6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2024-0456; FRL-10774-01-OW]

Announcement of Preliminary Regulatory Determinations for Contaminants on the Fifth Drinking Water Contaminant Candidate List

AGENCY: Environmental Protection Agency (EPA).

ACTION: Request for public comment.

SUMMARY: The Safe Drinking Water Act (SDWA), as amended in 1996, requires that the U.S. Environmental Protection Agency (EPA) determine whether to regulate at least five unregulated contaminants every five years. The decision to regulate or not to regulate a contaminant is known as a regulatory determination. In most cases, the contaminants chosen for regulatory determination are selected from the most recent Contaminant Candidate List (CCL), which the SDWA requires the EPA to publish every five years. This document presents the preliminary regulatory determinations and supporting rationale for contaminants listed on the EPA's fifth CCL (CCL 5).

Since the fourth round of regulatory determinations was published in March 2021 (86 FR 12272; USEPA, 2021a), the EPA has made determinations to regulate per- and polyfluoroalkyl substances (PFAS), including individual determinations for three PFAS: perfluorononanoic acid (PFNA), perfluorohexanesulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid and its ammonium salt (HFPO-DA, also known as GenX or GenX chemicals); and mixtures including two or more of these three PFAS and perfluorobutanesulfonic acid (PFBS). In April 2024, the agency issued a final National Primary Drinking Water Regulation that includes these four PFAS as well as perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) (89 FR 32532; USEPA, 2024a). In this *Federal Register* Notice (FRN), the EPA is making preliminary determinations not to regulate nine additional contaminants from CCL 5: 2-aminotoluene, cylindrospermopsin, ethoprop, microcystins, molybdenum, permethrin, profenofos, tebuconazole and tribufos. The EPA requests public comment on these preliminary determinations and other aspects of this FRN. The EPA also presents updates on additional contaminants from CCL 5, as well as on some of those that have been considered in previous rounds of regulatory determinations and for which the EPA has not yet made a regulatory determination. The agency is also presenting and requesting comment on the process and analyses used for this round of regulatory determinations (*i.e.*, RD 5), the supporting information, and the rationale used to make these preliminary decisions.

DATES: Comments must be received on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-OW-2024-0456, by any of the following methods:

- Federal eRulemaking Portal: *https://www.regulations.gov/* (our preferred method).

Follow the online instructions for submitting comments.

- Mail: Water Docket, Environmental Protection Agency, Mail Code: [28221T], 1200 Pennsylvania Ave. NW. Washington, DC 20460.
- Hand Delivery: EPA Docket Center, [EPA/DC] EPA West, Room 3334, 1301 Constitution Ave. NW. Washington DC. Such deliveries are only accepted during the Docket's normal hours of operation and special arrangements should be made for deliveries of boxed information.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/*, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the "Written Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: George Gardenier, Standards and Risk Management Division, Office of Ground Water and Drinking Water, MC: 4607M, Environmental Protection Agency, 1200 Pennsylvania Ave, NW Washington, DC 20460; telephone number: (202) 564-3333; email address: *gardenier.george@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Written Comments

Submit your comments, identified by Docket ID No. EPA-HQ-OW-2024-0456, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit

electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets*.

When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, *Federal Register* date and page number).
- Explain why you agree or disagree and suggest alternatives.
- Describe any assumptions and provide any technical information and data that you used.
- Provide specific examples to illustrate your concerns and suggest alternatives.
- Explain your views as clearly as possible.
- Make sure to submit your comments by the comment period deadline identified.

B. Does this Action Apply to Me?

Neither these preliminary regulatory determinations nor the final regulatory determinations, when published, impose any requirements on anyone. Instead, this action notifies interested parties of the EPA's preliminary regulatory determinations for nine unregulated contaminants for comment.

Abbreviations Used in This Document

Abbreviation	Meaning
AChE	Acetylcholinesterase
ADAF	Age Dependent Adjustment Factor
AM	Assessment Monitoring
ATSDR	Agency for Toxic Substances and Disease Registry
ATSDR MRL	ATSDR Minimal Risk Level
AWIA	America's Water Infrastructure Act
BAT	Best Available Technology
BMD	Benchmark Dose
$BMDL_{10}$	Lower 95% Confidence Limit on the Benchmark Dose Level Associated with a 10% Response
$BMDL_{1SD}$	Lower 95% Confidence Limit on the Benchmark Dose Level Associated with a Difference of One Standard Deviation from Controls
BW	Body Weight
CBI	Confidential Business Information
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
CCR	Consumer Confidence Report
CDR	Chemical Data Reporting

ChE	Cholinesterase
CRL	Cancer Risk Level
CSF	Cancer Slope Factor
CWA	Clean Water Act
CWS	Community Water System
CWSS	Community Water System Survey
DBP	Disinfection Byproduct
DDE	1,1-Dichloro-2,2-bis(p-chlorophenyl)ethylene
DWI	Drinking Water Intake
DWI-BW	Drinking Water Intake Adjusted for Body Weight
EF	Exposure Factor
EPA	U. S. Environmental Protection Agency
EPTC	S-Ethyl dipropylthiocarbamate
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
FQPA	Food Quality Protection Act
FR	Federal Register
FRN	Federal Register Notice
Gen X	Gen X Chemicals (*i.e.*, HFPO dimer acid and its ammonium salt), also known as (2,3,3,3-tetrafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)propanoic acid (CASRN 13252-13-6) or hexafluoropropylene oxide (HFPO) dimer acid (HFPO-DA) and 2,3,3,3-tetrafluoro-2-(1,1,2,2,3,3,3-heptafluoropropoxy)propanoate (CASRN 62037-80-3) or HFPO-DA dimer acid and its ammonium salt)

GWUDI	Groundwater Under the Direct Influence of Surface Water
HA	Health Advisory
HAA5	Sum of Five Haloacetic Acids
HAB	Harmful Algal Bloom
HCl	Hydrochloride
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
IUR	Inventory Update Reporting
K_{oc}	Organic Carbon Partitioning Coefficient
K_{ow}	Octanol-Water Partitioning Coefficient
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
NAS	National Academy of Sciences
NAWQA	National Water-Quality Assessment
NDBA	N-Nitrosodi-n-butylamine

NDEA	N-Nitrosodiethylamine
NDMA	N-Nitrosodimethylamine
NDPA	N-Nitroso-di-n-propylamine
NPYR	N-Nitrosopyrrolidine
NDWAC	National Drinking Water Advisory Council
NIRS	National Inorganics and Radionuclides Survey
NOAEL	No Observed Adverse Effect Level
NPDWR	National Primary Drinking Water Regulation
NRC	National Research Council
NRDC	Natural Resources Defense Council
NWIS	National Water Information System
OPP	Office of Pesticides Program
OW	Office of Water
PAD	Population-Adjusted Dose
PCCL	Preliminary Contaminant Candidate List
PDP	Pesticide Data Program
PFAS	Per- and Polyfluoroalkyl Substances
PFBA	Perfluorobutanoic acid
PFBS	Perfluorobutanesulfonic acid
PFHxS	Perfluorohexanesulfonic acid
PFNA	Perfluorononanoic acid
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctanesulfonic acid

PMP	Pilot Monitoring Program
PND	Postnatal Day
POD	Point of Departure
PPRTV	Provisional Peer-Reviewed Toxicity Value
PST	Pre-Screen Testing
PWS	Public Water System
RBC	Red Blood Cell
RD 1	Regulatory Determination 1
RD 2	Regulatory Determination 2
RD 3	Regulatory Determination 3
RD 4	Regulatory Determination 4
RD 5	Regulatory Determination 5
RDX	Royal Demolition eXplosive
RED	Reregistration Eligibility Decision
RfD	Reference Dose
RSC	Relative Source Contribution
RUP	Restricted Use Pesticide
SDWA	Safe Drinking Water Act
SS	Screening Survey
SSCT	Small System Compliance Technology
STORET	Storage and Retrieval Data System
TCP	Trichloropropane
TDI	Tolerable Daily Intake

TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TT	Treatment Technique
TTHM	Total Trihalomethanes
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
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
UF_S	Subchronic-to Chronic Exposure Duration Uncertainty Factor
USDA	United States Department of Agriculture
USEPA	United States Environmental Protection Agency
USGS	United States Geological Survey
WQP	Water Quality Portal
WQX	Water Quality Exchange

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II. Purpose and Background

A. What is the Purpose of This Action?

The purpose of this action is to request comment on the EPA's preliminary determinations not to regulate the following nine contaminants under the Safe Drinking Water Act: 2-aminotoluene, cylindrospermopsin, ethoprop, microcystins, molybdenum, permethrin, profenofos, tebuconazole and tribufos. As required by the SDWA, the EPA is seeking comment on these preliminary determinations. The agency is also presenting and requesting comment on the process and analyses used for this round of regulatory determinations (*i.e.,* RD 5), the supporting information, and the rationale used to make these preliminary decisions. It should be noted that the analyses associated with a regulatory determination are distinct from the more detailed analyses required to develop a National Primary Drinking Water Regulation (NPDWR).

B. Background on the CCL and Regulatory Determinations

1. Statutory Requirements for CCL and Regulatory Determinations

Section 1412(b)(1)(B)(i) of the SDWA requires the EPA to publish the CCL every five years after public notice and an opportunity to comment. The CCL is a list of contaminants which 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 the SDWA. SDWA section 1412(b)(1)(B)(ii) directs the EPA to determine, whether to regulate at least five contaminants from the CCL every five years. Under section 1412(b)(1)(A) of SDWA, the EPA may regulate a contaminant in drinking water if the Administrator determines that:

(i) the contaminant may have an adverse effect on the health of persons;

(ii) 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

(iii) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

SDWA 1412 (b)(1)(C) requires that the Administrator prioritize selection of contaminants that present the greatest public health concern. The Administrator, in making such selections, shall take into consideration, 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 than the general population.

If the EPA determines that these three statutory criteria are met and makes a final determination to regulate a contaminant (*i.e.*, a positive determination), the agency must publish a proposed Maximum Contaminant Level Goal (MCLG)[1] and NPDWR[2] within 24 months. After a proposal, the agency must publish a final MCLG and promulgate a final NPDWR (SDWA

[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. (40 CFR 141.2; 42 U.S.C. 300g-1)

[2] An NPDWR is a legally enforceable standard that applies to public water systems. An NPDWR sets a legal limit (called a maximum contaminant level or MCL) or specifies a certain treatment technique (TT) for public water systems for a specific contaminant or group of contaminants. The MCL is the highest level of a contaminant that is allowed in drinking water and is set as close to the MCLG as feasible using the best available treatment technology and taking cost into consideration.

section 1412(b)(1)(E)) within 18 months[3]. The EPA may also develop regulatory determinations and associated rulemakings outside of the SDWA mandated process.

2. The First Contaminant Candidate List (CCL 1) and Regulatory Determination (RD 1)

The EPA published the final CCL 1, which contained 60 chemical and microbiological contaminants, in the *Federal Register* (FR) on March 2, 1998 (63 FR 10273; USEPA, 1998). The agency published the final regulatory determinations for nine of the 60 CCL 1 contaminants in the FR on July 18, 2003 (68 FR 42898; USEPA, 2003). The agency determined not to regulate the following nine contaminants with NPDWRs: *Acanthamoeba*, aldrin, dieldrin, hexachlorobutadiene, manganese, metribuzin, naphthalene, sodium and sulfate. The agency posted information about *Acanthamoeba*[4] on the EPA's website and issued health advisories (HAs)[5] for manganese, sodium and sulfate.

3. The Second Contaminant Candidate List (CCL 2) and Regulatory Determination (RD 2)

The agency published the final CCL 2 in the FR on February 24, 2005 (70 FR 9071; USEPA, 2005a) and carried forward the 51 remaining chemical and microbial contaminants listed on CCL 1. The agency published the final regulatory determinations for 11 of the 51 CCL 2 contaminants in the FR on July 30, 2008 (73 FR 44251; USEPA, 2008a). The agency determined not to regulate the following 11 contaminants: boron, the dacthal mono- and di-acid

[3] The statute authorizes a nine-month extension of this promulgation date.

[4] Consumer information about *Acanthamoeba* for people who wear contact lenses can be found at *http://water.epa.gov/action/advisories/acanthamoeba/index.cfm.*

[5] Health advisories provide information on contaminants that can cause human health effects and are known or anticipated to occur in drinking water. The EPA's health advisories are non-enforceable and provide technical guidance to states agencies and other public health officials on health effects, analytical methodologies and treatment technologies associated with drinking water contamination. Health advisories can be found at *http://water.epa.gov/drink/standards/hascience.cfm.* See also SDWA Section 1412(b)(1)(F).

degradates, 1,1-dichloro-2,2-bis(*p*-chlorophenyl)ethylene (DDE), 1,3-dichloropropene (Telone), 2,4-dinitrotoluene, 2,6-dinitrotoluene, *S*-ethyl dipropylthiocarbamate (EPTC), fonofos, terbacil and 1,1,2,2-tetrachloroethane. The agency issued new or updated HAs for boron, dacthal degradates, 2,4-dinitrotoluene, 2,6-dinitrotoluene and 1,1,2,2-tetrachloroethane.

4. The Third Contaminant Candidate List (CCL 3) and Regulatory Determination (RD 3)

The agency published the final CCL 3, which listed 116 contaminants, in the FR on October 8, 2009 (74 FR 51850; USEPA, 2009a). In developing CCL 3, the EPA improved and built upon the process that was used for CCL 1 and CCL 2. The CCL 3 process was based on substantial expert input and recommendations from the National Academy of Sciences' (NAS) National Research Council (NRC) and the National Drinking Water Advisory Council (NDWAC) as well as input from the public. Based on these consultations and input, the EPA developed a multi-step process to select candidates for a final CCL, which included the following key steps:

(a) Building a broad universe;

(b) Screening the universe to select a Preliminary CCL (PCCL); and

(c) Classification of PCCL chemicals to select a CCL.

The agency published its preliminary regulatory determinations for contaminants listed on the CCL 3 in the FR on October 20, 2014 (79 FR 62715; USEPA, 2014). In that notice, the EPA made preliminary determinations for five of the 116 contaminants listed on the CCL 3, including a preliminary positive determination for strontium and preliminary negative determinations for dimethoate, 1,3-dinitrobenzene, terbufos and terbufos sulfone. 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. Additional discussion on strontium is provided in section V of this document.

The EPA also published an off-cycle final determination to regulate one CCL 3 contaminant, perchlorate, on February 11, 2011 (76 FR 7762; USEPA, 2011) during the RD 3 cycle (bringing the total number of final determinations to five).

5. The Fourth Contaminant Candidate List (CCL 4) and Regulatory Determination (RD 4)

The final CCL 4 was published on November 17, 2016 (81 FR 81099; USEPA, 2016b). The final CCL 4 consisted of 97 chemicals or chemical groups and 12 microbiological contaminants. Most CCL 4 contaminants were carried over from CCL 3. The EPA added two contaminants (manganese and nonylphenol) to the CCL 4 list based on nominations. The EPA removed 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 and strontium) and three pesticides with cancelled registrations (disulfoton, fenamiphos and molinate).

The EPA published its preliminary determinations for the fourth CCL in the *Federal Register* on March 10, 2020 (85 FR 14098; USEPA, 2020a). In that notice, the EPA made determinations for eight of the 109 contaminants on the CCL 4. The EPA determined to regulate two PFAS, perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS), and determined not to regulate six additional contaminants: 1,1-dichloroethane, acetochlor, methyl bromide, metolachlor, nitrobenzene and Royal Demolition eXplosive (RDX). The EPA published its final regulatory determinations for these contaminants on March 3, 2021 (86 FR

12272; USEPA, 2021a).

6. The Fifth Contaminant Candidate List (CCL 5)

The final CCL 5 was published on November 14, 2022 (87 FR 68060; USEPA, 2022a). The final CCL 5 consists of 66 chemicals, 3 chemical groups (cyanotoxins, disinfection byproducts (DBPs) and PFAS) and 12 microbial contaminants. The CCL 5 was developed based on the existing framework used for CCL 3 and CCL 4. For CCL 5, the EPA updated the CCL process to consider a larger number of contaminants, enhance transparency in the data evaluation, and improve efficiency of information transfer to other SDWA processes, such as regulatory determinations.

III. Approach and Overall Outcomes for RD 5

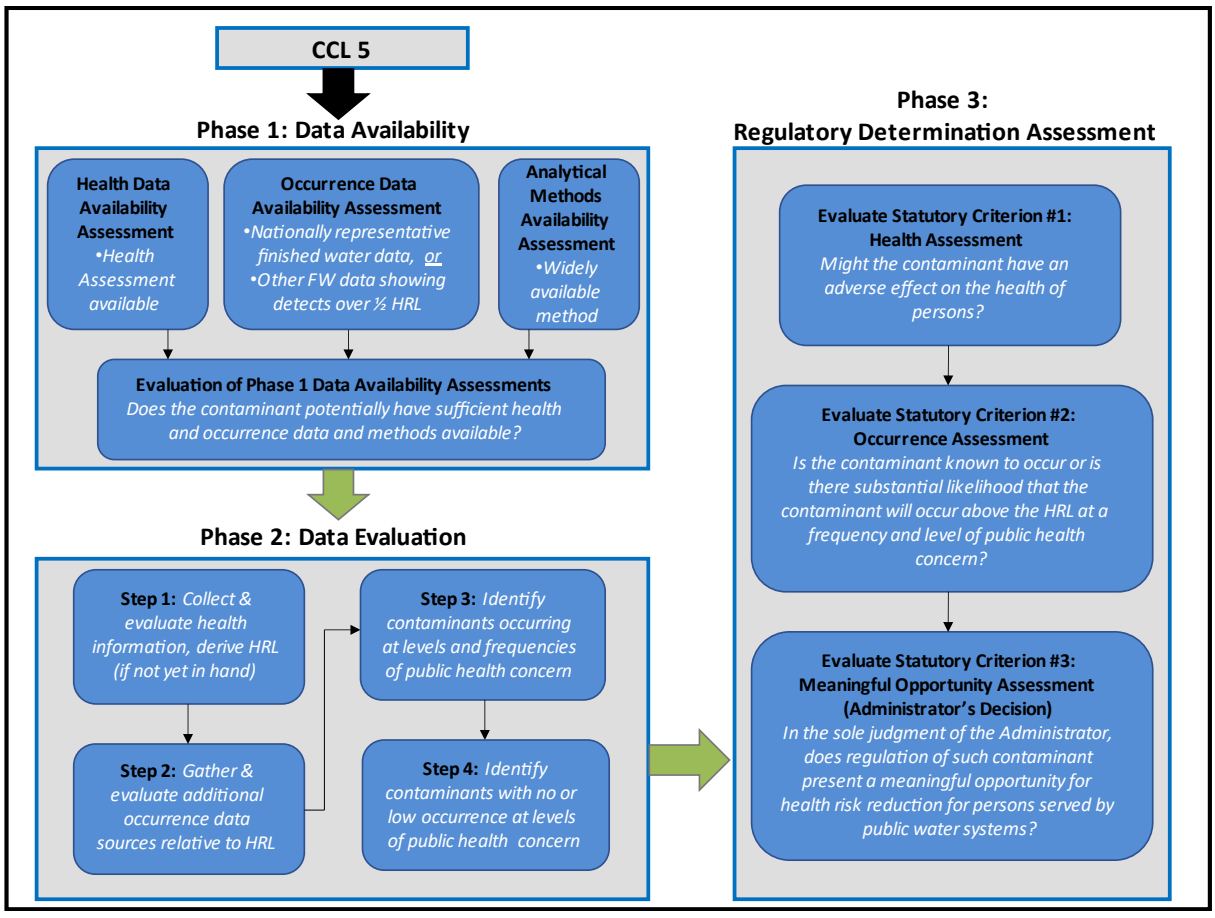
This section describes (a) the approach the EPA used to identify and evaluate contaminants for RD 5 along with the overall outcome of applying this approach, (b) the supporting RD 5 documentation and (c) the technical analyses and sources of health and occurrence information.

A. Summary of the Approach and Overall Outcomes for RD 5

The approach taken under RD 5 is similar to that used in previous rounds of regulatory determination and formalized in a written protocol under RD 3. The Regulatory Determination 5 Protocol, found in Appendix B of the *Regulatory Determination 5 Support Document* (USEPA, 2024b), like the RD 3 and RD 4 Protocols, describes a three-phase process. The three phases are: (1) the Data Availability Phase, (2) the Data Evaluation Phase and (3) the Regulatory Determination Assessment Phase. Figure 1 provides an overview of the process the EPA uses to identify which CCL 5 contaminants are candidates for regulatory determinations and the SDWA

statutory criteria considered in making the regulatory determinations. For more detailed information on the three phases of the RD 5 process, refer to the RD 5 Protocol in Appendix B of the *Regulatory Determination 5 Support Document* (USEPA, 2024b).

Figure 1: The Three Primary Phases of the RD 5 Process



1. Phase 1 (Data Availability Phase)

In Phase 1, the Data Availability Phase, the agency identifies contaminants that have sufficient health and occurrence data to proceed to Phase 2 and be included on a "short list" for

further evaluation. SDWA 1412(b)(1)(B)(ii)(II) requires that the EPA consider the best available public health information in making the regulatory determination.

To identify contaminant health effects data that are sufficient to make a regulatory determination regarding potential adverse health effect(s), the agency considers whether an EPA health assessment or an externally peer-reviewed health assessment from another agency is available, from which a health reference level (HRL)[6] sufficient to inform a regulatory determination can be derived. See section III.C.1 of this document for information about how HRLs are derived. To identify "qualifying" health assessments, the EPA conducted a systematic search in January 2023 for the EPA and other authoritative sources of human health effects assessments for each drinking water chemical contaminant on CCL 5. Health assessments are considered qualifying if they 1) derived one or more toxicity values (*e.g.*, oral reference value or oral 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 source that routinely develops health assessments (*e.g.*, Agency for Toxic Substances and Disease Registry [ATSDR]). If a qualifying health assessment is not available for a contaminant, the contaminant will not proceed to Phase 2. See section B.5.1.1 in Appendix B of the *Regulatory Determination 5 Support Document* for a list of sources of Health Effects Assessments (USEPA, 2024b).

[6] A health reference level (HRL) is a health-based concentration against which the agency evaluates occurrence data when making decisions about preliminary regulatory determinations. An HRL is not a final determination on establishing a protective level of a contaminant in drinking water for a particular population; it is derived prior to development of a complete health and exposure assessment.

After identifying the qualifying peer-reviewed health assessments for a chemical, the EPA followed a structured and transparent process to select the assessment(s) for both cancer and noncancer HRL derivation. The process included expert evaluations applying specific criteria. These criteria are designed to identify the assessment relevant to drinking water that was developed using comparable approaches to the EPA human health risk assessment methods and based on the best available science. The EPA used the results from the expert evaluations to select the health assessment used to derive the HRL for the chemical. In addition, the EPA applied expert judgement when evaluating a set of assessments for a given contaminant because certain health assessments and chemicals can present unique challenges. See section B.5.1.2 in Appendix B of the *Regulatory Determination 5 Support Document* for the decision-logic that was applied for all RD 5 chemicals (USEPA, 2024b).

To identify contaminant occurrence data that are sufficient to evaluate with respect to the frequency and level of occurrence in PWSs, the agency considers nationally representative finished drinking water data (samples collected after the water undergoes treatment) when available for making regulatory determinations. The following sources, administered or overseen by the EPA, include finished drinking water occurrence data that are considered nationally representative: (a) the fourth Unregulated Contaminant Monitoring Rule (UCMR 4); (b) the third Unregulated Contaminant Monitoring Rule (UCMR 3); (c) the second Unregulated Contaminant Monitoring Rule (UCMR 2); (d) the first Unregulated Contaminant Monitoring Rule (UCMR 1); (e) the Unregulated Contaminant Monitoring (UCM) program; and (f) the National Inorganics and Radionuclides Survey (NIRS)[7]. If a contaminant has occurrence data from a nationally

[7] Specific types of UCMR monitoring (*e.g.*, assessment monitoring and sometimes the screening survey) are considered nationally representative. These are described further in Section III.C.2.a.1 of this notice.

representative source, it passes the Occurrence Data Availability Assessment.

If nationally representative drinking water data are not available, the EPA identifies and evaluates other sources of finished water data, which may include other national assessments, regional data, state data and more localized finished water assessments. For more information on sources of occurrence that may be evaluated during the regulatory determination process, please refer to Chapter 2 of the *Regulatory Determination 5 Support Document* (USEPA, 2024b).

In Phase 1, the agency assesses whether the non-nationally representative finished water occurrence data show at least one detection at levels > ½ the HRL[8] for the critical endpoint. If a contaminant without nationally representative finished water occurrence data has non-nationally representative finished water occurrence data showing at least one detection > ½ HRL, the contaminant passes the Occurrence Data Availability Assessment. While there may be robust non-national data available for certain contaminants which can demonstrate substantial likelihood of occurrence at a frequency and level of public health concern (*e.g.*, see PFAS *Federal Register* Notice section III.C), the EPA does not rely on non-national data alone to determine that there is no or low potential for occurrence in the nation's PWSs because these data tend to be limited in scope and do not provide a sufficiently accurate picture of occurrence to support a negative determination.

If a widely available analytical method does not exist for monitoring occurrence of a contaminant in water, the contaminant will not be a viable candidate for regulation with a Maximum Contaminant Level (MCL). 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. In

[8] Note that the ½ HRL threshold is based on a recommendation from the NDWAC working grouping that provided recommendations on the first regulatory determination effort (USEPA, 2000a).

the Analytical Methods Availability Assessment, the EPA determines for each contaminant whether a widely available analytical method for monitoring, which employs technology that is commonly in use at numerous drinking water laboratories, exists. 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 still 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 evidence of occurrence.

The EPA also may consider issuing a regulatory determination for contaminant groups and/or mixtures that are a contaminant. The EPA has made final regulatory determinations for contaminant mixtures and regulated certain contaminants in drinking water collectively. For example, the EPA made a determination to regulate mixture combinations. containing two or more of the following PFAS: PFHxS PFNA, HFPO-DA (GenX chemicals), and PFBS. Additionally, the EPA has also established NPDWRs for groups of contaminants (*e.g.*, DBPs; for total trihalomethanes [TTHMs] and the sum of five haloacetic acids [HAA5], as well as radionuclides). After conducting the health and occurrence data availability assessments, the agency identifies those contaminants and contaminant groups that meet the following Phase 1 data availability criteria:

(a) An EPA health assessment or an externally peer-reviewed health assessment from another agency that conforms with the current EPA guidelines is available, from which an HRL can be derived;

(b) Either nationally representative finished drinking water occurrence data are available or other finished water occurrence data show occurrence at levels > ½ the HRL; and

(c) A widely available analytical method for monitoring is available.

If a contaminant or group meets these three criteria, it is placed on a "short list" and proceeds to Phase 2. After evaluating the 81 CCL 5 contaminants/groups of contaminants and strontium in Phase 1, the agency identified 35 contaminants to evaluate further in Phase 2 (contaminants listed in Table 1 of this document). PFHxS, PFNA and HFPO-DA received final positive regulatory determinations in conjunction with the development of the PFAS NPDWR and therefore are not included in the contaminants considered here as part of the preliminary RD 5. For RD 5, the EPA set January 31, 2023 as a cutoff date for selection of health assessments. Health assessments published after this date were not considered in RD 5.

Table 1. Contaminants Proceeding from Phase 1 to Phase 2
1,2,3-Trichloropropane
1,2,4-Trimethylbenzene
1,4-Dioxane
2-Aminotoluene (*o*-Toluidine)
alpha-Hexachlorocyclohexane
Boron
Carbaryl
Chlorate
Cobalt
Cylindrospermopsin
Dieldrin

Dimethoate
Diuron
Ethoprop
Legionella pneumophila
Lithium
Manganese
Methomyl
Microcystins
Molybdenum
N-Nitrosodi-n-butylamine (NDBA)
N-Nitrosodiethylamine (NDEA)
N-Nitrosodimethylamine (NDMA)
N-Nitroso-di-n-propylamine (NDPA)
N-Nitrosopyrrolidine (NPYR)
Perfluorobutanoic acid (PFBA)
Permethrin
Profenofos
Propachlor
Quinoline
Strontium
Tebuconazole
Terbufos

Tribufos
Vanadium

The remaining CCL 5 contaminants listed in Chapter 2 of the *Regulatory Determination 5 Support Document* (USEPA, 2024b) did not meet one or more of the Phase 1 data availability criteria described earlier in this section and were not considered further for RD 5.

2. Phase 2 (Data Evaluation Phase)

(a) Evaluation of Adverse Health Effects

This section describes the approach for deriving the HRL for the contaminants under consideration for regulatory determinations. HRLs are health-based drinking water concentrations against which the EPA evaluates occurrence data to determine if contaminants occur at levels of potential public health concern in drinking water. HRLs are not final values for establishing a protective level of a contaminant in drinking water for any particular population and are derived prior to the development of a complete health and exposure assessment for regulatory determination. More specific information about the potential for adverse health effects for each contaminant is presented in section IV.B of this action.

(i) Derivation of an HRL

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 reference dose (RfD) (or equivalent, such as an ATSDR minimal risk level) by an exposure factor (EF) (*i.e.*, drinking water intake rate adjusted for body weight [DWI-BW]) relevant to the target population and critical effect (USEPA, 2019a) and

multiplying by a 20% relative source contribution (RSC) (USEPA, 2000a). Consistent with HRL development for previous regulatory determinations, HRLs derived for RD 5 are rounded to one significant figure. The RSC is used to account for exposure via non-drinking water routes in deriving health-based drinking water concentrations for contaminants with threshold effects (noncarcinogens and nonlinear carcinogens). A 20% RSC is used for all RD 5 contaminants, consistent with other regulatory determination cycles (USEPA, 2021a), to derive the noncancer HRL because (1) HRLs are developed prior to completing the exposure assessment; and (2) a 20% RSC is the lowest that is applied for deriving health-based drinking water concentrations, therefore resulting in the most health protective HRL (USEPA, 2000a). Should a contaminant proceed to a 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, 2000a).

HRLs for contaminants with a threshold dose-response (non-cancer and nonlinear cancer endpoints) are calculated as follows:

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

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:

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

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 (USEPA, 2024b). For carcinogens with a MOA, the 2005 Cancer Guidelines recommend 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 earlier in this section) is used.

HRLs for carcinogenic contaminants with a known mutagenic MOA are calculated as follows:

$$HRL = \frac{CRL}{\sum_i (CSF * ADAF_i * \text{DWI-BW}_i * UA * F_i)}$$

The following terms are used in these questions:

HRL = Health Reference Level (mg/L), a non-regulatory health-based drinking water concentration levels of a specific contaminant at or below which is not anticipated to lead to adverse human health effects.

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 and can also refer to the maximum acceptable

concentration (MAC), ATSDR minimal risk level, point of departure (POD) / uncertainty factor (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 BW 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, 2000a) 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, – the target incidence used to establish lifetime exposure limits for carcinogens, set at one excess cancer case in a population of one million (1×10^{-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 MOA; 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 to convert the dose (*i.e.*, CSF) from mg of a chemical to µg of the chemical - ensures the ADAF-adjusted Unit Risk is in µg/L. This unit adjustment is not needed if the CSF is presented in $(ug/kg/day)^{-1}$ or if the desired units of the ADAF-adjusted concentration (*i.e.*, 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 provided both cancer and non-cancer toxicity values (*e.g.*, an oral reference value and oral CSF). When this situation occurred, the EPA selected the health assessments according to the criteria explained earlier in this section, derived a noncancer HRL and a cancer HRL based on noncancer and cancer health effects information, respectively, and then selected the most health protective (*i.e.*, lowest value) to serve as the final HRL (USEPA, 2000a).

(ii) 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 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, 2021b). 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 EFs for the development of HRLs.

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 examples, see USEPA, 2022b; USEPA, 2022c). The critical effect used as the basis for the oral reference value or oral CSF typically represents the health outcome at the lowest dose 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 selects the population or life stage with the highest DWI-BW because it is the most health protective. See section B.6.1.2 in Appendix B of the *Regulatory Determination 5 Support Document* for more information regarding the EPA's EF selection process (USEPA, 2024b).

(b) Occurrence Data Evaluation

In Phase 2, the agency collects additional data on occurrence (including finished drinking water data; ambient water data; data on use, production and release; and information on environmental fate and transport) and more thoroughly evaluates this information (based on factors enumerated in the following paragraphs) to identify contaminants that should proceed to Phase 3.

In Phase 2, the agency focuses its efforts on identifying those contaminants or contaminant groups that are occurring or have substantial likelihood to occur at levels and frequencies of public health concern in drinking water. As noted in section III.A, SDWA 1412(b)(1)(C) requires that the Administrator select contaminants that present the greatest public

health concern. To identify such contaminants, the agency considers the following information:

(a) How many samples (number and percentage) have detections > HRL and ½ HRL in the nationally representative and other finished water occurrence data?

(b) How many systems (number and percentage) have detections > HRL and ½ HRL in the nationally representative and other finished water occurrence data?

(c) Are there uncertainties or limitations with the data or analyses, such as the age of the dataset, the reporting threshold (*i.e.*, minimum reporting level [MRL[9]] > HRL), or representativeness of the data (*e.g.*, limited to a specific region), that may cause over- or underestimation of occurrence in finished water at levels and frequency of public health concern?

After identifying contaminants that are occurring at levels and frequencies of public health concern in drinking water to proceed to Phase 3 for a potential positive determination, the agency evaluates the remaining contaminants on the "short list" to determine which contaminants have no or low occurrence at levels of health concern that should proceed to Phase 3 for a potential negative determination. The agency considers the following information in selecting contaminants of no or low potential for public health concern to proceed to Phase 3:

(a) Does the contaminant have nationally representative finished drinking water data showing no or a low number or percent of detections > HRL?

(b) If a contaminant has other finished water data in addition to nationally representative finished water data, do these data suggest that there is no or low potential for occurrence

[9] 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.

in drinking water?[10]

(c) Does additional high-quality occurrence information support the conclusion that there is 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?

(d) Are critical gaps in health and occurrence information/data minimal?

After evaluating the "short list" contaminants (listed in Table 1 of this document), the agency identified 14 CCL 5 contaminants to proceed to Phase 3 (listed in Table 2 of this document). The contaminants are within one of the following Phase 2 data evaluation categories:

(a) A contaminant or part of a contaminant group occurring or likely to occur at levels and frequencies of public health concern, or

(b) A contaminant not occurring or not likely to occur at levels and frequencies of public health concern and no data gaps.

Table 2. Contaminants Proceeding from Phase 2 to Phase 3	
1,2,3-Trichloropropane	Molybdenum
1,4-Dioxane	Permethrin

[10] Note that other finished water data (*i.e.*, non-nationally-representative occurrence data) tend to be limited in scope and the EPA does not use these data alone to support a determination that the contaminant is not substantially likely to "occur in PWSs with a frequency and at levels of public health concern," which would therefore be a decision "not to regulate" (*i.e.*, negative determination).

2-Aminotoluene (*o*-Toluidine)	Profenofos
Cylindrospermopsin	Quinoline
Ethoprop	Strontium
Manganese	Tebuconazole
Microcystins	Tribufos

Note that the agency does not have a threshold for occurrence in drinking water that triggers whether a contaminant is occurring with a frequency and at levels of public health concern. An evaluation of this statutory criterion requires consideration of a number of factors, some of which include the health effect(s), the potency of the contaminant, the level at which the contaminant is found in drinking water, the frequency at which the contaminant is found, the geographic distribution (national, regional or local occurrence), other possible sources of exposure, and potential impacts on sensitive populations or lifestages. Given the many possible combinations of factors, a simple threshold is not viable.

The remaining CCL 5 contaminants did not proceed to Phase 3 and were not considered for RD 5 for reasons that may include of one or more of the following reasons:

(a) An updated health assessment completed by January 31, 2023 was not identified;

(b) Critical health effects gap (*e.g.*, lack of data to support quantification for the oral route of exposure);

(c) Lack of nationally representative finished water occurrence data and

lack of sufficient other data to demonstrate occurrence at levels and frequencies of public health concern;

(d) Critical occurrence data limitation or gap (*e.g.*, inconsistent results or trends in

occurrence data requiring further research; significant uncertainty in occurrence analyses or data);

or

e) The contaminant is being evaluated in other actions by the agency.

The agency continues to conduct research and collect information to fill the data and information gaps identified for these contaminants. Three contaminants that had previously received negative regulatory determinations have been re-listed on CCL 5 based on new health or occurrence information or a reevaluation of existing information. The EPA made determinations not to regulate dieldrin and manganese in RD 1 and dimethoate in RD 3. These contaminants were considered in RD 5. Based on preliminary RD 5 evaluations of dieldrin and dimethoate, the EPA is not proposing a change to its previous negative regulatory determinations for these two contaminants at this time. Manganese is further discussed in section V. Additionally, all 29 PFAS contaminants that have approved analytical methods are being monitored under the fifth Unregulated Contaminant Monitoring Rule (UCMR 5). The UCMR 5 occurrence data collection began in 2023 and ends in 2025.

3. Phase 3 (Regulatory Determination Assessment Phase)

Phase 3, the Regulatory Determination Assessment Phase, involves a complete evaluation of the statutory criteria for each contaminant or group of contaminants that proceed from Phase 2 and have sufficient information and data for making a regulatory determination. To meet the statutory requirement of making at least five regulatory determinations, in this phase, the agency evaluates the remaining contaminants against the following statutory criteria (SDWA 1412(b)(1)(A)):

(a) Statutory Criterion 1 – "The contaminant may have an adverse effect on the health of persons." To evaluate the first criterion, the EPA evaluates whether a contaminant has an EPA health assessment, or an externally peer-reviewed health assessment from another agency that is publicly available and conforms with current EPA guidelines, from which an HRL can be derived. The HRL derived in or from the health assessment takes into account the MOA, the critical health effect(s), the dose-response relationship for critical health effect(s) and impacts on sensitive population(s) or lifestages.

If an acceptable health assessment that demonstrates adverse health effects is available, 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 would receive a "yes" to the first criterion.)

(b) Statutory Criterion 2 – "The contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern." The EPA compares the occurrence data for each contaminant to the HRL to determine if the contaminant occurs at a frequency and levels of public health concern. The types of occurrence data used at this stage are described in section III.C.1, Evaluation of Contaminant Occurrence and Exposure, and in Appendix B of the *Regulatory Determination 5 Support Document* (USEPA, 2024b). The agency may consider the multiple factors when identifying contaminants or contaminant groups that are occurring at frequencies and levels of public health concern, including:

- How many samples (number and percentage) have detections > HRL in the nationally representative and other finished water occurrence data?
- How many systems (number and percentage) have detections > HRL in the nationally

representative and other finished water occurrence data, and, 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?

- Is the geographic distribution of the contaminant occurrence national, regional or localized?
- Are there significant uncertainties or limitations with the data or analyses, such as the age of the dataset, the MRL (*i.e.*, MRL > HRL), or representativeness of the data (*e.g.*, limited in scope to a specific region)?

(c) Statutory Criterion 3 – "In the sole judgment of the Administrator, regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems." The EPA evaluates the population exposed at the health level of concern along with several other factors to determine if regulation presents a meaningful opportunity for health risk reduction. Among other things, the EPA may consider the following factors in evaluating statutory criterion 3:

- What is the nature of the health effect(s) identified in statutory criterion 1?
- Are there sensitive populations that may be affected (evaluated either qualitatively or quantitatively[11])?

[11] If appropriate and available, the agency considers quantitative exposure data applicable to sensitive populations or lifestages when deriving HRLs for regulatory determinations. When data are not available on sensitive populations, the derivation of the RfD typically includes an uncertainty factor to account for the limitation in the database. Additionally, the EPA will use exposure factors relevant to the sensitive population in deriving the HRL. See Section III.C.1. Sensitive populations are also qualitatively considered by providing national prevalence estimates for a particular sensitive population, if available.

- Based on the occurrence information 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 RSC 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.*, lack of available treatment or analytical methods)?

If the Administrator, in their sole judgement, determines that there is a meaningful opportunity to reduce risk by regulating the contaminant in drinking water, then the agency answers "yes" to the third statutory criterion.

The agency may make a positive preliminary determination if the agency answers "yes" to all three statutory criteria in Phase 3 for a particular contaminant. Additionally, after identifying compounds occurring at frequencies and levels of public health concern, if any, 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 effect studies that could affect the derivation of an RfD or CSF identified through the systematic review process would then be placed in the docket at the time of the preliminary determination for public comment (discussed further in section IV of this document).

If, after considering public comment on the preliminary regulatory determination, the agency again answers "yes" to all three statutory criteria, the agency then may make a positive

final determination that regulation is appropriate and proceed to develop an MCLG and NPDWR. If a final positive determination is made, the agency has 24 months to publish a proposed MCLG and NPDWR and an additional 18 months to publish a final MCLG and promulgate a final NPDWR[12].

It should be noted that the analyses associated with a regulatory determination process are distinct from the more detailed analyses needed to develop an NPDWR. The development and promulgation of an NPDWR is a multi-step process, which includes deriving a proposed MCLG as well as conducting a statutorily required 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 EPA must also prepare a HRRCA which includes 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 a contaminant has sufficient information and the agency answers "no" to any of the three statutory criteria based on the available data, then the agency considers making a negative determination that an NPDWR is not appropriate for that contaminant at that time. A final determination not to regulate a contaminant is, by statute, a final agency action and is subject to judicial review. While a negative determination is considered a final agency action under SDWA

[12] The statute authorizes a nine-month extension of this promulgation date.

for a round of regulatory determinations, the contaminant may be relisted on a future CCL based on newly available health or occurrence information.

If a negative determination or no determination is made for a contaminant, the agency may decide to develop an HA, which provides non-regulatory concentration values for drinking water contaminants at which adverse health effects are not anticipated to occur over specific exposure durations (*e.g.*, one day, ten days, or a lifetime). The EPA's HAs 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. See SDWA section 1412(b)(1)(F).

After evaluating the CCL 5 contaminants in Table 3 of this document against the three SDWA criteria and considering the factors listed for each, the agency is making preliminary negative regulatory determinations for nine CCL 5 contaminants. Table 5 of this documentprovides a summary of the 14 contaminants evaluated for Phase 3 and the preliminary regulatory determination outcome for each contaminant. The agency seeks comment on the preliminary determination not to regulate nine contaminants (2-aminotoluene, cylindrospermopsin, ethoprop, microcystins, molybdenum, permethrin, profenofos, tebuconazole and tribufos). Section IV.B of this document provides a more detailed summary of the information and the rationale used by the agency to reach its preliminary decisions for these contaminants. At this time, the agency is not making preliminary regulatory determinations for five of the 14 contaminants that proceeded to Phase 3, namely1,2,3-trichloropropane (1,2,3-TCP), 1,4-dioxane, manganese, quinoline and strontium (see section V of this document for more information).

Table 3. Contaminants Evaluated in Phase 3 and the Regulatory Determination Outcome		
#	**Contaminant**	**Preliminary Determination Outcome**
1	2-Aminotoluene (*o*-Toluidine)	Negative Determination
2	1,2,3-Trichloropropane	No Determination
3	1,4-Dioxane	No Determination
4	Cylindrospermopsin	Negative Determination
5	Ethoprop	Negative Determination
6	Manganese	No Determination
7	Microcystins	Negative Determination
8	Molybdenum	Negative Determination
9	Permethrin	Negative Determination
10	Profenofos	Negative Determination
11	Quinoline	No Determination
12	Strontium	No Determination
13	Tebuconazole	Negative Determination
14	Tribufos	Negative Determination

In *National Resources Defense Council v. Michael S. Regan, Administrator, U.S. Environmental Protection Agency and Environmental Protection Agency (NRDC v. EPA),* 67 F.4th 397 (D.C. Cir., 2023), the D.C. Circuit Court of Appeals ruled that when the EPA finalizes a positive regulatory determination for a contaminant under the SDWA, the EPA must then

promulgate a regulation and the EPA does not have the ability to withdraw a final positive determination during the development of the proposed rule. This ruling presents a change to the EPA's understanding of the flexibilities afforded to the agency under the SDWA. Prior to this ruling, the EPA had understood that the agency could withdraw a positive determination if, during the more-detailed analyses conducted during the development of the proposed rule, for example, in the HRRCA, the EPA determined that the potential for health-risk reduction was less beneficial than initially predicted. Following the *NRDC v. EPA* ruling and the understanding now of the EPA's authorities under the SDWA, the agency will need to be more certain of the potential for health-risk reduction through regulation before making a determination to regulate a contaminant. As a result, the EPA will need to consider preliminary health benefits analysis information to support the finding that a positive determination would provide a meaningful opportunity for health risk reduction if the agency decides to regulate a contaminant under the SDWA. Therefore, the EPA is not making a regulatory determination for these five contaminants at this time, in order to gain an understanding of the potential for health-risk reduction by conducting additional analyses of the potential benefits and treatment feasibility prior to making positive determinations.

B. Supporting Documentation for the EPA's Preliminary Determination

For this action, the EPA prepared several supporting documents that are available for review and comment in the EPA Water Docket. These support documents include:

- The comprehensive regulatory support document, *Regulatory Determination 5 Support Document* (USEPA, 2024b), summarizes the information and data evaluated by the EPA on the physical and chemical properties, uses and environmental release, environmental fate, potential health effects, occurrence and exposure estimates, analytical methods,

treatment technologies and preliminary determinations. Additionally, Appendix B of the *Regulatory Determination 5 Support Document* describes the approach implemented by the agency to evaluate the CCL 5 contaminants in a three-phase process and select the contaminants for preliminary determinations for RD 5.

- A comprehensive technical occurrence support document for UCMR 4, *Occurrence Data from the Fourth Unregulated Contaminant Monitoring Rule (UCMR 4)* (USEPA, 2024c). This occurrence support document includes more detailed information about UCMR 4, how the EPA assessed the data quality, completeness and representativeness, and how the data were used to generate estimates of drinking water contaminant occurrence in support of these regulatory determinations.

C. Analyses Used to Support the Preliminary Regulatory Determinations

1. Evaluation of Contaminant Occurrence and Exposure

The EPA uses data from many sources to evaluate occurrence and exposure from drinking water contaminants. The discussion in this section focuses mainly on the following sources of finished drinking water occurrence data:

- Unregulated Contaminant Monitoring Rules (UCMR 1, 2, 3 and 4);
- UCM-State Program Rounds 1 and 2; and,
- Data collected by states.

Several of the primary sources of finished water occurrence data are designed to be statistically representative of the nation. These data sources include Assessment Monitoring (AM) data collected under UCMR 1-4 and Screening Survey (SS) data collected under UCMR 2 and 3.

The agency also evaluates supplemental sources of information on occurrence in drinking

water, information on occurrence in ambient and source water and information on contaminant production and release to augment and complement these primary sources of drinking water occurrence data. section III.C.1.a of this action provides a brief summary of the primary sources of finished water occurrence data and sections III.C.1.b and III.C.1.c provide brief summary descriptions of some of the supplemental sources of occurrence information and data. These descriptions do not cover all the sources that the EPA reviews and evaluates. For individual contaminants, the EPA reviews additional published reports and peer-reviewed studies that may provide the results of monitoring efforts in limited geographic areas. A summary of the occurrence data and the results or findings for each of the contaminants considered for regulatory determination is presented in section IV.B, the contaminant profiles section, and the data are described in further detail in the *Regulatory Determination 5 Support Document* (USEPA, 2024b).

(a) Primary Sources of Finished Drinking Water Occurrence Data

The following section provides a brief summary of the finished water occurrence data sources used in RD 5. Table 4 in section IV of this document lists the primary data source/finding used to evaluate each of the nine contaminants for which the EPA is making preliminary determinations in this *Federal Register* Notice. The contaminant-specific discussions in section IV of this document, provide more detailed information about the primary data source findings as well as any supplemental occurrence information.

Section V of this document provides more information about the five Phase 3 contaminants for which the EPA is not making a preliminary regulatory determination at this time: 1,4-dioxane, 1,2,3-TCP, manganese, quinoline and strontium.

- The Unregulated Contaminant Monitoring Rules (UCMR 1, UCMR 2, UCMR 3 and

UCMR 4)

The UCMR program is the EPA's primary vehicle for collecting monitoring data on the occurrence of unregulated contaminants in PWSs. SDWA section 1412 (b)(1)(B)(ii)(II) requires that the EPA include consideration of the data collected by the UCMR program in making regulatory determinations. The UCMR program is designed to collect nationally representative occurrence data in coordination with the CCL and regulatory determination processes. The UCMR sampling is limited by statute to no more than 30 contaminants every five years (SDWA section 1445(a)(2)). However, the National Defense Authorization Act for Fiscal Year 2020 provided a one-time exception to this limit by stating that PFAS monitored under UCMR 5 do not count toward the limit of 30 contaminants. The EPA published the lists and requirements for UCMR 1 on September 17, 1999 (64 FR 50556; USEPA, 1999), and the monitoring was conducted primarily during 2001-2005. The requirements for UCMR 2 were published on January 4, 2007 (72 FR 367; USEPA, 2007) with monitoring conducted primarily during 2008-2010. Requirements for UCMR 3 were published on May 2, 2012 (77 FR 26072; USEPA, 2012a); with monitoring conducted primarily during 2013-2015. Requirements for UCMR 4 were published on December 20, 2016 (81 FR 92666; USEPA, 2016c) with monitoring conducted primarily during 2018-2020. (The complete contaminant lists are available at: *https://www.epa.gov/dwucmr*.) On December 27, 2021, the EPA published UCMR 5, requiring certain PWSs to collect national occurrence data for 29 PFAS and lithium from 2023 through 2025 (86 FR 73131; USEPA, 2021c). The final UCMR 5 dataset is not complete at the time of these RD 5 preliminary determinations and will not conclude until December 31, 2026.

The UCMR program is designed as a three-tiered approach for monitoring contaminants related to the availability and complexity of analytical methods, laboratory capacity, sampling

frequency, relevant PWSs based on contaminants and other considerations (*e.g.*, cost/burden). AM is the primary tier and the largest in scope. The AM generally relies on analytical methods that use more common techniques and are expected to be widely available. SS monitoring is smaller in scope than the AM and generally pertains to monitoring with less established analytical techniques, such that laboratory capacity or cost may be a concern. A Pre-Screen Testing (PST) tier can be customized to meet specific monitoring objectives for a specific group of PWSs.

The EPA designed the AM sampling frame to ensure that sample results would support a high level of confidence and a low margin of error (see USEPA, 1999 and 2001a, for UCMR design details). The AM program includes PWSs from all 50 states, the District of Columbia, all five U.S. territories and Tribal lands across the EPA regions. The AM is required for all large and very large PWSs, those serving between 10,001 and 100,000 people and serving more than 100,000 people, respectively (*i.e.*, a census of all large and very large systems) and a national statistically representative sample of 800 small PWSs, those serving 10,000 or fewer people.[13] The small system sample is stratified and population-weighted and includes some other sampling adjustments such as allocating a selection of at least two systems from each state for spatial coverage. The design meets the data quality objective for overall exposure estimates (99% confidence level with ±1% error tolerance, at 1% exposure) while providing more precise occurrence estimates for categories of small systems. The AM, the primary tier, has been used

[13] Section 1445 of the Safe Drinking Water Act was recently amended by Pub. L. 115-270, America's Water Infrastructure Act of 2018 (AWIA), and now specifies that, effective October 23, 2021, subject to the availability of appropriations for such purpose and appropriate laboratory capacity, the EPA must require all systems serving between 3,300 and 10,000 persons to monitor and ensure that only a representative sample of systems serving fewer than 3,300 persons are required to monitor.

for all or a subset of contaminants in each UCMR cycle. With contaminant monitoring data from all large PWSs and a statistical, nationally representative sample of small PWSs, AM provides a robust dataset for evaluating national drinking water contaminant occurrence.

Each system conducts monitoring for 12 consecutive months during the three-year monitoring period. The rules typically require quarterly monitoring for surface water and groundwater under the direct influence of surface water (GWUDI) systems and twice-a-year, six-month-interval monitoring for groundwater systems, and include flexibilities for specialized sampling (*e.g.*, eight sample events for cyanotoxins in UCMR 4). Samples may be collected at different sampling points or locations within the PWS depending on the specific contaminant (*e.g.*, entry point to the distribution system). A brief outline of the structure of the UCMR efforts is provided in the paragraphs that follow.

UCMR 1 included both the AM and SS tiers. UCMR1 AM was conducted by approximately 3,100 large systems and approximately 800 small systems and resulted in over 33,900 sample results for each contaminant. The UCMR 1 SS design included approximately 640 UCMR1 SS PWSs randomly selected from those PWSs required to conduct AM and was designed to determine if additional monitoring would be needed. Samples from the 639 PWSs from throughout the nation provided over 2,300 results for each contaminant. While the statistical design of the SS is national in scope, the uncertainty in the results for contaminants that have low occurrence is relatively high. Therefore, the EPA looked for additional data to supplement the SS data for regulatory determinations in RD 2. After UCMR 1, the SS design was adapted to include more PWSs and to be representative of national occurrence.

UCMR 2 also included the AM and SS tiers. The UCMR 2 AM was conducted by approximately3,300 large systems and 800 small systems and resulted in over 32,000 sample

results for each contaminant. For the UCMR 2 SS, the EPA improved the design to include a census of all systems serving more than 100,000 people, a nationally representative, statistically selected sample of 320 PWSs serving between 10,001 and 100,000 people, and a nationally representative sample including approximately 480 small PWSs serving 10,000 or fewer people (72 FR 367, January 4, 2007, USEPA, 2007). With a total of approximately 1,200 systems participating in the SS, sufficient data were generated to provide a confident national estimate of contaminant occurrence and population exposure. The UCMR 2 SS PWSs provided between 11,100 to 18,100 sample results per contaminant (depending on the specific sampling design for the contaminant).

UCMR 3 included the AM, SS and PST tiers. The UCMR 3 AM was conducted by approximately 4,100 large systems and approximately 800 small systems and resulted in between 36,800 and 63,000 sample results for each contaminant (depending on the specific sampling design for the contaminant). The UCMR 3 SS monitoring was conducted by all large systems serving more than 100,000 people, a nationally representative sample of 320 large systems serving 10,001 to 100,000 people and a nationally representative sample of approximately 480 small water systems serving 10,000 or fewer people for a total of approximately 1,200 PWSs. The UCMR 3 SS PWSs provided over 11,700 sample result per contaminant. The UCMR 3 PST monitoring was conducted by approximately 800 PWSs including, transient noncommunity water systems that purchase all their finished water from another. See USEPA (2012a) and USEPA (2019b) for more information on the UCMR 3 study design and data analysis.

UCMR 4 involved only AM and did not include any SS or PST efforts. The UCMR 4 AM was conducted by approximately 4,200 large systems and two separate nationally representative statistical samples of approximately 800 small PWSs. One set of 800 small

systems monitored for cyanotoxins, while the second set of 800 small systems monitored for the remaining UCMR 4 contaminants.

Systems with surface water or GWUDI monitored for cyanotoxins and conducted eight sampling events over a period of four consecutive months. Cyanotoxin sampling was conducted during the period of March through November, when harmful algal bloom (HAB) events are more likely to occur in the Northern Hemisphere. Groundwater systems were excluded from cyanotoxin monitoring (USEPA, 2016c). Overall, the UCMR 4 AM resulted in approximately 35,000 to 63,000 sample results per contaminant (depending on the specific sampling design for the contaminant). (81 FR 92666; USEPA, 2016c)

The details of the occurrence data and the results or findings for each of the contaminants considered for regulatory determination are presented in section IV.B of this document, the contaminant profiles section, and are described in further detail in the *Regulatory Determination 5 Support Document* (USEPA, 2024b). The national design, the statistical sampling frame, any new analytical methods and the data analysis approach for the UCMR program have been peer-reviewed at different stages of development (see USEPA, 2001b, 2008b, 2015a, 2019b).

The fifth UCMR (UCMR 5) FRN, published December 2021, requires sample collection and analysis for 29 PFAS, including PFOA, PFOS, PFHxS, PFNA, HFPO-DA and PFBS, to occur between January 2023 and December 2025 using drinking water analytical methods developed by the EPA. Section 2021 of America's Water Infrastructure Act of 2018 (AWIA) (Public Law 115-270) amended SDWA and specifies that, subject to the availability of EPA appropriations for such purpose and sufficient laboratory capacity, the EPA must require all PWSs serving between 3,300 and 10,000 people to monitor and ensure that a nationally representative sample of systems serving fewer than 3,300 people monitor for the contaminants

in UCMR 5 and future UCMR cycles. All large water systems continue to be required to participate in the UCMR program. As data under the UCMR 5 are being collected concurrently with the RD 5 evaluation process, the complete UCMR 5 dataset is not available to inform the regulatory determinations in this preliminary RD 5 FRN. The EPA intends to evaluate the full UCMR 5 dataset when it is available and to consider making regulatory determinations for the included contaminants in the future.

The UCMR program serves as the primary occurrence data source for all nine preliminary determinations included in this FRN. Other examples of occurrence data sources considered to be nationally representative for RD 5 are listed here. These are described in more detail in Chapter 2 of the *Regulatory Determination 5 Support Document* (USEPA, 2024b).

- National Inorganics and Radionuclides Survey (NIRS)
- Unregulated Contaminant Monitoring (UCM) Program Rounds 1 and 2

(b) Supplemental Sources of Finished Drinking and Ambient Water Occurrence Data

The agency evaluates several sources of supplemental information related to contaminant occurrence in finished water and ambient and source waters to augment the primary drinking water occurrence data. Some of these sources were part of other agency information gathering efforts or submitted to the agency in public comment or suggested by stakeholders during previous CCL and regulatory determination efforts. These supplemental data are useful to evaluate the likelihood of contaminant occurrence in drinking water, to more fully characterize a contaminant's presence in the environment and potentially in source water and to evaluate any possible trends or spatial patterns that may need further review. In cases where there is a

sufficient amount of non-national data to illustrate contaminant occurrence at a national level, the EPA may use non-national data as the basis for a regulatory determination. The descriptions that follow do not cover all the sources that the EPA used. For individual contaminants, the EPA reviewed additional published reports and peer-reviewed studies that may have provided the results of monitoring efforts in limited geographic areas. A more detailed discussion of the supplemental sources of information/data that the EPA evaluated and the occurrence data for each contaminant can be found in the *Regulatory Determination 5 Support Document* (USEPA, 2024b).

Occurrence data were collected from other sources for consideration in RD 5 as well. Non-national occurrence data sources are also discussed in detail in Chapter 2 of the *Regulatory Determination 5 Support Document* and include:

- Individual states' data
- Community Water System Survey (CWSS) Data
- United States Department of Agriculture (USDA) Pesticide Data Program (PDP)
- United States Geological Survey (USGS) Pilot Monitoring Program (PMP)
- USGS National Water Quality Assessment (NAWQA)
- National Water Information System (NWIS)
- Water Quality Exchange (WQX) / Water Quality Portal (WQP) Data System (Formerly the Storage and Retrieval Data System [STORET])

(c) Supplemental Production, Use and Release Data

The agency reviews various sources of information to assess if there are changes or trends in a contaminant's production, use and release that may affect its presence in the environment and potential occurrence in drinking water. The cancellation of a pesticide or a clear

increase in production and use of a contaminant are trends that can inform the regulatory determination process. Examples of such sources are listed here. A more detailed discussion of the supplemental sources of information/data that the EPA evaluated and the occurrence data for each contaminant can be found in the *Regulatory Determination 5 Support Document* (USEPA, 2024b).

- Inventory Update Reporting (IUR) and Chemical Data Reporting (CDR) Program (*https://www.epa.gov/chemical-data-reporting*)
- Toxics Release Inventory (TRI) (*https://www.epa.gov/toxics-release-inventory-tri-program*)
- Pesticide Usage Estimates (*https://www.epa.gov/pesticides/pesticides-industry-sales-and-usage-2008-2012-market-estimates*)

IV. Contaminant-Specific Discussions for the RD 5 Preliminary Determinations

A. Summary of the Preliminary Regulatory Determinations

Based on the EPA's evaluation of the three SDWA criteria (discussed in section II.B.1 of this document), the agency is making preliminary determinations not to regulate nine contaminants. For each of the nine contaminants discussed in this section of this Document, Table 4 of this document summarizes information about the qualifying health assessment that was selected, the critical study, the critical effect and the associated oral reference value or oral CSF used to derive an HRL. Following Table 4, Table 5 of this document summarizes the primary occurrence information used to make these preliminary regulatory determinations. Section IV.B of this document provides a more detailed summary of the information and the rationale used by the agency to reach its preliminary decisions for these nine contaminants. For

more information about the five Phase 3 contaminants that are not receiving a preliminary regulatory determination, see section Vof this document.

Table 4. Health Effects Information for Contaminants Discussed in Section IV

RD 5 Contaminant	Qualifying Health Assessment Selected	Critical Study	Critical Effect	Oral Reference Value for Noncancer Effects, in mg/kg/day	Oral CSF, in $(mg/kg/day)^{-1}$	HRL, in µg/L
2-Aminotoluene	EPA PPRTV, 2012	Weisburger et al., 1978	Subcutaneous fibromas and fibrosarcomas in male rats and mice	n/a	0.016	2
Cylindrospermopsin	EPA OW HESD, 2015	Humpage and Falconer, 2002; Humpage and Falconer, 2003	Increased relative kidney weight in male mice	0.0001	n/a	0.6
Ethoprop	EPA OPP HHRA, 2015	Chartier et al., 2005	Inhibition of red blood cell (RBC) cholinesterase (ChE) in postnatal day (PND) 11 rat pups	6.5×10^{-5}	n/a	0.09
Microcystins *	EPA OW HESD, 2015	Heinze, 1999	Liver effects (increased liver weight, slight to moderate liver necrosis lesions and increased enzyme levels) in rats	5×10^{-5}	n/a	0.3
Molybdenum	ATSDR, 2020	Murray et al., 2014	Renal proximal tubule hyperplasia	0.06	n/a	100
Permethrin	EPA OPP HHRA, 2020	Wolansky et al., 2006	Decreased motor activity in adult male rats	0.44	n/a	3000
Profenofos	EPA OPP	Burdock	Inhibition of RBC	0.00012	n/a	0.7

	HHRA, 2015	et al., 1981	acetylcholinesterase (AChE) in adult rats			
Tebuconzole	EPA OPP HHRA, 2021	Becker and Biedermann, 1995	Increased incidence of skull/neural tube defects including abnormalities of the eyes, head and skull	0.03	n/a	200
Tribufos	EPA OPP HHRA, 2015	Sheets and Gilmore, 2001	Inhibition of RBC ChE in adult female rats	0.0002	n/a	1

*****Microcystin LR was used as a surrogate for deriving an oral reference value for all microcystin congeners.

Table 5. Occurrence Findings from Primary Data Sources

RD 5 Contaminant	HRL, µg/L	Primary Database	PWSs with at least 1 detection > ½ HRL	Population served by PWSs with at least 1 detection > ½ HRL	PWSs with at least 1 detection > HRL	Population served by PWSs with at least 1 detection > HRL
2-Aminotoluene	2	UCMR 4 AM	0 / 5,030 (0.00%)	0 / 249 M (0.00%)	0 / 5,030 (0.00%)	0 / 249 M (0.00%)
Cylindrospermopsin	0.6	UCMR 4 AM	3 / 3,484 (0.09%)	30,829 / 195 M (0.02%)	1 / 3,484 (0.03%)	10,174 / 195 M (0.01%)
Ethoprop	0.09	UCMR 4 AM	3 / 5,028 (0.06%)	75,032 / 249 M (0.03%)	1 / 5,028 (0.02%)	14,999 / 249 M (0.01%)
Microcystins	0.3	UCMR 4 AM	7 / 3,485 (0.20%)	119,725 / 195 M (0.06%)	7 / 3,485 (0.20%)	119,725 / 195 M (0.06%)
Molybdenum	100	UCMR 3 AM	29 / 4,922 (0.59%)	600,187 / 241 M (0.25%)	7 / 4,922 (0.14%)	148,678 / 241 M (0.06%)
Permethrin	3000	UCMR 4 AM	0 / 5,028 (0.00%)	0 / 249 M (0.00%)	0 / 5,028 (0.00%)	0 / 249 M (0.00%)
Profenofos	0.7	UCMR 4 AM	4 / 5,028 (0.08%)	85,728 / 249 M (0.03%)	1 / 5,028 (0.02%)	14,999 / 249 M (0.01%)
Tebuconazole	200	UCMR 4 AM	0 / 5,028 (0.00%)	0 / 249 M (0.00%)	0 / 5,028 (0.00%)	0 / 249 M (0.00%)
Tribufos	1	UCMR 4 AM	0 / 5,027 (0.00%)	0 / 249 M (0.00%)	0 / 5027 (0.00%)	0 / 249 M (0.00%)

B. Contaminant Profiles

1. 2-Aminotoluene

(a) Background

2-Aminotoluene (also referred to as *o*-toluidine or 2-methylaniline) is a synthetic aromatic amine and occurs as a colorless or light-yellow liquid. It is used in the manufacture of dyes, rubber vulcanization accelerators, pharmaceuticals and pesticides.

Production data for 2-aminotoluene are available from the EPA's IUR and CDR programs. Annual production and importation of 2-aminotoluene was last reported by IUR for 2005 to be in the range of 10 to <50 million pounds. From 2012 to 2019, annual production was in the range of 50 to 100 million pounds as reported under CDR. Industrial release data from TRI indicate that on-site surface water discharges have been at just under 200 pounds per year since 2009, with no more than six states reporting surface water discharges in a given year.

An overall removal half-life for 2-aminotoluene in Rhine River water was estimated to be approximately 1 day (IPCS, 1998). Volatilization from water surfaces is expected to be an important fate process. Based on these physical and chemical properties, 2-aminotoluene is unlikely to be environmentally persistent in surface water.

(b) Statutory Criterion 1 (Adverse Health Effects)

The EPA proposes to find that 2-aminotoluene meets the first SDWA statutory criterion for regulatory determinations: exposure to 2-aminotoluene may have an adverse effect on the health of persons. The health assessment selected for RD 5 is the 2012 EPA Provisional Peer-Reviewed Toxicity Value (PPRTV) (USEPA, 2012b) because it is the only qualifying peer-reviewed health assessment identified for 2-aminotoluene that derives an oral 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, 2005b; USEPA, 2012b).

In the 2012 EPA PPRTV (USEPA, 2012b), the EPA selected a chronic carcinogenicity diet study in mice and rats (Weisburger et al., 1978) as the critical study to derive an oral CSF for 2-aminotoluene (see section 3.3 of Chapter 3 in the *Regulatory Determination 5 Support Document* for more details about the critical study). Increased subcutaneous fibromas and fibrosarcomas in male rats was the critical effect selected for derivation of an oral CSF because it provided the most sensitive cancer endpoint (USEPA, 2012b). Because the Weisburger et al. (1978) study exposed experimental animals to *o*-toluidine hydrochloride (HCl), the EPA converted the oral CSF of 0.02 $(mg/kg\text{-}day)^{-1}$ *o*-toluidine HCl to account for the molecular weight difference of *o*-toluidine, resulting in a computed oral CSF of 0.016 $(mg/kg\text{-}day)^{-1}$ for o-toluidine (2-aminotoluene) (USEPA, 2012b).

Because exposure began during postnatal development (*i.e.*, at six to eight weeks of age) in the critical study (Weisburger et al., 1978), 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) of 0.0343 L/kg/day (USEPA, 2019a) to derive the HRL for 2-aminotoluene (see decision logic provided in section B.6.1.2 of the RD 5 Protocol, found in Appendix B of the *Regulatory Determination 5 Support Document*).

Following HRL derivation practices, the EPA derived an HRL for 2-aminotoluene of 2 µg/L after rounding to one significant figure, based on a one-in-a-million (10^{-6}) CRL, an oral CSF of 0.016 $(mg/kg/day)^{-1}$ (USEPA, 2012b) and a DWI-BW of 0.0343 L/kg/day (USEPA, 2019a).

These analyses formed the basis for the EPA's finding that 2-aminotoluene may have adverse effect on the health of persons and therefore that Statutory Criterion 1 is met.

(c) Statutory Criterion 2 (Occurrence)

The EPA proposes to find that 2-aminotoluene does not occur with a frequency and at levels of public health concern in PWSs based on the EPA's evaluation of the following occurrence information.

The primary occurrence data for 2-aminotoluene are nationally representative drinking water monitoring data from the UCMR 4 program (2018-2020). Under UCMR 4 AM, 37,517 samples collected from 5,030 PWSs were analyzed for 2-aminotoluene. Of these systems, 86 (1.71%) reported detections at or above the MRL of 0.007 µg/L. There were no detections greater than the HRL (2 µg/L) or the ½ HRL threshold (1 µg/L) (USEPA, 2024b). This comprehensive dataset suggests that 2-aminotoluene is not present in public water systems at concentrations that would pose a risk to human health.

Occurrence data for 2-aminotoluene in ambient water are available from the NWIS database and STORET. NWIS data show no detections of 2-aminotoluene in any of the 145 samples at 67 sites. The STORET data set had no detections of 2-aminotoluene out of 3 samples collected at 3 sites in 2021-2022.

Based on the evaluation of these data sources, the EPA finds that 2-aminotoluene does not occur and is not likely to occur in PWSs with a frequency and at levels of public health concern. Therefore, the EPA finds that Statutory Criterion 2 is not met.

(d) Statutory Criterion 3 (Meaningful Opportunity)

Regulating 2-Aminotoluene under the SDWA does not present a meaningful opportunity for health risk reduction for persons served by PWSs based on the estimated exposed population, including sensitive populations. UCMR 4 data indicate that the estimated population exposed to 2-aminotoluene at levels of public health concern is 0%. As a result, the agency finds that an

NPDWR for 2-aminotoluene does not present a meaningful opportunity for health risk reduction.

(e) Preliminary Regulatory Determination for 2-Aminotoluene

The agency is making a preliminary determination not to regulate 2-aminotoluene with an NPDWR after evaluating health, occurrence and other related information against the three SDWA statutory criteria. While data indicate that 2-aminotoluene may have an adverse effect on human health, the occurrence data indicate that 2-aminotoluene does not occur, nor is it likely to occur in PWSs with a frequency and at levels of public health concern.

Therefore, the agency has determined that regulating 2-aminotoluene with an NPDWR would not present a meaningful opportunity to reduce health risk for persons served by PWSs. The *Regulatory Determination 5 Support Document* (USEPA, 2024b) and the *Occurrence Data from the Fourth Unregulated Contaminant Monitoring Rule (UCMR 4)* (USEPA, 2024c) present additional information and analyses supporting the agency's evaluation of 2-aminotoluene.

2. Cylindrospermopsin

(a) Background

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. HABs of cyanobacteria in freshwater environments can release quantities of cyanotoxins, including cylindrospermopsin.

Cylindrospermopsin is a tricyclic alkaloid (USEPA, 2015b). Cylindrospermopsin is naturally produced in the environment by cyanobacteria genera including the cylindrospermopsin-producing species *Aphanizomenon*, *Dolichospermum* (previously *Anabaena*), *Lyngbya, Raphidiopsis* (previously *Cylindrosperopsis*) and *Umezakia* (USEPA, 2022d). 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).

Cylindrospermopsin may readily leach or be released from intact cyanobacterial cells into surrounding water. Field studies have found that from 24% to 100% of cylindrospermopsin can be extracellular (Chorus and Welker, 2021). Cylindrospermopsin is highly water-soluble (WHO, 2020a). 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. Bioaccumulation of cylindrospermopsin in freshwater organisms has been documented (Kinnear, 2010).

(b) Statutory Criterion 1 (Adverse Health Effects)

Exposure to cylindrospermopsin may have an adverse effect on the health of persons as supported by the health assessments identified for RD 5 (USEPA, 2015b; WHO, 2020a). The health assessment selected to derive an HRL for cylindrospermopsin is the 2015 EPA Office of Water (OW) Health Effects Support Document (HESD) (USEPA, 2015b) because it is an EPA peer-reviewed health assessment that derives an oral toxicity value and it uses the best available science in its evaluation of noncancer risk for cylindrospermopsin.

In the 2015 EPA OW HESD (USEPA, 2015b), the EPA selected an 11-week drinking water toxicity study in mice (Humpage and Falconer, 2002; Humpage and Falconer, 2003) as the critical study to derive an oral reference value (see section 4.3 of Chapter 4 in the *Regulatory*

Determination 5 Support Document for more details about the critical study). A No Observed Adverse Effect Level (NOAEL) of 30 mg/kg/day for increased relative kidney weight in mice was the critical effect and point of departure (POD) selected to derive an oral reference value because this was the most sensitive endpoint assessed in the critical study (USEPA, 2015b). A total UF of 300 was applied to the POD: an interspecies UF (UF_A) of 10, an intraspecies UF (UF_H) of 10 and a database UF (UF_D) of 3. After applying the total UF of 300 (details can be found in section 4.3 of Chapter 4 in the *Regulatory Determination 5 Support Document*), the oral reference value was calculated to be 0.0001 mg/kg/day (USEPA, 2015b) and the EPA selected this oral reference value to derive an HRL for RD 5.

The critical 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; Humpage and Falconer, 2003). The EPA extrapolated the body weight of the rodents to their approximate age to determine the most sensitive lifestage exposed (Jackson Labs, 2023). Because exposure was estimated to have begun during postnatal development (*i.e.*, at approximately six to eight weeks of age), 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) of 0.0343 L/kg/day (USEPA, 2019a) to derive the to derive the HRL for cylindrospermopsin (see decision logic provided in section B.6.1.2 of the RD 5 Protocol, found in Appendix B of the *Regulatory Determination 5 Support Document*).

Following HRL derivation practices, the EPA derived an HRL for cylindrospermopsin of 0.6 µg/L after rounding to one significant figure, based on an oral reference value of 0.0001 mg/kg/day (USEPA, 2015b), a DWI-BW of 0.0343 L/kg/day (USEPA, 2019a) and a 20% RSC

(USEPA, 2000a). Note that this value differs from the 10-day HA for bottle-fed infants and young children (0.7 µg/L) and the 10-day HA for school-age children through adults (3 µg/L). These HA values are considered protective of non-carcinogenic adverse health effects over a ten-day exposure to cylindrospermopsin in drinking water.

Based on these analyses, the EPA finds that cylindrospermopsin may have an adverse effect on the health of persons and therefore that Statutory Criterion 1 is met.

(c) Statutory Criterion 2 (Occurrence)

The EPA proposes to find that cylindrospermopsin does not occur with a frequency and at levels of public health concern in PWSs based on the EPA's evaluation of the following occurrence information.

Occurrence data for cylindrospermopsin in ambient water are available from the USGS NAWQA program, the USGS NWIS database, the EPA's legacy STORET Data System and several published studies. Additionally, a total of 18 states voluntarily adopted use of the One Health Harmful Algal Bloom System and entered 421 reports during 2016–2018 (Roberts et al., 2020). The majority of HAB events occurred during May-October (98%) and in freshwater bodies (90%). Cylindrospermopsin was reported as present in 4 (1%) of the 421 HAB events.

The primary occurrence data for cylindrospermopsin are nationally representative drinking water monitoring data from the UCMR 4 program (2018-2020). Under UCMR 4 AM, 35,425 samples collected from 3,484 PWSs were analyzed for cylindrospermopsin via EPA Method 545. Monitoring consisted of sampling finished drinking water in PWSs that use surface water or GWUDI. Groundwater systems were excluded from cyanotoxin monitoring. Monitoring occurred twice a month for four consecutive months during the period from March through November (for a total of eight sampling events). Sampling was conducted at entry points to the

distribution system.

In addition to analytical sample results, UCMR 4 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.

Reported UCMR 4 cylindrospermopsin concentrations ranged from 0.09 µg/L (the MRL) to 0.877 µg/L. Of these sampled systems, 12 (0.34% of systems, serving 0.23% 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 the ½ HRL threshold 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 from the population served by the PWSs participating in UCMR 4 to the national PWS-served population suggests that an estimated 34 PWSs serving around 488,000 people nationally have at least one detection of cylindrospermopsin while an estimated 14 PWSs serving 40,900 people nationally have at least one detection of cylindrospermopsin greater than the ½ HRL threshold and only 1 PWS, serving 10,200 people, has at least one detection greater than the HRL.

Based on the evaluation of these data sources, the EPA finds that cylindrospermopsin does not occur in PWSs with a frequency and at levels of public health concern. Therefore, the EPA finds that Statutory Criterion 2 is not met.

(d) Statutory Criterion 3 (Meaningful Opportunity)

Regulating cylindrospermopsin under the SDWA does not present a meaningful opportunity for health risk reduction for persons served by PWSs based on the estimated exposed population, including sensitive populations. The estimated PWS-served population exposed to

cylindrospermopsin at levels of public health concern is 0.01% based on UCMR 4 finished water data.

Conventional water treatment (consisting of coagulation, sedimentation, filtration and chlorination) can generally remove intact cyanobacterial cells and low levels of cyanotoxins from source waters. However, water systems may face challenges in providing drinking water during a severe bloom event when there are high levels of cyanobacteria and cyanotoxins in source waters. With proactive planning, diligent operations and maintenance and active management, PWSs can reduce the risks of cyanotoxins breaking through the treatment process and occurring in finished drinking water. Because these non-regulatory efforts to manage cyanotoxins are effective, the agency finds that an NPDWR for cylindrospermopsin does not present a meaningful opportunity for health risk reduction.

(e) Preliminary Regulatory Determination for Cylindrospermopsin

The EPA is making a preliminary determination not to regulate cylindrospermopsin with an NPDWR after evaluating health, occurrence and other related information against the three SDWA statutory criteria. While data suggest that cylindrospermopsin may have an adverse effect on human health, the occurrence data indicate that cylindrospermopsin is not occurring or not likely to occur in PWSs with a frequency and at levels of public health concern. Additionally, because conventional water treatment and continued efforts by water systems to manage cyanotoxins have proven effective, an NPDWR for cylindrospermopsin does not present a meaningful opportunity for health risk reduction.

2. Ethoprop

(a) Background

Ethoprop is an organophosphate (phosphorodithioate) pesticide and is used as an

insecticide and nematicide. Ethoprop was first registered in the U.S. in 1967 (USEPA, 2006a) and is used on vegetables, fruits and other plants, including potatoes, sweet potatoes, beans, cucumbers, cabbage, pineapples, bananas, plantains, tobacco and ornamentals. Environmental fate assessments with organic carbon partitioning coefficient (Koc) values of 70-120 L/kg suggest ethoprop is mobile in soil and water (NCBI, 2023a).

USGS estimates the usage of ethoprop has unevenly declined from 1992 to 2019, with less than 1 million pounds of ethoprop used per year since 2012 in the United States. According to USGS, ethoprop usage has been limited geographically in recent years, mainly to the Pacific Northwest and California.

(b) Statutory Criterion 1 (Adverse Health Effects)

Exposure to ethoprop may have an adverse effect on the health of persons as supported by the health assessment identified for RD 5 (USEPA, 2015c; USEPA, 2015d). For pesticide chemicals currently registered under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), including ethoprop, toxicity information from the EPA's Office of Pesticide Programs (OPP) Human Health Risk Assessments (HHRAs) was used as the basis for HRL derivation (USEPA, 2024b).

The health assessment selected to derive an HRL for ethoprop is the 2015 EPA OPP HHRA (USEPA, 2015c; USEPA, 2015d), which provided both cancer and noncancer toxicity values (*i.e.*, an oral reference value and oral CSF) for ethoprop. In 2023, OPP conducted exposure assessments for ethoprop to estimate human health risks resulting from registered uses (USEPA, 2023a). The cancer classification had 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, 2005b; 2023a). Although the critical study showed

suggestive cancer effects from exposure to ethoprop, there were no concerns for mutagenicity. As a result, OPP recommended using a non-linear (*i.e.*, RfD) approach as a protective measure of carcinogenic risk and did not conduct a new cancer assessment (USEPA, 2023a). Therefore, for RD 5 the EPA derived a noncancer HRL based on the oral reference value provided in the 2015 EPA OPP HHRA (USEPA, 2015c).

In the 2015 EPA OPP HHRA, the EPA selected a repeat-dosing gavage study in rats (Chartier et al., 2005) as the critical study to derive the oral reference value (see section 5.3 of Chapter 5 in the *Regulatory Determination 5 Support Document* for more details about the critical study). Benchmark dose (BMD) modeling was used to determine the lower 95% confidence limit on the BMD level associated with a 10% response ($BMDL_{10}$), the response in this case being inhibition of cholinesterase (ChE) activity (USEPA, 2015c). Inhibition of red blood cell (RBC) acetylcholinesterase (AChE) activity in postnatal day (PND) 11 males was the critical effect selected for derivation of the oral reference value because it was the most sensitive endpoint modeled (USEPA, 2015c). Therefore, the corresponding $BMDL_{10}$ of 0.0653 mg/kg/day was selected as the POD for ethoprop (USEPA, 2015c). 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 (FQPA) safety factor of 10 to account for uncertainty in the human dose-response relationship for neurodevelopmental effects (USEPA, 2015c). After applying the total UF (for more details about the selected UF, see section 5.3 of Chapter 5 in the *Regulatory Determination 5 Support Document*), the oral reference value was calculated to be 0.000065 mg/kg/day and the EPA selected this oral reference value to derive an HRL for ethoprop.

Because exposure began during early postnatal development (*i.e.*, 11 days of age) in the critical study (Chartier et al., 2005), 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) of 0.143 L/kg/day (USEPA, 2019a) to derive the HRL for ethoprop (see decision logic provided in section B.6.1.2 of the RD 5 Protocol, found in Appendix B of the *Regulatory Determination 5 Support Document*).

Following HRL derivation practices, the EPA derived an HRL for ethoprop of 0.09 µg/L after rounding to one significant figure, based on an oral reference value of 0.000065 mg/kg/day (USEPA, 2015c), a DWI-BW of 0.143 L/kg/day (USEPA, 2019a) and a 20% RSC (USEPA, 2000a).

Based on these analyses, the EPA finds that ethoprop may have an adverse effect on the health of persons and therefore that Statutory Criterion 1 is met.

(c) Statutory Criterion 2 (Occurrence)

The EPA proposes to find that ethoprop does not occur with a frequency and at levels of public health concern in PWSs based on the EPA's evaluation of occurrence information.

The primary occurrence data for ethoprop are nationally representative drinking water monitoring data from UCMR 4 (2018-2020). Ethoprop was found in 0.1% of systems (5 of 5,028) monitored in UCMR 4 AM. Of systems that reported results for ethoprop, three systems, or 0.06%, reported results above the ½ HRL threshold of 0.045 µg/L, and one system (0.02%) reported a result above the HRL (0.09 µg/L). Extrapolating the UCMR 4 data suggests that less than 0.01% of the national PWS-served population may be exposed to ethoprop in drinking water at levels above the HRL.

Based on the evaluation of these data sources, the EPA finds that ethoprop does not occur and is not likely to occur in PWSs with a frequency and at levels of public health concern. Therefore, the EPA finds that Statutory Criterion 2 is not met.

(d) Statutory Criterion 3 (Meaningful Opportunity)

The EPA proposes to find that ethoprop does not occur with a frequency and at levels of public health concern in PWSs based on the EPA's evaluation of the occurrence information. Therefore, regulation of ethoprop under the SDWA does not present a meaningful opportunity for health risk reduction for persons served by PWSs.

(e) Preliminary Regulatory Determination for Ethoprop

The agency is making a preliminary determination not to regulate ethoprop with an NPDWR after evaluating health, occurrence and other related information against the three SDWA statutory criteria. While data suggest that ethoprop may have an adverse effect on human health, the occurrence data indicate that ethoprop is not occurring or not likely to occur in PWSs with a frequency and at levels of public health concern. The *Regulatory Determination 5 Support Document* (USEPA, 2024b) and the *Occurrence Data from the Fourth Unregulated Contaminant Monitoring Rule (UCMR 4*) (USEPA, 2024c) present additional information and analyses supporting the agency's evaluation of ethoprop.

3. Microcystins

(a) Background

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. HABs of cyanobacteria in freshwater environments can release quantities of cyanotoxins, including microcystins.

Microcystins exist in multiple forms (congeners), based on variations in amino acid composition; there are approximately 100 known microcystin congeners (USEPA, 2015e). Microcystins are generally distinguished using letters that refer to the two variable amino acids.

Microcystin-LR, which includes leucine (L) and arginine (R) amino acids, is the most common congener and also the most intensively studied (USEPA, 2015e). Synonyms for microcystin-LR include cyanoginosin LR (NCBI, 2022).

The cyanobacteria genera *Anabaena*, *Fischerella*, *Gloeotrichia, Microcystis*, *Nodularia*, *Nostoc*, *Oscillatoria* and *Planktothrix* are known to include microcystin-producing species (USEPA, 2015e). Microcystins are the most common cyanotoxins found worldwide and they have been reported in surface waters in most of the U.S. (Funari and Testai, 2008 as cited in USEPA, 2015e). 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. 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, 2015f). Microcystins have the potential for bioconcentration and bioaccumulation in tissue (Machado et al., 2017).

(b) Statutory Criterion 1 (Adverse Health Effects)

Exposure to microcystin congeners microcystin-LA, microcystin-LW, microcystin-RR, microcystin-YR and microcystin-LR, referred to collectively throughout this document as "microcystins," may have an adverse effect on the health of persons as supported by the multiple health assessments identified for RD 5 (USEPA, 2015e; HC, 2017; WHO, 2020b). The health assessment selected for RD 5 is the 2015 EPA OW HESD (USEPA, 2015e) because it is an EPA

peer-reviewed health assessment that derives an oral toxicity value and uses the best available science in its evaluation of noncancer risk.

In the 2015 EPA OW HESD (USEPA, 2015e), the EPA selected a 28-day drinking water study in 11-week-old male rats (Heinze, 1999) as the critical study to derive an oral reference value (see section 6.3 of Chapter 6 in the *Regulatory Determination 5 Support Document* for more details about the critical study). A Lowest Observed Adverse Effect Limit (LOAEL) of 50 mg/kg/day for liver effects in rats orally exposed to microcystin-LR was identified as the critical effect and used to derive an oral reference value because this was considered the "most appropriate basis for quantitation as it was a common finding among oral toxicology studies" (USEPA, 2015e). 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, 2015e). A total UF of 1000 was applied to the POD: a UF_A of 10, a UF_H of 10, a LOAEL-to-NOAEL extrapolation UF (UF_L) of 3 and a UF_D of 3. After applying the total UF of 1000, the oral reference value was calculated to be 0.00005 mg/kg/day (USEPA, 2015e) and the EPA selected this oral reference value to derive an HRL for microcystins.

Because exposure in the critical study started post-adolescence (*i.e.*, at 11 weeks of age), the EPA used the DWI-BW EF representing the 90th percentile consumers-only, two-day average, direct and indirect community water consumption for adults (21 years and older) of 0.0336 L/kg/day (USEPA, 2019a) to derive the HRL for microcystins (see decision logic provided in section B.6.1.2 of the RD 5 Protocol, found in Appendix B of the *Regulatory Determination 5 Support Document*).

Following HRL derivation practices, the EPA derived an HRL for microcystins of 0.3

µg/L after rounding to one significant figure, based on an oral reference value of 0.00005 mg/kg/day (USEPA, 2015e), a DWI-BW of 0.0336 L/kg/day (USEPA, 2019a) and a 20% RSC (USEPA, 2000a).

Based on these analyses, the EPA finds that microcystins may have an adverse effect on the health of persons and therefore that Statutory Criterion 1 is met.

(c) Statutory Criterion 2 (Occurrence)

The EPA proposes to find that microcystins do not occur with a frequency and at levels of public health concern in PWSs based on the EPA's evaluation of the following occurrence information.

Occurrence data for microcystins in ambient water are available from the USGS NAWQA program, the USGS NWIS database, the EPA's legacy STORET Data System and several published studies. Additionally, a total of 18 states voluntarily adopted use of the One Health Harmful Algal Bloom System and entered 421 reports during 2016–2018 (Roberts et al., 2020). The majority of HAB events occurred during May-October (98%) and in freshwater bodies (90%). 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. Ambient water occurrence data are also available in the National Lakes Assessment. According to the 2017 report (USEPA, 2022e), microcystin was found in 21% of lakes. 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).

The primary occurrence data for microcystins are nationally representative drinking water monitoring data from the UCMR 4 program (2018-2020). Under UCMR 4 AM, 35,000 samples

were collected from 3,485 PWSs and analyzed for total microcystins via EPA Method 546.[14] 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. Monitoring occurred twice a month for four consecutive months from March through November (for a total of eight sampling events). Sampling was conducted at entry points to the distribution system.

In addition to analytical sample results, UCMR 4 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.

Reported UCMR 4 total microcystins concentrations ranged from 0.32 µg/L to 0.83 µg/L. Seven systems (0.20% of systems, serving 0.06% of the PWS-served population) reported at least one result at or above the MRL for total microcystins. Extrapolating these findings suggests that an estimated 29 PWSs serving 0.06% of the PWS-served population nationally may have detectable levels of total microcystins. While all reported results were above the HRL (0.3 µg/L), only eight of the 35,000 samples collected during UCMR 4 contained reportable concentrations of microcystins.

Based on the evaluation of these data sources, the EPA finds that microcystins do not occur and are not likely to occur in PWSs with a frequency and at levels of public health concern. Therefore, the EPA finds that Statutory Criterion 2 is not met.

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[14] Using EPA Method 546, UCMR 4 systems 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, systems were required to report values for the six included microcystin congeners at or above the EPA-defined MRLs for each individual congener using EPA Method 544. For more details, see USEPA (2024c).

(d) Statutory Criterion 3 (Meaningful Opportunity)

Regulating microcystins under the SDWA does not present a meaningful opportunity for health risk reduction for persons served by PWSs based on the estimated exposed population, including sensitive populations. The estimated population exposed to microcystins at levels of public health concern is 0.06% based on UCMR 4 finished water data.

Conventional water treatment (consisting of coagulation, sedimentation, filtration and chlorination) can generally remove intact cyanobacterial cells and low levels of cyanotoxins from source waters. However, water systems may face challenges in providing drinking water during a severe bloom event when there are high levels of cyanobacteria and cyanotoxins in source waters. With proactive planning, diligent operations and maintenance and active management, PWSs can reduce the risks of cyanotoxins breaking through the treatment process and occurring in finished drinking water. Because these non-regulatory efforts are effective, the agency finds that an NPDWR for microcystins does not present a meaningful opportunity for health risk reduction.

(e) Preliminary Regulatory Determination for Microcystins

The agency is making a preliminary determination to not regulate microcystins with an NPDWR after evaluating health, occurrence and other related information against the three SDWA statutory criteria. While data suggest that microcystins may have an adverse effect on human health, the occurrence data indicate that microcystins are not occurring or not likely to occur in PWSs with a frequency and at levels of public health concern. Additionally, because conventional water treatment and continued efforts by water systems to manage cyanotoxins have proven effective, an NPDWR for microcystins does not present a meaningful opportunity for health risk reduction.

5. Molybdenum

(a) Background

Molybdenum is a naturally occurring element, which, 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.

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; 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. Molybdenum is generally more mobile in water under alkaline conditions, with a greater potential for bioavailability through water exposure (ATSDR, 2020).

(b) Statutory Criterion 1 (Adverse Health Effects)

Exposure to molybdenum may have an adverse effect on the health of persons as supported by the health assessments identified for RD 5 (USEPA, 1992; WHO, 2011; ATSDR, 2020). The health assessment selected for RD 5 is the 2020 ATSDR Toxicological Profile (ATSDR, 2020) because it is the most recent peer-reviewed health assessment identified for molybdenum that derives an oral toxicity value, it uses the best available science in its evaluation of noncancer risk, and its toxicity value is based on a more recent critical study (Murray et al., 2014) than those of previous health assessments (USEPA, 1992; WHO, 2011).

In the 2020 ATSDR Toxicological Profile (ATSDR, 2020), ATSDR selected a 90-day dietary toxicity study in rats (Murray et al. 2014) as the critical study to derive an intermediate-duration oral reference value (see section 7.3 of Chapter 7 in the *Regulatory Determination 5*

Support Document for more details about the critical study). A NOAEL of 17 mg/kg/day for renal effects in female rats was identified as the critical effect to derive an oral reference value because this was the most sensitive endpoint identified (ATSDR, 2020). After applying the total UF of 100 and a modifying factor of 3, the intermediate-duration oral reference value was calculated to be 0.06 mg/kg/day. Because ATSDR did not derive a chronic-duration oral reference value, and 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), the EPA applied a UF for extrapolation from subchronic-to chronic exposure duration (UFs) of 3, per agency guidelines (USEPA, 2002), to the intermediate-duration oral reference value that was derived using the 90-day study. Therefore, the resulting oral reference value used to derive the HRL for molybdenum was calculated to be 0.02 mg/kg/day.

Because exposure began during postnatal development (approximately nine weeks of age), 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) of 0.0343 L/kg/day (USEPA, 2019a) to derive the HRL for molybdenum (see decision logic provided in section B.6.1.2 of the RD 5 Protocol, found in Appendix B of the *Regulatory Determination 5 Support Document*).

Following HRL derivation practices, the EPA derived an HRL for molybdenum of 100 µg/L after rounding to one significant figure, based on an oral reference value of 0.06 mg/kg/day (ATSDR, 2020), with an additional UFs of 3, a DWI-BW of 0.0343 L/kg/day (USEPA, 2019a) and a 20% RSC (USEPA, 2000a).

Based on these analyses, the EPA finds that molybdenum may have an adverse effect on the health of persons and therefore that Statutory Criterion 1 is met.

(c) Statutory Criterion 2 (Occurrence)

The EPA proposes to find that molybdenum does not occur with a frequency and at levels of public health concern in PWSs based on the EPA's evaluation of the following occurrence information.

The primary occurrence data for molybdenum are nationally representative drinking water monitoring data from the UCMR 3 program (2013-2015). Under UCMR 3 AM, 62,986 samples were collected from 4,922 PWSs and analyzed for molybdenum. Of these systems, 52% reported results at or above the MRL of 1 µg/L. Seven systems (0.14%) reported results above the HRL of 100 µg/L and 29 systems (0.59%) reported results above the ½ HRL threshold of 50 µg/L. Based on the UCMR 3 occurrence data set, a national estimate of 216 systems and 0.06% of the PWS-served population may be exposed to molybdenum in drinking water at levels exceeding the HRL.

Occurrence data for molybdenum in ambient water are available from the NAWQA program and NWIS database. Across the three cycles of NAWQA, molybdenum was detected in 45% to 100% of samples. The HRL was exceeded in a single surface water sample (in Cycle 1) and in 0.12% to 0.26% of groundwater samples across the three cycles. Non-NAWQA NWIS data for molybdenum include 47 finished water samples from 29 sites. The highest reported finished water concentration (52.5 µg/L) exceeds the ½ HRL threshold but not the HRL. The median concentration of NWIS detections was 1.64 µg/L.

For additional information on occurrence data available for molybdenum in drinking water please see section 7.4 of Chapter 7 in the *Regulatory Determination 5 Support Document* (USEPA, 2024b).

Based on the evaluation of these data sources, the EPA finds that molybdenum does not

occur and is not likely to occur in PWSs with a frequency and at levels of public health concern. Therefore, the EPA finds that Statutory Criterion 2 is not met.

(d) Statutory Criterion 3 (Meaningful Opportunity)

Regulating molybdenum under the SDWA does not present a meaningful opportunity for health risk reduction for persons served by PWSs based on the estimated exposed population, including sensitive populations. UCMR 3 data indicate that the estimated population exposed to molybdenum above the HRL is 0.08%. As a result of the low occurrence above the HRL, the agency finds that an NPDWR for molybdenum does not present a meaningful opportunity for health risk reduction.

(e) Preliminary Regulatory Determination for Molybdenum

The agency is making a preliminary determination not to regulate molybdenum with an NPDWR after evaluating health, occurrence and other related information against the three SDWA statutory criteria. While data suggest that molybdenum may have an adverse effect on human health, the occurrence data indicate that molybdenum is not occurring or not likely to occur in PWSs with a frequency and at levels of public health concern. The *Regulatory Determination 5 Support Document* (USEPA, 2024b) and the *Occurrence Data from the Third Unregulated Contaminant Monitoring Rule (UCMR 3)* (USEPA, 2019b) present additional information and analyses supporting the agency's evaluation of molybdenum.

7. Permethrin

(a) Background

Permethrin is a pyrethroid pesticide primarily used as an insecticide, with various synonyms including ambush and corsair. It was first registered in the U.S. in 1979.

Sources of permethrin include agricultural usage and industrial activities. TRI provides insight into industrial releases of permethrin. There have been no reported surface water discharges since 2005. Permethrin usage in agriculture has been estimated by USGS to have peaked in 1995 with 1.4 million pounds, with a gradual decrease to steady usage between around 600,000 and 800,000 pounds annually throughout 2001-2019.

The EPA's assessments of permethrin include its chemical and physical properties, such as very low solubility in water (0.006 mg/L) and K_{oc} values of 10,471 – 86,000 L/kg, which suggest that permethrin will be of low mobility in soil and less likely to partition to water. Biodegradation is expected to be rapid in various environmental conditions, since the half-life of permethrin in sediment/seawater is < 2.5 days, while the half-life of permethrin in a model ecosystem at 15-19 degrees Celsius and a pH of 7.7 was 1.1 - 3.6 days.

(b) Statutory Criterion 1 (Adverse Health Effects)

Exposure to permethrin may have an adverse effect on the health of persons as supported by the health assessment identified for RD 5 (USEPA, 2020b; USEPA, 2020c). For pesticide chemicals currently registered under FIFRA, including permethrin, toxicity information from EPA’s OPP HED HHRAs was used as the basis for HRL derivation (USEPA, 2023c).

The health assessment selected to derive an HRL for permethrin is the 2020 EPA OPP HHRA (USEPA, 2020ba; USEPA, 2020c). Following the approach described in the EPA’s *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005b), permethrin was classified in the health assessment as having “Suggestive Evidence of Carcinogenic Potential” based on lung adenomas in female mice. However, due to the lack of increased hazard from repeated/chronic exposure to permethrin, the acute risk estimate derived from the non-linear approach is protective of chronic toxicity, including carcinogenicity, that could result from permethrin

exposure (USEPA, 2020c). Therefore, the EPA selected an acute gavage study in rats (Wolansky et al., 2006) as the critical study to derive an oral reference value (see section 8.3 of Chapter 8 in the *Regulatory Determination 5 Support Document* for more details about the critical study). BMD modeling was performed to derive a lower 95% confidence limit on the BMD level associated with a difference of one standard deviation from controls ($BMDL_{1SD}$) for decreased motor activity (Wolansky et al., 2006), which was identified as the critical effect for dietary exposure, as this was the most sensitive endpoint measured (USEPA, 2020c). The $BMDL_{1SD}$ was calculated to be 44 mg/kg. A total UF of 100 was applied to the POD: a UF_H of 10 and a UF_A of 10. After applying the total UF of 100, the oral reference value was calculated to be 0.44 mg/kg/day (USEPA, 2020c) and the EPA selected this oral reference value to derive an HRL for permethrin.

Because exposure began during postnatal development (*i.e.*, at approximately nine weeks of age) in the critical study (Wolansky et al., 2006), 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) of 0.0343 L/kg/day (USEPA, 2019a) to derive the HRL for permethrin (see decision logic provided in section B.6.1.2 of the RD 5 Protocol, found in Appendix B of the *Regulatory Determination 5 Support Document,* USEPA, 2024b).

Following HRL derivation practices, the EPA derived an HRL for permethrin of 3,000 µg/L after rounding to one significant figure, based on an oral reference value of 0.44 mg/kg/day (USEPA, 2020b; USEPA, 2020c), a DWI-BW of 0.0343 L/kg/day (USEPA, 2019a) and a 20% RSC (USEPA, 2000a).

Based on these analyses, the EPA finds that permethrin may have an adverse effect on the health of persons and therefore that Statutory Criterion 1 is met.

(c) Statutory Criterion 2 (Occurrence)

The EPA proposes to find that permethrin does not occur with a frequency and at levels of public health concern in PWSs based on the EPA's evaluation of occurrence information.

The primary occurrence data for permethrin are nationally representative drinking water monitoring data from the UCMR 4 program (2018-2020). Under UCMR 4 AM, 37,291 samples collected from 5,028 PWSs were analyzed for permethrin. Permethrin was detected in 0.26% of systems at or above the MRL of 0.04 µg/L. There were no reported results above the HRL of 3,000 µg/L or above the ½ HRL threshold. This comprehensive dataset suggests that permethrin is not present in public water systems at concentrations that would pose a risk to human health.

To supplement the data obtained from UCMR 4, the EPA also reviewed ambient water data from the USGS NAWQA program. NAWQA Cycle 2 showed no detections of permethrin. NAWQA Cycle 3 showed detections of permethrin in 2 of 11 sites (18%) with no results above the HRL.

Based on the evaluation of these data sources, the EPA finds that permethrin does not occur and is not likely to occur in PWSs with a frequency and at levels of public health concern. Therefore, the EPA finds that Statutory Criterion 2 is not met.

(d) Statutory Criterion 3 (Meaningful Opportunity)

Regulating permethrin under the SDWA does not present a meaningful opportunity for health risk reduction for persons served by PWSs based on the estimated exposed population, including sensitive populations. UCMR 4 findings indicate the estimated population exposed to permethrin at levels of public health concern is 0%.

(e) Preliminary Regulatory Determination for Permethrin

The agency is making a preliminary determination to not regulate permethrin with an

NPDWR after evaluating health, occurrence and other related information against the three SDWA statutory criteria. While data suggest that permethrin may have an adverse effect on human health, the occurrence data indicate that permethrin is not occurring or not likely to occur in PWSs with a frequency and at levels of public health concern.

Therefore, the agency has made the preliminary determination that an NPDWR for permethrin would not present a meaningful opportunity to reduce health risk for persons served by PWSs. The *Regulatory Determination 5 Support Document* (USEPA, 2024b) presents additional information and analyses supporting the agency's evaluation of permethrin.

7. Profenofos

(a) Background

Profenofos is an organophosphate pesticide that is applied as an insecticide. Synonyms for profenofos include curacron and selecron (NCBI, 2023b). Profenofos was first registered in the U.S. in 1982 (USEPA, 2008c). Profenofos registration was canceled in 2018 and it currently has no active labels in the EPA's Pesticide Product and Label System database (USEPA, 2023c). USGS Pesticide Use Maps show cotton is the sole crop to which profenofos was applied in the years before cancellation; usage diminished since the mid-1990s and ceased around 2011 according to these records.

Environmental fate assessments indicate that low to slight mobility in soil and transport to water is expected based on K_{oc} values. Volatilization from water is not expected to occur based on the contaminant's Henry's Law Constant; thus it will remain once present in water (NCBI, 2023b). In soil and water, biodegradation may occur, but profenofos is stable to photolysis in these media and is not likely to degrade with exposure to sunlight.

(b) Statutory Criterion 1 (Adverse Health Effects)

Exposure to profenofos may have an adverse effect on the health of persons as supported by the health assessment identified for RD 5 (USEPA, 2015d; USEPA, 2015g). For pesticide chemicals currently registered under FIFRA, including profenofos, toxicity information from EPA OPP HED HHRAs was used as the basis for HRL derivation (USEPA, 2024b).

The health assessment selected to derive an HRL for profenofos is the 2015 EPA OPP HHRA (USEPA, 2015d; USEPA, 2015g). The EPA selected a chronic toxicity and carcinogenicity study in rats (Burdock et al., 1981) as the critical study to derive an oral reference value for profenofos (see section 9.3 of Chapter 9 in the *Regulatory Determination 5 Support Document* for more details about the critical study). A $BMDL_{10}$ of 0.12 mg/kg/day based on RBC AChE inhibition was identified as the critical effect and POD for dietary exposure, as this was the most sensitive endpoint measured (USEPA, 2015g). After applying the total UF of 1,000, the oral reference value was calculated to be 0.00012 mg/kg/day (USEPA, 2015g) and the EPA selected this oral reference value to derive an HRL for profenofos.

The EPA extrapolated the body weight of the rodents to their approximate age at the onset of exposure in the critical study (Burdock et al., 1981) to determine the most sensitive lifestage exposed. Because exposure was estimated to have begun during postnatal development (*i.e.*, at approximately seven to eight weeks of age), 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) of 0.0343 L/kg/day (USEPA, 2019a) to derive the HRL for profenofos (see decision logic provided in section B.6.1.2 of the RD 5 Protocol, found in Appendix B of the *Regulatory Determination 5 Support Document*).

Following HRL derivation practices, the EPA derived an HRL for profenofos of 0.7 µg/L after rounding to one significant figure, based on an oral reference value of 0.00012 mg/kg/day

(USEPA, 2015d; USEPA, 2015g), a DWI-BW of 0.0343 L/kg/day (USEPA, 2019a) and a 20% RSC (USEPA, 2000a).

Based on these analyses, the EPA finds that profenofos may have an adverse effect on the health of persons and therefore that Statutory Criterion 1 is met.

(c) Statutory Criterion 2 (Occurrence)

The EPA proposes to find that profenofos does not occur with a frequency and at levels of public health concern in PWSs after evaluation of information from the following sources: UCMR 4, Consumer Confidence Reports (CCRs) from PWSs, USDA PDP, USGS PMP.

The primary occurrence data for profenofos are nationally representative drinking water monitoring data from the UCMR 4 program (2018-2020). The MRL for profenofos was 0.3 µg/L. Under UCMR AM, 37,287 samples collected from 5,028 PWSs were analyzed for profenofos and profenofos was detected in only four systems (0.08%). One system reported a result above the HRL of 0.7 µg/L. This comprehensive dataset suggests that profenofos is not present in public water systems at concentrations that would pose a risk to human health.

Ambient water data from the USGS NAWQA program and NWIS database were evaluated. In NAWQA Cycle 1, profenofos was not detected in any samples at any sites. In Cycle 2, profenofos was detected only once, in surface water, and the detection was below the HRL. In Cycle 3, profenofos was detected in 0.06% of both groundwater and surface water samples. The highest concentration observed in surface water is less than the ½ HRL threshold. In NWIS, profenofos was detected in a single surface water sample representing 0.2% of surface water sites. There were no detections in groundwater. The single surface water detection had a profenofos concentration of 0.00019 µg/L, which is less than the ½ HRL threshold.

Based on the evaluation of these data sources, the EPA finds that profenofos does not

occur and is not likely to occur in PWSs with a frequency and at levels of public health concern. Therefore, the EPA finds that Statutory Criterion 2 is not met.

(d) Statutory Criterion 3 (Meaningful Opportunity)

Regulating profenofos under the SDWA does not present a meaningful opportunity for health risk reduction for persons served by PWSs based on the estimated exposed population. The estimated population exposed to profenofos at levels of public health concern in drinking water is less than 0.005%.

(e) Preliminary Regulatory Determination for Profenofos

The agency is making a preliminary determination not to regulate profenofos with an NPDWR after evaluating health, occurrence and other related information against the three SDWA statutory criteria. While data suggest that profenofos may have an adverse effect on human health, occurrence data indicate that profenofos is not occurring or not likely to occur in PWSs with a frequency and at levels of public health concern.

Therefore, the agency has determined that an NPDWR for profenofos would not present a meaningful opportunity to reduce health risk for persons served by PWSs. The *Regulatory Determination 5 Support Document* (USEPA, 2024b) presents additional information and analyses supporting the agency's evaluation of profenofos.

8. Tebuconazole

(a) Background

Tebuconazole is a monochlorobenzene, triazole and tertiary alcohol that is used as a fungicide. It was first registered by the EPA in 1983 (USEPA, 2023d). Synonyms for tebuconazole include folicur, terbutrazole, ethyltrianol and fenetrazole (NCBI, 2023c).

The USGS provides estimates for annual usage of U.S. pesticides, including

tebuconazole. The USGS pesticide use data show that there has been an increase in tebuconazole use 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 (USGS, 2023).

Tebuconazole is expected to have a high likelihood of partitioning to water based on its Henry's Law Constant, and volatilization from water is not expected (NCBI, 2023c). Tebuconazole is expected to be persistent in soils and water based on the soil aerobic metabolism half-life of approximately 800 days, as well as resistance to photolysis in water and soil (USEPA, 2000b; NCBI, 2023c).

(b) Statutory Criterion 1 (Adverse Health Effects)

Exposure to tebuconazole may have an adverse effect on the health of persons as supported by the health assessment identified for RD 5 (USEPA, 2021d; USEPA, 2021e). For pesticide chemicals currently registered under the FIFRA, including tebuconazole, toxicity information from EPA OPP HED HHRAs was used as the basis for HRL derivation (USEPA, 2024b).

The health assessment selected to derive an HRL for tebuconazole is the 2021 EPA OPP HHRA (USEPA, 2021d; USEPA, 2021e). The EPA selected a developmental toxicity study in mice (Becker and Biedermann, 1995) as the critical study to derive the oral reference value (see section 10.3 of Chapter 10 in the *Regulatory Determination 5 Support Document* for more details about the critical study). A NOAEL of 3 mg/kg/day for increased incidence of fetal skull and neural tube defects was identified as the critical effect and POD, as this was the most sensitive endpoint measured after gestational exposure to tebuconazole via gavage (USEPA, 2021d). A total UF of 100 was applied to the POD: a UF_A of 10 and a UF_H of 10 (USEPA, 2021d). After applying the total UF of 100, the oral reference value was calculated to be 0.03 mg/kg/day and

the EPA selected this oral reference value to derive an HRL for tebuconazole.

Because the mice in the critical study (Becker and Biedermann, 1995) were exposed to tebuconazole during gestation only (*i.e.*, gestation days 6 through 15), the EPA determined that the critical effect in the fetus corresponds with gestational exposure in humans. The EPA used 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) of 0.0354 L/kg/day (USEPA, 2019a) to derive the HRL for tebuconazole, as it is more health protective (*i.e.*, greater) than the DWI-BW for pregnant women (0.0333 L/kg/day) (USEPA, 2019a) (see decision logic provided in section B.6.1.2 of the RD 5 Protocol, found in Appendix B of the *Regulatory Determination 5 Support Document*).

Following HRL derivation practices, the EPA derived an HRL for tebuconazole of 200 µg/L after rounding to one significant figure, based on an oral reference value of 0.03 mg/kg/day (USEPA, 2021d; USEPA, 2021e), a DWI-BW of 0.0354 L/kg/day (USEPA, 2019a) and a 20% RSC (USEPA, 2000a).

Based on these analyses, the EPA finds that tebuconazole may have an adverse effect on the health of persons and therefore that Statutory Criterion 1 is met.

(c) Statutory Criterion 2 (Occurrence)

The EPA proposes to find that tebuconazole does not occur with a frequency and at levels of public health concern in PWSs based on the EPA's evaluation of the following occurrence information.

The primary occurrence data for tebuconazole are nationally representative drinking water monitoring data from the UCMR 4 program (2018-2020). Under UCMR 4 AM, 37,286 samples collected from 5,028 PWSs were analyzed for tebuconazole. Tebuconazole was found at

or above the MRL of 0.2 µg/L in three of the 5,028 systems, or 0.06%. However, there were no exceedances of the HRL (200 µg/L) or the ½ HRL threshold (USEPA, 2024b). Reported results ranged from 0.21 to 1.96 µg/L. This comprehensive dataset suggests that tebuconazole is not present in public water systems at concentrations that would pose a risk to human health.

To understand the impact of tebuconazole use post UCMR 4, the EPA assessed ambient water and limited finished water data collected after 2020. Sources of such data include CCRs from Community Water Systems (CWSs), PWSs, USDA PDP, the NAWQA program, the NWIS database, STORET and several published studies. Data on tebuconazole were available from CCRs prepared by five CWSs from 2018 to 2021; tebuconazole was not detected in any system. Tebuconazole was included in the USDA PDP from 2001 to 2013, where it was detected in 2.11% of 2,656 raw water samples and 2.18% of 3,575 finished water samples, but no detected concentrations exceeded the ½ HRL threshold or the HRL (USDA, 2022). Cycle 2 and Cycle 3 of the NAWQA program found tebuconazole in surface water (17.97% to 26.48% of samples) and groundwater (0% to 0.11% of samples), but no concentrations exceeded the ½ HRL threshold or the HRL (WQP, 2023). Non-NAWQA NWIS data (1991– 023) show no detected concentration greater than the ½ HRL threshold or the HRL in ambient water (WQP, 2023). Analysis of STORET data from 2003 to 2016 shows that in 2,021 samples tested for tebuconazole there were no detectable concentrations (WQP, 2023).

Based on the evaluation of these data sources, the EPA finds that tebuconazole does not occur and is not likely to occur in PWSs with a frequency and at levels of public health concern. Therefore, the EPA finds that Statutory Criterion 2 is not met.

(d) Statutory Criterion 3 (Meaningful Opportunity)

Regulating tebuconazole under the SDWA does not present a meaningful opportunity for

health risk reduction for persons served by PWSs based on the estimated exposed population, including sensitive populations. The estimated population exposed to tebuconazole at levels of public health concern is 0%, based on UCMR 4 finished water data from 2018-2020.

(e) Preliminary Regulatory Determination for Tebuconazole

The agency is making a preliminary determination not to regulate tebuconazole with an NPDWR after evaluating health, occurrence and other related information against the three SDWA statutory criteria. While data suggest that tebuconazole may have an adverse effect on human health, the occurrence data indicate that tebuconazole is not occurring or not likely to occur in PWSs with a frequency and at levels of public health concern and that regulation of such contaminant does not present a meaningful opportunity for health risk reduction served by PWSs. The *Regulatory Determination 5 Support Document* (USEPA, 2024b) and the *Occurrence Data from the Fourth Unregulated Contaminant Monitoring Rule (UCMR 4)* (USEPA, 2024c) present additional information and analyses supporting the agency's evaluation of tebuconazole.

9. Tribufos

(a) Background

Tribufos is a thiophosphate pesticide that is used as an insecticide and cotton defoliant. It was first registered for use in the United States in 1961 (USEPA, 2009b). The EPA conducted a Reregistration Eligibility Decision (RED) for tribufos in July 2006, which included a comprehensive review of the available data on its environmental and human health effects (USEPA, 2006b). Tribufos is not listed on the EPA's most recent list of Restricted Use Pesticides (RUP) (USEPA, 2022f). Synonyms for tribufos include butifos, butiphos, butyl phosphorotrithioate and tribuphos (NCBI, 2023d).

According to TRI data for tribufos from the years 1995-2022, on-site surface water discharges peaked in 1999 at 161 pounds and no discharges have been reported since 2007, with specific usage data indicating fluctuations based on agricultural demand and cotton acreage with an overall reduction in usage since 1999. The reports highlight the targeted and seasonal application of tribufos, reflecting its specific role in cotton production rather than widespread use throughout the year (USEPA, 2024b).

Environmental fate assessments with organic carbon partitioning coefficient (K_{oc}) values of 4,870-12,684 L/kg suggest that tribufos will have little to no mobility in soil (NCBI, 2023d). Its strong adsorption to soil organic matter suggests limited mobility in soil, minimizing leaching into water. Tribufos is less mobile in soil and tends to remain near the application site. Persistence depends on various factors, including degradation and environmental conditions (USEPA, 2024b).

(b) Statutory Criterion 1 (Adverse Health Effects)

Exposure to tribufos may have an adverse effect on the health of persons as supported by the health assessment identified for RD 5 (USEPA, 2015h; USEPA, 2015i). For pesticide chemicals currently registered under FIFRA, including tribufos, toxicity information from EPA OPP HED HHRAs was used as the basis for HRL derivation (USEPA, 2024b).

The health assessment selected to derive an HRL for tribufos is the 2015 EPA OPP HHRA (USEPA, 2015h; USEPA, 2015i). The EPA selected a subchronic oral neurotoxicity study in rats (Sheets and Gilmore, 2001) as the critical study to derive an oral reference value for tribufos (see section 11.3 of Chapter 11 in the *Regulatory Determination 5 Support Document* for more details about the critical study). BMD modeling was performed to determine a $BMDL_{10}$ for inhibition of RBC ChE in adult female rats. The $BMDL_{10}$ of 0.19 mg/kg/day was identified as

the critical effect and POD, as this was the most sensitive endpoint measured (USEPA, 2015h). A total UF of 1,000 was applied to the POD: a UF_A of 10, a UF_H of 10 and an FQPA safety factor of 10 to account for uncertainty in the human dose-response relationship for neurodevelopmental effects. After applying the total UF of 1,000, the oral reference value was calculated to be 0.0002 mg/kg/day (USEPA, 2015h) and the EPA selected this oral reference value to derive an HRL for tribufos.

Because exposure began during postnatal development (*i.e.*, at eight weeks of age) in the critical study (Sheets and Gilmore, 2001), 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) of 0.0343 L/kg/day (USEPA, 2019a) to derive the HRL for tribufos (see decision logic provided in section B.6.1.2 of the RD 5 Protocol, found in Appendix B of the *Regulatory Determination 5 Support Document*).

Following HRL derivation practices, the EPA derived an HRL for tribufos of 1 µg/L after rounding to one significant figure, based on an oral reference value of 0.0002 mg/kg/day (USEPA, 2015h; USEPA, 2015i), a DWI-BW of 0.0343 L/kg/day (USEPA, 2019a) and a 20% RSC (USEPA, 2000a).

Based on these analyses, the EPA finds that tribufos may have an adverse effect on the health of persons and therefore that Statutory Criterion 1 is met.

(c) Statutory Criterion 2 (Occurrence)

The EPA proposes to find that tribufos does not occur with a frequency and at levels of public health concern in PWSs based on the EPA's evaluation of the following occurrence information.

The primary occurrence data for tribufos are nationally representative drinking water

monitoring data from the UCMR 4 program (2018-2020). Tribufos was found at or above the MRL of 0.07 µg/L in 3 (0.008%) of the 37,269 AM samples analyzed during this monitoring period. The estimated population exposed to tribufos at levels of public health concern is 0%. Detected concentrations ranged from 0.0742 µg/L to 0.4 µg/L. These detections were found at three large systems, representing 0.06% of systems participating in the monitoring program. There were no exceedances of the HRL or the ½ HRL threshold. This comprehensive dataset suggests that tribufos is not present in PWSs at concentrations that would pose a risk to human health.

Based on the evaluation of the available data, the EPA finds that tribufos does not occur and is not likely to occur in PWSs with a frequency and at levels of public health concern. Therefore, the EPA finds that Statutory Criterion 2 is not met.

(d) Statutory Criterion 3 (Meaningful Opportunity)

Regulating tribufos under the SDWA does not present a meaningful opportunity for health risk reduction for persons served by PWSs based on the estimated exposed population, including sensitive populations. The agency finds that an NPDWR for tribufos does not present a meaningful opportunity for health risk reduction.

The assessment also took into consideration the use patterns and regulatory actions related to tribufos, which have led to a decrease in its application and potential release into the environment. These factors, combined with the lack of detection in the UCMR 4 program, support the conclusion that tribufos does not currently represent a risk to public health for persons served by PWSs.

(e) Preliminary Regulatory Determination for Tribufos

The agency is making a preliminary determination to not regulate tribufos after

evaluating health, occurrence and other related information against the three SDWA statutory criteria. While data suggest that tribufos may have an adverse effect on human health, the occurrence data indicate that tribufos is not occurring or not likely to occur in PWSs with a frequency and at levels of public health concern. Therefore, the agency has determined that an NPDWR for tribufos would not present a meaningful opportunity to reduce health risk for persons served by PWSs. The *Regulatory Determination 5 Support Document* (USEPA, 2024b) presents additional information and analyses supporting the agency's evaluation of tribufos.

V. Status of the Agency's Evaluation of 1,2,3-Trichloropropane, 1,4-Dioxane, Manganese, Quinoline and Strontium

A. Ongoing Evaluation of Additional Phase 3 Contaminants

In addition to the nine contaminants discussed in section IV of this document for which the EPA is making preliminary negative determinations, there are five additional contaminants that were evaluated according to the RD 5 Protocol and proceeded to Phase 3 based on the robust available health effects and occurrence data for finished drinking water: 1,2,3-TCP, 1,4-dioxane, manganese, quinoline and strontium. As discussed earlier in section III.A.3 of this document, in order to make a positive determination, the EPA must show that a contaminant meets all three statutory criteria relating to health effects, occurrence and meaningful opportunity for health risk reduction, while the agency makes a negative determination if any one of the criteria is not met.

The EPA is continuing to analyze the available health and occurrence data for these contaminants to evaluate whether they occur at levels of public health concern in finished drinking water and to characterize the potential meaningful opportunity for health risk reduction if they were to be regulated under the SDWA. Therefore, the EPA is not making preliminary determinations for these five contaminants at this time. As noted in section III.A.3 of this

document, the 2023 panel ruling from the D.C. Circuit Court of Appeals in *NRDC v. EPA* (D.C. Cir., 2023) established that the agency cannot withdraw a positive determination even if evidence identified during the rulemaking would change the EPA's conclusion of the potential for meaningful opportunity for health risk reduction by regulating a contaminant. Prior to this ruling, formal evaluation of the potential health benefits and analysis of the availability and feasibility of treatment options were conducted during the rule development process as part of the HRRCA. Because of the 2023 ruling, however, the EPA now has concluded that while the SDWA does not require a full HRRCA as part of regulatory determination prior to rule development, the agency will need to conduct preliminary benefits analyses, treatment feasibility analyses or both prior to making determinations for contaminants that may warrant regulation under the SDWA. The EPA will evaluate for each contaminant the population exposed at the health level of concern along with several other factors to determine if regulation presents a meaningful opportunity for health risk reduction. Therefore, the EPA intends to conduct such analyses for each of these five contaminants prior to making regulatory determinations, in order to better understand whether there would be a meaningful opportunity for health risk reduction for persons served by PWSs if the contaminant were to be regulated.

B. Phase 3 Contaminant Updates

1. 1,2,3-Trichloropropane

1,2,3-Trichloropropane (1,2,3-TCP) is a synthetic chemical used as an industrial solvent, a cleaning and degreasing agent and a synthesis intermediate.

Since the EPA last provided an update on the evaluation of 1,2,3-TCP in the RD 4 FRN (USEPA, 2021a), the EPA has continued work on the evaluation of this contaminant. Work has

focused on addressing issues related to the analytical method MRL being substantially higher than the level of public health concern which presents uncertainty in assessing the potential contaminant concentrations and exposure analysis. The fact that the MRL is much higher than the HRL suggests that there may be a substantial amount of occurrence of 1,2,3-TCP at levels of public health concern in water systems that would not show up in the occurrence data, as any measurement results below the MRL would not be reported. The EPA did not make a regulatory determination for 1,2,3-TCP during RD 4 due to this analytical method limitation, and the agency needs lower-level occurrence information prior to making a preliminary regulatory determination for 1,2,3-TCP. Method development work is underway to lower the MRL for 1,2,3-TCP under Method 524.3, which would enable reporting of concentrations closer to levels of public health concern. The EPA intends to consider new information related to the improved analytical method in future regulatory determination efforts to assess whether there would be a meaningful opportunity for health risk reduction if the EPA were to regulate 1,2,3-TCP in drinking water.

2. 1,4-Dioxane

1,4-Dioxane is a cyclic aliphatic ether that is used as a solvent and a solvent stabilizer. As a solvent it is used in such products as inks, coatings, adhesives, oils, resins, waxes, and dyes (USEPA, 2024b). The EPA is continuing its efforts to evaluate 1,4-dioxane to determine in what manner to regulate this contaminant under SDWA and under the Toxic Substances Control Act (TSCA). The EPA evaluated 1,4-dioxane in RD 4 but did not make a regulatory determination at that time (USEPA, 2021a), referencing the status of the TSCA risk evaluation and the Health Canada health effects assessment, which had not been finalized at that time (Health Canada, 2018). During the timeframe of preliminary RD 5 evaluation, the EPA finalized the 2024

Supplement to the 2020 Risk Evaluation and a revised Risk Determination for 1,4-dioxane under the TSCA program. In the TSCA Risk Evaluation, which covers all conditions of use of 1,4-dioxane, the EPA found that 1,4-dioxane presents risk to the general population via drinking water sourced from surface water contaminated both by industrial discharges of 1,4-dioxane and down-the-drain releases of products that contain 1,4-dioxane (generated as an unintentional byproduct). Under section 6 of TSCA, if at the end of the TSCA risk evaluation process, the EPA determines that a chemical presents an unreasonable risk to health or the environment, the agency must immediately start the risk management process to reduce or eliminate these risks. TSCA directs the EPA to coordinate actions taken under TSCA with actions taken under other federal laws administered by the EPA, such as the Clean Water Act (CWA) and the SDWA. TSCA section 9 also provides that, if the EPA Administrator determines that a risk to health or the environment associated with a chemical substance could be eliminated or reduced to a sufficient extent by actions taken under those other Federal laws, the EPA must use those other laws unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under TSCA. Input from all stakeholders is critical to the risk management process under TSCA. The EPA is committed to developing risk management actions for chemicals in a way that is transparent and includes proactive, meaningful outreach and education with the public and other stakeholders. The EPA is working collaboratively across programs to address the unreasonable risk identified under TSCA and has determined that the risk to human health associated with 1,4-dioxane exposure via drinking water sourced from surface water contaminated with both industrial discharges and down-the-drain releases of products containing 1,4-dioxane is best managed by coordinating actions under both TSCA and SDWA.

As described in the EPA Administrator's memorandum "Coordinated Risk Management Action on 1,4-Dioxane under section 9(b) of the Toxic Substances Control Act" released alongside the TSCA's program's final 2024 Supplement to the 2020 Risk Evaluation and the revised Risk Determination for 1,4-dioxane, after the agency's regulatory action to address this risk under TSCA is implemented, the EPA will re-evaluate under SDWA whether there is any remaining risk that presents a meaningful opportunity for health risk reduction by regulating 1,4-dioxane in drinking water.

3. Manganese

Manganese is a naturally occurring element and is ubiquitous in the environment as a component of over 100 minerals (ATSDR, 2012). Manganese compounds are used in a variety of industrial production processes and applications – production data from 2011 to 2019 from the EPA's CDR Program shows that fifteen manganese substances were produced or imported in quantities greater than one million pounds in at least one year and that elemental manganese was produced in quantities greater than 500 million pounds in 2018 (USEPA, 2024b).

The EPA made a negative regulatory determination for manganese in RD 1 (USEPA, 2003). Since then, new health effects information developed for the 2021 World Health Organization's (WHO) *Guidelines for Drinking Water Quality* indicates exposure to elevated levels of manganese in drinking water contributes to increased risk for adverse neurological effects, such as behavioral and sensorimotor effects (WHO, 2021). Nationally representative occurrence data in finished drinking water were collected for manganese in UCMR 4 (USEPA, 2024c). The EPA continues to evaluate the health effects and occurrence data for manganese and will conduct preliminary benefits analysis and treatment feasibility analysis to inform the potential meaningful opportunity for health risk reduction if manganese were to be regulated

under the SDWA in the future.

4. Quinoline

Quinoline is an aromatic heterocyclic amine used to make paints, dyes and other chemicals. Quinoline is also used as a solvent, anatomical specimen preservative, corrosion inhibitor, antimalarial drug and flavoring agent.

Nationally representative finished water occurrence data for quinoline was collected under UCMR4. The analytical method MRL for quinoline is greater than the level of public health concern thus there is uncertainty regarding the frequency at which quinoline occurs at levels of public health concern in PWSs. Therefore, the EPA needs more information prior to making a preliminary regulatory determination for quinoline.

The EPA continues to evaluate the health effects and occurrence data for quinoline and plans to conduct additional analyses of health benefits and possible treatment feasibility to inform whether regulating quinoline under SDWA would present a meaningful opportunity for health risk reduction to persons served by PWSs.

5. Strontium

Strontium is a naturally occurring element, an alkaline earth metal typically found in the form of mineral compounds. Stable strontium tends to dissolve in water, and therefore water in contact with strontium-laden soils may also contain strontium.

Since the RD 4 FRN was published in 2021, (USEPA, 2021a) the EPA has continued to conduct additional work to evaluate the health risks and the potential for health risk reduction if strontium were to be regulated with an NPDWR. For the preliminary RD 5 evaluation, the EPA identified the 2019 *Health Canada Guidelines for Drinking Water Quality* (HC, 2019), because it is the most recent health assessment identified for strontium and uses the best available science

in its evaluation of noncancer risk. The EPA continues to evaluate the UCMR 3 occurrence data in light of the newer health effects information to determine whether there would be a meaningful opportunity for health risk reduction if strontium were to be regulated under the SDWA. In addition, the EPA understands that strontium may co-occur with beneficial calcium in some drinking water systems and treatment technologies that remove strontium may also remove calcium. The agency is evaluating the effectiveness of treatment technologies under different water conditions, including calcium concentrations.

The EPA continues to evaluate the health effects and occurrence data for strontium and plans to conduct additional analyses of health benefits and possible treatment feasibility to inform whether regulating strontium under SDWA would present a meaningful opportunity for health risk reduction to persons served by PWSs.

In summary, the EPA is not making regulatory determinations at this time for these five contaminants in this document. In light of the decision announced in *NRDC v. EPA* (D.C. Cir., 2023), the EPA plans to conduct preliminary health benefits analyses to inform whether there would be a potential meaningful opportunity for health risk reduction through regulation of a contaminant with an NPDWR. In addition, the EPA continues to evaluate the effectiveness and feasibility of treatment methods to lower concentrations of these contaminants from drinking water systems.

VI. The EPA's Request for Comments and Next Steps

The EPA invites commenters to submit any relevant data or information pertaining to the preliminary regulatory determinations identified in this document, as well as other relevant comments. The EPA will consider the public comments and any new, relevant data submitted for

the contaminants discussed in this document and in the supporting rationale.

The data and information requested by the EPA include peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices, and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the review justifies use of the data).

Peer-reviewed data are studies/analyses that have been reviewed by qualified individuals (or organizations) who are independent of those who performed the work, but who are collectively equivalent in technical expertise (*i.e.*, peers) to those who performed the original work. A peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria and conclusions pertaining to the specific major scientific or technical work products and the documentation that supports them (USEPA, 2015j).

Specifically, the EPA is requesting comment and information related to the following aspects:

- The health effects information considered by the agency in making the preliminary determinations described in this Document. The EPA requests commenters identify any additional peer reviewed studies that could inform the final regulatory determination.
- Drinking water occurrence information considered by the agency in making the preliminary determinations described in this document. The EPA requests commenters identify any additional data and studies on the occurrence of these contaminants in drinking water.

The EPA intends to evaluate the public comments received on the nine preliminary determinations and issue final regulatory determinations. If the agency makes a final

determination to regulate any of the contaminants, the EPA intends to propose an NPDWR within 24 months and promulgate a final NPDWR within 18 months following the proposal.[15] In addition, the EPA will also consider information provided in public comment about the five contaminants discussed in section V of this document to inform potential future regulatory determinations.

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[15] The statute authorizes a nine-month extension of this promulgation date.

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