is observed in the offspring itself, not the dam.

- When the critical effect is observed in the adult female (i.e., the rodent dam) after exposure from pregnancy through lactation, the three potential corresponding human life stages are:
 - females of reproductive age (13 to < 50 years) who may be or become pregnant;
 - pregnant women, which includes exposure to the developing embryo and fetus; and
 - lactating women.

In this case, the EPA selected lactating women as the sensitive life stage for HRL derivation because the DWI-BW for this life stage is the most health protective (0.0469 L/kg_{bw}/day) (USEPA, 2019).

- When the critical effect is observed in adult rodents, but the exposure began during postnatal development, specifically during the age range of 4 to 10 weeks, the EPA considers the potential corresponding human age group to be birth to <21 years. Various studies indicate that rats and mice at 4-10 weeks old are in the growth stage corresponding to juvenile/childhood and adolescence in humans (Ghasemi et al., 2021; Wang et al., 2020). The EPA selected birth to <21 years because the EPA defines childhood in humans as the period from conception, infancy, and early childhood through adolescence, until 21 years of age (USEPA, 2021c). Further, it is difficult to determine exactly when rodents transition to adolescence and adulthood (Ghasemi et al., 2021; Wang et al., 2020). The selected age range, children from birth to <21 years, has a DWI-BW of 0.0343 L/kg_{bw}/day (JIFSAN, 2023; USEPA, 2019).
- When the critical study assesses an effect in adult rodents, but the exposure began after postnatal development, specifically beginning at 10 weeks or older, or if the critical study reports that exposure was exclusively in adults, then the EPA considers the potential corresponding human age range to be adults 21 years and older. Although windows of development can vary by species and strain, various rat and mouse studies describe that adulthood begins at about 70 days (Ghasemi et al., 2021; Wang et al., 2020). The selected age range of adults 21 years and older has a DWI-BW of 0.0336 L/kg_{bw}/day (JIFSAN, 2023; USEPA, 2019).
- Finally, in cases where critical studies do not report the age of the experimental rodents when exposure/dosing began, the EPA makes the following assumptions based on other available data reported in the study to select the most appropriate EF:
 - When the rodent weight at the onset of exposure is reported, the EPA extrapolates weight to age based on conversion charts published for rats

(NCKU, 1998; Taconic Biosciences, 2023) and mice (Jackson Labs, 2023) and selects the appropriate EF based on the estimated age when exposure began.

- When the critical study only reports that rodents were “young” and it is a chronic/lifetime (i.e., 2-year) non-developmental study, the EPA assumes the rodents were weaned (>3 weeks of age). For the reasons described above regarding rodents aged 4-10 weeks (Ghasemi et al., 2021; Wang et al., 2020), the EPA applies the EF for children (i.e., birth to <21 years) (JIFSAN, 2023; USEPA, 2019).
- In rat or mouse studies reporting that dosing began at weaning or describing the rodents as “weanling” without providing their age, the EPA assumes that weaning occurred at ~3 weeks. While the age of weaning for rats and mice in toxicological studies varies (in the range of post-natal days 16-28), it is common to wean rats or mice at post-natal day 21 (3 weeks), as noted in Ghasemi et al. (2021). Based on the available information about corresponding human life stages, 3 week old rats and mice correspond to the infancy life stage in humans (Ghasemi et al., 2021; Wang et al., 2020). The EPA considers dosing that begins at ~3 weeks of age to correspond to the human infancy life stage and therefore applies the EF for infants (i.e., birth to <1 year).

Exhibit B-9: EPA Exposure Factors for Drinking Water Intake / Body Weight Applied in RD 5 HRLs for Chemical Contaminants with Rodent Toxicology Study-Based HRLs

Populations or Life Stages	DWI-BW (L/kg _{bw} /day)	Description of Exposure Metric	Source
Infants, birth to <1 year	0.143	90th percentile direct and indirect consumption of community water, consumer-only two-day average.	2019 <i>Exposure Factors Handbook</i> Chapter 3, Table 3-21, NHANES 2005–2010 (USEPA, 2019)
Children, birth to <21 years	0.0343	90th percentile direct and indirect consumption of community water, consumer-only two-day average.	JIFSAN (2023), corresponding to 2019 <i>Exposure Factors Handbook</i> Chapter 3, Table 3-21, NHANES 2005–2010 (USEPA, 2019)
Adults, 21 years and older	0.0336	90th percentile direct and indirect consumption of community water, consumer-only two-day average.	JIFSAN (2023), corresponding to 2019 <i>Exposure Factors Handbook</i> Chapter 3, Table 3-21, NHANES 2005–2010 (USEPA, 2019)
Females of reproductive age, 13 to < 50 years	0.0354	90th percentile direct and indirect consumption of community water, consumer-only two-day average.	2019 <i>Exposure Factors Handbook</i> Chapter 3, Table 3-63, NHANES 2005–2010 (USEPA, 2019)

Populations or Life Stages	DWI-BW (L/kg _{bw} /day)	Description of Exposure Metric	Source
Pregnant women	0.0333	90th percentile direct and indirect consumption of community water, consumer-only two-day average.	2019 <i>Exposure Factors Handbook</i> Chapter 3, Table 3-63, NHANES 2005–2010 (USEPA, 2019)
Lactating women	0.0469	90th percentile direct and indirect consumption of community water, consumer-only two-day average.	2019 <i>Exposure Factors Handbook</i> Chapter 3, Table 3-63, NHANES 2005–2010 (USEPA, 2019) ^a

Notes: L/kg_{bw}/day = liter per kilogram body weight per day.

^a These estimates are less statistically reliable. This determination in the EFH is based on guidance published in the *Joint Policy on Variance Estimation and Statistical Reporting Standards on NHANES III and CSFII Reports: Human Nutrition Information Service (HNIS)/National Center for Health Statistics (NCHS) Analytical Working Group Recommendations* (NCHS, 1993).

B.6.1.2.2 Exposure Factor Selection for Mutagenic Carcinogens

For mutagenic carcinogens, age-specific DWI-BW EFs that align with the ADAF age-groups (birth to <2 years; 2 to < 16 years; 16 to 70 years) are applied from Chapter 3 of the EFH (USEPA, 2019), as shown in Exhibit B-10 below.

Exhibit B-10: EPA Exposure Factors for Drinking Water Intake / Body Weight Applied in RD 5 HRLs for Mutagenic Carcinogens to Account for Early Life Susceptibility

Life Stages	DWI-BW (L/kg _{bw} /day)	Description of Exposure Metric	Source
ADAF age-group: birth to <2 years			
Birth to < 1 month	0.220 ^a	90th percentile direct and indirect consumption of community water, consumer-only two-day average.	2019 <i>Exposure Factors Handbook</i> Chapter 3, Table 3-21, NHANES 2005–2010 (USEPA, 2019)
1 to < 3 months	0.192 ^a		
3 to < 6 months	0.143 ^a		
6 to < 12 months	0.113		
1 to < 2 years	0.049		
ADAF age-group: 2 to <16 years			
2 to < 3 years	0.051	90th percentile direct and indirect consumption of	2019 <i>Exposure Factors Handbook</i> Chapter 3, Table 3-

Life Stages	DWI-BW (L/kg _{bw} /day)	Description of Exposure Metric	Source
		community water, consumer- only two-day average.	21, NHANES 2005–2010 (USEPA, 2019)
3 to < 6 years	0.039		
6 to < 11 years	0.031		
11 to < 16 years	0.025		
ADAF age-group: 16 to 70 years			
16 to < 18 years	0.024	90th percentile direct and indirect consumption of community water, consumer- only two-day average.	JIFSAN (2023), corresponding to 2019 <i>Exposure Factors Handbook</i> Chapter 3, Table 3- 21, NHANES 2005–2010 (USEPA, 2019)
18 to < 21 years	0.025		
21 to < 70 years	0.034		

Notes: L/kg_{bw}/day = liter per kilogram body weight per day.

^a These estimates are less statistically reliable. This determination is based on guidance published in the *Joint Policy on Variance Estimation and Statistical Reporting Standards on NHANES III and CSFII Reports: Human Nutrition Information Service (HNIS) / National Center for Health Statistics (NCHS) Analytical Working Group Recommendations* (NCHS, 1993).

B.6.2 Phase 2--Step 2: Gather and Evaluate Additional Occurrence Data Sources Relative to the HRL

In this step, the Agency compiles, analyzes, and evaluates all available information and data that shed light on occurrence and potential occurrence in the nation's drinking water. These data may include nationally representative and non-nationally-representative finished water occurrence data and ambient and source water occurrence data (evaluated relative to the HRL threshold, ½ the HRL, and the minimum reporting level or MRL), as well as data and information on production, use, release to the environment, and fate and transport. Analyses could include modeling to characterize the distribution of concentrations below the MRL (see Section B.7.2). This information will be used in steps 3 and 4 of Phase 2 (see B.6.3 and B.6.4), and also in Phase 3 if a contaminant proceeds to that phase.

B.6.3 Phase 2--Step 3: Identify Contaminants Occurring at Levels and Frequencies of Public Health Concern

In this step, the Agency will identify contaminants and groups occurring at levels and frequencies of public health concern that will proceed to Phase 3, the *Regulatory Determination Assessment Phase* for a potential positive determination. The candidate contaminants identified

in this step will be the highest priority for RD 5. The Agency will consider the following information when identifying these contaminants:

- How many samples (number and percent) have detections > HRL and > ½ HRL in nationally representative and other finished water occurrence data?
- How many systems (number and percent) have detections > HRL and > ½ HRL in nationally representative and other finished water occurrence data?
- Are there uncertainties or limitations with the data or analyses, involving (for example) the age of the dataset, analytical method limitations (i.e., MRL > HRL), or representativeness of the data (e.g., limited to a specific region) that may cause misestimation of occurrence in finished water at levels and frequency of public health concern? If the HRL is lower than detection or reporting limits, parametric statistical modeling techniques may be available that could estimate (with quantified uncertainty) occurrence at the level of the HRL.

B.6.4 Phase 2--Step 4: Identify Contaminants That Have No or Low Occurrence at Levels of Public Health Concern

After identifying contaminants that are occurring at levels and frequencies of public health concern (Section B.6.3), the Agency will evaluate the remaining contaminants on the short list to identify contaminants with no to low occurrence at levels of health concern that should proceed to Phase 3 for a potential negative determination. Because the primary goal of Regulatory Determination is to focus on contaminants of public health concern, potential negative determinations are a lower priority than potential positive determinations. The Agency will consider the following information in selecting contaminants of no or low potential for public health concern to proceed to Phase 3:

- Does the contaminant have nationally representative finished water data showing no or low number and percent of detections > HRL? (As noted above, while non-nationally-representative data showing high levels and frequency of occurrence can support a positive determination, nationally representative finished water data showing no or low occurrence is required to make a negative determination.)
- If a contaminant has other finished water data in addition to nationally representative finished water data, does it support no or low potential for occurrence in drinking water?
- Does additional occurrence information of high quality support low or no occurrence or potential for occurrence in drinking water? For example, is the occurrence in ambient/source water at levels below the HRL? How are releases to the environment or use/production changing over time?
- Are there minimal critical information/data gaps after evaluating the available health or occurrence data?

B.6.5 Phase 2--Step 5: Identify Contaminants that Do Not Proceed to Phase 3 and Have Information or Data Gaps to Be Addressed

Those contaminants and groups that do not proceed to Phase 3 (in steps 3 or 4 of Phase 2, described above) because of data gaps, and receive no regulatory determination, will be considered for the next CCL. These contaminants are recognized as having information gaps by the EPA. Other actions at the EPA can help fill information gaps (e.g., including a contaminant on the next round of UCMR, developing an analytical method, or conducting a health assessment).

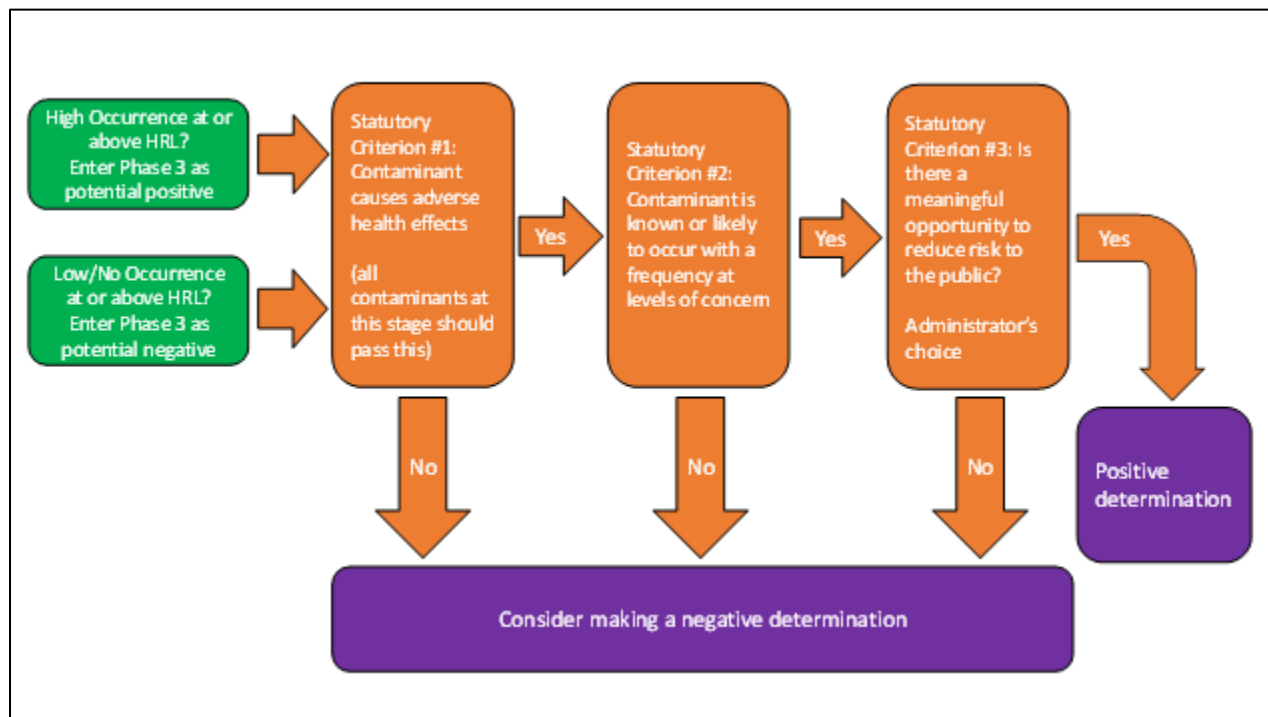
B.7 Phase 3: Regulatory Determination Assessment

The *Regulatory Determination Assessment Phase* involves a complete evaluation of the statutory criteria for each contaminant or group of contaminants that have passed Phase 2 and have sufficient information and data for making a regulatory determination. In this phase, the Agency evaluates the following statutory criteria:

- **Statutory Criterion #1:** Might the contaminant have an adverse effect on the health of persons?
- **Statutory Criterion #2:** Is the contaminant known to occur or is there a substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern?
- **Statutory Criterion #3:** In the sole judgment of the Administrator, does regulation of such contaminant present a meaningful opportunity for health risk reduction for persons served by PWSs?

The following sections discuss the factors that the Agency considers in evaluating each of the three statutory criteria. Note that the third statutory criterion requires the judgment of the Administrator. See Exhibit B-11 for an overview of Phase 3.

Exhibit B-11: Regulatory Determination 5 Phase 3 Flowchart



B.7.1 Evaluation of Statutory Criterion #1 (Adverse Health Effect)

For criterion #1, the Agency evaluates whether a contaminant has a publicly available EPA health assessment or an externally peer-reviewed health assessment from another agency conforming with current EPA guidelines, from which an HRL can be derived. The HRL derived

in or from the health assessment takes into account many of the key elements that are considered when evaluating the first criterion, which include the MOA, the critical health effect(s), the dose-response relationship for critical health effect(s) and impacts on sensitive population(s) or life stages. As noted earlier, an HRL is not a final determination on establishing a protective level of a contaminant in drinking water for a particular population. The HRL is derived prior to development of a complete health and exposure assessment and can be considered a screening value. The HRL is a health-based concentration against which the EPA compares the concentrations of a contaminant found in PWSs to determine if the levels are of potential public health concern.

If an acceptable health assessment is available, demonstrating adverse health effects, the Agency answers “yes” to the first statutory criterion. Otherwise, the Agency answers “no” to the first statutory criterion. (In practice, it is expected that any contaminant that reaches Phase 3 will receive a “yes” to the first criterion.)

B.7.2 Evaluation of Statutory Criterion #2 (Known or Likely Occurrence in PWSs with a Frequency and Level of Concern)

The occurrence data for each contaminant will be compared to the HRL to determine if the contaminant occurs at a frequency and levels of public health concern. The following factors, further refined from the previous phase and categorized by importance, will be considered when identifying contaminants or contaminant groups that are known or likely to occur at a frequency and at levels of public health concern:

Factors of Primary Consideration

- How many samples (number and percent) have detections > HRL in nationally representative and other finished water occurrence data?
- How many systems (number and percent) have detections > HRL in nationally representative and other finished water occurrence data?
- Is the geographic distribution of contaminant occurrence national, regional, or localized?
- In addition to the number of systems, what type of systems does the contaminant occur in? Does the contaminant occur in large or small systems? Does the contaminant occur in surface or groundwater systems?
- Are there significant uncertainties or limitations with the data or analyses, involving (for example) the age of the dataset, the use of analytical methods that cannot quantify occurrence at concentrations as low as the HRL, or representativeness of the data (e.g., limited in scope to a particular region)?

Additional Factors of Consideration

- How many samples (number and percent) have detections > ½ HRL in the nationally representative and other finished water occurrence data?
- How many systems (number and percent) have detections > ½ HRL in the nationally representative and other finished water occurrence data?
- How many samples (number and percent) have detections > HRL and ½ HRL in the ambient/source water occurrence data?
- How many monitoring sites (number and percent) have detections > HRL and ½ HRL in the ambient/source water occurrence data?
- Are production and use trends for the contaminant increasing or decreasing?

- How many pounds are discharged annually to surface water and released to the environment?
- Do the environmental fate and transport parameters indicate that the contaminant would persist and be mobile in water?
- Is the contaminant introduced by water treatment processes that provide public health benefits such that it is relevant to risk-balancing considerations?
- Are there additional uncertainties or limitations with the data and analyses that should be considered?

Occurrence will be evaluated relative to $\frac{1}{2}$ of the HRL (in addition to the full HRL) as a conservative estimate of occurrence at or approaching levels of public health concern. Occurrence analyses undertaken during Phase 2 will be examined, and additional analyses (e.g., more narrowly focused, or using more sophisticated methodologies) may be conducted during Phase 3 to further inform an understanding of the contaminant's occurrence.

If the Agency finds that a contaminant is known to occur or there is a substantial likelihood of occurrence at a frequency and levels of health concern in PWSs informed by the factors listed above, then the Agency answers “yes” to the second statutory criterion. Otherwise, the Agency answers “no” to the second statutory criterion.

An important consideration in this evaluation is the detection limit (DL) and the reporting level (RL), sometimes designated as an MRL, used in monitoring for drinking water contaminants. The DL is the minimum concentration of a contaminant in water that can be reliably differentiated from the signal arising from a blank (i.e., at which the contaminant can be determined to be present). It may not be possible to achieve reliable quantitation at the DL. The RL is a concentration at or above which results are reported by a laboratory or a study and is generally a concentration at which reliable quantitation is possible. The MRL is the minimum concentration that is required to be reported quantitatively in a study. The MRL is set at a value that takes into account typical laboratory capabilities to reliably and cost-effectively detect and quantify a compound. If the HRL is equal to or greater than the MRL, any occurrence at or above the HRL can be reliably quantified and reported with confidence. If the HRL is less than the MRL, any reported concentration (commonly called a “detection”) is necessarily greater than the HRL. Occurrence at concentrations that exceed the HRL but are below the MRL often go unreported. A variety of approaches can be used to estimate the occurrence below the MRL, including fitting an appropriate distribution model using the quantified occurrence data above the MRL.

In the case of non-threshold carcinogens, if there is little to no occurrence above an MRL that is greater than the HRL, and the MRL is within the 10^{-4} to 10^{-6} risk range, the Agency can make a decision for the second statutory criterion as long as this limitation is noted and other information/data are considered (e.g., contaminant manufacturing trends, trends in the amount released to the environment, occurrence in ambient water, etc.).

B.7.3 Evaluation of Statutory Criterion #3 (Meaningful Opportunity)

For statutory criterion #3, the Administrator decides, in his or her sole judgement, whether a drinking water regulation for a contaminant or group presents a meaningful opportunity for health risk reduction for persons served by PWSs. The EPA Administrator may consider factors such as the following when evaluating statutory criterion #3:

- What is the nature of the health effect(s) identified in statutory criterion #1 and are there sensitive populations that may be affected (evaluated either qualitatively or quantitatively)?
- Based on the occurrence information evaluated for statutory criterion #2, including the number of systems potentially affected, what is the national population exposed or served by systems with levels > HRL and ½ HRL?
- For non-carcinogens, are there other sources of exposure that should be considered (i.e., what is the relative source contribution from drinking water)?
- What is the geographic distribution of occurrence (e.g., local, regional, national)?
- Are there any uncertainties or limitations in the health and occurrence information or analyses that should be considered?
- Are there any limiting considerations related to technology (e.g., treatment or analytical methods)?

After evaluating these factors, if the Administrator determines that there is a meaningful opportunity to reduce risk by regulating the contaminant or group in drinking water, then the Agency will answer “yes” to the third statutory criterion.

B.7.4 Making a Regulatory Determination Decision

If the Agency answers “yes” to all three statutory criteria, then the Agency makes a positive preliminary determination. Additionally, after identifying compounds occurring at frequencies and levels of public health concern, the Agency may initiate a systematic literature review to identify new studies that may influence the derivation of an RfD or CSF. The list of potentially relevant health effects studies that could affect the derivation of an RfD or CSF identified through the systematic review process will be placed in the docket at the time of the preliminary determination for public comment.

If, after considering input provided during the public comment period, the Agency again answers “yes” to all three statutory criteria, the Agency then may make a positive final determination that regulation is appropriate. After a positive determination is finalized, the Agency has 24 months to publish a proposed MCLG and NPDWR and then 18 months to publish a final MCLG and promulgate a final NPDWR (SDWA Section 1412(b)(1)(E)). (SDWA permits the Agency to extend the promulgation date by an additional nine months if needed.) The regulatory determination process outlined in this document is distinct from the analyses needed to develop an NPDWR. The development and promulgation of an NPDWR is a multi-step process. This process includes deriving a proposed MCLG as well as conducting a health risk reduction cost analysis (HRRCA), and conducting other analyses required to propose an MCL or a TT approach to reduce contaminant levels in water systems. As part of the proposal, the Agency must identify best available technologies (BATs), small system compliance technologies (SSCTs), and approved analytical methods if it proposes an enforceable MCL. Alternatively, if the EPA proposes a TT instead of an MCL, the Agency must identify the TT. The required HRRCA will include an extensive evaluation of the treatment costs and monitoring costs at a system level and aggregated at the national level. Thus, a decision to regulate is the beginning of the Agency’s regulatory development process, not the end.

If the Agency answers “no” to one or more of the three statutory criteria, then the Agency considers making a negative determination: a determination that an NPDWR is not appropriate for the contaminant at this time. A final determination not to regulate a contaminant is, by

statute, a final Agency action and is subject to judicial review. The Agency may also elect to issue no determination for a contaminant in Phase 3. For example, the Agency may find that additional information is required to make a positive or negative regulatory determination or may decide to evaluate the contaminant outside the Regulatory Determination process (e.g., together with related regulated contaminants as part of the Six-Year Review process).

Only positive determinations and negative determinations count toward the statutory requirement that five determinations be made each cycle.

If a negative determination or no determination is made for a contaminant, the Agency may decide to develop a Health Advisory (HA). HAs provide concentration values for drinking water contaminants at and below which adverse health effects are not anticipated to occur over specific exposure durations (e.g., one day, ten days, several years, or a lifetime). The EPA's HAs are non-enforceable and non-regulatory. They provide technical information to states' agencies and other public health officials on health effects, analytical methodologies, and treatment technologies associated with drinking water contamination.

While a negative determination is considered a final Agency action for this round of regulatory determination, the contaminant may be relisted on a future CCL based on newly available health or occurrence information.

See Exhibit B-12 for a summary of possible Regulatory Determination outcomes.

Exhibit B-12: Regulatory Determination Outcomes

• Positive Determination (Phase 3) • Affirmative determination for all three criteria • Begin process to develop a drinking water regulation • Negative Determination (Phase 3) • Negative determination for any one of the three criteria • Considered a final agency action • Drinking water regulation not developed • Health Advisory is a non-regulatory option • New data can prompt inclusion in the next or a future CCL • No Regulatory Determination (Phase 1, 2, 3) • Insufficient data, contaminant will be evaluated on a separate timetable • May be included on next CCL • Health Advisory is a non-regulatory option	Positive determination								
	<table> <tr> <th>#</th><th>Outcome</th></tr> <tr> <td>1</td><td>✓</td></tr> <tr> <td>2</td><td>✓</td></tr> <tr> <td>3</td><td>✓</td></tr> </table>	#	Outcome	1	✓	2	✓	3	✓
#	Outcome								
1	✓								
2	✓								
3	✓								
	Negative determination (one example)								
	<table> <tr> <th>#</th><th>Outcome</th></tr> <tr> <td>1</td><td>✓</td></tr> <tr> <td>2</td><td>✗</td></tr> <tr> <td>3</td><td>✗</td></tr> </table>	#	Outcome	1	✓	2	✗	3	✗
#	Outcome								
1	✓								
2	✗								
3	✗								

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