



**Screening Document
for the Fourth
Preliminary
Contaminant
Candidate List
(PCCL 4)**

Office of Water (4607M)
EPA 815-R-16-008
November 2016

Contents

1.0 Introduction	1
2.0 Summary of the CCL 3 Chemicals Screening Process	3
2.1 Health Effects Data Elements	4
2.2 Occurrence Data Elements.....	6
2.3 Selection of the PCCL	7
3.0 Screening the Nominated Chemicals from the CCL 4 Universe to the PCCL	8
4.0 Summary of the CCL 3 Microbes Screening Process and Screening of the Nominated Microbes from the CCL 4 Universe to the PCCL 4	8
5.0 References	10
6.0 Appendices	A1-1
Appendix 1. Screening Data for the Nominated Chemicals in the CCL 4 Universe.....	A1-1

Exhibits

Exhibit 1: Partition for Screening the Universe 4

Exhibit 2: Potency Measures for Universe Data Element Partitioned Based on Toxicity
(mg/kg/day or mg/kg) 5

Exhibit 3: Partitioning of Cancer Data Based on TD50 Values and Weight of Evidence..... 6

Exhibit 4: Criteria for a Chemical to Pass to the PCCL 7

Acronyms and Abbreviations

<	Less than
≤	Less than or equal to
>	Greater than
≥	Greater than or equal to
μ	Microgram, one
μg/L	Micrograms per liter
ADI	Acceptable Daily Intake
AWWARF	American Water Works Association Research Foundation
CASRN	Chemical Abstract Services Registry Number
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
CE	Clear evidence of carcinogenicity
CUS/IUR	Chemical Update System/Inventory Update Rule
DBP-CAN	EPA Water Disinfection By-Products with Carcinogenicity Estimates
DSSTOX	Distributed Structure-Searchable Toxicity Database Network
E	Equivocal
EE	Equivocal evidence of carcinogenicity
EPA	United States Environmental Protection Agency
EPA HA	EPA Health Advisory
FR	<i>Federal Register</i>
g	Gram
H	High probability of causing cancer
HM	High moderate probability of causing cancer
IARC	International Agency for Research on Cancer
ITER	International Toxicity Estimates for Risk
JECFA	Joint FAO/WHO Expert Committee on Food Additives
kg	Kilogram
L	Liter
lbs	Pounds
LD ₅₀	Lethal dose 50; an estimate of a single dose that is expected to cause the death of 50 percent of the exposed animals; it is derived from experimental data.
M	Moderate probability of causing cancer
LM	Low moderate probability of causing cancer
LOAEL	Lowest Observed Adverse Effect Level

MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
mg/kg	Milligrams per kilogram body weight
mg/kg/day	Milligrams per kilogram body weight per day
mg/L	Milligrams per liter
MRDD	Maximum Recommended Daily Dose
N	Negative
NAWQA	National Water Quality Assessment
NE	No evidence of carcinogenicity
NCI	National Cancer Institute
NCFAP	National Center for Food and Agricultural Policy
NDWAC	National Drinking Water Advisory Council
NIRS	National Inorganics and Radionuclides Survey
NOAEL	No Observed Adverse Effect Level
NPDWR	National Primary Drinking Water Regulations
NRC	National Academy of Science's National Research Council
NREC	National Reconnaissance of Emerging Contaminants
NTP	National Toxicology Program
OPP	Office of Pesticide Programs
P	Positive
PFOA	Perfluorooctanoic acid
PWS	Public water system
QSAR	Quantitative Structure Activity Relationship
RfD	Reference dose
RAIS	Risk Assessment Information System
RTECS	Registry of Toxic Effects of Chemical Substances
SDWA	Safe Drinking Water Act
SE	Some evidence of carcinogenicity
TD ₅₀	Tumorigenic dose 50; The dose-rate which if administered chronically for the standard life-span of the species will have a 50% probability of causing tumors at some point during that period.
TRI	Toxics Release Inventory
US	United States of America
WHO	World Health Organization
yr	Year

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 the agency 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: <http://www2.epa.gov/ccl/contaminant-candidate-list-3-ccl-3> or at <http://www.regulations.gov> (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 Goal¹ (MCLG) and NPDWR². After the proposal, the agency has 18 months to publish and promulgate a final MCLG and NPDWR (SDWA section 1412(b)(1)(E))³.

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). A more detailed description of the CCL data sources collected by EPA may be found in the support document "Data Sources for the Fourth Contaminant Candidate List (CCL 4)" (USEPA, 2016c). 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.

¹ 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).

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 analytical methods and taking cost into consideration.

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

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 “Final Comment Response Document for the Fourth Drinking Water Contaminant Candidate List (Categorized Public Comments)” document that is available in the docket (USEPA, 2016e).

This document focuses on describing the second step in the CCL 4 process, in which EPA applied screening criteria to the nominated contaminants in the CCL 4 Universe to identify a Preliminary CCL (PCCL) based on a contaminant’s potential to occur in public water systems and the potential for public health concern. Appendix 1 shows the health effects and occurrence data used to screen the nominated chemicals in the CCL 4 Universe to the PCCL 4.

2.0 Summary of the CCL 3 Chemicals Screening Process

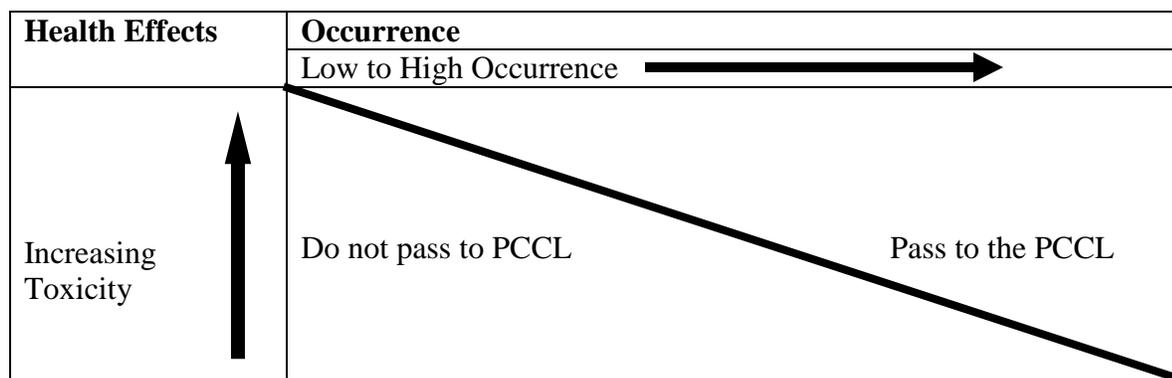
This section summarizes the process developed under CCL 3 to screen chemicals from the Universe to the PCCL. A more detailed description of the screening process can be found in the CCL 3 support document: “Final Contaminant Candidate List 3 Chemicals: Screening to a PCCL” (USEPA, 2009c). EPA developed criteria to screen chemicals from the CCL 3 Universe to the PCCL 3. These screening criteria utilized available data (e.g., occurrence and health) to examine a chemical’s health effects relative to its occurrence.

The health effects information used included quantitative, descriptive or categorical information. Within the aforementioned categories, there were various types of reported health related values

(e.g., RfD, LOAEL, NOAEL, LD50 or cancer classifications) from several data sources. A list and detailed description of the data sources used in CCL 3 can be found in “Final Contaminant Candidate List 3 Chemicals: Identifying the Universe” (USEPA, 2009b).

The occurrence information also included many types of available data representative of a chemical’s potential to occur in water. Occurrence data ranged from concentrations in finished drinking water from PWSs, to concentrations of a chemical in ambient water, to environmental release and production data. The basic framework EPA used in screening is shown in Exhibit 1. EPA categorized the CCL Chemical Universe contaminants by their toxicity along the vertical axis and by their occurrence on the horizontal axis. This allows for separation of chemicals into those that move to the PCCL based on their toxicity and occurrence properties (e.g., upper right in Exhibit 1) and those that are not further evaluated and remain in the CCL Chemical Universe (e.g., lower left in Exhibit 1). EPA used a set of test chemicals to develop the screening criteria. This set of chemicals included regulated and unregulated chemicals that provided comprehensive information on health effects and occurrence in finished and/or ambient water as well as environmental release and production volume. EPA then used these criteria to select chemicals for the PCCL for further consideration.

Exhibit 1: Partition for Screening the Universe



2.1 Health Effects Data Elements

EPA evaluated the toxicity information and health effects data compiled from the data sources in the Universe and these data varied greatly. Some of these data are quantitative (e.g., RfD, LOAEL, NOAEL, LD₅₀) and some are descriptive (e.g., cancer classifications or predictions). EPA designed the screening process to accommodate both types of health effects data. The agency also considered adverse health effects that may pose a greater risk to life stages and other sensitive groups which represent a meaningful portion of the population. Adverse health effects associated with infants, children, pregnant women, the elderly, and individuals with a history of serious illness were evaluated as part of the screening criteria.

EPA divided the chemicals in the Universe into five toxicity categories for screening based upon the distribution of the toxicity value for each type of quantitative data element and/or the

qualitative information on cancer weight-of-evidence. The five toxicity categories are designated 1 through 5, with Toxicity Category 1 containing chemicals in the most toxic grouping and Toxicity Category 5 the least toxic grouping. Based upon the distribution of the chemicals for each quantitative data element, EPA selected ranges of toxicity values for each toxicity category that differed based upon the type of data element used. For example, the range of toxicity values that places a LOAEL in Toxicity Category 1 differs from the values used to place LD₅₀ values into Toxicity Category 1. Placing contaminants into Toxicity Categories allows for a comparison of the relative toxicity of contaminants that have different types of available data. Exhibit 2 displays the ranges for each non-cancer health effects data element and their respective Toxicity Categories.

Exhibit 2: Potency Measures for Universe Data Element Partitioned Based on Toxicity (mg/kg/day or mg/kg)

	RfD	NOAEL	LOAEL	MRDD	LD ₅₀
Toxicity Category 1	<0.0001	<0.01	<0.01	<0.01	<1
Toxicity Category 2	0.0001 - <0.001	0.01 - < 1	0.01 - <1	0.01 - < 1	1 - <50
Toxicity Category 3	0.001 - <0.05	1 - <10	1 - <10	1 - <10	50 - <500
Toxicity Category 4	0.05 - <0.1	10 - < 1000	10 - <1000	10 - < 1000	500 - <5000
Toxicity Category 5	≥0.1	≥1000	≥1000	≥1000	≥5000

EPA used descriptive (or categorical) cancer data to group data elements into toxicity categories that provide gradation based upon the strength of the data. Sources for the descriptive cancer data included:

- US EPA Cancer Groupings
- International Agency for Research on Cancer (IARC) Cancer Groupings
- National Toxicology Program weight-of-evidence findings from cancer bioassays
- National Cancer Institute (NCI) weight-of-evidence findings from cancer bioassays
- EPA Water Disinfection By-Products with Carcinogenicity Estimates (DBP-CAN) groupings based on carcinogenic potential derived from Quantitative Structure Activity Relationship (QSAR) projections and expert judgment

EPA partitioned the cancer-related data elements in the Universe as described in Exhibit 3. The cancer data placed chemicals in only the three highest Toxicity Categories. EPA did not use quantitative measures of dose-response for carcinogenicity in the screening criteria because more chemicals can be analyzed using the descriptive data than by cancer slope factors. In addition, EPA did not use descriptors indicating lack of carcinogenic potential or insufficient data to determine carcinogenic potential in categorizing chemicals because those descriptors apply only to the cancer endpoint and do not consider non-cancer effects associated with exposure to the chemical.

Exhibit 3: Partitioning of Cancer Data Based on TD50 Values and Weight of Evidence

	TD ₅₀	EPA	IARC /HC	NTP	NCI	DSS-Tox
Toxicity Category 1	<0.1	Group A; Human Carcinogen	Group 1	CE 2 species/2 sexes; or 2 species; or 2 sexes	P 2 species/2 sexes; or 2 species; or 2 sexes	H
Toxicity Category 2	0.1 - 100	Groups B1 and B2; Likely carcinogens	Group 2A	Combinations of CE, SE, EE, and NE	Combinations of P, E and N	HM
Toxicity Category 3	>100	Group C; Suggestive evidence of carcinogenicity	Group 2B	Combinations of SE, EE, and NE	Combinations of E and N	M and LM

** Cancer data placed chemicals in only the three highest Toxicity Categories

CE = clear evidence, SE = some evidence, EE = equivocal evidence, NE = no evidence P = positive, N = Negative, E = equivocal

H = high probability, HM = high to medium probability, M = medium probability, LM = medium to low probability

EPA chose a conservative approach to categorize each chemical's toxicity for screening and evaluated all the available health effects dose-response and categorical data elements for a given chemical in the screening process. Chemicals were assigned to the highest toxicity category indicated after an evaluation of all the available data. Accordingly, if a chemical had just one data element that places it in Toxicity Category 1, it was categorized as such even if some of the other data elements for that same chemical may place it in a lower toxicity category. For example, if a chemical is classified as a 2A carcinogen by IARC it will be placed in Toxicity Category 2 using the descriptive cancer data even if a quantified LOAEL from a different study places it in Toxicity Category 3.

2.2 Occurrence Data Elements

EPA evaluated the occurrence data elements for each chemical and placed them on the horizontal axis of the screening table. In assessing the data, EPA found that the data elements that represent a chemical's potential to occur in drinking water vary greatly. EPA's goal was to determine which data elements best represented the potential to occur in drinking water. EPA considered and evaluated data elements in the following categories:

- Finished Water – measures of concentration and frequency of detections
- Ambient Water – measures of concentration and frequency of detections
- Total Releases in the Environment – pounds per year and number of states
- Pesticide Application Rates – pounds per year and number of states
- Production volume – pounds per year

In addition to evaluating the quantitative data elements listed above, EPA also considered chemicals with descriptive data based upon their likelihood of occurring in drinking water. Examples of descriptive occurrence data elements include characterization as a disinfection by-product or a drinking water treatment chemical.

EPA used the following hierarchal approach to select the occurrence data element used to screen a chemical:

Finished Water = Ambient Water > Environmental Release Data > Production Data.

The highest data elements in the hierarchy are the finished and ambient water data; the lowest is production data. Environmental release data from TRI and pesticide application data occupy the middle position in the hierarchy. EPA also decided that when multiple data values exist for the chemicals within a given component of the hierarchy, the most conservative data value is used. For example, in the case of a chemical that has finished water data and ambient water data, EPA selected the highest available numerical concentration value as the occurrence screening data element.

2.3 Selection of the PCCL

The last step in the screening process used the health effects and occurrence data elements shown in Exhibit 4 to establish the PCCL. As mentioned earlier, the health data elements were grouped into 5 toxicity categories and the highest toxicity category indicated after an evaluation of all the available data for a particular chemical was used in screening. EPA selected the highest available data element in the occurrence hierarchy to screen the contaminant. Because the chemicals were evaluated using a hierarchical approach for their occurrence elements, EPA developed separate criteria for each of the occurrence elements. EPA tested the screening criteria using a set of 200 chemicals including regulated and prior CCL chemicals and some chemicals from the Universe that had fairly complete data for all of the occurrence data elements. EPA screened these test chemicals and then adjusted the position of the PCCL selection line. In general, the PCCL selection line was positioned so that regulated chemicals and most prior CCL chemicals would be selected for the PCCL.

Exhibit 4: Criteria for a Chemical to Pass to the PCCL

Health Effects	Occurrence (by data type)		
	Finished/Ambient Water Concentrations	Release Amount (per year)	Production Volume (per year)
Toxicity Category 1	All Concentrations	All Amounts	All Amounts
Toxicity Category 2	≥ 1 µg/l	≥ 10,000 lbs/yr	≥ 500,000 lbs/yr
Toxicity Category 3	≥ 10 µg/l	≥ 100,000 lbs/yr	≥ 10 M lbs/yr
Toxicity Category 4	≥ 100 µg/l	≥ 1 M lbs/yr	≥ 50 M lbs/yr
Toxicity Category 5	≥ 1000 µg/l	≥ 10 M lbs/yr	≥ 100 M lbs/yr

3.0 Screening the Nominated Chemicals from the CCL 4 Universe to the PCCL 4

EPA received nominations for 59 unique contaminants for the CCL 4 including 54 chemicals and five microbials (see section 4.0). Forty three of the nominated chemicals were included in the CCL 4 Universe. Forty of the nominated chemicals were previously included in the CCL 3 Universe, and were carried forward to the CCL 4 Universe. In addition to these forty, EPA has added three nominated chemicals to the CCL 4 Universe (octylphenol ethoxylate, oxacillin and virginiamycin) based on health effects and/or occurrence data that was newly available since the development of the CCL 3. A complete list of the nominated contaminants for the CCL 4 can be found in the support document: “Summary of Nominations for the Fourth Contaminant Candidate List (CCL 4)” (USEPA, 2016a).

EPA screened all of the nominated chemicals in the CCL 4 Universe including any new information submitted with the nomination according to the screening criteria developed for CCL 3, and based on that evaluation; twenty of the nominated chemicals were included in the PCCL 4. Eighteen of those 20 chemicals were also included in the PCCL 3. Two nominated chemicals (manganese and nonylphenol) were added to the PCCL 4 based on the information submitted with the nominations. The data used to screen the nominated chemicals from the CCL 4 Universe to the PCCL 4, and whether or not the chemical moved from the Universe to the PCCL 4 is shown in Appendix 1 of this document.

EPA received supplemental data for individual contaminants through 27 public comments on the Draft CCL 4. Ultimately, those supplemental data were not used to screen contaminants for the Final PCCL 4 because the data used in screening the Draft CCL 4 (for the nominated contaminants) or the Final CCL 3 (for the carried forward contaminants) were higher in the data hierarchy than the data elements received with the public comments for all contaminants except for saxitoxin. In the case of saxitoxin, the data received with the public comments allowed for it to be screened and for EPA to create a contaminant information sheet. Cyanotoxins were listed on CCL 3 and the Draft CCL 4, and remain as a group on the Final CCL 4.

4.0 Summary of the CCL 3 Microbes Screening Process and Screening of the Nominated Microbes from the CCL 4 Universe to the PCCL 4

The microbial CCL 3 Universe was defined as microbes that are known to cause disease in humans. A literature review identified a list of 1,415 known human pathogens including bacterial, viral, protozoan, helminth and fungal pathogens (Taylor et al., 2001). This list was recommended as the basis of the microbial CCL 3 Universe. EPA requested nominations from the public for additions to the microbial CCL 3 Universe, and two microbes and two viral groups were added to the list through the nomination process (USEPA, 2006; USEPA, 2009e). EPA also added six fungi that did not appear on the list of Taylor et al. (2001) but were identified in

drinking water distribution systems, thus bringing the total number of microbes in the CCL 3 Universe to 1,425 pathogens. These microbes remain in the CCL 4 Universe.

The National Academy of Science's National Research Council (NRC) workgroup report did not make specific recommendations for selection and screening of microbial contaminants to a PCCL, and because occurrence data for microbes are not readily available to support the screening process envisioned by the NRC workgroup, the agency requested further study of these issues by a workgroup convened by the National Drinking Water Advisory Council (NDWAC). The NDWAC recommended selecting microbial contaminants for the PCCL based upon an assessment of occurrence attributes and health effects attributes relating to the plausibility of pathogen presence, survival, and transport through drinking water resulting in disease manifestations from drinking water exposure. These recommendations are described further in, "National Drinking Water Advisory Council Report on the CCL Classification Process" (NDWAC, 2004).

Selection of microbes from the CCL Universe for placement on the PCCL is based upon exclusionary screening criteria that assess the potential of water-related transmission (occurrence) and the plausibility of causing waterborne disease by ingestion, inhalation or dermal contact (health effects). Microbes that met any of the exclusionary criteria were not included on the PCCL. The screening criteria developed for CCL 3, which are listed below, were also used for CCL 4.

Criterion 1: Anaerobes (microorganisms that cannot survive in oxygenated environments)

Criterion 2: Fastidious or obligate intracellular pathogens (environmental survival in water implausible)

Criterion 3: Pathogens exclusively transmitted by direct or indirect contact with blood or body fluids (including sexually transmitted diseases)

Criterion 4: Pathogens transmitted by vectors

Criterion 5: Microflora indigenous to the gastrointestinal tract, skin and mucous membranes

Criterion 6: Pathogens transmitted solely by respiratory secretions

Criterion 7: Pathogens whose life cycle is incompatible with drinking water transmission

Criterion 8: Pathogens where drinking water-related transmission is not implicated

Criterion 9: Natural habitat is in the environment without epidemiological evidence of drinking water-related disease

Criterion 10: Pathogens not endemic to North America

Criterion 11: A genus and species or serotype may be chosen to represent a group of closely related organisms

Criterion 12: Current taxonomy does not support the classification listed by Taylor et al. (2001).

Four of the five nominated microbial contaminants, with the exception of heterotrophic plate count bacteria, (e.g. *Vibrio cholerae*, *Toxoplasma gondii*, *Naegleria fowleri* and Adenovirus) were on the PCCL 3 and are being carried forward to the PCCL 4 since no new data were found that would support a change to the contaminants listed in the PCCL 3. For additional information on the screening process please see “Final Contaminant Candidate List 3 Microbes: Screening to the PCCL” (USEPA, 2009f). For detailed information on the scoring protocols used to rank the nominated pathogens on the PCCL to produce a CCL please see “Final Contaminant Candidate List 3 Microbes: PCCL to CCL Process” (USEPA, 2009g) and for the most recent versions of the contaminant information sheets, which summarize the data used for scoring the microbial contaminants nominated for CCL 4 see “Contaminant Information Sheets (CISs) for the Final Fourth Contaminant Candidate List (CCL 4)” (USEPA, 2016c).

5.0 References

- National Drinking Water Advisory Council (NDWAC). 2004. National Drinking Water Advisory Council Report on the CCL Classification Process to the U. S. Environmental Protection Agency, May 19, 2004
- 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 (See electronic Appendix A, No. 1411, pp. 1-9).
- USEPA. 2006. Request for Nominations of Drinking Water Contaminants for the Contaminant Candidate List. *Federal Register*. Vol. 71. No. 199. p. 60704. October 16, 2006.
- USEPA. 2009a. Drinking Water Contaminant Candidate List 3—Final Notice. *Federal Register*. Vol. 74. No 194. p. 51850. October 8, 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. 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. Data Sources for the Fourth Contaminant Candidate List (CCL 4). EPA 815-R-16-007. 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.

6.0 Appendices

Appendix 1. Screening Data for the Nominated Chemicals in the CCL 4 Universe

Appendix 1 presents the CASRN, names of the nominated contaminants in the CCL 4 Universe, the health effects and occurrence data elements that were used in their screening. The CCL 4 Screening Notes column includes a brief explanation of whether or not the chemical made the PCCL 4, and if it did not make the PCCL 4, the reason is included (i.e., the chemical failed based on the screening criteria, or incomplete data were available, so the chemical could not be screened). Some chemicals had some type of occurrence/ health information that allowed them to be included in the CCL 4 Universe, but this data was not sufficient for screening. An example of this is a chemical that was an analyte in a supplemental occurrence study, but was not detected; therefore, no concentration value was available to be used in the screening process. Thus, this chemical would remain in the Universe. The screening process is summarized in the text of this report, and a detailed description of the screening process developed under CCL 3 can be found in the “Final Contaminant Candidate List 3 Chemicals: Screening to a PCCL” (USEPA, 2009c). The screening data for contaminants on CCL 4 that were carried forward from CCL 3 (i.e., not the contaminants nominated for CCL 4) can be found in the CCL 3 Screening document (USEPA, 2009c, see Appendix 2).

When the health effects data element is designated as Cancer Studies NTP, the results shown are from cancer assays for two species and two sexes (male rat/female rat/ male mouse/female mouse) The NTP cancer data were partitioned into Toxicity Categories as described in Exhibit 3 of this document and the data source is described further in USEPA, 2009b. For the occurrence data elements, the release data may be either national TRI data or pesticide application data. The notation “FW/AW” indicates the data are finished or ambient water data. Also noted, for some contaminants, supplemental data were used.

Further data and information for the nominated contaminants that made the CCL 4 are available in the Contaminant Information Sheets (USEPA, 2016c) available in the docket.

Appendix 1. Screening Data for the Nominated Chemicals in the CCL 4 Universe

Substance Key	CASRN	Common Name	Health Effect/Toxicity Data Used For CCL 4 Screening					Occurrence Data Used For CCL 4 Screening				CCL 4 Screening Notes
			Health Effect Data Element	Value	Units	Data Source	Toxicity Screening Category	Occurrence Data Element	Value	Units	Data Source	
74233	77439760	3-chloro-4-dichloromethyl-5-hydroxy-2(5H)-furanone	Lethal Dose 50 (LD50)	120	Mg/kg	RTECS	Toxicity Category 3	No Occurrence data for screening				Incomplete data for screening/ remains in CCL 4 Universe
6535	319846	alpha-Hexachlorocyclohexane	Risk Specific Dose (RSD)	0.000002	mg/kg-day	ITER	Toxicity Category 1	FW/AW-Max Value	0.21	ug/L	NAWQA	Makes PCCL 4
3200	86500	Azinphos-methyl	Lowest Observed Adverse Effect Level (LOAEL)	0.91	mg/kg-day	RTECS	Toxicity Category 2	FW/AW-Max Value	3.37	ug/L	NAWQA	Makes PCCL 4
28242	25057890	Bentazon	Reference Dose (RfD)	0.03	mg/kg-day	OPP	Toxicity Category 3	FW/AW-Max Value	11.46	ug/L	NAWQA	Makes PCCL 4
2918	80057	Bisphenol A (BPA)	Lowest Observed Adverse Effect Level (LOAEL)	2.5	mg/kg-day	RTECS	Toxicity Category 3	FW/AW-Max Value	12	ug/L	Kolpin et al., 2002 (Max)	Makes PCCL 4
12023	1689845	Bromoxynil	Reference Dose (RfD)	0.015	mg/kg-day	OPP	Toxicity Category 3	FW/AW-Max Value	6.1	ug/L	NAWQA	Fails Screen/ remains in CCL 4 Universe
3168	85687	Butyl benzyl phthalate	Cancer Studies, NTP	IS/P/P/N	blank	NTP	Toxicity Category 2	Production Volume	>50M - 100M	lbs/yr	CUS/IUR	Makes PCCL 4
2448	63252	Carbaryl	Lowest Observed Adverse Effect Level (LOAEL)	0.23	mg/kg-day	RTECS	Toxicity Category 2	FW/AW-Max Value	33.5	ug/L	NAWQA	Makes PCCL 4
12375	1897456	Chlorothalonil	Cancer Studies, NTP	P/P/N/N	blank	NTP	Toxicity Category 1	FW/AW-Max Value	0.71	ug/L	NAWQA	Makes PCCL 4
14098	2921882	Chlorpyrifos	Reference Dose (RfD)	0.0003	mg/kg-day	OPP	Toxicity Category 2	FW/AW-Max Value	0.57	ug/L	NAWQA	Fails Screen/ remains in CCL 4 Universe
3122	84742	Dibutyl phthalate	Tolerable Daily Intake (TDI)	0.063	mg/kg-day	ITER	Toxicity Category 4	Release	177,489	lbs/yr	TRI	Fails Screen/ remains in CCL 4 Universe
5106	115322	Dicofol	Tumorigenic Dose 50 (TD50)	32.9	mg/kg-day	DSSTOX	Toxicity Category 2	Release	788,527	lbs/yr	NCFAP	Makes PCCL 4

**Screening Document for the Fourth
Preliminary Contaminant Candidate List (PCCL 4)**

Substance Key	CASRN	Common Name	Health Effect/Toxicity Data Used For CCL 4 Screening					Occurrence Data Used For CCL 4 Screening				CCL 4 Screening Notes
			Health Effect Data Element	Value	Units	Data Source	Toxicity Screening Category	Occurrence Data Element	Value	Units	Data Source	
3114	84617	Dicyclohexyl phthalate	No HE data for screening					Production Volume	>500K - 1M	lbs/yr	CUS/IUR	Incomplete data for screening/ remains in CCL 4 Universe
3118	84662	Diethyl phthalate	No Observed Adverse Effect Level (NOAEL)	750	mg/kg-day	ITER	Toxicity Category 4	FW/AW-Med Value	0.2	ug/L	NREC	Fails Screen/ remains in CCL 4 Universe
30533	28553120	Di-isononyl phthalate	Lowest Observed Adverse Effect Level (LOAEL)	402	mg/kg-day	RTECS	Toxicity Category 4	Production Volume	>10M - 50M	lbs/yr	CUS/IUR	Fails Screen/ remains in CCL 4 Universe
5769	131113	Dimethyl phthalate	Reference Dose (RfD)	10	mg/kg-day	RAIS	Toxicity Category 5	Release	414093	lbs/yr	TRI	Fails Screen/ remains in CCL 4 Universe
5200	117840	Di-n-octyl phthalate	Reference Dose (RfD)	0.04	mg/kg-day	RAIS	Toxicity Category 3	Production Volume	>1M - 10M	lbs/yr	CUS/IUR	Fails Screen/ remains in CCL 4 Universe
5104	115297	Endosulfan	No Observed Adverse Effect Level (NOAEL)	0.7	mg/kg-day	ITER	Toxicity Category 2	Release	1,604,700	lbs/yr	NCFAP	Makes PCCL 4
12839	2164172	Fluometuron	Reference Dose (RfD)	0.01	mg/kg-day	EPA HA	Toxicity Category 3	FW/AW-Max Value	37.8	ug/L	NAWQA	Makes PCCL 4
6584	330552	Linuron	Lowest Observed Effect Level (LOEL)	0.63	mg/kg-day	ITER	Toxicity Category 2	FW/AW-Max Value	1.4	ug/L	NAWQA	Makes PCCL 4
5402	121755	Malathion	No Observed Effect Level (NOEL)	0.23	mg/kg-day	ITER	Toxicity Category 2	FW/AW-Max Value	9.58	ug/L	NAWQA	Makes PCCL 4
18823	7439965	Manganese	No Observed Adverse Effect Level (NOAEL)	0.14	mg/kg-day	ITER	Toxicity Category 2	FW/AW	1,314	ug/L	NIRS	Makes PCCL 4
6419	298000	Methyl parathion	Reference Dose (RfD)	0.0002	mg/kg-day	EPA HA	Toxicity Category 2	FW/AW-Max Value	0.521	ug/L	NAWQA	Fails Screen/ remains in CCL 4 Universe
11918	1634044	Methyl tert-butyl ether	Tolerable Daily Intake (TDI)	0.01	mg/kg-day	ITER	Toxicity Category 3	FW/AW-Max Value	23,000	ug/L	NAWQA	Makes PCCL 4
76859	101043372	Microcystin-LR	Reference Dose (RfD)	0.000003	mg/kg-day	Ueno et al., 1999	Toxicity Category 1	FW/AW	1,200	ug/L	AWWARF, 2001 (Max)	Makes PCCL 4
28410	25154523 ¹	Nonylphenol	Lowest Observed Adverse Effect Level (LOAEL)	2	mg/kg-day	RTECS	Toxicity Category 3	FW/AW-Max Value	40	ug/L	Kolpin et al., 2002 (Max)	Makes PCCL 4

**Screening Document for the Fourth
Preliminary Contaminant Candidate List (PCCL 4)**

Substance Key	CASRN	Common Name	Health Effect/Toxicity Data Used For CCL 4 Screening					Occurrence Data Used For CCL 4 Screening				CCL 4 Screening Notes
			Health Effect Data Element	Value	Units	Data Source	Toxicity Screening Category	Occurrence Data Element	Value	Units	Data Source	
20331	9016459	Nonylphenol ethoxylate	Lethal Dose 50 (LD50)	1310	mg/kg	RTECS	Toxicity Category 4	FW/AW-Median Value	1	ug/L	NREC	Fails Screen/ remains in CCL 4 Universe
29943	27193288	Octylphenol	No HE data for screening					Production Volume	>10M - 50M	lbs/yr	CUS/IUR	Incomplete data for screening/ remains in CCL 4 Universe
20418	9036195	Octylphenol ethoxylate	Lethal Dose 50 (LD50)	3500	mg/kg	RTECS	Toxicity Category 4	Production Volume	< 500,000 lbs	lbs/yr	CUS/IUR	Fails Screen/ remains in CCL 4 Universe
81717	66795	Oxacillin	Maximum Recommended Daily Dose (MRDD)	100	mg/kg-day	DSSTOX	Toxicity Category 4	No Occurrence data for screening				Incomplete data for screening/ remains in CCL 4 Universe
75565	61336	Penicillin	Maximum Recommended Daily Dose (MRDD)	25	mg/kg-day	DSSTOX	Toxicity Category 4	No Occurrence data for screening				Incomplete data for screening/ remains in CCL 4 Universe
6614	335671	Perfluorooctanoic acid (PFOA)	Lowest Observed Adverse Effect Level (LOAEL)	0.46	mg/kg-day	Lau et al., 2006	Toxicity Category 2	FW/AW	7.2	ug/L	Emmett et al., 2006 (Max)	Makes PCCL 4
35815	52645531	Permethrin	No Observed Effect Level (NOEL)	5	mg/kg-day	ITER	Toxicity Category 3	Release	1,068,390	lbs/yr	NCFAP	Makes PCCL 4
9544	732116	Phosmet	Lethal Dose 50 (LD50)	26	mg/kg	RTECS	Toxicity Category 2	Release	1,336,387	lbs/yr	NCFAP	Makes PCCL 4
2334	57830	Progesterone	Acceptable Daily Intake (ADI)	0.03	mg/kg-day	JECFA	Toxicity Category 3	FW/AW	0.199	ug/L	Kolpin et al., 2002 (Max)	Fails Screen/ remains in CCL 4 Universe
95000	35523898	Saxitoxin ²	No Observed Effect Level (NOEL)	0.0005	mg/kg	EFSA, 2009	Toxicity Category 1	FW/AW	0.064	ug/L	Ohio Algal Toxin Results (Max)	Makes PCCL 4
2343	58220	Testosterone	Acceptable Daily Intake (ADI)	0.002	mg/kg-day	JECFA	Toxicity Category 3	FW/AW	0.214	ug/L	Kolpin et al., 2002 (Max)	Fails Screen/ remains in CCL 4 Universe
2202	52686	Trichlorfon	Reference Dose (RfD)	0.002	mg/kg-day	OPP	Toxicity Category 3	Release	861	lbs/yr	TRI	Fails Screen/ remains in CCL 4 Universe
4164	101202	Triclocarban	No Observed Adverse Effect Level (NOAEL)	25	mg/kg-day	OCSPP	Toxicity Category 4	Production Volume	>1M - 10M	lbs/yr	CUS/IUR	Fails Screen/ remains in CCL 4 Universe

Substance Key	CASRN	Common Name	Health Effect/Toxicity Data Used For CCL 4 Screening					Occurrence Data Used For CCL 4 Screening				CCL 4 Screening Notes
			Health Effect Data Element	Value	Units	Data Source	Toxicity Screening Category	Occurrence Data Element	Value	Units	Data Source	
14798	3380345	Triclosan	Lethal Dose 50 (LD50)	3700	mg/kg	RTECS	Toxicity Category 4	FW/AW-Median Value	0.19	ug/L	NREC	Fails Screen/ remains in CCL 4 Universe
75792	1401690	Tylosin	Lethal Dose 50 (LD50)	800	mg/kg	RTECS	Toxicity Category 4	FW/AW-Median Value	0.04	ug/L	NREC	Fails Screen/ remains in CCL 4 Universe
75932	11006761	Virginiamycin	No HE data for screening					No Occurrence data for screening				Incomplete data for screening/ remains in CCL 4 Universe

¹ The organization that nominated "nonylphenol" for CCL 4 provided the CASRN of 25451-52-3. The name "nonylphenol" does not allow for a definitive identification of chemical structure since nonylphenol can exhibit two forms of isomerism. There are at least five CASRNs known to be associated with "nonylphenol:" in addition to 25154-52-3 (which represents n-nonylphenol with the ortho-, meta-, or para-substitution unspecified), other CASRNs include: 104-40-5 (4-n-nonylphenol); 84852-15-3 (4-nonylphenol, branched); 91672-41-2 (2-nonylphenol, branched); and 139-84-4 (3-n-nonylphenol). None of these five CASRNs are adequately general enough to represent both forms of isomerism. For the sake of consistency, the CASRN provided by the nominator was selected and the additional possible CASRNs and structures are delineated here.

² Saxitoxin was evaluated as a result of input from public comments. It is included on CCL 4 as part of the group of cyanotoxins.

AWWARF - Carmichael, W.W. 2001. Assessment of Blue-Green Algal Toxins in Raw and Finished Drinking Water. Denver, CO: American Water Works Association Research Foundation

CUS/IUR - Chemical Update System/ Inventory Update Rule

DSSTOX - Distributed Structure-Searchable Toxicity Database Network

Emmett et al., 2006 - Emmett, et al., 2006. J. Occ. Env. Med. Little Hocking, OH

EPA HA - EPA Health Advisory

ITER - International Toxicity Estimates for Risk

JECFA - Joint FAO/WHO Expert Committee on Food Additives

Kolpin et al., 2002 - Kolpin, D.W., et al., 2002. Env. Sci. & Technol., 36(6), pp. 1202-1211.

Lau et al., 2006 - Lau, 2006. Tox. Sci., 90, 2, pp. 510-518.

NAWQA - National Water Quality Assessment

NCFAP - National Center for Food and Agricultural Policy

NIRS - National Inorganics and Radionuclides Survey

NREC - National Reconnaissance of Emerging Contaminants

NTP - National Toxicology Program; Values: P=positive; N=negative; IS=insufficient study. Results for male rat/female rat/male mouse/female mouse.

OCSPP - Office of Chemical Safety and Pollution Prevention

OPP - Office of Pesticide Programs

RAIS - Risk Assessment Information System

RTECS - Registry of Toxic Effects of Chemical Substances

TRI - Toxics Release Inventory

Ueno et al., 1999 - Ueno, Y., Y. Makita, S. Nagata et al. 1999. Environ. Toxicol. 14(1):45-55