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#### **Acronyms and Abbreviations**

ATSDR Agency for Toxic Substances and Disease Registry

AWWA American Water Works Association

CASRN Chemical Abstract Services Registry Number

CAPHG California Public Health Goals

CDC Centers for Disease Control and Prevention

CCL Contaminant Candidate List

CCL 1 EPA's First Contaminant Candidate List
CCL 2 EPA's Second Contaminant Candidate List
CCL 3 EPA's Third Contaminant Candidate List
CCL 4 EPA's Fourth Contaminant Candidate List

CSTE Council of State and Territorial Epidemiologists
CUS/IUR Chemical Update System/Inventory Update Rule

CWSs Community Water Systems
DRI Dietary Reference Intake

EPA United States Environmental Protection Agency
FDA United States Food and Drug Administration

FR Federal Register

GAMA California State Water Resources Control Board's Groundwater Ambient

Monitoring Assessment

GDWQ WHO Guidelines for Drinking-water Quality
HHBPs Human Health Benchmark for Pesticides
IARC International Agency for Research on Cancer

IOM Institute of Medicine

IRIS Integrated Risk Information System
ITER International Toxicity Estimates of Risk
LOAEL Lowest Observed Adverse Effect Level
MADL Maximum Allowable Daily Levels
MCL Maximum Contaminant Level

MCLG Maximum Contaminant Level Goal MCM Manual of Clinical Microbiology

MMWR Morbidity and Mortality Weekly Report

MRL Minimum Risk Level

NAWQA National Water Quality Assessment

NCOD National Contaminant Occurrence Database NDWAC National Drinking Water Advisory Council

NOAEL No Observed Adverse Effect Level

NPDWRs National Primary Drinking Water Regulations

NREC National Reconnaissance of Emerging Contaminants

NSRL No Significant Risk Level NTP National Toxicology Program

OEHHA Office of Environmental Health Hazard Assessment

OPP Office of Pesticide Programs

ORD U.S. EPA Office of Research and Development

OSRTI Office of Superfund Remediation and Technology Innovation

OSWER Office of Solid Waste and Emergency Response

PCCL Preliminary Candidate Contaminant List

PDP Pesticide Data Program

PPCPs Pharmaceuticals and Personal Care Products

ppm Parts per million

PPRTVs Provisional Peer Reviewed Toxicity Values

PWS Public Water System

RDAs Recommended Dietary Allowances
RED Reregistration Eligibility Document

REL Reference Exposure Levels
RfC Reference concentration

RfD Reference dose

RoC Report on Carcinogens SDWA Safe Drinking Water Act

STORET EPA's Storage and Retrieval System
SWRCB State Water Resources Control Board

TRI Toxics Release Inventory
TSCA Toxic Substances Control Act

ULs Upper Intake Levels

USDA United States Department of Agriculture

USGS United States Geological Survey
WBDO Waterborne Disease Outbreak
WHO World Health Organization

#### 1.0 Introduction

Section 1412(b)(1) of the Safe Drinking Water Act (SDWA), as amended in 1996, requires EPA to publish the Contaminant Candidate List (CCL) every five years. The SDWA specifies that the list include contaminants that are not subject to any proposed or promulgated National Primary Drinking Water Regulations (NPDWRs), are known or anticipated to occur in public water systems (PWSs) and may require regulation under the SDWA. EPA uses this list of unregulated contaminants to help identify priority contaminants for regulatory decision making and to prioritize research and data collection efforts. SDWA also requires the agency to consult with the scientific community, including the Science Advisory Board and provide notice and opportunity for public comment prior to the publication of the Final CCL. In addition, SDWA directs the agency to consider the health effects and occurrence information for unregulated contaminants to identify those contaminants that present the greatest public health concern related to exposure from drinking water.

EPA published the third CCL (CCL 3), which listed 116 contaminants on October 8, 2009 (74 FR 51850 (USEPA, 2009a)). In developing the CCL 3, EPA implemented a multi-step process to select contaminants for the final CCL 3, which included the following key steps:

- 1) The identification of a broad universe of potential drinking water contaminants (CCL 3 Universe);
- 2) Screening the CCL 3 Universe to a Preliminary CCL (PCCL) using screening criteria based on the potential to occur in PWSs and the potential for public health concern;
- 3) Evaluation of the PCCL contaminants based on a more detailed review of the occurrence and health effects data using a scoring and classification system to identify a final list of 116 CCL 3 contaminants; and
- 4) Incorporating public input and expert review in the CCL 3 process.

Steps 1, 2 and 3 in the process are described in detail in the CCL 3 support documents:

- "Final Contaminant Candidate List 3 Chemicals: Identifying the Universe" (USEPA, 2009b):
- "Final Contaminant Candidate List 3 Chemicals: Screening to a PCCL" (USEPA, 2009c);
- "Final Contaminant Candidate List 3 Chemicals: Classification of the PCCL to the CCL" (USEPA, 2009d);
- "Final Contaminant Candidate List 3 Microbes: Identifying the Universe" (USEPA, 2009e);
- "Final Contaminant Candidate List 3 Microbes: Screening to the PCCL" (USEPA, 2009f); and
- "Final Contaminant Candidate List 3 Microbes: PCCL to CCL Process" (USEPA, 2009g).

These documents can be found on the EPA web site at: <a href="http://www2.epa.gov/ccl/contaminant-candidate-list-3-ccl-3">http://www.regulations.gov</a> (docket ID: EPA-HQ-OW-2007-1189).

After a Final CCL is published, SDWA section 1412(b)(1)(B)(ii) as amended in 1996, requires EPA at five year intervals to make determinations of whether to regulate or not to regulate no fewer than five contaminants from the CCL in a process called regulatory determination. This is a separate process from the listing of contaminants on the CCL. The 1996 SDWA Amendments specify three criteria to determine whether a contaminant may require regulation:

- the contaminant may have an adverse effect on the health of persons;
- 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; and
- in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

If EPA determines that these three statutory criteria are met and makes a final determination to regulate a contaminant, the agency has 24 months to publish a proposed Maximum Contaminant Level Goal<sup>1</sup> (MCLG) and NPDWR<sup>2</sup>. After the proposal, the agency has 18 months to publish and promulgate a final MCLG and NPDWR (SDWA section 1412(b)(1)(E))<sup>3</sup>.

On February 11, 2011, as a separate action, the agency issued a positive regulatory determination for perchlorate, a chemical listed in CCL 1, CCL 2 and CCL 3 (76 FR 7762 (USEPA, 2011)). In January 2016 (81 FR 13 (USEPA, 2016a)) the agency made final determinations not to regulate four contaminants: dimethoate; 1,3-dinitrobenzene; terbufos; and terbufos sulfone and delayed the final determination of strontium pending analysis of additional data. These six contaminants were not listed on the Draft CCL 4, pending their final determinations, and therefore are also not included on the Final CCL 4.

In May 2012, EPA sought public input by requesting nominations of contaminants to be considered for inclusion on the CCL 4 (77 FR 27057 (USEPA, 2012)). EPA reviewed the nominations and supporting information provided by nominators to determine if any new data were provided that had not been previously evaluated for CCL 3. The agency also collected additional data for the nominated contaminants, when it was available, from both CCL 3 data sources that had been updated and from new data sources that were not available at the time of CCL 3. A complete list of references provided by nominators can be found in the support document "Summary of Nominations for the Fourth Contaminant Candidate List (CCL 4)" (USEPA, 2016b). EPA evaluated the nominated contaminants utilizing the best available health effects and occurrence data and the same process for screening and scoring contaminants that was used for CCL 3.

A summary of the process and data used to screen the contaminants nominated for CCL 4 from the CCL 4 Universe to the PCCL 4 is included in the "Screening Document for the Fourth

<sup>&</sup>lt;sup>1</sup> The 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. Maximum contaminant level goals are non-enforceable health goals." (40 C.F.R. 141.2; 42 U.S.C. 300g-1).

<sup>&</sup>lt;sup>2</sup> 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 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 analytical methods and taking cost into consideration.

<sup>&</sup>lt;sup>3</sup> The statute authorizes a nine month extension of this promulgation date.

Preliminary Contaminant Candidate List (PCCL 4)" (USEPA, 2016c). The document "Contaminant Information Sheets (CISs) for the Final Fourth Contaminant Candidate List (CCL 4)" (USEPA, 2016d) summarizes the process used to select contaminants from the PCCL for the CCL and presents the CISs for the contaminants on the Final CCL 4. The purpose of the CISs is to summarize the data used to evaluate and select contaminants for the Final CCL 4.

The Draft CCL 4 was published on February 4, 2015(80 FR 6076 (USEPA, 2015)), and includes 100 chemicals or chemical groups and 12 microbes. EPA conducted an abbreviated evaluation and selection process for the CCL 4. This abbreviated CCL 4 process includes a three pronged approach: (1) carrying forward CCL 3 contaminants (minus those with regulatory determinations), (2) seeking and evaluating nominations from the public for additional contaminants to consider and (3) evaluating any new data for those contaminants with previous negative regulatory determinations from CCL 1 or CCL 2 for potential inclusion on the CCL 4.

EPA requested comment on the Draft CCL 4 and on how to further improve upon the selection process developed for CCL 3 as a tool for future CCLs. The agency received 27 public comment letters on the Draft CCL 4. EPA considered all public comments and evaluated the data and information provided by commenters in determining the Final CCL 4. EPA used the same process used in the CCL 3 to screen and score any contaminants with new data or information provided by commenters. Based on these analyses, EPA is not listing three cancelled pesticides (disulfoton, fenamiphos, and molinate) on the Final CCL 4 that were included on the Draft CCL 4 because these chemicals are not known or anticipated to occur in PWSs and are not anticipated to require regulation. With the exception of these three pesticides, all of the contaminants listed on the Draft CCL 4 are listed on the Final CCL 4. EPA has responded to all public comments in the "Comment Response Document for the Fourth Drinking Water Contaminant Candidate List (Categorized Public Comments)" document that is available in the docket (USEPA 2016e).

The Final CCL 4 includes 97 chemicals or chemical groups (i.e., cyanotoxins) and 12 microbes.

The purpose of this document is to provide a description of the data sources that EPA collected or updated, and or new information for CCL 4. This document briefly summarizes the process, which was developed under CCL 3, used to evaluate the new data sources which was developed under CCL 3.

#### 2.0 Summary of the Process for Evaluating Chemical Data Sources

As previously described, EPA collected additional data for the nominated contaminants and contaminants with previous negative regulatory determinations (from Regulatory Determinations 1 & 2), when it was available, from both CCL 3 data sources that had been updated and from new data sources that were not available at the time of CCL 3. EPA used the same process developed under CCL 3 for evaluating new data sources for potential inclusion in the CCL 4 process. The process is summarized in this section, and a more detailed description of this process can be found in the CCL 3 supporting document: "Final Contaminant Candidate List 3 Chemicals: Identifying the Universe" (USEPA, 2009b).

EPA used four assessment factors (relevance, completeness, redundancy and retrievability) to evaluate and identify data sources that would be used to make up the CCL 3 Chemical Universe. These assessment factors ensure that the data sources are: relevant to the CCL process, complete in basic documentation, not redundant with other data sources and are formatted for automated retrieval. These factors were based upon the National Drinking Water Advisory Council's (NDWAC) recommendation that data sources should:

- 1. Have data and information about actual or potential occurrence of contaminants in drinking water or source water and/or about health effects;
- 2. Focus on readily available data (e.g., those that could be automatically retrieved); and
- 3. Meet EPA's minimum guidelines for documentation and quality.

The relevance assessment factor addresses the NDWAC and National Research Council principles for the CCL 3 Universe and evaluates whether a data source contains information on demonstrated or potential occurrence of contaminants in the environment and/or demonstrated or potential human health effects. The completeness assessment evaluates whether the data source provides complete, minimum documentation and quality requirements. NDWAC recommended that each source should include: 1) the name of a person to contact about the data source (or contact information); 2) a description of the data elements; 3) information on how the data were obtained; and 4) meaningfulness and relevance of the data. The "meaningfulness and relevance" NDWAC recommendation is addressed by the relevance assessment factor, so it is not included in the completeness assessment. Also, data sources that provide documentation of peer review are considered to satisfy the completeness criteria. The redundancy assessment factor evaluates whether data sources contain information that is identical to (i.e., duplicate information) other, more comprehensive data sources. An example of a redundant source would be data contained in a state or regional data source that were copied from a more comprehensive or representative national data source. Therefore, to be considered redundant, a data source must contain data identical with respect to the identity of the original data gatherer, time, place, method, outcome and data manipulation or modification. The retrievability assessment factor is an evaluation of whether the data in a source are formatted for automated retrieval. For example, if data are stored in a tabular format, they may be extracted and formatted using software tools and imported directly into a database for further use.

Each data source was accessed online (or as provided by the source proprietor) and reviewed. Basic information about the data source, its purpose and the data elements it contained was compiled and documented. Every source was evaluated using all four assessment factors. For a complete list and description of the 40 primary data sources and 64 supplemental data sources used for CCL 3, please refer to "Final CCL 3 Chemicals: Identifying the Universe" (USEPA, 2009b).

#### 3.0 Chemical Data Sources Evaluated for CCL 4

This section lists both the chemical data sources that were used for CCL 3 and were updated for CCL 4 and the new data sources evaluated for CCL 4 that were not available at the time of CCL 3. EPA evaluated each of the new data sources for CCL 4 according to the four assessment

factors that are described in Section 2. A more detailed description of each of these data sources including an explanation of whether the new data sources met each of the four assessment factors can be found in Appendix 1. Data provided by public commenters was also evaluated for three of the assessment factors listed in Section 2 (the exception was retrievablity because the commenter provided the data directly). Data used to evaluate contaminants on the CCL 4 (including data provided during nominations and public comments) can be found on the CISs for each contaminant (USEPA, 2016d).

Occurrence data was collected for the nominated contaminants from updated CCL 3 data sources including:

- 2006 production data collected in the Chemical Update System (CUS) under the Inventory Update Rule (IUR),
- 2010 data from the Toxics Release Inventory (TRI),
- 2003-2009 data from the U.S. Department of Agriculture's (USDA) Pesticide Data Program (PDP), and
- EPA's Storage and Retrieval (STORET) data as of January 2013.

Additional occurrence data for the nominated contaminants were collected from data sources that are new since the CCL 3 including:

- USGS studies that focused on contaminant occurrence in source waters for public water systems (Hopple et al., 2009, and Kingsbury et al., 2008) and water quality in public-supply wells (Toccalino et al., 2010);
- Individual State public water supply data provided to EPA during the second Six-Year Review of regulated contaminants (for the time period covering 1998-2005) from States including: CA, FL, IL, NC, OH, Region 9 Tribes, SD, TX and WI;
- Data from the California State Water Resources Control Board's Groundwater Ambient Monitoring Assessment (GAMA) program; and
- New data from a literature review of published studies on pharmaceuticals, personal care products and other contaminants.

In addition to health effects data provided by the nominators, EPA searched for health effects data for the nominated contaminants from data sources used in CCL 3 that may have been updated including:

- EPA's Integrated Risk Information System (IRIS) program,
- EPA's Office of Pesticide Programs (OPP),
- Agency for Toxic Substances and Disease Registry (ATSDR),
- California EPA (Office of Environmental Health Hazard Assessment),
- Institute of Medicine (IOM),
- National Toxicology Program (NTP), and
- World Health Organization (WHO).

EPA also considered new or updated health effects information contained in the agency's Office of Superfund Remediation and Technology Innovation (OSRTI) Provisional Peer Reviewed Toxicity Values (PPRTVs).

#### 4.0 Microbial Data Sources Evaluated for CCL 4

This section outlines the data sources and approaches used to develop the microbial CCL from the Universe through the final CCL. Because of the inherent differences between microbes and chemicals and differences in the availability of tabulated data containing the data elements required for screening evaluations, it was necessary to rely upon text-based resources for processing microbes.

The Microbial CCL 3 Universe was defined as all known human pathogens and the compilation of Taylor et al. (2001) served as a practical starting point. This list includes 1,415 bacteria, viruses, protozoa, helminths and fungi known to be pathogenic for humans based upon literature review. This list was supplemented by adding six fungi isolated from drinking water distribution systems that did not appear on the Taylor list and with 2 nominations from the scientific community (from CCL 3). Since the publication of CCL 3, there have been no updates to Taylor et al. (2001), so the CCL 3 Universe is being carried forward to the Final CCL 4.

During CCL 3, text-based resource materials, such as The Manual of Clinical Microbiology (MCM), 9th Edition, were used to inform the screening and scoring process. The MCM 10th edition was published in 2011 (MCM, 2011). The MCM is a two-volume peer reviewed reference that is written by an international team of subject experts. EPA reviewed the latest edition of the MCM for changes that would affect the outcome of the nominated microbes in CCL 4. No new data were found that would result in a different outcome for any of the nominated microbes.

For CCL 3, web searches were also conducted to identify authoritative online databases which could be used to document screening decisions (e.g., Universe to PCCL). While it is possible that these sources may contain updated information regarding nomenclature or classification, new data detailing a fundamental change in characteristics were not found for use in CCL 4. Thus, the criteria used for exclusion of microbes during CCL 3 remain valid. For more information on the screening criteria developed under CCL 3 and used for CCL 4, please see "Final Contaminant Candidate List 3 Microbes: Screening to the PCCL" (USEPA, 2009f).

The MCM (2011) was one of the main sources of information used to inform the scoring of the PCCL microbes (both for CCL3 and CCL4). EPA also conducted a literature search covering the time period between CCL 3 and CCL 4 (2007-2012). The literature search focused on health effects and occurrence of the nominated microbial contaminants in water. No new data were found as a result of the literature search that would support a change to the CCL 3 scores, thus the scores remain the same for CCL 4. For more information on the scoring protocols developed under CCL 3 and used for CCL 4, please see "Final Contaminant Candidate List 3 Microbes: PCCL to CCL Process" (USEPA, 2009g).

For Waterborne Disease Outbreaks (WBDOs), the primary source for scoring data was the Center for Disease Control (CDC) Morbidity and Mortality Weekly Reports (MMWR). CDC, EPA and the Council of State and Territorial Epidemiologists (CSTE) maintain a collaborative surveillance system for collecting and periodically reporting data related to occurrences and causes of WBDOs. These reports from the CDC are published periodically in the MMWR. For the CCL 3, EPA used CDC's MMWR summaries from 1998-2004 as the source for the WBDO scoring protocol. The same process was used for CCL 4, however the data were updated through 2008 (CDC, 2008; CDC, 2011).

#### 5.0 References

- CDC. 2008. Surveillance for Waterborne Disease and Outbreaks Associated with Drinking Water and Water not Intended for Drinking United States, 2005-2006. MMWR 57 (SS-9); 1-72 (Table 4, p. 45; Table 5 p. 46).
- CDC. 2011. Surveillance for Waterborne Disease and Outbreaks Associated with Drinking Water United States, 2007-2008. MMWR 60 (SS-12); 1-80 (Table 4, p. 45; Table 5 p. 46).
- Murray, P. R., E. J. Baron, J. H. Jorgensen, M. A. Pfaller, and R. H Yolken (ed.) The Manual of Clinical Microbiology, 10th edition, American Society for Microbiology, Washington, DC Vol. 2; pp. 3129.
- Taylor, L. H., S. M. Latham, and M. E. Woolhouse. 2001. Risk factors for human disease emergence Philosophical Transactions of the Royal Society of London B. Vol. 356, pp. 983-989
- USEPA. 2009a. Drinking Water Contaminant Candidate List 3—Final Notice. Federal Register. Vol. 74. No 194. p.51850, October 18, 2009.
- USEPA, 2009b. Final Contaminant Candidate List 3 Chemicals: Identifying the Universe. EPA. 815-R-09-006. August 2009.
- USEPA, 2009c. Final Contaminant Candidate List 3 Chemicals: Screening to a PCCL. EPA 815-R-09-007. August 2009.
- USEPA, 2009d. Final Contaminant Candidate List 3 Chemicals: Classification of PCCL to the CCL. EPA 815-R-09-008. August 2009.
- USEPA, 2009e. Final Contaminant Candidate List 3 Microbes: Identifying the Universe. EPA 815-R-09-008. August 2009.
- USEPA, 2009f. Final Contaminant Candidate List 3 Microbes: Screening to the PCCL. EPA 815-R-09-008. August 2009.

- USEPA, 2009g. Final Contaminant Candidate List 3 Microbes: PCCL to CCL Process. EPA 815-R-09-009. August 2009.
- USEPA, 2012. Request for Nominations of Drinking Water Contaminants for the Fourth Contaminant Candidate List. Federal Register Vol. 77. No 89. p. 27057, May 8, 2012.
- USEPA. 2014. Announcement of Preliminary Regulatory Determination for Contaminants on the Third Drinking Water Contaminant Candidate List. Federal Register. Vol. 79, No. 202, p. 62716, October 20, 2014.
- USEPA. 2015. Drinking Water Contaminant Candidate List 4—Draft. Federal Register. Vol. 80 No. 23, p 6076, February 4, 2015.
- USEPA. 2016a. Announcement of Final Regulatory Determinations for Contaminants on the Third Drinking Water Contaminant Candidate List. Federal Register. Vol. 81 No. 1, p 13, January 4, 2016.
- USEPA. 2016b. Summary of Nominations for the Fourth Contaminant Candidate List (CCL 4). EPA 815-R-16-006. November, 2016.
- USEPA. 2016c. Screening Document for the Fourth Preliminary Contaminant Candidate List 4. (PCCL 4) EPA 815-R-16-008. November, 2016.
- USEPA. 2016d. Contaminant Information Sheets (CISs) for the Final Fourth Contaminant Candidate List (CCL 4). EPA 815-R-16-003. November, 2016.
- USEPA. 2016e. Comment Response Document for the Fourth Drinking Water Contaminant Candidate List (Categorized Public Comments). EPA 815-R-16-004. November, 2016.

#### **Appendices** 6.0

#### **Appendix 1. CCL 4 Data Source Descriptions**

Appendix 1 lists the data sources evaluated for CCL 4 including both CCL 3 data sources that had been updated and new data sources that were not available at the time of CCL 3. This appendix provides a brief description of each data source, gives the proprietor information, contact information, type of data elements contained in the data source, provides an explanation of whether each data source meets the four assessment factors and provides a source URL, if applicable.

#### **Data Sources for Chemical Contaminants**

**Data Source Name Data Source Description**  12th Report on Carcinogens - NTP

The Report on Carcinogens (RoC) is a congressionally-mandated document that is prepared by the National Toxicology Program (NTP) for the Secretary of the U.S. Department of Health and Human Services. The RoC is updated periodically, and the 12th RoC (released in 2011) contains profiles for 240 substances, including 54 substances that are

known to be human carcinogens and 186 substances that are

reasonably anticipated to be human carcinogens. The substance profiles contain data regarding carcinogenicity, genotoxicity, mechanisms of action in people and/or in animals, the potential for human exposure to these substances, federal regulations to limit exposures,

physical/chemical properties, use and production. (Description adapted

from website.)

National Toxicology Program, National Institute of Environmental Health **Proprietor** 

Sciences

**Contact Information** Dr. Ruth M. Lunn

Director, Report on Carcinogens Center

National Toxicology Program

Mailing Address: MD K2-14, P.O. Box 12233

Research Triangle Park, NC 27709

Courier Address: 530 Davis Drive, Room 2006

Morrisville, NC 27560 T Phone: (919) 316-4637 Fax: (919) 541-0144 Email: lunn@niehs.nih.gov

Type of Data Elements

Name, CASRN, International Agency for Research on Cancer (IARC) cancer class, toxicological study data, molecular weight, specific gravity, vapor pressure, vapor density, Melting Point, Boiling Point, log Kow, dissociation constant, use, production, critical effect, exposure potential,

releases, occupational exposure limits

Source URL

#### Data Sources for the Fourth Contaminant Candidate List 4 (CCL 4)

Relevance Explanation

This source is considered relevant for the CCL Universe because it contains data elements from toxicological studies.

**Completeness Explanation Redundancy Explanation** 

It meets considerations because it is peer reviewed.

This source is not redundant.

Retrievability Explanation

This source does not meet retrievability criteria because the data are not formatted for automated retrieval.

http://ntp.niehs.nih.gov/?objectid=03C9AF75-E1BF-FF40-

DBA9EC0928DF8B15

**Data Source Name** 

Agency for Toxics Substances and Disease Registry Minimal Risk Levels (MRLs)

**Data Source Description** 

The ATSDR Minimal Risk Levels (MRLs) were developed as an initial response to Congressional mandate. Following discussions with scientists within the Department of Health and Human Services (HHS) and the EPA, ATSDR chose to adopt a practice similar to that of the EPA's Reference Dose (RfD) and Reference Concentration (RfC) used for deriving substance-specific health guidance levels for non-neoplastic endpoints. An MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse noncancer health effects over a specified duration of exposure. These substance-specific estimates, which are intended to serve as screening levels, are used by ATSDR health assessors and other responders to identify contaminants and potential health effects that may be of concern at hazardous waste sites. It is important to note that MRLs are not intended to define clean-up or action levels for ATSDR or other Agencies.

During the development of toxicological profiles, MRLs are derived when ATSDR determines that reliable and sufficient data exist to identify the target organ(s) effected or the most sensitive health effect(s) for a specific duration for a given route of exposure to the substance. MRLs are based on noncancer health effects only and are not based on a consideration of cancer effects. Inhalation MRLs are exposure concentrations expressed in units of parts per million (ppm) for gases and volatiles or milligrams per cubic meter for particles. Oral MRLs are expressed as daily human doses in units of milligrams per kilogram per day. Radiation MRLs are expressed as external exposures in units of millisieverts.

ATSDR uses the no-observed-adverse-effect-level/uncertainty factor (NOAEL/UF) approach to derive MRLs for hazardous substances. They are set below levels that, based on current information, might cause adverse health effects in the people most sensitive to such substanceinduced effects. MRLs are derived for acute (1-14 days), intermediate (>14-364 days), and chronic (365 days and longer) exposure durations, and for the oral and inhalation routes of exposure. Currently MRLs for the dermal route of exposure are not derived because ATSDR has not yet identified a method suitable for this route of exposure. MRLs are generally based on the most sensitive substance-induced end point considered to be of relevance to humans. ATSDR does not use serious health effects (such as irreparable damage to the liver or kidneys, or birth defects) as a basis for establishing MRLs. Exposure to a level above the MRL does not mean that adverse health effects will occur.

Proposed MRLs undergo a rigorous review process. They are reviewed by the Health Effects/MRL Workgroup within the Division of Toxicology; an expert panel of external peer reviewers; the agency wide MRL Workgroup, with participation from other federal agencies, including EPA; and are submitted for public comment through the toxicological profile public comment period. Each MRL is subject to change as new information becomes available concurrently with updating the toxicological profile of the substance. MRLs in the most recent toxicological profiles supersede previously published levels. As of the date last accessed for CCL update, 120 inhalation MRLs, 189 oral MRLs and 6 external radiation MRLs have been derived. (Description adapted from website.)

**Proprietor** 

**Contact Information** 

Agency for Toxic Substances and Disease Registry

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Atlanta, Georgia 30333Telephone: 404-498-0705

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Type of Data Elements Relevance Explanation Name, CASRN, MRL (chronic, intermediate, acute)

This source is considered relevant for the CCL Universe because it contains data elements (MRL) derived from toxicological studies.

Completeness Explanation
Redundancy Explanation

It meets considerations because it is peer reviewed.

These data are also represented in the ATSDR Toxicological Profiles; however, these data are tabular while the Profiles are monographic. This source meets retrievability criteria because it is in tabular format.

Retrievability Explanation
Source URL

http://www.atsdr.cdc.gov/mrls/index.html

Data Source Name

# **Background document for development of WHO Guidelines** for Drinking-water Quality

**Data Source Description** 

The fourth edition of the World Health Organization's Guidelines for Drinking-water Quality are intended to support the development and implementation of risk management strategies that will ensure the safety of drinking-water supplies through the control of hazardous constituents of water. WHO has been issuing drinking water guidelines for over 50 years.

WHO informs the public through the establishment of health-based targets, catchment-to-consumer water safety plans and independent surveillance. The first WHO document dealing specifically with public drinking-water quality was published in 1958 as International Standards for Drinking-water and was revised in 1963 and in 1971. In 1984–1985, the first edition of the WHO Guidelines for Drinking-water Quality (GDWQ) was published in three volumes. Second editions of these volumes were published in 1993, 1996 and 1997. Addenda to Volumes 1 and 2 of the second edition were published in 1998 addressing selected chemicals. An addendum on microbiological aspects reviewing selected microorganisms was published in 2002. The third edition of the GDWQ was published in 2004, the first addendum to the third edition was

published in 2006 and the second addendum to the third edition was published in 2008. The fourth edition was published in 2011.

The GDWQ are subject to a rolling revision process. Through this process, microbial, chemical and radiological aspects of drinking-water are subject to periodic review and documentation related to aspects of protection and control of public drinking water quality is accordingly prepared and updated. (Description adapted from website and document

introduction.)

ProprietorWorld Health OrganizationContact InformationWorld Health Organization

Avenue Appia 20 1211 Geneva 27 Switzerland

Telephone: + 41 22 791 21 11 Facsimile (fax): + 41 22 791 31 11

Type of Data Elements Name, CASRN, chemical properties, concentration data, guideline value,

Tolerable Daily Intake, NOAEL

Relevance Explanation This source is considered relevant for the CCL Universe because it

contains data elements from toxicological studies.

Completeness Explanation It meets considerations because it is peer reviewed.

**Redundancy Explanation** This source is not redundant.

Retrievability Explanation This source does not meet retrievability criteria because the data are not

formatted for automated retrieval.

Source URL <a href="http://www.who.int/water\_sanitation\_health/dwq/guidelines/en/">http://www.who.int/water\_sanitation\_health/dwq/guidelines/en/</a>

Data Source Name

California EPA Office of Environmental Health Hazard
Assessment (OEHHA)

Data Source Description The Toxicity Criteria Database from California EPA OEHHA contains

information on over 260 chemicals. The database reports information that includes the following: cancer potency information (oral/inhalation slope factors), chronic and acute Reference Exposure Levels (RELs), California Public Health Goals (CAPHG), California Proposition 65 No Significant Risk Levels (NSRLs) and Maximum Allowable Daily Levels (MADLs). The "Technical Support Document for Describing Available Cancer Potency Factors (TSD)" contains cancer unit risks and potency factors for 121 of the 201 carcinogenic substances or groups of

substances for which emissions must be quantified in the Air Toxics Hot Spots program. The purpose of this document is to provide a summary of the data supporting the carcinogenic potential of the substance or group of substances and to provide the calculation procedure used to derive the estimated unit risk and cancer potency factors. For the complete document, go to: http://www.oehha.ca.gov/air/cancer\_guide/TSD2.html to download. No new data was identified for use in CCL 4. (Description

adapted from website.)

Proprietor California Office of Environmental Health Hazard Assessment

Contact Information Office of Environmental Health Hazard Assessment

California Environmental Protection Agency

1515 Clay Street, 16th Floor Oakland, California 94612

(510) 622-3200

Type of Data Elements Critical effect, CAMCL, CAPHG, cancer risk, cancer groups, MADL,

NSRL, REL, slope factor, unit risk

Relevance Explanation This source is considered relevant for the CCL Universe because it

contains data elements derived from toxicological studies.

**Completeness Explanation** It meets considerations because it is peer reviewed.

Redundancy Explanation
Retrievability Explanation

This source is not redundant.

**Retrievability Explanation** This source meets retrievability criteria because it is in tabular format

Source URL <a href="http://www.oehha.ca.gov/risk/ChemicalDB/index.asp">http://www.oehha.ca.gov/risk/ChemicalDB/index.asp</a>

## Data Source Name Chemical Update System (CUS)/Inventory Update Reporting (IUR) rule

Data Source Description The Chemical Update System (CUS) database contains confidential data

reported by industry (approximately 1,200 companies) as a partial update of the Toxic Substances Control Act (TSCA) Inventory. Data reported under the Inventory Update Reporting (IUR) rule were stored in the CUS database. Under the IUR, manufacturers and importers were required to report company information (e.g., plant site name, address and Data Universal Numbering System and chemical information (e.g.,

CAS registry number, Premanufactures Number/Bonafide/Test
Marketing Exemption Application or Confidential Chemicals Ident

Marketing Exemption Application or Confidential Chemicals Identification System Assession Number and production volume) for chemicals they manufactured or imported in excess of 25,000 pounds (up from 10,000

pounds in 2002) in the previous fiscal year. U.S. Environmental

Protection Agency (EPA) released the 2006 IUR rule (currently called the Chemical Data Reporting (CDR) rule) information on more than 6,200 chemicals in commerce. EPA had previously compiled the 1998 and 2002 IUR data for CCL 3. EPA downloaded the 2006 IUR data in August, 2010 for use in CCL 4. The CUS database contains comprehensive use and exposure information on the most widely used chemicals in the

United States. (Description adapted from website.)

**Proprietor** EPA

Contact Information E-mail: TSCA Hotline (tsca-hotline@epamail.epa.gov)

TSCA Hotline Phone: 202-554-1404 IUR/CDR Helpline Phone: 202-564-3012

Type of Data Elements Production Volume

**Relevance Explanation** This source is considered relevant for the CCL Universe because it

contains information on production volume, which may indicate potential

occurrence.

Completeness Explanation It meets considerations because it meets all NDWAC minimum data

requirements.

**Redundancy Explanation** This source is not redundant.

Retrievability Explanation This source meets retrievability criteria because it is in tabular format.

Source URL

http://www.epa.gov/cdr/

**Data Source Name** 

Dietary Reference Intakes for Vitamin A, Vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium, and Zinc - Institute of Medicine

**Data Source Description** 

This volume is from a series issued by the National Academy of Sciences on dietary reference intakes (DRIs). This series provides recommended intakes, such as Recommended Dietary Allowances (RDAs) and Tolerable Upper Intake Levels (ULs), for maintaining nutritionally adequate diets for individuals in the United States and Canada based on factors such as age and gender. In addition, the ULs will help a consumer know how much is "too much" of a nutrient.

Recommendations have been made for the following: vitamins A and K, iron, iodine, chromium, copper, manganese, molybdenum, zinc and other potentially beneficial trace elements such as boron to determine the roles, if any, they play in health. (Description adapted from website.)

**Proprietor** 

National Academy of Sciences – Institute of Medicine

**Contact Information** 

Geraldine Kennedo

Administrative Assistant, Food and Nutrition Board

Phone: 202-334-1732 Fax: 202-334-2316

E-mail:gkennedo@nas.edu

Keck Center

W700

500 Fifth St. NW

Washington, DC 20001

Type of Data Elements Relevance Explanation Name, DRIs, RDAs, ULs.

This source is not redundant.

contains data elements from toxicological studies.

**Completeness Explanation Redundancy Explanation Retrievability Explanation** 

It meets considerations because it is peer reviewed.

This source does not meet retrievability criteria because the data are not formatted for automated retrieval. However, this source was only used

This source is considered relevant for the CCL Universe because it

for the UL for manganese, thus retrievability was not an issue.

Source URL A-Vitamin-K-Arsenic-Boron-Chromium-Copper-Iodine-Iron-Manganese-

http://www.iom.edu/Reports/2001/Dietary-Reference-Intakes-for-Vitamin-

Molybdenum-Nickel-Silicon-Vanadium-and-Zinc.aspx

**Data Source Name** 

**EPA Office of Water Literature Search for Supplemental Water** Occurrence Data for Pharmaceuticals, Personal Care **Products and Other Contaminants** 

**Data Source Description** 

As part of its ongoing assessment of pharmaceuticals in the environment, and particularly in water, the USEPA Office of Water's, Office of Science and Technology has been conducting a search and

review of peer-reviewed, published journal literature for studies dealing with the occurrence of pharmaceuticals and personal care products (PPCPs) in the environment. The literature review included 171 papers that were published between 2001 through 2010. For CCL 4, EPA reviewed the literature found in the search to identify papers that present supplemental occurrence data for ambient water or drinking water that were not previously considered under CCL 3. Many of the studies were highly localized in scope, so were only evaluated as supplemental data if other more comprehensive studies were not available. Many of the studies involved waste waters and media other than water and these were not used for CCL 4. The Office of Ground Water and Drinking Water, to supplement the journal literature, reviewed 14 studies published by the USGS since CCL 3 (since late 2008) on PPCPs and other contaminants for possible additional supplemental data (http://toxics.usgs.gov/).

**Proprietor** 

U.S. EPA

**Contact Information** 

Octavia Conerly

USEPA – Office of Science and Technology

Email: conerly.octavia@epa.gov

Meredith Russell

USEPA- Office of Ground Water and Drinking Water

Email: russell.meredith@epa.gov

**Type of Data Elements** 

Measured contaminant concentrations from water samples, number of samples and/or sites with samples, number of detections, type of sites and samples, etc.

**Relevance Explanation** 

This source is considered relevant for the CCL Universe because it contains data elements for supplemental contaminant occurrence in water, which may indicate potential occurrence in drinking water.

Completeness Explanation
Redundancy Explanation

It meets considerations because the studies were peer-reviewed.

This source is not redundant though some, but not all, data may overlap among papers by the same authors. This source may also overlap with prior published USGS reports and the NAWQA and NREC data, collected for CCL 3.

**Retrievability Explanation** 

Data not retrievable. This source contains tabulated occurrence data that

can be copied and formatted.

Source URL

Not applicable

**Data Source Name** 

# **Groundwater Ambient Monitoring and Assessment (GAMA) Program**

Data Source Description

The GAMA Program is California's comprehensive groundwater quality monitoring program conducted cooperatively with USGS. The GAMA data used in this analysis are from water samples from public drinking water supply wells (i.e., untreated "source water"). Major groundwater supply basins are a specific focus of the GAMA program. The main goals of the program are to improve statewide groundwater monitoring and to increase the availability of groundwater quality information to the public. GAMA collects data by testing the untreated or raw water in different types of wells for naturally-occurring and man-made chemicals. In 2000 the State Water Resources Control Board (SWRCB) created the ambient monitoring program to better understand California's groundwater quality

issues. The GAMA Program was later expanded, resulting in a plan to monitor and assess groundwater quality in basins that account for over 95% of the state's groundwater use. GAMA Program projects have analyzed thousands of water samples for hundreds of chemicals – many of the chemicals at ultra-low detection limits requiring state-of-the-art facilities and methods. GAMA compiles these test results with existing groundwater quality data from several agencies into a publicly-accessible internet database, GeoTracker GAMA. There are four active GAMA projects: Priority Basin Project, Domestic Well Project, Special Studies Project, and GeoTracker GAMA.

California State Water Resources Control Board (SWRCB)/U.S. **Proprietor** 

Geological Survey (USGS)

**Contact Information** John Borkovich

> jborkovich@waterboards.ca.gov **GAMA Program Manager**

916-341-5779

**Type of Data Elements** Drinking water (source water) occurrence concentrations

Relevance Explanation This source is considered relevant for the CCL Universe because it

contains measurements of contaminants in water, demonstrating

occurrence.

This source meets completeness considerations because it meets all **Completeness Explanation** 

NDWAC minimum data requirements.

**Redundancy Explanation** This source is not redundant.

Retrievability Explanation This source contains tabulated occurrence data that can be downloaded

and analyzed.

Source URL http://www.waterboards.ca.gov/gama/

Hopple, et al., 2009. Anthropogenic Organic Compounds in **Data Source Name Source Water of Selected Community Water Systems that** 

Use Groundwater, 2002-05 - USGS

**Data Source Description** As part of the NAWQA program, Hopple et al. (2009) conducted studies

> to analyze 258 anthropogenic organic compounds in groundwater used as source waters for community water systems (CWSs). Most of the 258 compounds analyzed are unregulated in drinking water. In Phase 1 of the sampling, source water samples were collected between October 2002 and July 2005 from 221 wells that withdraw from 12 aguifers across the U.S. In Phase 2 of the sampling, USGS collected source and finished water samples from 94 wells at selected CWSs between June 2004 and September 2005. These samples were analyzed for a smaller subset of

compounds, which occurred most frequently, or were found at relatively

high concentrations in Phase 1 of the sampling.

Reference: Hopple, J.A., Delzer, G.C., and Kingsbury, J.A., 2009, Anthropogenic organic compounds in source water of selected community water systems that use groundwater, 2002-05: U.S. Geological Survey Scientific Investigations Report 2009–5200, 74 p.

United States Geological Survey (USGS)

**Proprietor** 

Contact Information

Director, USGS South Dakota Water Science Center

1608 Mt. View Rd.
Rapid City, SD 57702
Phone: (605) 394–3200
Web: <a href="http://sd.water.usgs.gov">http://sd.water.usgs.gov</a>
Email: <a href="mailto:dc\_sd@usgs.gov">dc\_sd@usgs.gov</a>

**Type of Data Elements** 

Measured contaminant concentrations from water samples, number of

samples/sites with samples, number of detections, etc.

Relevance Explanation

This source is considered relevant for the CCL Universe because it contains data elements for contaminant occurrence in source water

obtained from ground water resources.

Completeness Explanation
Redundancy Explanation

It meets all considerations because it is peer reviewed.

This source is not redundant though some, but not all, data may overlap with Toccalino *et al.* and with the NAWQA database analyzed separately

for CCL 3.

Retrievability Explanation

This source contains tabulated occurrence data that can be copied and

formatted.

Source URL

http://pubs.usgs.gov/sir/2009/5200/

# Data Source Name Data Source Description

#### **Integrated Risk Information System (IRIS)**

EPA's IRIS Program is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the agency's regulatory activities. The IRIS database contains information for more than 550 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides toxicity values and qualitative information for chronic cancer and noncancer health effects, including:

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

Government and private entities use IRIS by combining IRIS toxicity values with specific exposure information to help characterize public health risks of chemical substances and thereby support risk management decisions designed to protect public health.

EPA Office of Research and Development: ORD, National Center for **Proprietor** 

**Environmental Assessment** 

**Contact Information** U.S. EPA Risk Information Hotline at telephone 1-301-345-2870, or fax

to 1-301-345-2876, or

by email to Hotline.IRIS@epamail.epa.gov

Type of Data Elements Name, Synonyms, CASRN, RfC, RfD, Slope Factor (inhalation, oral),

Unit Risk (inhalation, oral), NO(A)EL, LO(A)EL, Benchmark

Concentration/ Dose (BMC/D), Benchmark Dose Limit (BMDL), Critical

effect

Relevance Explanation This source is considered relevant for the CCL Universe because it

contains data elements from toxicological studies.

**Completeness Explanation** It meets all considerations because it is peer reviewed.

**Redundancy Explanation** For CCL 4, IRIS is available electronically and retrievable. During CCL 3,

the toxicological data for IRIS were available in tabular format from ITER (International Toxicity Estimates of Risk) (data source #110) and RAIS-

Health Effects (data source #178) (see USEPA, 2009b. Final

Contaminant Candidate List 3 Chemicals: Identifying the Universe.) Hence, there is some overlap and redundancy but each also provides

additional information not available elsewhere.)

**Retrievability Explanation** For CCL 4, IRIS is available electronically and retrievable. During CCL 3

> this source contained monographs that were not formatted for automated retrieval. However, the toxicological data from this source have been compiled for electronic retrieval in ITER and were obtained from there for

CCL 3. IRIS monographs were used to confirm the IRIS/ITER data.

Source URL http://www.epa.gov/iris/index.html

**Data Source Name** Kingsbury, et al., 2008. Anthropogenic Organic Compounds

in Source Water of Nine Community Water Systems that

Withdraw from Streams, 2002-05 - USGS

**Data Source Description** As part of the NAWQA program, Kingsbury et al. (2008) conducted

> studies to analyze 258 anthropogenic organic compounds in surface waters used as source waters for nine CWSs. In Phase 1 of the studies, source water samples were collected between 2002 and 2004 from nine CWSs served by streams across the U.S. In Phase 2 of the studies, USGS collected source and finished water samples at eight of the nine

CWSs between 2004 and 2005.

Reference: Kingsbury, J.A., Delzer, G.C., and Hopple, J.A., 2008. Anthropogenic organic compounds in source water of nine community water systems that withdraw from streams, 2002-05: U.S. Geological

Survey Scientific Investigations Report 2008–5208, 66 p.

United States Geological Survey (USGS) **Proprietor** 

**Contact Information** Director, USGS South Dakota Water Science Center

> 1608 Mt. View Rd. Rapid City, SD 57702 Phone: (605) 394-3200

Web: http://sd.water.usgs.gov Email: dc\_sd@usgs.gov

Type of Data Elements Water occurrence data elements, measured concentrations, number of

sites, number of detections, etc.

Relevance Explanation This source is considered relevant for the CCL Universe because it

contains data elements for contaminant occurrence in source water

obtained from surface water resources.

Completeness Explanation It meets all considerations because it is peer reviewed.

**Redundancy Explanation** This source is not redundant (though some, but not all, data may overlap

with the NAWQA database analyzed separately for CCL 3).

Retrievability Explanation This source contains tabulated occurrence data that can be copied and

formatted.

Source URL <a href="http://pubs.usgs.gov/sir/2008/5208/">http://pubs.usgs.gov/sir/2008/5208/</a>

# Data Source Name Data Source Description

**Proprietor** 

#### Office of Pesticide Programs (OPP) Health Effects Data

EPA's Office of Pesticide Programs publishes health effects data in a variety of sources, including Reregistration Eligibility Decision (RED) Documents and Health Assessments. "When EPA completes the review and risk management decision for a pesticide that is subject to reregistration (i.e., one initially registered before November 1984), EPA generally issues a RED document. The RED summarizes the risk assessment conclusions and outlines any risk reduction measures necessary for the pesticide to continue to be registered in the U.S." There are REDs for over 176 pesticides currently. Two other types of documents – the Interim RED and Tolerance RED may also be issued. The IRED is issued when a pesticide is undergoing reregistration, requires a reregistration eligibility decision, and also needs a cumulative assessment. A TRED may be issued if no changes in the tolerances for a pesticide are required as a result of EPA's review.

EPA has also developed human health benchmarks (HHBPs) for approximately 363 pesticides to enable states, tribes, water systems, the public and other stakeholders to better determine whether the detection of a pesticide in drinking water or source waters for drinking water may indicate a potential health risk. The HHBP table includes pesticide active ingredients for which Health Advisories or enforceable National Primary Drinking Water Regulations (e.g., maximum contaminant levels) have not been developed. For pesticides with HHBPs, EPA checked the source document used to develop the HHBP to determine if there were any new or updated health effects data for CCL 4. These source documents can be found by clicking on the pesticide name at the following link:

http://www.epa.gov/pesticides/hhbp (Description adapted from website.)

EPA Office of Pesticide Programs

Contact Information US Environmental Protection Agency

Office of Pesticide Programs Washington, DC 20460 Telephone 703-308-8000

Type of Data Elements Name, Synonyms, Drinking Water Level of Concern, Population Adjusted

Dose, (RfD), Safety Factors, Lethal Concentration, Lethal Dose, LO(A)EL, Margin of Exposure, NO(A)EL, highest dose tested

Relevance Explanation This source is considered relevant for the CCL Universe because it

contains data elements from toxicological studies

Source URL

## Data Sources for the Fourth Contaminant Candidate List 4 (CCL 4)

Completeness Explanation Redundancy Explanation Retrievability Explanation It meets considerations because it is peer reviewed.

This source is not redundant.

This source does not meet retrievability criteria because the data are not

formatted for automated retrieval.

http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

**Data Source Name** 

Office of Solid Waste and Emergency Response (OSWER) Provisional Peer-Reviewed Toxicity Values for Superfund (PPRTV)

**Data Source Description** 

The Provisional Peer-Reviewed Toxicity Values (PPRTVs) currently represent the second tier of human health toxicity values for the EPA Superfund and Resource Conservation and Recovery Act hazardous waste programs. A PPRTV is a toxicity value derived for use in the Superfund Program when such value is not available in EPA's Integrated Risk Information System (IRIS). PPRTVs are derived after a review of the relevant scientific literature using the methods, sources of data and guidance for value derivation used by the EPA IRIS Program. All provisional peer-reviewed toxicity values receive internal review by EPA scientists and external peer review by independent scientific experts. PPRTVs differ from IRIS values in that PPRTVs do not undergo a multiprogram internal agency review, inter-agency review, or public comment. Additionally, IRIS values are generally intended to be used in all EPA programs, while PPRTVs are developed specifically for the Superfund Program.

The development of PPRTVs enables OSWER to make informed clean-up decisions regarding the screening of chemicals of concern, conduct human health risk assessments and evaluate alternative clean-up actions at federal and state Superfund sites, which can lead to improvements in human and ecological health in the vicinity of Superfund sites, as well as improved economic conditions and quality of life for nearby communities. PPRTVs are also used by EPA's regions when making site specific clean-up decisions.

PPRTVs are prepared on an ongoing basis for those substances found at clean-up sites and for which no IRIS value is available. The purpose of PPRTV documents are to provide hazard and dose-response assessments pertaining to chronic and subchronic exposures to substances of concern, present the major conclusions reached in the hazard identification and derivation of the PPRTVs and characterize the overall confidence in these conclusions and toxicity values. PPRTV assessments are updated approximately on a 5-year cycle for new data or methodologies that might impact the toxicity values or characterization of potential for adverse human health effects and are revised as appropriate. (Description adapted from website.)

**Proprietor** 

U.S. EPA Office of Solid Waste and Emergency Response / Office of Superfund Remediation and Technology Innovation & U.S. EPA Office of Research and Development (ORD)/ National Center for Environmental Assessment (NCEA)

**Contact Information** 

Annette Gatchett ORD/ NCEA

Gatchett.Annette@epa.gov

Michele Burgess OSWER/ OSRTI

Burgess.Michele@epa.gov

Type of Data Elements Name, Synonyms, CASRN, RfC, RfD, LOAEL, Critical effect, Cancer

classification

Relevance Explanation This source is considered relevant for the CCL Universe because it

contains data elements from toxicological studies.

Completeness Explanation This source meets all completeness considerations because it is peer

reviewed.

**Redundancy Explanation** This source is not redundant.

Retrievability Explanation Data are retrievable by EPA but require special processing and analysis

for CCL use.

Source URL <a href="http://hhpprtv.ornl.gov/index.html">http://hhpprtv.ornl.gov/index.html</a>

Data Source Name
Data Source Description

#### Pesticide Data Program

The USDA Pesticide Data Program (PDP) has developed a national pesticide residue database. PDP was initiated in 1991 to collect data on pesticide residues in food with sampling conducted on a statistically defensible representation of pesticide residuals in the United States food supply. Sampling and testing are conducted on fruits and vegetables, select grains, milk and (as of 2001) drinking water. The PDP drinking water sampling program was initiated at community water systems (CWSs) in New York and California in 2001. Since then, the drinking water sampling program has expanded, though the States where sampling occurs may differ from year to year. At one time or another, CWSs in 27 states and Washington, D.C. contributed raw and/or finished water data to the program. The sampling frame is designed to provide coverage in regions of interest for at least two years, to reflect the seasonal and climatic variability during growing seasons. PDP works with EPA and the American Water Works Association (AWWA) to identify specific water treatment facilities to be monitored. EPA reviews the PDP data on the occurrence of select contaminants in untreated and treated water. The CWSs selected for sampling tend to be small- and mediumsized systems (primarily CWSs serving less than 50,000 persons), systems served by surface water, and systems located in regions of heavy agriculture. The number of sites and samples has varied during different sampling periods. Sampling of untreated water in addition to treated water began in 2004. EPA had previously compiled the 2001 and 2002 PDP data for CCL 3. EPA compiled the 2003 through 2009 PDP data used in CCL 4 in December, 2011. (Description adapted from website.)

Proprietor
Contact Information

USDA PDP Staff:

Agricultural Marketing Service

Science & Technology, Monitoring Programs Office

8609 Sudley Road, Suite 206

Manassas, VA 20110 Director: Martha Lamont Phone: (703) 330-2300 ext. 17

Fax: (703) 369-0678

Deputy Director: Diana Haynes Phone: (703) 330-2300 ext. 34

Fax: (703) 369-0678

E-mail: amsmpo.data@ams.usda.gov

Type of Data Elements

Total Samples Analyzed, Samples with Residues Detected, Percent of Samples with Detections, Pesticides Detected, Residues Detected, Total Residue Detections, % of Samples with Detects, Minimum Value Detected (ppm), Maximum Value Detected (ppm), Number of Detections of Pesticides in Drinking Water, Pesticides Detected Above Limit of

Quantification in Drinking Water

Relevance Explanation

This source is considered relevant for the CCL Universe because it contains measurements of pesticide residues in water, demonstrating occurrence.

**Completeness Explanation** 

It meets considerations because it meets all NDWAC minimum data requirements (i.e., contact information for an administrator of the data source, a list of data elements in the data source, and an explanation of how the data were generated).

Redundancy Explanation
Retrievability Explanation

This source is not redundant.

Source URL

This source meets retrievability criteria because it is in tabular format.

http://www.ams.usda.gov/science/pdp/index.htm

Data Source Name
Data Source Description

#### **State Drinking Water Data Sets**

For EPA's Second Six-Year Review of drinking water regulations, EPA requested (through an ICR) that primacy agencies submit drinking water compliance occurrence data to EPA that was collected during 1998-2005. Eight states (CA, FL, IL, NC, OH, SD, TX, and WI) and the Region 9 tribes also submitted PWS occurrence data for unregulated contaminants in addition to the data for regulated contaminants. EPA was able to supplement these data on unregulated contaminants by downloading additional publicly available monitoring data from State Web sites (specifically, from Florida and Wisconsin). The result was a collection of unregulated contaminant monitoring data from nine states (eight states and one tribal entity; this support document uses the term "state" for SDWA primacy entities for convenience) The nine data sets vary in the range of monitoring dates (in some cases extending beyond the 1998-2005 period of interest for Six-Year Review), the number of contaminants monitored, the number of systems reporting monitoring, and the number of samples taken. The data sets vary widely in the number of PWSs sampled in each State relative to the total number of PWSs in that State. Hence, these data are used only to augment and complement any national drinking water data and to assess any unique occurrence that may suggest a need for further review.

**Proprietor** EPA OGWDW; The Cadmus Group, Inc.

Contact Information Erin Mateo

The Cadmus Group 100 5<sup>th</sup> Ave Suite 100 Waltham, MA 02451 Phone: 617-673-7000

Type of Data Elements Drinking water occurrence concentrations, number of PWSs with

samples, etc.

Relevance Explanation This source is considered relevant for the CCL Universe because it

contains measurements of contaminants in water, demonstrating occurrence. Most data are available for regulated contaminants. Some

data are available for unregulated contaminants.

requirements.

**Redundancy Explanation** This source is partially redundant, since data for contaminants that are

regulated in drinking water are available as part of the National

Contaminant Occurrence Database (NCOD) - Six Year.

**Retrievability Explanation** Data are retrievable by EPA but require special processing and analysis

for CCL use.

Source URL Internet source not available

Data Source Name
Data Source Description

#### STORET - STORage and RETrieval

STORET is a water quality, biological, and physical property data warehouse, containing information collected from over 60 organizations including States, tribes, watershed groups, other Federal Agencies, volunteer groups and universities. The extent of national coverage and data completeness varies from parameter to parameter. Many (though not all) sample results are accompanied by information on sample location (e.g., latitude, longitude, state, county, Hydrologic Unit Code and a brief site identification), sample date, the medium sampled (e.g., water, sediment, fish tissue) and the name of the organization that sponsored the monitoring. In addition, there can be information on why the data were gathered; sampling and analytical methods used; the laboratory used to analyze the samples; the quality control checks used when sampling, handling the samples, and analyzing the data; and the personnel responsible for the data. All data supplied to EPA since January 1, 1999 have been placed in the STORET Data Warehouse. Data supplied to EPA before 1999 are stored in the Legacy STORET Data Center. EPA downloaded STORET data for use in CCL 4 in January, 2013. (Description adapted from website.)

EPA

Contact Information

Type of Data Elements

**Proprietor** 

STORET User Assistance: 1-800-424-9067 or STORET@epa.gov Water occurrence data elements, measured concentrations, number of

sites, number of detections, etc.

**Relevance Explanation** 

This source is considered relevant for the CCL Universe because it contains measurements of contaminants in water, demonstrating

occurrence.

Redundancy Explanation

This source is not redundant.

**Retrievability Explanation** 

Data are retrievable by EPA but require special processing and analysis

for CCL use.

Source URL

http://www.epa.gov/storet/

**Data Source Name** 

Toccalino, et al., 2010. Quality of Source Water from Public-Supply Wells in the United States, 1993–2007 - USGS

**Data Source Description** 

As part of USGS's National Water Quality Assessment (NAWQA) program, water samples were collected from source (untreated) ground water from 932 public water system wells located in parts of 40 NAWQA Study Units in 41 states. Each well was sampled once between 1993 and 2007. Water samples were analyzed for up to 215 regulated and unregulated contaminants and several water-quality properties (e.g., hardness). The public wells sampled in this study represented 629 unique PWSs, representing 0.5% of the approximately 140,000 ground water-supplied PWSs, but nearly 25% of the population served by ground water supplied PWSs in the United States.

Reference: Toccalino, P.L., Norman, J.E., and Hitt, K.J., 2010, Quality of source water from public-supply wells in the United States, 1993–2007: U.S. Geological Survey Scientific Investigations Report 2010-5024, 206

p.

**Proprietor** 

United States Geological Survey (USGS)

**Contact Information** 

Chief, National Water-Quality Assessment Program

U.S. Geological Survey 413 National Center 12201 Sunrise Valley Drive Reston, Virginia 20192

http://water.usgs.gov/nawqa/studies/public\_wells/

Type of Data Elements

Measured contaminant concentrations from water samples, number of

samples/sites/PWSs with samples, number of detections, etc.

**Relevance Explanation** 

This source is considered relevant for the CCL Universe because it contains data elements for contaminant occurrence in source water

obtained from public-supply wells.

**Completeness Explanation** 

It meets all considerations because it is peer reviewed.

**Redundancy Explanation** 

This source is not redundant though some, but not all, data may overlap with Hopple *et al.* and with the NAWQA database analyzed separately

for CCL 3.

**Retrievability Explanation** 

This source contains tabulated occurrence data that can be copied and

formatted.

Source URL

http://pubs.usgs.gov/sir/2010/5024/

# Data Source Name Data Source Description

#### The Toxics Release Inventory (TRI)

TRI contains information from almost 20,000 U.S. companies and government facilities that report their air, land and water releases of industrial chemicals and other waste management activities. TRI also contains some information about source reduction efforts. This database's information on releases to water is a valuable source of potential occurrence data for screening drinking water contaminants for the CCL. It includes many categories of air, land, and water release data for the years 1988 through 2010. As of 2010, the TRI toxic chemical list contains 498 individually listed chemicals. EPA downloaded the 2010 TRI data (used in CCL 4) in March 2012. Facilities may also revise or withdraw submittals that they have made under TRI. This may explain why data for a given chemical and year (i.e., pounds released and number of states where a chemical was released) were sometimes observed during the compilation of CCL 3 to change over time after initial release of the data to the public (Description adapted from website.)

**Proprietor** EPA

Contact Information (800) 424-9346 - select option 3

(703) 412-9810 - Wash. DC metro area

(800) 553-7672 - TDD Email: tri.us@epa.gov

Type of Data Elements
Relevance Explanation

Pounds per year of chemical releases to air, land and water

This source is considered relevant for the CCL Universe because it contains information on chemical releases, which may indicate potential

occurrence.

**Completeness Explanation** 

It meets considerations because it is peer reviewed.

This source is not redundant.

Redundancy Explanation
Retrievability Explanation

This source meets retrievability criteria because it is in tabular format.

Retrievability Explanatio

Source URL

http://www.epa.gov/triexplorer/

#### **Data Sources for Microbial Contaminants**

**Data Source Name** 

# Center for Disease Control and Prevention's Morbidity and Mortality Weekly Reports (MMWR)

**Data Source Description** 

Since 1971, CDC, EPA and the Council of State and Territorial Epidemiologists (CSTE) have maintained a collaborative surveillance system for collecting and periodically reporting data related to occurrences and causes of Water Borne Disease Outbreaks (WBDOs). These reports from the CDC are published periodically in the MMWR. For CCL 3 EPA used CDC's MMWR summaries as the source for the WBDO scoring protocol. The summaries include data on outbreaks associated with drinking water, recreational water, water not intended for drinking (excluding recreational water) and water use of unknown intent. Public health agencies are responsible for investigating outbreaks and reporting them voluntarily to CDC using a standard form. Only data on outbreaks associated with drinking water, water not intended for drinking (excluding recreational water) and water use of unknown intent are

summarized in this report. CDC and EPA acknowledge that the WBDOs reported in the surveillance system represent only a portion of the burden of illness associated with drinking water exposure. The surveillance information does not include endemic waterborne disease risks. (Description adapted from website.)

**Proprietor** CDC

Contact Information Division of Foodborne, Waterborne, and Environmental Diseases,

National Center for Emerging and Zoonotic Infectious Diseases,

CDC, 1600 Clifton Road, N.E., MS C-9,

Atlanta, GA 30333.

Telephone: 404-639-1700; E-mail: healthywater@cdc.gov

Type of Data Elements Waterborne outbreak data

**Relevance Explanation** This source is considered relevant for the CCL process because it contains information on drinking water outbreaks caused by microbial

contaminants which is a major component of the scoring process.

**Completeness Explanation** It meets considerations because it is peer reviewed.

**Redundancy Explanation** This source is not redundant.

**Retrievability Explanation** This source meets retrievability criteria because it is in tabular format.

Source URL <a href="http://www.cdc.gov/mmwr/indss">http://www.cdc.gov/mmwr/indss</a> 2011.html

Data Source Name EPA Literature Search for Supplemental Data for Microbial

Contaminants

Data Source Description As part of its ongoing assessment of microbes in drinking water, EPA

conducted a literature review of peer-reviewed, published journal literature for health effects and occurrence data for nominated microbes from 2007 through 2012. EPA reviewed all relevant research reports found to identify papers that might present data for the nominated microbes that might help inform CCL 4. EPA also reviewed studies

submitted and referenced by nominators.

**Proprietor** U.S. EPA

**Contact Information** Cesar Cordero

Email: cordero.cesar@epa.gov

Type of Data Elements Health effects, drinking water occurrence data elements

Relevance Explanation This source is considered relevant for the CCL process because it

contains information on health effects and occurrence in water.

Completeness Explanation It meets considerations because the studies were peer-reviewed.

**Redundancy Explanation** This source is not redundant (though some, but not all, data may overlap

among papers by the same authors).

Retrievability Explanation Data not retrievable. This source contains written and tabulated data that

can be copied and formatted.

Source URL Not applicable

Data Source Name
Data Source Description

#### Manual of Clinical Microbiology (MCM), 10th Edition

The 10th edition of the MCM is the result of collaborative efforts of 22 editors and more than 267 authors from around the world, all experienced researchers and practitioners in medical and diagnostic microbiology. The manual has been brought fully up to date, resulting in 149 chapters containing the latest research findings, infectious agents, methods, practices and safety guidelines. Now entering its fifth decade the Manual strives to continue to be the leading, most authoritative reference for the "real-world" practice of clinical microbiology. This publication builds on the content of past editions. The process requires about 3 years of careful planning, design, writing and review of chapters

before the final phases of copyediting, composition, printing and binding.

(Description adapted from website.)

Proprietor ASM Press, Washington, DC

**Contact Information** James Versalovic

Microbiology Laboratories Texas Children's Hospital

Houston, Texas

Type of Data Elements Production Volume

Relevance Explanation This source is considered relevant for the CCL Universe because it

contains health effects and occurrence information on microbial

pathogens.

Completeness Explanation It meets considerations because it is peer reviewed.

**Redundancy Explanation** This source is not redundant.

**Retrievability Explanation** This source is not automatically retrievable. It is a book available for

purchase.

Source URL <a href="http://mcm10.asmpress.org/">http://mcm10.asmpress.org/</a>