6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[EPA-HQ-OW-2018-0594; FRL-7251-01-OW]

Drinking Water Contaminant Candidate List 5—Draft

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability; request for comments.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is publishing a draft list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations for public review and comment. These contaminants are known or anticipated to occur in public water systems and may require regulation under the Safe Drinking Water Act (SDWA). This draft list is the Fifth Contaminant Candidate List (CCL 5) published by the agency since the SDWA amendments of 1996. The Draft CCL 5 includes 66 chemicals, 3 chemical groups (per- and polyfluoroalkyl substances (PFAS), cyanotoxins, and disinfection byproducts) and 12 microbial contaminants. EPA seeks comment on the Draft CCL 5 and on improvements implemented in the CCL 5 process for consideration in developing future CCLs.

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

ADDRESSES: You may send comments, identified by Docket ID Number EPA-HQ-OW-2018-0594, by any of the following methods:

Federal eRulemaking Portal: https://www.regulations.gov (our preferred method). Follow the online instructions for submitting comments.

Mail: U.S. Environmental Protection Agency, EPA Docket Center, Water Docket, Environmental Protection Agency, Mail code: 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

Hand Delivery / Courier (by scheduled appointment only): EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, D.C. 20004. The Docket Center's hours of operations are 8:30 a.m. to 4:30 p.m., Monday through Friday (except federal holidays).

Instructions: All submissions received must include the Docket ID No. EPA-HQ-OW-2018-0594 for this rulemaking. Comments received may be posted without change to https://www.regulations.gov, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the "Public Participation" heading of the SUPPLEMENTARY INFORMATION section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via https://www.regulations.gov, as there may be delay in processing mail. Hand deliveries and couriers may be received by scheduled appointment only. For further information of EPA Docket Center Services and the current status, please visit us online at https://www.epa.gov/dockets.

FOR FURTHER INFORMATION CONTACT: For information on chemical contaminants contact Kesha Forrest, Office of Ground Water and Drinking Water, Standards and Risk Management Division, at (202) 564-3632 or email forrest.kesha@epa.gov. For information on microbial contaminants contact Nicole Tucker, Office of Ground Water and Drinking Water, Standards and Risk Management Division, at (202) 564-1946 or email tucker.nicole@epa.gov. For more information visit https://www.epa.gov/ccl.

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I. General Information

A. *Does this Action Impose Any Requirements on Public Water Systems*?

The Draft Contaminant Candidate List 5 (CCL 5) and the Final CCL 5, when published, will not impose any requirements on regulated entities.

B. *Public Participation*

Submit your comments, identified by Docket ID No. EPA-HQ-OW-2018-0594, at https://www.regulations.gov (our preferred method), or the other methods identified in the ADDRESSES section of this document. Once submitted, comments cannot be edited or removed from the docket. EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will

generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit https://www.epa.gov/dockets/commenting-epa-dockets.

EPA is temporarily suspending its Docket Center and Reading Room for public visitors, with limited exceptions, to reduce the risk of transmitting COVID-19. Our Docket Center Staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via https://www.regulations.gov/ as there may be a delay in processing mail. Hand deliveries or couriers will be received by scheduled appointment only. For further information and updates on EPA Docket Center services, please visit us online at https://www.epa.gov/dockets.

EPA continues to carefully monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our federal partners so that we can respond rapidly as conditions change regarding COVID-19.

C. *What Should I Consider as I Prepare My Comments for EPA*?

You may find the following suggestions helpful for preparing your comments:

Explain your views as clearly as possible.

Describe any assumptions that you used.

Provide any technical information and/or data you used that support your views.

Provide full references for any peer reviewed publication you used that support your views.

Provide specific examples to illustrate your concerns.

Offer alternatives.

Make sure to submit your comments by the comment period deadline. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the

first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Purpose, Background, and Statutory Requirements of this Action

This section briefly summarizes the purpose of this action, the statutory requirements, previous activities related to the CCL and the approach used to develop the Draft CCL 5.

A. *What is the Purpose of This Action*?

The purpose of this action is to present EPA's Draft CCL 5 and the rationale for the selection process used to make the list. This Draft CCL 5, when finalized, is subsequently used to make regulatory determinations on whether to regulate at least five contaminants from the CCL with national primary drinking water regulations (NPDWRs) under the Safe Drinking Water Act (SDWA), section 1412(b)(1)(B)(ii). This action only addresses the Draft CCL 5. The regulatory determinations process for contaminants on the CCL is a separate agency action. EPA requests comment on the Draft CCL 5 and on improvements implemented in the CCL 5 process for consideration in developing future CCLs .

B. *Background and Statutory Requirements for CCL, Regulatory Determinations and Unregulated Contaminant Monitoring*

1. Contaminant Candidate List

SDWA section 1412(b)(1)(B)(i), as amended in 1996, requires EPA to publish the CCL every five years. The SDWA specifies that the list must include contaminants that are not subject to any proposed or promulgated NPDWRs, are known or anticipated to occur in public water systems (PWSs), and may require regulation under the SDWA. The unregulated contaminants considered for listing shall include, but not be limited to, hazardous substances identified in section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) of 1980, and substances registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The SDWA directs EPA 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. The statute further directs EPA to take into consideration the effect of contaminants upon subgroups that comprise a meaningful portion of the general population (such as infants, children, pregnant women, the elderly, and individuals with a history of serious illness or other subpopulations) that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population. EPA considers age-related subgroups as "lifestages" in reference to a distinguishable time frame in an individual's life characterized by unique and relatively stable behavioral and/or physiological characteristics that are associated with development and growth. Thus, childhood is viewed as a sequence of stages, from conception through fetal development, infancy and adolescence (see http://www2.epa.gov/children/early-life-stages).

2. Regulatory Determinations

SDWA section 1412(b)(1)(B)(ii), as amended in 1996, requires EPA, at five-year intervals, to make determinations of whether or not to regulate no fewer than five contaminants from 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 public water systems 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 public water systems.

If, after considering public comment on a preliminary determination, EPA makes a determination to regulate a contaminant, the agency will initiate the process to propose an NPDWR.[1] In that case, the statutory time frame provides for EPA proposal of a regulation within 24 months and action on a final regulation within 18 months of proposal.

3. Unregulated Contaminant Monitoring Rule

SDWA section 1445(a)(2), as amended in 1996, requires that once every five years, beginning in 1999, EPA issues a new list of no more than 30 unregulated contaminants to be monitored in drinking water by PWSs. Monitoring is required by all PWSs serving more than 10,000 persons. The SDWA, as amended by America's Water Infrastructure Act of 2018, expands the requirements of the program and specifies that, subject to availability of appropriations and laboratory capacity, the UCMR program shall include all systems serving between 3,300 and 10,000 persons and a nationally representative sample of PWSs serving fewer than 3,300 persons. The program would continue to require monitoring by PWSs serving more than 10,000 persons. The SDWA also requires EPA to enter the monitoring data into the publicly available National Contaminant Occurrence Database (NCOD). This national occurrence data is used to inform regulatory decisions for emerging contaminants in drinking water. Since the development of the UCMR program, EPA has issued four UCMRs. The UCMR 1 was published in the **Federal Register** on September 17, 1999 (64 FR 50556, USEPA, 1999), and required monitoring for 26 contaminants from 2001 to 2005. The UCMR 2 was published in the **Federal Register** on January 4, 2007 (72 FR 368, USEPA, 2007), and required monitoring for 25 contaminants from 2008 to 2010. The UCMR 3 was published in the **Federal Register** on May 2, 2012 (77 FR 26072, USEPA, 2012a), and required monitoring for 30 contaminants: 28 chemicals and two viruses from 2013 to 2015. The UCMR 4 was published in the **Federal**

[1] 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 taking cost into consideration.

Register on December 20, 2016 (81 FR 92666, USEPA, 2016a), and required monitoring for 30 contaminants from 2018 to 2020. Seventeen of the contaminants being monitored under the UCMR 4 were included on the CCL 4 and 13 chemicals or chemical groups monitored under the UCMR 4 are included on the Draft CCL 5. EPA published the UCMR 5 proposal in the **Federal Register** on March 11, 2021 (86 FR 13846, USEPA, 2021a). The proposed UCMR 5 would require monitoring for 29 per- and polyfluoroalkyl substances (PFAS) and lithium in drinking water from 2023 to 2025. The Draft CCL 5 includes all of the contaminants that are proposed for monitoring on the UCMR 5.

C. Interrelationship of the CCL, Regulatory Determinations, and Unregulated Contaminant Monitoring

The CCL is the first step in the SDWA regulatory framework for screening and evaluating the subset of contaminants that may require future regulation. The CCL serves as the initial screening of potential contaminants to consider for regulatory determinations. However, inclusion on the CCL does not mean that any particular contaminant will necessarily be regulated in the future.

The UCMR provides a mechanism to obtain nationally representative occurrence data for contaminants in drinking water. Historically, most unregulated contaminants chosen by EPA for monitoring have been selected from the CCL. When selecting contaminants for monitoring under the UCMR, EPA considers the availability of health effects data and the need for national occurrence data for contaminants, as well as analytical method availability, availability of analytical standards, sampling costs, and laboratory capacity to support a nationwide monitoring program. The contaminant occurrence data collected under the UCMR serves to better inform future CCLs and regulatory determinations. Contaminants on the CCL are evaluated based on health effects and occurrence information and those contaminants with sufficient information to make a regulatory determination are then evaluated based on the three statutory criteria in SDWA section 1412(b)(1), to determine whether a regulation is required (called a positive

determination) or not required (called a negative determination). Under the SDWA, EPA must make regulatory determinations for at least five contaminants listed on the CCL every five years. For those contaminants without sufficient information to allow EPA to make a regulatory determination, the agency encourages research to provide the information needed to fill the data gaps to determine whether to regulate the contaminant.

This action addresses only the CCL 5 and not the UCMR or regulatory determinations.

D. Summary of Previous CCLs and Regulatory Determinations

1. The First Contaminant Candidate List

The first CCL (CCL 1) was published on March 2, 1998 (63 FR 10274, USEPA, 1998). The CCL 1 was developed based on recommendations by the National Drinking Water Advisory Council (NDWAC) and reviewed by technical experts. It contained 50 chemicals and 10 microbial contaminants/groups.

2. The Regulatory Determinations for CCL 1 Contaminants

EPA published its final regulatory determinations for a subset of contaminants listed on the CCL 1 on July 18, 2003 (68 FR 42898, USEPA, 2003). EPA identified 9 contaminants from the 60 contaminants listed on the CCL 1 that had sufficient data and information available to make regulatory determinations. The nine contaminants were Acanthamoeba, aldrin, dieldrin, hexachlorobutadiene, manganese, metribuzin, naphthalene, sodium, and sulfate. EPA determined that no regulatory action was appropriate or necessary for any of the nine contaminants at that time. EPA subsequently issued guidance on Acanthamoeba and Health Advisories for manganese, sodium, and sulfate.

3. The Second Contaminant Candidate List

EPA published the Final CCL 2 on February 24, 2005 (70 FR 9071, USEPA, 2005). EPA carried forward the 51 remaining chemical and microbial contaminants from the CCL 1 (that did not have regulatory determinations) to the CCL 2.

4. The Regulatory Determinations for CCL 2 Contaminants

EPA published its final regulatory determinations for a subset of contaminants listed on the CCL 2 on July 30, 2008 (73 FR 44251, USEPA, 2008). EPA identified 11 contaminants from the 51 contaminants listed on the CCL 2 that had sufficient data and information available to make regulatory determinations. The 11 contaminants were boron, the dacthal mono- and di-acid degradates, 1,1-dichloro-2,2-bis (p-chlorophenyl) ethylene (DDE), 1,3-dichloropropene, 2,4-dinitrotoluene, 2,6-dinitrotoluene, s-ethyl propylthiocarbamate (EPTC), fonofos, terbacil, and 1,1,2,2-tetrachloroethane. EPA made a final determination that no regulatory action was appropriate or necessary for any of the 11 contaminants. New or updated Health Advisories were subsequently issued for: boron, the dacthal degradates, 2,4- dinitrotoluene, 2,6- dinitrotoluene, and 1,1,2,2- tetrachloroethane.

5. The Third Contaminant Candidate List

EPA published the Final CCL 3 on October 8, 2009 (74 FR 51850, USEPA, 2009). In developing the CCL 3, EPA implemented an improved, stepwise process which built on the previous CCL process and was based on expert input and recommendations from the National Academy of Sciences' National Research Council (NRC), the National Drinking Water Advisory Council (NDWAC), and the Science Advisory Board (SAB). The CCL 3 contained 104 chemicals or chemical groups and 12 microbial contaminants.

6. The Regulatory Determinations for CCL 3 Contaminants

On February 11, 2011, EPA published in the **Federal Register** (76 FR 7762, USEPA, 2011) a determination that perchlorate (a CCL 3 contaminant) met the criteria for regulating a contaminant under the SDWA based upon the information available at that time. On January 4, 2016, EPA published in the **Federal Register** (81 FR 13, USEPA, 2016b) final determinations not to regulate four additional CCL 3 contaminants–dimethoate, 1,3-dinitrobenzene, terbufos and terbufos sulfone.

EPA published a proposed rulemaking for perchlorate in the **Federal Register** on June 26, 2019 (85 FR 43990, USEPA, 2019a), and sought public input on regulatory alternatives for

perchlorate, including withdrawal of the previous regulatory determination. Based on the evaluation of public comments, and review of the updated scientific data, EPA withdrew the 2011 regulatory determination and made a final determination not to regulate perchlorate on July 21, 2020 (85 FR 43990, USEPA, 2020). EPA is reviewing this final determination in accordance with President Biden's Executive Order No. 13990 (86 FR 7037, Executive Office of the President, 2021).

7. The Fourth Contaminant Candidate List

EPA published the Final CCL 4 in the **Federal Register** on November 17, 2016 (81 FR 81099, USEPA, 2016c). The Final CCL 4 contained 97 chemicals or chemical groups and 12 microbial contaminants. All contaminants listed on the Final CCL 4 were carried forward from CCL 3, except for manganese and nonylphenol, which were nominated by the public to be included on the CCL 4. For information about publicly nominated contaminants for the CCL 5, see Section III.C.1 of this document.

8. The Regulatory Determinations for CCL 4 Contaminants

On March 3, 2021, EPA published final regulatory determinations for eight contaminants on the CCL 4 (86 FR 12272, USEPA, 2021b). EPA made final determinations to regulate perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA) in drinking water and to not regulate six contaminants 1,1-dichloroethane, acetochlor, methyl bromide (bromomethane), metolachlor, nitrobenzene, and 1,3,5-Trinitro-1,3,5-triazinane (RDX).

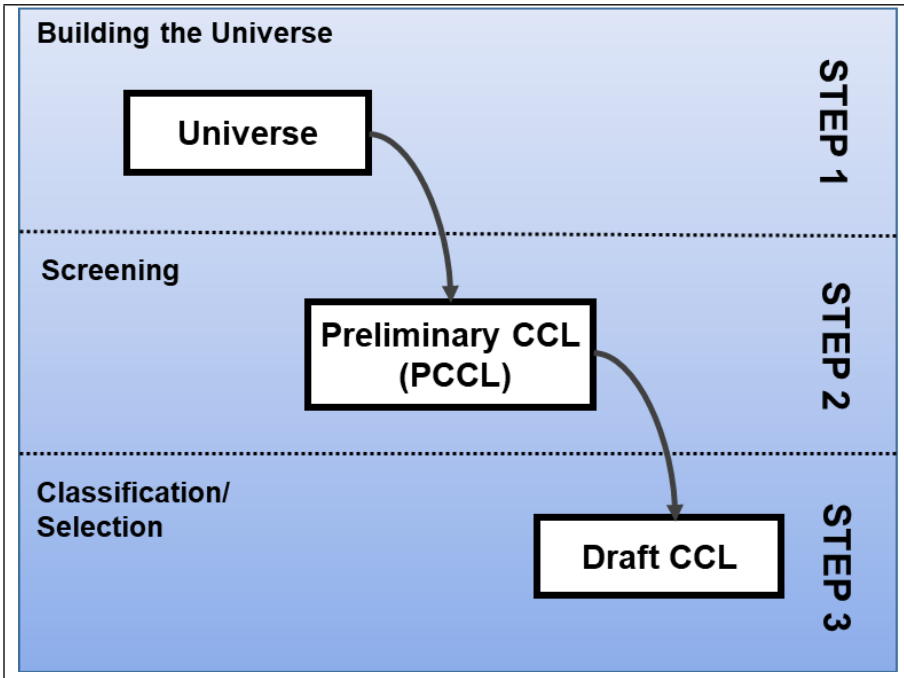
E. *Summary of the Approach Used to Identify Contaminants for the Draft CCL 5*

In developing the Draft CCL 5, EPA followed the stepwise process used in developing the CCL 3 and CCL 4, which was based on expert input and recommendations from the SAB, NRC and NDWAC. Note that EPA used an abbreviated process for the CCL 4 by carrying forward the CCL 3 contaminants (81 FR 81099, USEPA, 2016c). In each cycle of the CCL, EPA attempts to improve the CCL development process in response to comments from the SAB and the public. Therefore, in developing the Draft CCL 5, EPA implemented improvements to the

CCL process to better identify, screen, and classify potential drinking water contaminants. EPA's approach utilizes the best available data to characterize the occurrence and adverse health risks a chemical may pose from potential drinking water exposure.

Exhibit 1 illustrates a generalized 3-step process EPA applied to both chemical and microbial contaminants for the Draft CCL 5. The agency began with a large Universe of contaminants, screened it down to a Preliminary CCL 5, then finally selected the Draft CCL 5. The specific execution of particular steps differed in detail for the chemical and microbial contaminants. Each step of the Draft CCL 5 process and associated number of chemical and microbial contaminants are described in Section III of this document.

Exhibit 1—Generalized Draft CCL 5 Development Process and Contaminant Counts

	Number of Chemical Contaminants	Number of Microbial Contaminants
	~22,000	1,435
	275	35
	66 + 3 chemical groups	12

1. Chemical Contaminants

EPA followed 3 three-step process illustrated in Exhibit 1 to identify chemicals for inclusion on the Draft CCL 5. These steps included:

Step 1. Building a broad universe of potential drinking water contaminants (called the CCL 5 Chemical Universe). EPA evaluated 134 data sources and identified 43 that were related to potential drinking water chemical contaminants and met established CCL assessment factors. From these data sources, EPA identified and extracted occurrence and health effects data for the 21,894 chemicals that form the CCL 5 Chemical Universe.

Step 2. Screening the CCL 5 Chemical Universe to identify a list of chemicals that should be further evaluated (called the Preliminary CCL 5 (PCCL 5)). EPA established and applied a data-driven screening points system to identify and prioritize a subset of chemicals with the greatest potential for public health concern. The agency also incorporated publicly nominated chemicals to the PCCL 5.

Step 3. Classifying PCCL 5 chemicals to select the Draft CCL 5 chemicals. EPA compiled occurrence and health effects information for use by two evaluation teams of EPA scientists. The evaluation teams reviewed this information for each chemical before reaching a group decision on whether to list a chemical on the Draft CCL 5.

A more detailed description of the processes used to develop the Draft CCL 5 of chemicals using these steps can be found in the Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) - Chemical Contaminants (USEPA, 2021c).

2. Microbial Contaminants

EPA followed the 3-step process illustrated in Exhibit 1 to identify microbes for inclusion on the Draft CCL 5. For microbial contaminants, these steps included:

Step 1. Building a broad universe of all microbes that may cause human disease.

Step 2. Screening that universe of microbial contaminants to produce a PCCL 5.

Step 3. Selecting the Draft CCL 5 microbial list by ranking the PCCL 5 contaminants based on occurrence in drinking water (including waterborne disease outbreaks) and human health effects.

This approach is similar to that used by EPA for the CCL 3, with updates made to the microbial screening process in response to SAB and stakeholder comments. EPA re-examined all 12 microbial exclusionary screening criteria used in previous CCLs and modified one criterion for the CCL 5. More details on the screening process are presented in the Technical Support Document for the Draft Fifth Candidate List (CCL 5)–Microbial Contaminants (USEPA, 2021d). (Note, referred to as the Microbial Technical Support Document thereafter.)

F. *What is Included on the Draft CCL 5*?

The Draft CCL 5 includes 81 contaminants or groups (Exhibits 2a, 2b, and 2c). The list is comprised of 69 chemicals or chemical groups and 12 microbes. The 69 chemicals or chemical groups include 66 chemicals recommended for listing following an improved process to evaluate the PCCL, one group of cyanotoxins, one group of disinfection byproducts (DBPs), and one group of PFAS chemicals. The 12 microbes include 8 bacteria, 3 viruses, and 1 protozoa recommended for listing based on the scores for waterborne disease outbreaks, occurrence, health effects, and recommendations from various experts.

Exhibit 2a—Chemical Contaminants on the Draft CCL 5

Chemical Name	CASRN[1]	DTXSID[2]
1,2,3-Trichloropropane	96-18-4	DTXSID9021390
1,4-Dioxane	123-91-1	DTXSID4020533
17-alpha ethynyl estradiol	57-63-6	DTXSID5020576
2,4-Dinitrophenol	51-28-5	DTXSID0020523
2-Aminotoluene	95-53-4	DTXSID1026164
2-Hydroxyatrazine	2163-68-0	DTXSID6037807
4-Nonylphenol (all isomers)	25154-52-3	DTXSID3021857
6-Chloro-1,3,5-triazine-2,4-diamine	3397-62-4	DTXSID1037806
Acephate	30560-19-1	DTXSID8023846
Acrolein	107-02-8	DTXSID5020023
alpha-Hexachlorocyclohexane (alpha-HCH)	319-84-6	DTXSID2020684
Anthraquinone	84-65-1	DTXSID3020095
Bensulide	741-58-2	DTXSID9032329
Bisphenol A	80-05-7	DTXSID7020182
Boron	7440-42-8	DTXSID3023922
Bromoxynil	1689-84-5	DTXSID3022162
Carbaryl	63-25-2	DTXSID9020247

Chemical Name	CASRN[1]	DTXSID[2]
Carbendazim (MBC)	10605-21-7	DTXSID4024729
Chlordecone (Kepone)	143-50-0	DTXSID1020770
Chlorpyrifos	2921-88-2	DTXSID4020458
Cobalt	7440-48-4	DTXSID1031040
Cyanotoxins[3]	Multiple	Multiple
Deethylatrazine	6190-65-4	DTXSID5037494
Desisopropyl atrazine	1007-28-9	DTXSID0037495
Desvenlafaxine	93413-62-8	DTXSID40869118
Diazinon	333-41-5	DTXSID9020407
Dicrotophos	141-66-2	DTXSID9023914
Dieldrin	60-57-1	DTXSID9020453
Dimethoate	60-51-5	DTXSID7020479
Disinfection byproducts (DBPs)[4]	Multiple	Multiple
Diuron	330-54-1	DTXSID0020446
Ethalfluralin	55283-68-6	DTXSID8032386
Ethoprop	13194-48-4	DTXSID4032611
Fipronil	120068-37-3	DTXSID4034609
Fluconazole	86386-73-4	DTXSID3020627
Flufenacet	142459-58-3	DTXSID2032552
Fluometuron	2164-17-2	DTXSID8020628
Iprodione	36734-19-7	DTXSID3024154
Lithium	7439-93-2	DTXSID5036761
Malathion	121-75-5	DTXSID4020791
Manganese	7439-96-5	DTXSID2024169
Methomyl	16752-77-5	DTXSID1022267
Methyl tert-butyl ether (MTBE)	1634-04-4	DTXSID3020833
Methylmercury	22967-92-6	DTXSID9024198
Molybdenum	7439-98-7	DTXSID1024207
Norflurazon	27314-13-2	DTXSID8024234
Oxyfluorfen	42874-03-3	DTXSID7024241
Per- and polyfluoroalkyl substances (PFAS)[5]	Multiple	Multiple
Permethrin	52645-53-1	DTXSID8022292
Phorate	298-02-2	DTXSID4032459
Phosmet	732-11-6	DTXSID5024261
Phostebupirim	96182-53-5	DTXSID1032482
Profenofos	41198-08-7	DTXSID3032464
Propachlor	1918-16-7	DTXSID4024274
Propanil	709-98-8	DTXSID8022111
Propargite	2312-35-8	DTXSID4024276
Propazine	139-40-2	DTXSID3021196
Propoxur	114-26-1	DTXSID7021948
Quinoline	91-22-5	DTXSID1021798
Tebuconazole	107534-96-3	DTXSID9032113
Terbufos	13071-79-9	DTXSID2022254
Thiamethoxam	153719-23-4	DTXSID2034962
Tri-allate	2303-17-5	DTXSID5024344

Chemical Name	CASRN[1]	DTXSID[2]
Tribufos	78-48-8	DTXSID1024174
Tributyl phosphate	126-73-8	DTXSID3021986
Trimethylbenzene (1,2,4-)	95-63-6	DTXSID6021402
Tris(2-chloroethyl) phosphate (TCEP)	115-96-8	DTXSID5021411
Tungsten	7440-33-7	DTXSID8052481
Vanadium	7440-62-2	DTXSID2040282

[1] Chemical Abstracts Service Registry Number (CASRN) is a unique identifier assigned by the Chemical Abstracts Service (a division of the American Chemical Society) to every chemical substance (organic and inorganic compounds, polymers, elements, nuclear particles, etc.) in the open scientific literature. It contains up to 10 digits, seperated by hyphens into three parts.
[2] Distributed Structure Searchable Toxicity Substance Identifiers (DTXSID) is a unique substance identifier used in EPA's CompTox Chemicals database, where a substance can be any single chemical, mixture or polymer.
[3] Toxins naturally produced and released by some species of cyanobacteria (previously known as "blue-green algae"). The group of cyanotoxins includes, but is not limited to: anatoxin-a, cylindrospermopsin, microcystins, and saxitoxin.
[4] This group includes 23 unregulated DBPs as shown in Exhibit 2b.
[5] This group is inclusive of any PFAS (except for PFOA and PFOS). For the purposes of this document, the structural definition of PFAS includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R''. Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R'') can be hydrogen (USEPA, 2021f).

Exhibit 2b—Unregulated DBPs in the DBP Group on the Draft CCL 5

Chemical Name	CASRN	DTXSID
Haloacetic Acids		
Bromochloroacetic acid (BCAA)	5589-96-8	DTXSID4024642
Bromodichloroacetic acid (BDCAA)	71133-14-7	DTXSID4024644
Dibromochloroacetic acid (DBCAA)	631-64-1	DTXSID3031151
Tribromoacetic acid (TBAA)	75-96-7	DTXSID6021668
Haloacetonitriles		
Dichloroacetonitrile (DCAN)	3018-12-0	DTXSID3021562
Dibromoacetonitrile (DBAN)	3252-43-5	DTXSID3024940
Halonitromethanes		
Bromodichloronitromethane (BDCNM)	918-01-4	DTXSID4021509
Chloropicrin (trichloronitromethane, TCNM)	76-96-2	DTXSID0020315
Dibromochloronitromethane (DBCNM)	1184-89-0	DTXSID00152114
Iodinated Trihalomethanes		
Bromochloroiodomethane (BCIM)	34970-00-8	DTXSID4021503
Bromodiiodomethane (BDIM)	557-95-9	DTXSID70204235
Chlorodiiodomethane (CDIM)	638-73-3	DTXSID20213251
Dibromoiodomethane (DBIM)	557-68-6	DTXSID60208040
Dichloroiodomethane (DCIM)	594-04-7	DTXSID7021570
Iodoform (triiodomethane, TIM)	75-47-8	DTXSID4020743
Nitrosamines		
Nitrosodibutylamine (NDBA)	924-16-3	DTXSID2021026

N-Nitrosodiethylamine (NDEA)	55-18-5	DTXSID2021028
N-Nitrosodimethylamine (NDMA)	62-75-9	DTXSID7021029
N-Nitrosodi-n-propylamine (NDPA)	621-64-7	DTXSID6021032
N-Nitrosodiphenylamine (NDPhA)	86-30-6	DTXSID6021030
Nitrosopyrrolidine (NPYR)	930-55-2	DTXSID8021062
Others		
Chlorate	14866-68-3	DTXSID3073137
Formaldehyde	50-00-0	DTXSID7020637

Exhibit 2c—Microbial Contaminants on the Draft CCL 5

Microbial Name	**Microbial Class**
Adenovirus	Virus
Caliciviruses	Virus
Campylobacter jejuni	Bacteria
Escherichia coli (O157)	Bacteria
Enteroviruses	Virus
Helicobacter pylori	Bacteria
Legionella pneumophila	Bacteria
Mycobacterium abscessus	Bacteria
Mycobacterium avium	Bacteria
Naegleria fowleri	Protozoa
Pseudomonas aeruginosa	Bacteria
Shigella sonnei	Bacteria

III. Developing the Draft CCL 5

A. *Approach Used to Identify Chemical Candidates for the Draft CCL 5*

The SDWA directs EPA to consider health effects and occurrence information on unregulated contaminants to identify those that present the greatest public health concern related to exposure from drinking water. EPA gathered this information into a data directory that supports the evaluation of contaminants over the three steps of the CCL 5 development process, as outlined in Section II.E.1 of this document.

1. Building the Chemical Universe

The goal of the first step of the CCL 5 development process for chemical candidates is to identify a broad universe of potential drinking water contaminants. EPA began the CCL 5 development process by compiling data sources to identify chemicals that would form a broad CCL 5 Chemical Universe (e.g., a list of contaminants identified through health and occurrence data sources that are relevant, complete, retrievable, and not redundant). EPA compiled data sources identified from the CCL 3 and the CCL 4, along with data sources recommended by the CCL 5 EPA workgroup and subject matter experts. Information on how EPA addressed data sources provided through the public nomination process is described in Section III.C.1 of this document. As a result of this effort, EPA identified 134 potential data sources and further assessed their potential use for the CCL 5 development process. EPA accessed each potential data source online and evaluated them using the following assessment factors:

Relevance: The data source contains information on demonstrated or potential health effects, occurrence, or potential occurrence of contaminants using surrogate information (e.g., environmental release, environmental fate and transport properties);

Completeness: The data source either (a) has been peer-reviewed, or (b) provides a description of the data, information on how the data were obtained, and contact information regarding the data source;

Redundancy: The data source does not contain information identical to other more comprehensive data sources also being considered; and,

Retrievability: The data are formatted for automated retrieval (e.g., data are stored in a tabular format) and publicly accessible.

Out of the 134 potential data sources, 43 met all four assessment factors and were therefore considered "primary data sources" that were used to build the CCL 5 Chemical Universe. Data sources that met the first three assessment factors but were not retrievable were set aside as potential supplemental sources, some of which were used as part of the CCL 5 classification process, as discussed further in this section as well as Sections III.A.4 and III.C of

this document. More information on how data sources were assessed and extracted is provided in Sections 2.2 and 2.3, respectively, of the Chemical Technical Support Document (USEPA, 2021c).

EPA downloaded data from the 43 primary data sources and categorized them as sources of health effects (Exhibit 3) or occurrence (Exhibit 4) data. In total, 21,894 chemicals were identified from the 43 primary data sources.

Out of the 43 primary data sources, EPA identified 17 sources of health effects data that met the assessment factors of relevance, completeness, redundancy, and retrievability. One additional health effects data source, the Hazardous Substances Data Bank (HSDB), did not meet the retrievability factor but was designated as a primary data source. The HSDB is a data rich source, and the only source of Lethal Dose, 50% (LD50s) for the CCL 5 development process.

Therefore, additional effort was taken to extract this data, as was done with the CCL 3 development process (USEPA, 2009a). These 18 data sources, listed in Exhibit 3, include both qualitative and quantitative data.

Exhibit 3—CCL 5 Health Effects Primary Data Sources

Data Source	Agency or Author[1]
Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Levels (MRLs)	Centers for Disease Control and Prevention (CDC)
Cancer Potency Data Bank	National Library of Medicine, U.S. Department of Health and Human Services (HHS)
Drinking Water Standards and Health Advisory Tables	EPA
Guidelines for Canadian Drinking Water Quality	Health Canada
Guidelines for Drinking-Water Quality	World Health Organization (WHO)
Hazardous Substances Data Bank	National Library of Medicine, HHS
Health-Based Screening Levels (HBSLs)	U.S. Geological Survey (USGS)
Human Health-Based Water Guidance Table	Minnesota Department of Health
Human Health Benchmarks for Pesticides	EPA
Integrated Risk Information System (IRIS)	EPA
International Agency for Research on Cancer Classifications	WHO
Maximum Recommended Daily Dose (MRDD) Database	U.S. Food and Drug Administration (FDA)

National Recommended Water Quality Criteria – Human Health Criteria	EPA
National Toxicology Program (NTP) Cancer Classifications	HHS
Provisional Peer-Reviewed Toxicity Values (PPRTVs)	EPA
Screening Levels for Pharmaceuticals	FDA Drugs@FDA database, National Institutes of Health (NIH) DailyMed Database
Toxicity Criteria Database	California Environmental Protection Agency (CalEPA) Office of Environmental Health Hazard Assessment
Toxicity Reference Database (ToxRefDB)	EPA

[1] References for the data sources listed in Exhibit 3 are provided in Appendix N of the Chemical Technical Support Document (USEPA, 2021c).

EPA identified 25 sources of occurrence related data that met the assessment factors of relevance, completeness, redundancy, and retrievability. These data sources, listed in Exhibit 4, include both qualitative and quantitative data.

Exhibit 4—CCL 5 Occurrence Primary Data Sources

Data Source	Agency or Author[1]
ATSDR Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Substance Priority List	CDC
Chemical Data Reporting (CDR) Results	EPA
"Concentrations of prioritized pharmaceuticals in effluents from 50 large wastewater treatment plants in the US and implications for risk estimation"	Kostich et al. 2014
Disinfection By-product Information Collection Rule (DBP ICR)	EPA
"Evaluating the extent of pharmaceuticals in surface waters of the United States using a National-scale Rivers and Streams Assessment survey"	Batt et al. 2016
"Expanded target-chemical analysis reveals extensive mixed-organic-contaminant exposure in U.S. streams"	Bradley et al. 2017
Federal Insecticide Fungicide, and Rodenticide Act (FIFRA) List	EPA
"Legacy and emerging perfluoroalkyl substances are important emerging water contaminants in the Cape Fear River Watershed of North Carolina"	Sun et al. 2016

National Health and Nutrition Examination Survey (NHANES)	CDC
National Inorganics and Radionuclides Survey (NIRS)	EPA
National Water Information System (NWIS)	Water Quality Portal, USGS
National Water-Quality Assessment (NAWQA)	Water Quality Portal, USGS
"Nationwide reconnaissance of contaminants of emerging concern in source and treated drinking waters of the United States"	Glassmeyer et al. 2017
"Nationwide reconnaissance of contaminants of emerging concern in source and treated drinking waters of the United States: Pharmaceuticals"	Furlong et al. 2017
Pesticide Data Program	U.S. Department of Agriculture (USDA)
Pesticide Use Estimates	USGS
"Pharmaceutical manufacturing facility discharges can substantially increase the pharmaceutical load to US wastewaters"	Scott et al. 2018
"Predicting variability of aquatic concentrations of human pharmaceuticals"	Kostich et al. 2010
"Reconnaissance of mixed organic and inorganic chemicals in private and public supply tapwaters at selected residential and workplace sites in the United States"	Bradley et al. 2018
Surface Water Database (SURF)	California Department of Pesticide Regulation
"Suspect screening and non-targeted analysis of drinking water using point-of-use filters"	Newton et al. 2018
Toxics Release Inventory (TRI)	EPA
Unregulated Contaminant Monitoring Rule (UCMR) Cycles 1-3	EPA
UCMR Cycle 4	EPA
Unregulated Contaminant Monitoring-State (UCM-State) Rounds 1 and 2	EPA

[1] References for the data sources listed in Exhibit 4 are provided in Appendix N of the Chemical Technical Support Document (USEPA, 2021c).

To ensure consistency and accuracy of the data across such a large data directory with a multitude of sources, EPA utilized the Distributed Structure–Searchable Toxicity Substance Identifiers (DTXSIDs) and tools provided in EPA's CompTox Chemicals Dashboard (Williams et al., 2017). This dashboard provides easy access to results from several models developed by EPA and others that predict toxicity endpoints, physicochemical properties, and environmental fate and exposure parameters for specific chemicals, as well as tools to efficiently and accurately match chemicals with DTXSIDs. With these tools and identifiers, EPA was able to match a

chemical that may have been reported differently (i.e., with different names or other identifiers) across CCL 5 data sources to one DTXSID. EPA linked these identifiers with descriptors that characterize toxicological and occurrence information, referred to as "data elements," to ensure that data for each chemical would be available for use in later steps of the CCL 5 development process. EPA also considered the CompTox Chemicals Dashboard as a supplemental data source, as described in Section 2.4.3 of the Chemical Technical Support Document (USEPA, 2021c).

While building the CCL 5 Chemical Universe, EPA took several steps to ensure that the chemical identifiers were accurate, and that the data elements gathered across sources were uniform and comparable, as described in Section 2.4.4 of the Chemical Technical Support Document (USEPA, 2021c). The result of the first step of the CCL 5 development process was the CCL 5 Chemical Universe that provided a starting point for screening chemicals for inclusion on the PCCL 5, as described in Section III.A.2 of this document.

At later stages in the CCL 5 development process, EPA also collected data from supplemental data sources, which, along with data from the 43 primary data sources, was used to aid in further evaluation of chemicals for listing on the Draft CCL 5. As described in Section 2.2.3 of the Chemical Technical Support Document (USEPA, 2021c), supplemental sources were used to fill data gaps as part of the CCL 5 classification step (see Section III.A.3 of this document). For example, EPA conducted literature searches to identify peer-reviewed studies that are considered supplemental data sources to aid in the evaluations of chemicals of interest (see Section III.A.3.a of this document). Supplemental data could also come from sources cited in public nominations (see Section III.C of this document). While these sources could most often not be efficiently or effectively incorporated into the screening process, they were often an important source of detail and description that supported CCL 5 listing decisions. This effort to combine data collected from primary data sources along with data from supplemental data sources resulted in the most comprehensive data compilation for universe chemicals collected for

any CCL iteration to date. For more information about the specific iterative steps taken to build the CCL 5 Chemical Universe, see Chapter 2 of the Chemical Technical Support Document (USEPA, 2021c).

2. Screening Chemicals to a PCCL

The goal of the second step of the CCL 5 development process was to screen chemicals for inclusion on the PCCL 5 using the data compiled in Step 1. The PCCL 5 is comprised of the top scoring universe chemicals that were advanced for further evaluation and publicly nominated chemicals. A number of top scoring chemicals and publicly nominated chemicals were not included on the PCCL 5 because they had ongoing agency actions or did not warrant further evaluation, such as canceled pesticides as described in this section.

a. Screening the Chemical Universe

EPA developed a screening process to determine which contaminants require further consideration through the PCCL to CCL step. EPA modified the CCL 3 screening process for this CCL cycle to accommodate new data types and sources that have become available, but maintained the framework of screening chemicals to the PCCL based on their available toxicity properties and occurrence data(USEPA, 2009b). To screen chemicals for the CCL 5, EPA developed a transparent and reproducible scoring rubric and point-based screening system. This point-based screening system is an improvement over the Toxicity Categories and Occurrence Hierarchies developed for the CCL 3 (USEPA, 2009b) because it incorporates data from all the available data elements identified for use in screening rather than relying on an individual data element that indicates the highest toxicity or occurrence for a chemical.

EPA developed a scoring rubric to assign points across health effects and occurrence data elements based on 1) the relevance of the data element to drinking water exposure and 2) the relative toxicity or relative occurrence indicated by the value of a chemical's data element compared to the values of that data element for all other chemicals, as described here and in more detail in Section 3.2 of the Chemical Technical Support Document (USEPA, 2021c). EPA

used this scoring rubric to assign points to health effects and occurrence data elements and calculate cumulative point scores, called "screening scores," for each chemical. EPA then used these screening scores as a tool to prioritize chemicals along with statistical models and analyses to inform the PCCL 5. The statistical models and analyses are described in Section III.A.4.d of this document and Section 4.6 of the Chemical Technical Support Document (USEPA, 2021c). During the CCL 5 development process, EPA compiled 68 different data elements that could be assigned points or used as supplementary data for individual chemicals. Of these 68 data elements, EPA assigned points to 22 data elements related to health effects and 13 data elements related to occurrence, but did not assign points to the remaining 33 data elements. Generally, EPA did not assign points to data elements if:

The data element was not available for a large number of chemicals.

The data element was not considered highly relevant to hazards associated with drinking water.

The data element required chemical-specific data manipulation (e.g., unit conversions requiring chemical molecular weight) and/or was not comparable to others in the universe.

Another data element extracted from the same data source and describing the same data was assigned points.

Or, the data element was not relevant to unregulated chemicals.

Many of the data elements assigned points in CCL 5 are the same data elements that were used in the CCL 3 screening and classification processes. These data elements include health effects information such as categories of cancer classifications and toxicity values (e.g., Reference Dose (RfD), No Observed Adverse Effect Level (NOAEL), Lowest Observed Adverse Effect Level (LOAEL), and Lethal Dose, 50% (LD50)), as well as occurrence information such as measures of chemical concentration and frequency of detections in drinking water, production volume, and chemical release data. There are also new data elements related to

both health and occurrence endpoints that EPA included in the CCL 5 screening process that were not available in a retrievable format or not used in previous CCL cycles, including National Health and Nutrition Examination Survey (NHANES) biomonitoring data and results from EPA's ToxCast in vitro screening assays. EPA designed the CCL 5 screening process to accommodate quantitative, calculated, and descriptive types of data. A full list of the data elements assigned points for the CCL 5 screening process is described in Chapter 3 of the Chemical Technical Support Document (USEPA, 2021c).

EPA divided the CCL 5 health effects and occurrence data elements that were assigned points into five categories, referred to as "tiers," based on the relevance of the data to public health concerns over drinking water exposure. Tier 1 contains data most relevant to understanding potential drinking water risk and Tier 5 contains data that provide indirect indication of potential risk associated with drinking water exposure. For example, Tier 1 health effects data elements include RfD, cancer slope factor (CSF), and chronic benchmark value, which are generally only available for chemicals that have relevant risk or hazard assessments from at least one health agency. Tier 1 occurrence data element is the screening Hazard Quotient (sHQ), a calculated data element based on the ratio of the maximum concentration of a chemical in finished drinking water (the occurrence element most applicable to drinking water risk) to the lowest (i.e., most health-protective) health screening level for a chemical (see Section 3.2 of the Chemical Technical Support Document (USEPA, 2021c) for more details). The list of data elements assigned points for CCL 5 screening purposes and their corresponding tier is presented in Exhibit 5.

Exhibit 5 — Tiers of Health and Occurrence Data Elements Assigned Points During the CCL 5 Screening Process

Tier	Data Element
Health Effects Data Elements	
Tier 1	Reference dose (RfD), cancer slope factor (CSF), chronic benchmark
Tier 2	Chronic no observed adverse effect level (NOAEL), chronic lowest observed adverse effect level (LOAEL)

Tier 3	Numeric cancer classification[1], subchronic benchmark, subchronic RfD
Tier 4	Acute benchmark, acute RfD, subchronic NOAEL, subchronic LOAEL, MRDD, mined literature for neurotoxins[2], human neurotoxicants[2], developmental neurotoxins[2], developmental neurotoxins (*in vivo*)[2], androgen receptor chemicals[2]
Tier 5	TD_{50}, LD_{50}, percent active in ToxCast assays[2], PubMed articles[2]
Occurrence Data Elements	
Tier 1	Screening hazard quotient
Tier 2	National finished water detection rates
Tier 3	National ambient water detection rates, non-national finished water detection rates
Tier 4	Non-national ambient water detection rates
Tier 5	Chemical release quantity, estimated pesticide application rate, chemical production volume, presence on FIFRA and CERCLA lists, NHANES blood, urine, and serum concentrations, OPERA model biodegradation half-life[2]

[1] EPA converted categorial cancer classifications to a numeric scheme (1-3) which were assigned screening points. See Section 2.4.4 of the Chemical Technical Support Document (USEPA, 2021c) for more information.

[2] These data elements were extracted from the CompTox Chemicals Dashboard.

A more detailed discussion on the inclusion and exclusion of data elements for point assignment is included in Chapter 3 of the Chemical Technical Support Document (USEPA, 2021c).

For a specific chemical, the number of points assigned to each individual data element depends on the relative toxicity or relative occurrence indicated by the data element compared to values of that data element available for all other chemicals in the universe. Further descriptions of data element category calculations and point assignments can be found in Section 3.3.2 of the Chemical Technical Support Document (USEPA, 2021c). Altogether, a chemical can receive points for each data element in every tier. The lower tiers of information are assigned fewer points because the data elements included in these tiers are considered less relevant to hazards associated with chemical exposure via drinking water.

EPA developed the screening points system to ensure the agency considers chemicals of emerging concern in drinking water in addition to well-studied chemicals with more robust human health and drinking water occurrence data. The point system allows a chemical with limited health effects data, but high occurrence, to be included on the PCCL 5. Similarly, a chemical with limited or no drinking water occurrence data but with health effects information potentially indicating higher toxicity could also be included in the PCCL. The screening score for a chemical is the sum of health effects and occurrence points assigned for each data element. The maximum screening score a chemical could be assigned is 14,050.

EPA identified the 250 highest scoring chemicals for inclusion in the PCCL 5 and further evaluation for listing on the Draft CCL 5. This resulted in all chemicals scoring at or above 3,320 points were advanced for further consideration for the Draft CCL 5. Because three chemicals (2,4-Dinitrophenol, Phosmet, and 4-Androstene-3,17-dione) have the same screening score of 3,320, a total of 252 chemicals were advanced for further consideration and potential inclusion on the PCCL 5 (note: the 252 chemicals are referred to as the "top 250" in this document). EPA validated the selection of the top 250 highest scoring chemicals and the screening score framework using a statistical modeling approach. A complete description of the results of this approach can be found in Section 4.6 of the Chemical Technical Support Document (USEPA, 2021c).

b. Publicly Nominated Chemicals

EPA *added* 53 publicly nominated chemicals to the 252 highest scoring chemicals to be included on the PCCL. Publicly nominated chemicals are described further in Section III.C of this document and Section 3.6 of the Chemical Technical Support Document (USEPA, 2021c).

c. Chemicals Excluded from the PCCL

i. Regulatory Determinations

In March 2021, under the fourth Regulatory Determination process, EPA made final regulatory determinations for eight chemicals including: PFOS; PFOA; 1,1-dichloroethane;

acetochlor; methyl bromide (bromomethane); metolachlor; nitrobenzene; and RDX (86 FR 12272, USEPA, 2021b). EPA also made a preliminary positive determination on strontium under the third Regulatory Determination process (79 FR 62715, USEPA, 2014). Therefore, EPA excluded these nine chemicals from the PCCL 5.

ii. Canceled Pesticides

EPA evaluated canceled pesticides and excluded those that are not persistent in the environment from the PCCL 5. The persistence and occurrence of canceled pesticides were evaluated by their biodegradation half-life, end-of-use date, and the timeframe of monitoring data in finished and/or ambient water. Canceled pesticides were assigned a persistence score based on the scale described in EPA's 2012 TSCA Work Plan Chemicals: Methods Document (USEPA, 2012b). Canceled pesticides' biodegradation half-life information was downloaded from EPA's CompTox Chemicals Dashboard. Based on half-life ranges, a persistence score of 1 to 3 was assigned to each canceled pesticide with 1 indicative of lowest persistence and 3 highest persistence. A canceled pesticide received a persistence score of 1, 2, or 3 if its half-life was less than two months, greater than or equal to two months, or greater than six months, respectively.

Additionally, end-of-use dates of canceled pesticides were compared to the dates of occurrence monitoring data in finished and/or ambient water. Only the occurrence monitoring data collected after the end-of-use dates were used to determine if a canceled pesticide had any detects and/or data spikes that would pose a public health concern. A canceled pesticide was included in the PCCL if it received a persistence score of 3 and had detects in finished or ambient water, or if it received a score of 1 or 2 but had detects in finished water. A canceled pesticide was excluded from the PCCL if it received a score of 1 or 2 and had no detects in finished water or no or few detects in ambient water.

In total, 26 canceled pesticides were assessed for persistence. Four pesticides, including dieldrin, aldrin, chlordecone (kepone), and ethion, were assigned a persistence score of 3 and showed detects in finished or ambient water; thus, they were included in the PCCL 5. Alpha-

hexachlorocyclohexane, although received a persistence score of 1, was also included in the PCCL 5 because it had detects in the UCMR 4 occurrence data (collected 2018-2019). Alpha-hexachlorocyclohexane is an organochloride, which is one of the isomers of hexachlorocyclohexane, and is a byproduct of the production of the canceled insecticide lindane.

The 21 remaining pesticides were assigned a score of 2 or 1 and showed no or very few detections in finished or ambient water; and therefore were excluded from the PCCL 5. Their finished or ambient water monitoring results were consistent with the low persistence scores, indicating that these canceled pesticides are likely of low public health concern.

d. Summary of the PCCL

The resulting PCCL 5 is comprised of a total of 275 chemicals. As shown in Exhibit 6, the PCCL 5 includes 252 of the highest scoring chemicals and 53 publicly nominated chemicals, of which 30 were excluded because they had other ongoing agency actions or did not warrant further evaluation. A summary of the PCCL 5 is included in Section 3.8 of the Chemical Technical Support Document (USEPA, 2021c).

Exhibit 6—Chemical Counts on Draft PCCL 5 and Draft CCL 5

Counting Process	Number of Chemicals	Total Count
Highest scoring chemicals (screened from Universe)	252	275 (PCCL)
(+) Add public nominated chemicals (not screened)	53	
(-) Exclude chemicals with Regulatory Determinations	9	
(-) Exclude canceled pesticides	21	
(-) Exclude Disinfection Byproducts (listed as a chemical group instead)	23	214 (Reviewed by Evaluation Teams)
(-) Exclude cyanotoxins (listed as a chemical group instead)	7	
(-) Exclude PFAS (listed as a chemical group instead)	18	
(-) Exclude public nominated chemicals lacking occurrence Data	13	
Evaluation Teams' Listing Recommendation		66
Draft CCL 5 Chemicals		66 and 3 groups

3. Classification of PCCL Chemicals to Select the Draft CCL

In the third step of the CCL 5 process, chemical contaminants screened to the PCCL 5 in Step 2 passed through a classification process. Classification is the process by which the agency incorporates the knowledge and evaluation of EPA scientists, referred to as "chemical evaluators," to narrow the PCCL down to a draft CCL. During this process, chemical evaluators assessed health and occurrence data on the PCCL 5 chemical contaminants and reached a consensus on whether to recommend them for listing on the Draft CCL 5.

To facilitate the classification process, EPA conducted health and occurrence literature searches to gather supplemental data for the remaining PCCL 5 chemicals. For more information, see Sections III.A.3.i and III.C.2 of this document, and Section 4.2.1.1 of the Chemical Technical Support Document (USEPA, 2021c).

Literature searches acquired supplemental health effects and/or occurrence data from qualifying studies that may not have been available in a retrievable format during the identification of the universe. The supplemental data resources encountered during the literature searches were compiled by chemical, and relevant health effects and occurrence data metrics were imported into a standardized document format, called the Contaminant Information Sheet (CIS) (USEPA, 2021e).

EPA formed two evaluation teams to review the qualifying health effects and occurrence information provided in supplemental studies and on the CISs to make consensus listing recommendations for the PCCL 5 chemicals. Each evaluation team was composed of seven chemical evaluators with professional experience and expertise in relevant technical fields, including public health, public policy, toxicology, chemistry, biology, and pesticide exposure.

The supplemental studies provided to the chemical evaluators during the review process can be found in the EPA docket at https://www.regulations.gov (Docket ID No. EPA-HQ-OW-2018-0594). The CISs can be viewed in the Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) - Contaminant Information Sheets, hereafter referred to as the CIS Technical Support Document (USEPA, 2021e).

The following sections provide a detailed explanation of the classification process broken down into individual components.

a. Supplemental Data Collection

Primary data sources play a crucial role in the entire CCL process (see Section III.A.1 of this document); however, it is often necessary to gather and extract data from supplemental sources to aid in further evaluation of chemicals for listing on the Draft CCL 5. As described in Section III.A.1 of this document, EPA assessed data sources for potential use in the CCL 5 development process and set aside, as supplemental sources, those that met the relevance, completeness, and redundancy assessment factors but were not retrievable. EPA utilized these supplemental sources to fill data gaps as part of the CCL classification process. EPA also identified supplemental sources from data sources cited in public nominations (see Section III.C.1 of this document) and conducted literature searches to identify further supplemental occurrence and health effects data as described in this section.

i. Occurrence

For PCCL 5 chemicals that reached the classification step but lacked national drinking water data within the last 10 years, EPA conducted a search of peer-reviewed literature relevant to the occurrence of contaminants in drinking water to identify studies that provided supplemental occurrence data for drinking water or ambient water not captured in the primary data sources. The literature review was limited to journal articles published between 2010 and 2020.

Each of the supplemental data sources was reviewed to determine the availability of data for any of the PCCL 5 chemicals that required further evaluation through the CCL 5 classification process. EPA identified and compiled 12 supplemental literature sources for contaminant occurrence in drinking and ambient water. All supplemental occurrence data identified through the literature search were included in the CISs. More information on CISs can

be found in Section III.A.4.c of this document and in the CIS Technical Support Document (USEPA, 2021e).

EPA's occurrence literature search was conducted in a systematic manner to fill the occurrence data gaps for contaminants on the PCCL. For example, EPA did not conduct occurrence literature searches for PCCL chemicals that had national drinking water occurrence data from the UCMR 3 or UCMR 4. These chemicals were considered to already have the best available occurrence data to inform whether a contaminant was known to occur in public water systems and therefore supplemental drinking or ambient water occurrence data was not needed. A full description of the occurrence literature search protocol and a list of supplemental occurrence literature utilized for CCL 5 can be found in the Appendix E of the Chemical Technical Support Document (USEPA, 2021c). In addition to supplemental occurrence data extracted through a targeted literature search, EPA compiled additional occurrence data from the 2006 Community Water Systems Survey (CWSS) (USEPA, 2009c; 2009d), EPA's Third Six-Year Review (SYR 3) (USEPA, 2017), and modeled concentrations from EPA's Office of Pesticide Programs (OPP).

The 2006 CWSS gathered data on the financial and operating characteristics of a random sample of CWSs nationwide. Systems serving more than 500,000 people were included in the sample, and systems in that size category were surveyed about concentrations of unregulated contaminants in their raw and finished water. EPA supplemented the data set by gathering additional information on contaminant occurrence at the systems in this size category from publicly available sources. The 2006 CWSS was used as supplemental source for the CCL 5 because the information is not statistically representative for the purpose of the CCL evaluation. For the SYR 3, EPA requested, through an Information Collection Request (ICR), that primacy agencies voluntarily submit drinking water compliance monitoring data collected during 2006-2011 to EPA. Some primacy agencies submitted occurrence data for unregulated contaminants in addition to the data on regulated contaminants. EPA extracted drinking water data on PCCL 5

chemicals from the SYR 3 ICR data, and supplemented these data by downloading additional publicly available monitoring data from state websites. These data were used as a supplemental data source and were included on the CISs.

Modeled concentration data were gathered for pesticides on the PCCL 5 that lack nationally representative drinking and/or nationally representative ambient water data. The modeled concentrations, known as estimated environmental concentrations (EECs) or estimated drinking water concentrations (EDWCs), of pesticides in water are often included in EPA's OPP registration and re-registration evaluation documentation, but are not in a retrievable format that could be efficiently extracted for all CCL 5 Chemical Universe pesticides.

Specific information on the systematic occurrence literature review, SYR 3 ICR, and state occurrence monitoring data sets, 2006 CWSS data set, and OPP modeled concentrations used in the Draft CCL 5 can be found in Section 4.2.1 of the Chemical Technical Support Document (USEPA, 2021c).

The data search efforts did not yield occurrence data for 13 publicly nominated chemicals that were lacking occurrence data in the CCL 5 Chemical Universe. As a result, these chemicals were not evaluated for listing on the Draft CCL 5 (Exhibit 6). More information is provided on this decision in Section III.C.2 of this document and Section 4.2.1.1 of the Chemical Technical Support Document (USEPA, 2021c).

ii. Health Effects

EPA developed the rapid systematic review (RSR) protocol to identify supplemental health effects data for PCCL 5 chemicals. The RSR process encompassed the identification of health effects information, including epidemiological and toxicological data, as well as physiologically-based pharmacokinetic models, and subsequent extraction of relevant data elements (i.e., NOAELs and LOAELs) that could be used to derive toxicity values and CCL Screening Levels, further described in Section III.A.4.b.i of this document. The CCL 5 RSR

process was designed to allow for screening and data synthesis of a large number of chemicals in a relatively short time frame. As such, the RSR process was comprised of:

A targeted chemical-specific literature search;

Machine learning-based screening to identify relevant literature;

A streamlined full-text review and study quality evaluation of relevant literature; and,

Data extraction components of traditional systematic reviews.

Studies targeted by the RSR literature search included those deemed relevant to health effects found in animal models after repeated oral exposure lasting at least 28 days. Epidemiological studies were also identified and catalogued for future use (i.e., for Regulatory Determination). If available, NOAELs and LOAELs, along with their corresponding health effects, were extracted from all relevant studies. These toxicity values were populated on the CISs and were used as a supplemental source of information for chemical evaluators to understand potential health effects that could result from chronic exposure to PCCL 5 chemicals. A detailed description of the RSR process can be found in Section 4.2.1 of the Chemical Technical Support Document (USEPA, 2021c).

b. Calculated Data Elements

i. Health Reference Levels and CCL Screening Levels

Health Reference Levels (HRLs) and CCL Screening Levels are referred to collectively as "health concentrations." Health concentrations are non-regulatory health-based toxicity values, expressed as concentrations of a contaminant in drinking water (in µg/L), which a person could consume over a lifetime and be unlikely to experience adverse health effects. HRLs are based on data elements (toxicity values including RfD, population-adjusted dose (PAD), CSF, etc.) extracted from "qualifying" health assessments, peer-reviewed, publicly available health assessments published by EPA and other health agencies. Assessments used to derive HRLs generally follow methodology that is consistent with EPA's current guidelines and guidance

documents, are externally reviewed by experts in the field, and have been used during EPA regulatory efforts in the past. CCL Screening Levels are based on data elements (toxicity values including RfD equivalents, CSF equivalents, etc.) extracted from "non-qualifying" health assessments, publicly available assessments that are published by health agencies and provide valuable health information, but do not necessarily follow standard EPA methodologies and/or are not externally peer-reviewed. Alternatively, CCL Screening Levels can be based on data elements (NOAEL or LOAEL) extracted from peer-reviewed studies identified through the CCL 5 RSR process previously described.

The process for determining the toxicity value most appropriate for use in deriving the health concentration is similar to the process EPA uses for Regulatory Determination. Generally, EPA relies on its most recently published health assessment as the source of these toxicity values unless a qualifying assessment from another source incorporates new scientific information published after the publication date of the most recent EPA health assessment. If no qualifying health assessments are available, EPA extracts toxicity values from the most recently published non-qualifying health assessment. If no qualifying or non-qualifying health assessments are available, EPA relies on toxicity values extracted from studies identified through the health effects RSR process.

For carcinogens, the derived health concentration is the one-in-a-million cancer risk expressed as a drinking water concentration. For non-carcinogens, health concentrations are obtained by dividing the RfD (or equivalent) by an exposure factor, also known as the drinking water intake (DWI), and multiplying by a 20% relative source contribution (USEPA, 2000). All health concentrations were converted to units of µg/L to compare with CCL 5 occurrence concentrations and for use in derivation of the final Hazard Quotient. If a chemical had no available qualifying or non-qualifying health assessments or studies identified through the RSR process, or the available health assessments did not provide toxicity values, EPA did not derive a health concentration.

The health concentration used to derive the hazard quotient is presented on the summary page of the CIS alongside the critical effect and data element from which it was derived. EPA also provides health concentrations derived from supplementary assessments on the second page of the CIS as additional resources. Refer to Section 4.3.1 of the Chemical Technical Support Document (USEPA, 2021c) for more information about the sources and process for derivation of CCL 5 health concentrations.

ii. Final Hazard Quotients

Final hazard quotients (fHQ) are an important metric used in the evaluation of PCCL chemicals during the classification step. The fHQ is the ratio of a chemical's 90th percentile (of detections) water concentration over its health concentration (HRL or CCL screening level) at which no adverse effects are expected to occur. The fHQ serves as a benchmark for chemical evaluators to gauge the potential level of concern posed by the exposure to each chemical in drinking water.

A relatively higher fHQ value for a given chemical can generally be interpreted as an increase to the level of concern for exposure to the chemical in drinking water; as the ratio increases beyond 0, the expected exposure concerns also increase; an fHQ value equal to or greater than 1.0 indicates a chemical with water concentration exceeding its health concentration.

EPA followed the CCL 3 and CCL 4 protocol to select the concentration input values for the ratio as closely as possible while incorporating newly available data sources. Depending on data availability, the fHQ was calculated by first using the 90th percentile of detections from national drinking water monitoring data sources, such as UCMR. If the 90th percentile was not available, EPA used the next highest percentile (95th or 99th) or maximum reported concentration value. For contaminants that lacked finished water data but had robust ambient water monitoring data from sources such as NAWQA, the ratio was developed by using the ambient water concentration. Similarly, if the 90th percentile was not available, the next highest percentile or maximum reported concentration was used. If no measured water data were

available, EPA used modeled water data for pesticides developed by EPA's OPP to calculate the fHQ. For contaminants with no water data (either measured or modeled), the occurrence to health concentration ratio could not be calculated and the entry for the fHQ was left blank on the CIS.

Similarly, HRLs were the preferred health concentration used to derive the fHQ. If a chemical did not have data available to calculate an HRL, a CCL screening level was used to derive the fHQ. For chemicals with no relevant health effects data (i.e., no HRL or CCL screening level), the occurrence to health concentration ratio could not be calculated and the entry for the fHQ was left blank on the CIS.

A more detailed description of the protocol used to calculate the final hazard quotients for CCL 5 can be found in Section 4.3.2 the Chemical Technical Support Document (USEPA, 2021c).

iii. Attribute Scores

During the CCL process, EPA evaluates relatively new and emerging contaminants not currently subject to EPA drinking water regulations. Some of these contaminants do not have readily available information on their health effects in humans and animal models and/or their occurrence in water. Recognizing the need to establish consistent relationships and enable comparison among different types of data, EPA developed a scaling system of attribute scores for the CCL 3 based on recommendations from the National Academy of Science's National Research Council (NRC, 2001) and the National Drinking Water Advisory Council (NDWAC, 2004). Attributes are defined as the properties used to categorize contaminants based on their potential to cause adverse health effects and occur in drinking water. The associated scores for these attributes provide a consistent, comparative framework for evaluation purposes that accommodate a variety of input data.

The health effects of a contaminant are categorized using the attributes of potency and severity, while the actual or potential occurrence of a contaminant is categorized using the attributes of prevalence and magnitude.

Potency reflects the potential for a chemical to cause adverse health effects based on the dose required to elicit the most sensitive adverse effect. Severity is a descriptive measure of the adverse health effect associated with the potency score. Unlike the other attributes, which are numerical, severity is categorical; contaminants are assigned to one of eight severity categories (non-cancer effects, no adverse effects, cosmetic effects, carcinogen with a linear mode of action, carcinogen with a mutagenic mode of action, carcinogen with a non-linear mode of action, reproductive and developmental effects, or reduced longevity) depending on the reported health endpoint.

Prevalence provides some indicator of how widespread the occurrence of the contaminant is in the environment, such as the percentage of public water systems or sample locations in a study reporting detections.

Magnitude describes the quantity of a contaminant that may be in the environment (e.g. median concentration of detections or pounds applied annually). When direct occurrence data are not available, EPA uses Persistence-Mobility data as surrogate indicators of potential occurrence of a contaminant. Persistence-Mobility is defined by chemical properties that measure or estimate environmental fate characteristics of a contaminant and affect their likelihood to occur in water.

EPA used the attribute scoring developed for CCL 3 to evaluate PCCL 5 chemicals, with some adjustments made to the calibrations for potency and descriptions for severity. Those adjustments, along with the scoring scales and categories, are explained in detail in the Chemical Technical Support Document (USEPA, 2021c).

c. Evaluation Team Listing Decision Process

The EPA scientists on the two evaluation teams shared a broad range of professional experience and expertise across the agency and with the CCL process. These "chemical evaluators" were provided training, which included a detailed overview of the goals and general principles of the CCL process, types of data, and materials compiled to aid in evaluating chemicals for listing, the evaluation process steps, and the format of the discussion meetings. Of the 275 PCCL 5 chemicals, the evaluation teams reviewed 214 chemicals (Exhibit 6). The evaluation teams did not review 7 cyanotoxins, 23 DBPs, and 18 PFAS chemicals because they were listed as three chemical groups on the Draft CCL 5 (as discussed further in Section III.A.3.e of this document). Additionally, the evaluation teams did not evaluate the 13 publicly nominated chemicals due to lack of occurrence data.

The chemical evaluators on the two evaluation teams met over 20 times between March 19 and July 2, 2020, to discuss their individual reviews and reach consensus listing decisions as a group for batches of approximately 10-20 chemicals per batch. To prepare for these discussion meetings, the chemical evaluators independently reviewed the relevant health effects and occurrence information on CISs for each chemical in a batch. For each chemical on the PCCL 5 that was evaluated for potential listing, a CIS was developed to summarize the data and assist the chemical evaluators in making listing recommendations for the Draft CCL 5. Each CIS presents the health and occurrence data gathered from primary and supplemental data sources, as well as health and occurrence statistical measures described in Section III.A.4.b of this document. CISs also include additional information about the contaminant, such as the identity of the contaminant and its usage, whether it was subject to past negative regulatory determinations, listed on past CCLs, and publicly nominated for the CCL 5. Due to the inclusion of more data in the CCL 5 process, CISs for the Draft CCL 5 contain more information than those of past CCLs. CISs for contaminants evaluated for the Draft CCL 5 and further information on what data the CISs provide can be found in the CIS Technical Support Document (USEPA, 2021e).

Upon completing their independent reviews, the chemical evaluators submitted their listing decisions along with written justifications through a survey tool. The results from the survey were collected and tabulated before each facilitated group discussion. Numerical values were assigned to the individual evaluator's listing decision for each chemical (i.e., 1 = No List, 2 = No List?, 3 = List?, and 4 = List) so that an average listing decision could be calculated. A question mark (?) signified that the chemical evaluator was leaning toward listing (List?) or toward not listing (No List?) but had some uncertainty. These average listing decisions helped inform the facilitator and the chemical evaluators of their collective decisions and guided the teams towards making the final listing recommendations for each chemical. In total, the evaluation teams recommended 66 chemicals for listing on the Draft CCL 5. A more detailed description of the team listing process can be found in Section 4.5 of the Chemical Technical Support Document (USEPA, 2021c).

d. Logistic Regression

EPA conducted statistical analyses and developed a simple logistic regression model to validate the selection of the top 250 highest scoring chemicals for inclusion on the PCCL 5 and provide diagnostic feedback on the screening system during the evaluation team meetings. EPA hypothesized that screening scores have a positive association with listing decisions, and that the higher the screening score of a PCCL 5 chemical, the higher the probability of the chemical being recommended for listing by the evaluation teams. Additional analyses and logistic regression models were developed to further examine the efficacy of the screening scores and to determine additional factors, such as fHQs and health and occurrence attribute scores, associated with listing decisions.

The simple logistic regression models the statistical relationship between screening scores and the evaluation teams' list or not list decision. The model was used to obtain probabilities of listing at the highest screening score (top of the PCCL 5) and screening score directly below the PCCL 5 top 250. Results of this analysis indicate chemicals with higher

screening scores are more likely to be listed than chemicals with lower screening scores. The predicted mean probability of listing at the top of the PCCL 5 is 0.90 and at the screening score directly below the PCCL 5 top 250 is 0.12. A full description of the modeling approach and results can be found in Section 4.6.2 of the Chemical Technical Support Document (USEPA, 2021c).

Following the evaluation team decisions, EPA explored other factors that may have impacted listing decisions and further evaluated how well the screening scores performed as a predictor of listing decisions. To accomplish this, EPA compiled a dataset that contained the chemical screening scores, health effects and occurrence attribute scores, fHQs, and other information. See Section 4.6.1 of the Chemical Technical Support Document (USEPA, 2021c) for details on the compiled dataset used in the statistical analyses. The first step of the analysis was to calculate descriptive statistics for each variable stratified by listing decision. Next, several simple logistic regression models were explored to obtain odds ratios (OR) and establish statistical significance of the predictor variables. Lastly, an area under the curve - receiver operator characteristic (AUC-ROC) curve analysis was conducted to examine the performance of simple logistic regression models and multivariable logistic models as predictors of listing decisions. The results of the simple logistic regression found the screening scores, attributes scores, and fHQs (adjusted for outliers) to be statistically significant predictors of listing decisions. The AUC-ROC analysis provided further evidence that the screening scores were a moderate-to-good predictor of listing decisions (AUC = 0.72) and led to the discovery of a multivariable logistic regression model that was a very good-to-excellent predictor of listing decisions (AUC = 0.89). A complete description of the results of the statistical analyses conducted for the Draft CCL 5 can be found in Section 4.6 of the Chemical Technical Support Document (USEPA, 2021c).

e. Chemical Groups on the Draft CCL 5

In addition to the 66 chemicals recommended for listing on the Draft CCL 5 by the evaluation teams (Exhibit 6), EPA proposes to list three chemical groups (cyanotoxins, DBPs, and PFAS) instead of listing them as individual chemicals. These chemical groups have been identified as agency priorities and contaminants of concern for drinking water under other EPA actions. Listing these three chemical groups on the Draft CCL 5 does not necessarily mean that EPA will make subsequent regulatory decisions for the entire group. EPA will evaluate scientific data on the listed groups, subgroups, and individual contaminants included in the group to inform any regulatory determinations for the group, subgroup, or individual contaminants in the group. Addressing the public health concerns of cyanotoxins in drinking water remains a priority as specified in the 2015 Algal Toxin Risk Assessment and Management Strategic Plan for Drinking Water (USEPA, 2015). Cyanotoxins are toxins naturally produced and released by some species of cyanobacteria (previously known as "blue-green algae"), were listed on the CCL 3 and CCL 4 as a group. EPA is listing a cyanotoxin group on the Draft CCL 5, identical to the CCL 3 and CCL 4 listing. The group of cyanotoxins includes, but is not limited to: anatoxin-a, cylindrospermopsin, microcystins, and saxitoxin. Cyanotoxins were also monitored under the UCMR 4.

EPA is also proposing to list 23 unregulated DBPs (as shown in Exhibit 2b) as a group on the Draft CCL 5. DBPs are formed when disinfectants react with naturally-occurring materials in water. Under the Stage 2 Disinfectants and Disinfection Byproducts Rule, there are currently 11 regulated DBPs from three subgroups that include four trihalomethanes, five haloacetic acids, and two inorganic compounds (bromate and chlorite). Under the Six-Year Review 3 (SYR 3), EPA identified 10 regulated DBPs (all but bromate) as "candidates for revision" (USEPA, 2017). For the Draft CCL 5, the group of 23 unregulated DBPs were either publicly nominated or among the top 250 chemicals. Listing these unregulated DBPs as a group on the Draft CCL 5 would be consistent with the decision that EPA has identified a number of microbial and

disinfection byproduct (MDBP) drinking water regulations as candidates for revision in the agency's SYR 3 .

PFAS are a class of synthetic chemicals that are most commonly used to make products resistant to water, heat, and stains and are consequently found in industrial and consumer products like clothing, food packaging, cookware, cosmetics, carpeting, and fire-fighting foam (AAAS, 2020; USEPA, 2018b). Over 4,000 PFAS have been manufactured and used globally since the 1940s (USEPA, 2019b), which would make listing PFAS individually on the Draft CCL 5 difficult and challenging. EPA proposes to list PFAS as a group inclusive of any PFAS (except for PFOA and PFOS). For the purposes of this document, the structural definition of PFAS includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R''. Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R'') can be hydrogen (USEPA, 2021f). This proposal is responsive to public nominations which stated that EPA should "include PFAS chemicals as a class on CCL 5." This action is in keeping with the agency's commitment to better understand and ultimately reduce the potential risks caused by this broad class of chemicals. Including the broad group of PFAS on the Draft CCL 5 demonstrates the agency's commitment to prioritizing and building a strong foundation of science on PFAS while working to harmonize multiple authorities to address the impacts of PFAS on public health and the environment. EPA is also committed to a flexible approach and working collaboratively with states, tribes, water systems, and local communities that have been impacted by PFAS.

B. *Approach Used to Identify Microbial Candidates for the Draft CCL 5*

1. Building the Microbial Universe

EPA defined the microbial Universe for the CCL 5 as all known human pathogens. The microbial Universe was built on the CCL 3 and the CCL 4 Universe of 1,425 pathogens. EPA conducted a literature search, sought input from subject matter experts, and reviewed

nominations for additional microbes to add to the Universe. As a result, 14 organisms were added to the CCL 5 Microbial Universe (Exhibit 7).

Changes to nomenclature of the microbes were made as necessary (in most cases combining two species into one organism group), making the total number of organisms in the microbial Universe 1,435. The full CCL 5 microbial Universe list is available in the Technical Support Document for the Draft fifth Contaminant Candidate List (CCL 5) - Microbial Contaminants (USEPA, 2021d).

Exhibit 7—Microbial Contaminants Added to the Microbial Universe for the CCL 5

Microbial Contaminant	Microbe Class
Alloscardovia omnicolens	Bacteria
Elizabethkingia anophelis	Bacteria
Neoehrlichia mikurensis	Bacteria
Parachlamydia acanthamoebae	Bacteria
Waddia chondrophila	Bacteria
Human bocavirus	Virus
Human coronavirus SARS-CoV-2	Virus
KI polyomavirus	Virus
Kobuvirus	Virus
Lujo virus	Virus
Parovovirus 4	Virus
WU polyomavirus	Virus
Botrytsis cinerea	Fungi
Epiccocum purpurascens	Fungi

2. Screening the Microbial Universe to the PCCL

During the CCL 3 process, EPA developed 12 screening criteria (Exhibit 8) to focus the Universe of all human pathogens to only those pathogens that could be transmitted through drinking water. Screening is based on a pathogen's epidemiology, geographical distribution, and biological properties in their host and in the environment. All pathogens that are not excluded by any screening criteria are moved to the PCCL. In addition, any pathogen documented to cause disease transmitted through drinking water regardless of the screening criteria, is also considered for the PCCL. The screening criteria restrict the microbial PCCL to human pathogens that may cause drinking water-related diseases resulting from ingestion of, inhalation of, or dermal contact

with drinking water. For the Draft CCL 5, EPA re-evaluated the screening criteria for applicability to microbes and reviewed certain criterion in depth per recommendations received from the SAB and stakeholders during the development of the CCL 3 and the CCL 4. In particular, Criterion 1 (anaerobes), Criterion 9 (natural habitat is in the environment without epidemiological evidence of drinking water-related disease) and Criterion 10 (not endemic to North America) were closely re-evaluated based on previous comments for the CCL 3 and the CCL 4 from NDWAC, SAB, and the public. Upon further evaluation, EPA did not find supporting evidence to modify Criterion 1 and Criterion 10.

EPA modified the screening Criterion 9 to include pathogens on the PCCL with nosocomial infections where drinking water is implicated due to recent increases in and recognition of antimicrobial resistance and nosocomial infections. Modifying Criterion 9 addresses a SAB comment that the screening criteria for the CCL 4 microbial process were too restrictive. As a result, Criterion 9 was modified to include pathogens that cause nosocomial infections where drinking water is implicated so that it is less restrictive.

Exhibit 8—Screening Criteria for Pathogens

All anaerobes.
Obligate intracellular fastidious pathogens.
Transmitted by contact with blood or body fluids.
Transmitted by vectors.
Indigenous to the gastrointestinal tract, skin and mucous membranes.
Transmitted solely by respiratory secretions.
Life cycle incompatible with drinking water transmission.
Drinking water-related transmission is not implicated.
Natural habitat is in the environment without epidemiological evidence of drinking water-related disease **and without evidence of drinking water-related nosocomial infection.**

Not endemic to North America.

Represented by a pathogen for the entire genus or species (that are closely related).

Current taxonomy changed from taxonomy used in Universe.

Bolded text indicates the modification made to Criterion 9.

Based upon the screening criteria, 1,400 of the 1,435 pathogens were excluded; therefore 35 pathogens advanced to the PCCL. The results of the screening process are summarized in Exhibit 9. The criteria and results of the screening process are discussed in greater detail in the Technical Support Document for the DraftFifth Contaminant Candidate List (CCL 5) – Microbial Contaminants (USEPA, 2021d).

Exhibit 9—Application of 12 Screening Criteria to Pathogens in the Microbial CCL Universe

Pathogen Class	Total	Screening Criteria and Number of Pathogens Screened out per Criterion												Pathogens screened out	On PCCL
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**		
Bacteria	545	121	16	10	38	121	7	0	29	150	2	28	5	527	18[1]
Viruses	225	0	0	29	104	0	20	1	20	0	36	8	0	218	7
Protozoa[2]	66	0	0	1	29	3	0	4	7	7	0	6	0	59	7
Helminths	286	0	0	0	25	0	0	105	0	0	156	0	0	286	0
Fungi	313	0	0	0	0	12	3	0	0	295	0	0	0	310	3
Total	**1,435**	**121**	**16**	**40**	**196**	**136**	**30**	**110**	**56**	**452**	**194**	**42**	**5**	**1400**	**35**

[1] NTM are included on the PCCL as a group.
[2] *Cryptosporidium* and *Giardia* (both protozoa) are considered to be regulated by the Long Term Surface Water Treatment Rule (LT-2); even though counted in the Microbial universe, they were not evaluated for screening.

3. The PCCL to Draft CCL Process

Pathogens on the PCCL were scored for placement on the Draft CCL 5. In developing the CCL 3, EPA devised a scoring system to assign a numerical value to each pathogen on the PCCL. Each pathogen on the PCCL was scored using three scoring protocols, one protocol each for waterborne disease outbreaks (WBDO), occurrence in drinking water, and health effects. The higher of the WBDO score or the occurrence score was added to the normalized health effects score to produce a composite pathogen score. Pathogens receiving high scores were considered for placement on the CCL.

EPA normalized the health effects score so that occurrence and health effects had equal weight in determining the ranking of the Draft CCL. The equal weighting of occurrence and health effects information closely mirrors the risk estimate methods used by EPA in drinking water regulation development. This scoring system prioritizes and restricts the number of pathogens on the CCL to only those that have been strongly associated with drinking water-related disease. Pathogens that scored low will remain on the PCCL until additional occurrence data, epidemiological surveillance data, or health effects data become available to support their reevaluation. It is important to note that pathogens for which there are no documented WBDO in drinking water earn a low score under the protocols. Pathogens that have caused a WBDO and have health effects data are rank higher than pathogens that only have health effect data but no evidence of a WBDO. The following sections describe the three protocols used to score the pathogens on the PCCL and the process by which the scores are combined.

a. Waterborne Disease Outbreak (WBDO) Protocol

The Centers for Disease Control and Prevention (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 occurrence and causes of WBDOs since 1971. In recent years, CDC has developed National Outbreak Reporting System (NORS) (CDC, 2020a) for WBDO reporting, in collaboration with CSTE and EPA, to improve the quality, quantity, and availability of data submitted to the Waterborne Disease and Outbreak Surveillance System (WBDOSS). For the Draft CCL 5, EPA used CDC's NORS as the primary data source for the WBDO protocol. Reports from the CDC system were published periodically in Morbidity and Mortality Weekly Report (MMWR) until 2017. For the CCL 3 and the CCL 4, EPA used MMWRs for the WBDO protocol.

For the Draft CCL 5, EPA used CDC's NORS for more recent outbreak information due to the most recent MMWR being published in 2014. For the WBDO protocol (Exhibit 10), a pathogen is scored as having a WBDO(s) in the U.S. if that pathogen is listed in a CDC

waterborne disease drinking water surveillance summary (i.e., on NORS from 2009-2017). Outbreaks that occurred in 2009 and after were used to capture microbes causing concern since the publication of the CCL 3. A pathogen with multiple WBDOs listed by CDC was given the highest score under this protocol. In addition, EPA scored non-CDC reported WBDOs and WBDOs outside the U.S. with lower scores. WBDOs outside the U.S. were scored when information was available from World Health Organization or other peer-reviewed publications.

In addition, 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 (CDC, 2008). The surveillance information does not include endemic waterborne disease risks, nor are reliable estimates available of the number of unrecognized WBDOs and associated cases of illness. Therefore, EPA also considered the non-CDC data as indicating a WBDO (even though CDC did not list it in their NORS) if the data showed a link between human illness defined by a common water source, a common time period of exposure and/or similar symptoms. Additionally, EPA considered the use of molecular typing methods to link patients and environmental isolates.

Exhibit 10—Waterborne Disease Outbreak Scoring Protocol

Category	Score
Has caused multiple (2 or more) documented WBDOs in the U.S. as reported by CDC surveillance between 2009-2017	5
Has caused at least one documented WBDO in the U.S. as reported by CDC surveillance 2009-2017	4
Has caused documented WBDOs at any time in the U.S.	3
Has caused documented WBDOs in countries other than the U.S.	2
Has never caused WBDOs in any country, but has been epidemiologically associated with water-related disease	1

b. Occurrence Protocol

The second attribute of the scoring process evaluates the occurrence of a pathogen in drinking water and source water. Because water-related illness may also occur in the absence of recognized outbreaks, EPA scored the occurrence (direct detection) of microbes using cultural, immunochemical, or molecular detection of pathogens in drinking water under the Occurrence Protocol (Exhibit 11). Occurrence characterizes pathogen introduction, survival, and distribution in the environment. Occurrence implies that pathogens are present in water and that they may be capable of surviving and moving through water to cause illness in persons exposed to drinking water by ingestion, inhalation, or dermal contact.

Pathogen occurrence is considered broadly to include treated drinking water, and all waters using a drinking water source for recreational purposes, ground water, and surface water bodies. This attribute does not characterize the extent to which a pathogen's occurrence poses a public health threat from drinking water exposure.

Exhibit 11—Occurrence and Health Effects Scoring Protocols for Pathogens

Category	Score
Occurrence Scoring Protocol	
Detected in drinking water in the U.S.	3
Detected in source water in the U.S.	2
Not detected in the U.S.	1
Health Effects Scoring Protocol	
Does the organism cause significant mortality (> 1/1,000 cases)?	7
Does the organism cause pneumonia, meningitis, hepatitis, encephalitis, endocarditis, cancer, or other severe manifestations of illness necessitating long term hospitalization (> week)?	6
Does the illness result in long term or permanent dysfunction or disability (e.g., sequelae)?	5
Does the illness require short term hospitalization? (< week)?	4
Does the illness require physician intervention?	3
Is the illness self-limiting within 72 hours (without requiring medical intervention)?	2
Does the illness result in mild symptoms with minimal or no impact on daily activities?	1

c. Health Effects Protocol

EPA's health effects protocol evaluates the extent or severity of human illness produced by a pathogen across a range of potential endpoints. The seven-level hierarchy developed for this protocol (Exhibit 11) begins with mild, self-limiting illness (score of 1) and progresses to death (score of 7).

The final outcome of a host-pathogen relationship resulting from drinking water exposure is a function of viability, infectivity, and pathogenicity of the microbe to which the host is exposed and the host's susceptibility and immune response. SDWA directs EPA to consider subgroups of the population at greater risk of adverse health effects (i.e., sensitive populations) in the selection of unregulated contaminants for the CCL. Sensitive populations may have increased susceptibility and may experience increased severity of symptoms, compared to the general population. The SDWA refers to several categories of sensitive populations including children and infants, elderly, pregnant women, and persons with a history of serious illness. Health effects for individuals with marked immunosuppression (e.g., primary or acquired severe immunodeficiency, transplant recipients, individuals undergoing potent cytoreductive treatments) are not included in this health effect scoring. While such populations are considered sensitive subpopulations, immunosuppressed individuals often have a higher standard of ongoing health care and protection required than the other sensitive populations under medical care. More importantly, nearly all pathogens have very high health effect scores for the markedly immunosuppressed individuals; therefore, there is little differentiation between pathogens based on health effects for the immunosuppressed subpopulation.

This protocol scores the representative or common clinical presentation for the specific pathogen for the population category under consideration. Pathogens may produce a range of illness from asymptomatic infection to fulminate illness progressing rapidly to death. Scoring decisions are based upon the more common clinical presentation and clinical course for the population under consideration, rather than the extremes. EPA used recently published clinical microbiology manuals (Carroll et al., 2019; Murray et al., 2011) as the primary data source for

the common clinical presentation. These manuals took a broad epidemiological view of health effects rather than focusing on narrow research investigations or single cases.

To obtain a representative characterization of health effects in all populations, EPA evaluated (separately) the general population and four sensitive populations (children, elderly, pregnant woman, and persons with chronic diseases) as to the common clinical presentation of illness for that population. EPA added the general population score to the highest score among the four sensitive subpopulations for an overall health effects score. The resulting score reflects that sensitive populations have increased risk for waterborne diseases.

d. Combining Protocol Scores to Rank Pathogens

EPA scored and ranked the microbes on the PCCL using the three attribute scoring protocols for WBDOs, occurrence, and health effects. These protocols are designed in a hierarchical manner so that each pathogen is evaluated using the same criteria and that the criteria range for each protocol varies from high to low significance. The three attribute scores are then combined into a total score.

EPA scored pathogens first using the WBDO and occurrence protocols, and then selected the higher score of the two scores. Selection of the higher score from the WBDO or occurrence protocol elevates pathogens that have been detected in drinking water or source water in the U.S. (occurrence score of 2 or 3) above pathogens that have caused WBDOs in other countries but not in the U.S. (WBDO score of 2).

The CCL selection process placed more weight on pathogens causing recent WBDOs than on those detected in drinking water without documented waterborne disease from that exposure. Direct detection of pathogens indicates the potential for waterborne transmission of disease. Documented WBDOs provide an additional weight of evidence that illness was transmitted and that there was a waterborne route of exposure.

Next, pathogens were scored using the Health Effects Protocol. The pathogen's score for the general population was added to the highest score among the four sensitive populations to produce a sum score between 2 and 14.

Finally, EPA normalizes the Health Effects score and WBDO/Occurrence score because these are of equal importance. The highest possible score for WBDO/Occurrence is 5 and the highest possible Health Effects score is 14. To equalize this imbalance, EPA multiplies the health effect score by 5/14. Combining health effects data with the WBDO/occurrence data by adding the scores from these protocols provides a system that evaluates both the severity of potential disease and the potential magnitude of exposure through drinking water. Exhibit 12 presents the scores for all the 35 PCCL pathogens.

Exhibit 12—Scores for all the PCCL 5 Pathogens

Pathogen	Ranking	WBDO	Occurrence	Normalized health score	Total score[1]
Naegleria fowleri	1	5	3	5.0	10.0
Legionella pneumophila	2	5	3	3.6	8.6
Escherichia coli (O157)	3	5	3	3.2	8.2
Pseudomonas aeruginosa	4	5	3	3.2	8.2
Helicobacter pylori	5	1	3	5.0	8.0
Campylobacter jejuni	6	5	3	2.5	7.5
Mycobacterium abcessus	7	4	3	3.2	7.2
Shigella sonnei	8	4	3	3.2	7.2
Caliciviruses	9	5	3	2.1	7.1
Mycobacterium avium	10	4	3	2.9	6.9
Adenovirus	11	2	3	3.6	6.6
Enterovirus	12	2	3	3.6	6.6
Pantoea agglomerans	13	4	3	2.5	6.5
Hepatitis A virus	14	3	2	3.2	6.2
Arcobacter butzleri	15	4	3	2.1	6.1
Fusarium solani	16	1	3	2.9	5.9
Nontuberculous Mycobacteria (NTM)	17	3	3	2.9	5.9
Hepatitis E virus	18	2	1	3.6	5.6
Cyclospora cayetanensis	19	3	3	2.5	5.5
Rotavirus	20	2	3	2.5	5.5
Salmonella enterica	21	3	3	2.5	5.5
Toxoplasma gondii	22	2	1	3.2	5.2
Aspergillus fumigatus group	23	1	3	2.1	5.1

Pathogen	Ranking	WBDO	Occurrence	Normalized health score	Total score[1]
Entamoeba histolytica	24	3	3	2.1	5.1
Exophiala jeanselmei	25	1	3	2.1	5.1
Vibrio cholerae	26	3	3	2.1	5.1
Aeromonas hydrophila	27	1	3	1.8	4.8
Plesiomonas shigelloides	28	3	3	1.8	4.8
Blastocystis hominis	29	4	1	0.7	4.7
Acinetobacter baumannii	30	1	2	2.5	4.5
Comanonas testosteroni	31	1	2	2.5	4.5
Yersinia enterocolitica	32	3	3	1.4	4.4
Astrovirus	33	2	2	1.4	3.4
Microsporidia	34	1	2	1.4	3.4
Isospora belli	35	2	1	1.1	3.1

[1] Total Score = Normalized Health Score + the higher of WBDO or Occurrence.

e. Selection of the Draft CCL Microbes

The 35 PCCL pathogens, listed in Exhibit 12, are ranked according to an equal weighting of their summed scores for normalized health effects and the higher of the individual scores for WBDO and occurrence in drinking water. EPA believes this ranking indicates the most important pathogens to consider for the Draft CCL 5. To determine which of the 35 PCCL pathogens should be the highest priority for EPA's drinking water program and included on the Draft CCL 5, EPA considered scientific factors and the opportunity to advance public health protection. The factors included the PCCL scores for WBDO, occurrence, and health effects; and comments and recommendations from the various expert panels, including EPA’s internal workgroup and CDC subject matter experts. The evaluation prioritizes the pathogens that provide the best opportunities to advance public health protection. After consideration of these factors, EPA has decided to include in the Draft CCL 5 the 12 highest ranked pathogens shown in Exhibit 12. The selection of microbial pathogens for the CCL 5 was similar to the method used for the CCL 3 and the CCL 4 with the exception that with the CCL 5, there were no “natural” break points in the ranked scores for the 35 pathogens.

EPA believes that the overall rankings strongly reflect the best available scientific data and high quality expert input employed in the CCL selection process, and therefore should be important factors in helping to identify the top priority pathogens for the Draft CCL 5.

f. Organisms Covered by Existing Regulations

According to Section 1412(b)(1) of the 1996 SDWA Amendments, EPA must select CCL contaminants that "at the time of publication, are not subject to any proposed or promulgated national primary drinking water regulation." In promulgating regulations for contaminants in drinking water, EPA can set either a legal limit (maximum contaminant level or MCL) and require monitoring for the contaminant in drinking water or, for those contaminants that are difficult to measure, EPA can establish a treatment technique requirement. The Surface Water Treatment Rule (54 FR 27486, USEPA, 1989a) established maximum contaminant level goals (MCLGs) of zero for Legionella, Giardia, and viruses because any amount of exposure to these contaminants represents some public health risk. Since measuring disease-causing microbes in drinking water was not considered to be feasible at the time of the development of the SWTR, EPA established treatment technique requirements for these contaminants. The purpose of subsequent treatment technique requirements (Interim Enhanced Surface Water Treatment Rule (63 FR 69478, USEPA 1998a), Long Term 1 Surface Water Treatment Rule (67 FR 1813, USEPA, 2002a), and the Long Term 2 Surface Water Treatment Rule (71 FR 654, USEPA, 2006a), which included an MCLG of zero for Cryptosporidium, is to reduce disease incidence associated with Cryptosporidium and other pathogenic microorganisms in drinking water. These rules apply to all public water systems that use surface water or ground water under the direct influence of surface water.

The Ground Water Rule (GWR) (71 FR 65573; USEPA, 2006c) set treatment technique requirements to control for viruses (and pathogenic bacteria) because it was not feasible to monitor for viruses (or pathogenic bacteria) in drinking water. Under the GWR, if systems detect total coliforms in the distribution system, they are required to monitor for a fecal indicator (E.

coli, coliphage, or enterococci) in the source water. If fecal contamination is found in the source water, the system must take remedial action to address contamination.

EPA considered Legionella and specific viruses in CCL even though they are regulated under the Surface Water Treatment Rules (SWTR). In this draft document, EPA proposes to specifically list Legionella pneumophila, the primary pathogenic bacterium, on the Draft CCL 5 because it has been identified in numerous WBDOs and is the most common cause of reported drinking water-associated outbreaks in the U.S. Furthermore, reported Legionnaires' disease has increased 10-fold in the last 20 years (CDC, 2020b). A recent National Academies of Science report estimated 52,000-70,000 cases of Legionnaires' disease annually, with 3-30% mortality (NASEM, 2020).

EPA is also proposing to list certain viruses on the Draft CCL 5. Viruses include a wide range of taxa and different viral taxa have been implicated in various WBDOs for which EPA did not have dose response or treatment data when promulgating its treatment technique requirements.

Even though there are MCLGs for Legionella and viruses, and these contaminants are subject to limitations as a class through the treatment techniques under the Surface Water Treatment Rules, there are no monitoring, treatment, or notification requirements within those NPDWRs that are specific to Legionella pneumophila or the specific viruses listed on CCL5 (although systems may use coliphage for source water monitoring for ground water systems). Therefore, EPA considers Legionella pneumophila and the specific viruses listed on CCL5 to be unregulated contaminants for purposes of eligibility for the CCL. Additionally, EPA received public nomination for viruses and Legionella for the Draft CCL 5, with Legionella pneumophila receiving the highest number of nominations.

C. *Summary of Nominated Candidates for the Draft CCL 5*

EPA sought public nominations in a **Federal Register** notice on October 5, 2018, for unregulated chemical and microbial contaminants to be considered for possible inclusion in the

CCL 5 (83 FR 50364, USEPA, 2018a). In accordance with the SDWA, which directs EPA to consider health effects and occurrence information when deciding whether to place contaminants on the CCL, EPA asked that nominations include responses to the following questions:

What is the contaminant's name, CAS registry number, and/or common synonym (if applicable)? Please do not nominate a contaminant that is already subject to a national primary drinking water regulation.

What are the data that you believe support the conclusion that the contaminant is known or anticipated to occur in public water systems? For example, provide information that shows measured occurrence of the contaminant in drinking water or measured occurrence in sources of drinking water or provide information that shows the contaminant is released in the environment or is manufactured in large quantities and has a potential for contaminating sources of drinking water. Please provide the source of this information with complete citations for published information (i.e., author(s), title, journal, and date) or contact information for the primary investigator.

What are the data that you believe support the conclusion that the contaminant may require regulation? For example, provide information that shows the contaminant may have an adverse health effect on the general population or that the contaminant is potentially harmful to subgroups that comprise a meaningful proportion of the population (such as children, pregnant women, the elderly, individuals with a history of serious illness, or others). Please provide the source of this information with complete citations for published information (i.e., author(s), title, journal, and date) or contact information for the primary investigator.

EPA compiled and reviewed the information from the nominations process to identify the contaminants nominated and any sources of supporting data submitted that could be used to supplement the data gathered by EPA to inform selection of the Draft CCL 5.

EPA received nominations for 89 unique contaminants for the CCL 5, including 73 chemicals and 16 microbes. Nominated contaminants included chemicals used in commerce,

pesticides, disinfection byproducts, pharmaceuticals, naturally occurring elements, biological toxins, and waterborne pathogens. Contaminants nominated for consideration for the CCL 5 are shown in Exhibit 13.

EPA received nominations from 29 different organizations and/or individuals. There were three general types of nominations: specific individual chemicals, specific individual organisms, and groups of contaminants (e.g., PFAS). Seven chemicals and eight microbes were nominated by more than one organization or individual. Legionella pneumophila received the most nominations, nominated by 18 organizations or individuals. Among chemicals, perfluorononanoic acid (PFNA), PFOS, and PFOA received the most nominations, each nominated by three organizations or individuals. In addition to individual contaminants, groups of contaminants were nominated, such as brominated haloacetic acids known as "HAA6Br," cyanotoxins, GenX chemicals (hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt), all the PFAS approved by the EPA Method 537.1, PFAS, and the top 200 prescribed drugs of 2016 and their parents and metabolites. A public commenter also proposed that all CCL 4 contaminants be retained on the CCL 5.

EPA also received recommendations for the CCL process. All public nominations can be viewed in the EPA docket at https://www.regulations.gov (Docket ID No. EPA-HQ-OW-2018-0594). A more detailed summary of the nomination process is included in Section 3.6 of the Chemical Technical Support Document (USEPA, 2021c) and in Section 2.1 of the Microbial Technical Support Document (USEPA, 2021d).

Exhibit 13—Contaminants Nominated for Consideration on the Draft CCL 5:

Nominated Chemical Contaminant

Chemical Name	CASRN	DTXSID
1,1-Dichloroethane	75-34-3	DTXSID1020437
1,4-Dioxane	123-91-1	DTXSID4020533
1-Phenylacetone[1]	103-79-7	DTXSID1059280

Chemical Name	CASRN	DTXSID
2-(N-Methylperfluorooctane sulfonamido)acetic acid (Me-PFOSA-AcOH)	2355-31-9	DTXSID10624392
2-(N-Ethyl perfluorooctane sulfonamido) acetic acid (Et-PFOSA-AcOH)	2991-50-6	DTXSID5062760
2-[(8-Chloro-1,1,2,2,3,3,4,4,5,5,6,6,7,7,8,8-Hexadecafluorooctyl)oxy]-1,1,2,2-tetrafluoroethane-1-sulfonic acid (11Cl-PF3OUdS)	763051-92-9	DTXSID40892507
3-Hydroxycarbofuran	16655-82-6	DTXSID2037506
3-Monoacetylmorphine[1]	29593-26-8	DTXSID30183774
4,8-Dioxa-3H-perfluorononanoic acid (ADONA)	919005-14-4	DTXSID40881350
6-Monoacetylmorphine[1]	2784-73-8	DTXSID60182154
Ammonium perfluoro-2-methyl-3-oxahexanoate	62037-80-3	DTXSID40108559
Anatoxin A	64285-06-9	DTXSID50867064
Azinphos-methyl	86-50-0	DTXSID3020122
Benzoic acid[1]	65-85-0	DTXSID6020143
Benzoic acid glucuronide[1]	19237-53-7	DTXSID90940901
Bromochloroacetic acid (BCAA)	5589-96-8	DTXSID4024642
Bromochloroiodomethane (BCIM)	34970-00-8	DTXSID9021502
Bromodichloroacetic acid (BDCAA)	71133-14-7	DTXSID4024644
Bromodichloronitromethane (BDCNM)	918-01-4	DTXSID4021509
Bromodiiodomethane (BDIM)	557-95-9	DTXSID70204235
Chlorate	14866-68-3	DTXSID3073137
Chlorodibromoacetic acid (CDBAA)	5278-95-5	DTXSID3031151
Chloro-diiodo-methane (CDIM)	638-73-3	DTXSID20213251
Chloropicrin (trichloro-nitromethane; TCNM)	76-06-2	DTXSID0020315
Chlorpyrifos	2921-88-2	DTXSID4020458
Cylindrospermopsin	143545-90-8	DTXSID2031083
Dibromochloronitromethane (DBCNM)	1184-89-0	DTXSID00152114
Dibromoiodomethane (DBIM)	593-94-2	DTXSID60208040
Dichloroiodomethane (DCIM)	594-04-7	DTXSID7021570
Fluoxetine	5491-89-3	DTXSID7023067
Gemfibrozil	25812-30-0	DTXSID0020652
Heroin	561-27-3	DTXSID6046761

Chemical Name	CASRN	DTXSID
Hippuric acid[1]	495-69-2	DTXSID9046073
Hydromorphone[1]	466-99-9	DTXSID8023133
Hydromorphone-3-glucuronide[1]	No CASRN	NO_DTXSID
Hydroxyamphetamide[1]	103-86-6	DTXSID3023134
Isodrin (Pholedrine, 4-Hydroxymethamphetamine)[1]	465-73-6	DTXSID7042065
Manganese	7439–96–5	DTXSID2024169
Methamphetamine[1]	537-46-2	DTXSID8037128
Microcystin LA	96180-79-9	DTXSID3031656
Microcystin LR	101043-37-2	DTXSID3031654
Microcystin LW	No CASRN	DTXSID70891285
Microcystin RR	111755-37-4	DTXSID40880085
Microcystin YR	101064-48-6	DTXSID00880086
Molybdenum	7439–98–7	DTXSID1024207
Morphine	57-27-2	DTXSID9023336
Morphine-3-glucuronide	20290-09-9	DTXSID80174157
Morphine-6-glucuronide[1]	20290-10-2	DTXSID40174158
N-Nitrosodiethylamine (NDEA)	55-18-5	DTXSID2021028
N-Nitrosodimethylamine (NDMA)	62-75-9	DTXSID7021029
N-Nitroso-di-n-propylamine (NDPA)	621-64-7	DTXSID6021032
N-Nitrosodiphenylamine (NDPhA)	86-30-6	DTXSID6021030
N-Nitrosopyrrolidine (NPYR)	930-55-2	DTXSID8021062
Perfluoro(2-((6-chlorohexyl)oxy)ethanesulfonic acid) (9Cl-PF3ONS)	756426-58-1	DTXSID80892506
Perfluoro-2-methyl-3-oxahexanoic acid	13252-13-6	DTXSID70880215
Perfluorobutane sulfonic acid (PFBS)	375-73-5	DTXSID5030030
Perfluorobutyric acid (PFBA)	375-22-4	DTXSID4059916
Perfluorodecanoic acid (PFDeA/PFDA)	335-76-2	DTXSID3031860
Perfluorododecanoic acid (PFDoA)	307-55-1	DTXSID8031861
Perfluoroheptanoic acid (PFHpA)	375-85-9	DTXSID1037303
Perfluorohexane sulfonic acid (PFHxS)	355-46-4	DTXSID7040150
Perfluorohexanoic acid (PFHxA)	307-24-4	DTXSID3031862
Perfluorononononanoic acid (PFNA)	375-95-1	DTXSID8031863
Perfluorooctanesulfonamide (PFOSA)	754-91-6	DTXSID3038939

Chemical Name	CASRN	DTXSID
Perfluorooctane sulfonic acid (PFOS)	1763-23-1	DTXSID3031864
Perfluorooctanoic acid (PFOA)	335-67-1	DTXSID8031865
Perfluorotetradecanoic acid (PFTA)	376-06-7	DTXSID3059921
Perfluorotridecanoic acid (PFTrDA)	72629-94-8	DTXSID90868151
Perfluoroundecanoic acid (PFUA/PFUnA)	2058-94-8	DTXSID8047553
Phenylpropanolamine[1]	37577-28-9	DTXSID4023466
Strontium	7440-24-6	DTXSID3024312
Tribromoacetic acid (TBAA)	75-96-7	DTXSID6021668
Triiodomethane (TIM)	75-47-8	DTXSID4020743

[1]Thirteen nominated chemicals did not have available water occurrence data, even after a systematic literature search was conducted, and therefore were not evaluated for listing on the Draft CCL 5. See Section 4.2.1.1 of the Chemical Technical Support Document for more information.

Nominated Microbial Contaminants

Microbial Name
Adenovirus
Aeromonas hydrophila
Caliciviruses
Campylobacter jejuni
Enterovirus
Escherichia coli (0157)
Helicobacter pylori
Hepatitis A virus
Legionella pneumophila
Mycobacterium species predominantly found in drinking water
Mycobacterium avium
Naegleria fowleri
Non-tuberculous Mycobacterium (NTM)
Pseudomonas aeruginosa
Salmonella enterica
Shigella sonnei

1. Data Sources for the Nominated Chemical and Microbial Contaminants

a. Chemical Nominations

EPA reviewed the public nominations for the 73 chemicals and determined which nominated chemicals were already included in the CCL 5 Chemical Universe and which ones were not. If a chemical was already part of the CCL 5 Chemical Universe, this meant that EPA had identified and extracted health effects and occurrence data on this chemical from primary data sources in Step 1, Building the Chemical Universe. However, most of these chemicals did not have sufficiently high screening scores and therefore required additional data to evaluate them. For the nominated chemicals that were not included in the CCL 5 Chemical Universe, they would require further data collection to be evaluated for listing on the Draft CCL 5. To identify additional data for these nominated chemicals, EPA assessed data sources cited with public nominations using the assessment factors described in Section III.A.1 of this document and extracted health effects and occurrence data from sources that were relevant, complete, and not redundant. Sources that met these three assessment factors were considered supplemental data sources and could serve as references to fill any data gaps for particular chemical contaminants during Step 3 of the CCL 5 process (see Section III.A.3 of this document). EPA also conducted literature searches to identify additional health effects and occurrence data; more information can be found on the literature searches in Section III.A.3.a of this document and in Chapter 4 of the Chemical Technical Support Document (USEPA, 2021c). A complete list of supplemental sources can be found in Appendix B of the Chemical Technical Support Document (USEPA, 2021c).

b. Microbial Nominations

EPA reviewed the nominated microbial contaminants and the supporting information provided by nominators to determine if any new data were provided that had not been previously evaluated. EPA also collected additional data for the nominated microbial contaminants, when available, from both the CCL 3 and CCL 4 data sources that had been updated and from literature searches covering the time between the CCL 4 and the CCL 5 (2016–2019). If new

data were available, EPA screened and scored the microbial contaminants nominated for CCL 5 using the same process that was used for the CCL 3 and the CCL 4. There were no new publicly nominated microbial data sources for the CCL 5. A more detailed description of the data sources used to evaluate microbial contaminants for the Draft CCL 5 can be found in the Microbial Technical Support Document (USEPA, 2021d).

2. Listing Outcomes for the Nominated Chemical Contaminants

EPA reviewed the nominated chemical contaminants and identified which chemicals were (i) not already on the PCCL 5, and (ii) not subject to proposed or promulgated NPDWRs, and needed to be considered for further analysis. EPA did not add publicly nominated groups like "the top 200 most prescribed drugs in 2016 and their parents and metabolites" to the PCCL 5 because health effects and occurrence data must be linked to specific individual contaminants in order to be evaluated. However, individual chemicals in a nominated group could still be listed on the PCCL if they were also nominated individually or if they were part of the CCL 5 Chemical Universe and screened to the PCCL.

EPA could not identify occurrence data for 13 nominated chemicals (Exhibit 13) from either primary or supplemental data sources nor was data provided in the public nominations. Without available data regarding measured occurrence in water or relevant data provided by the nominators, the two evaluation teams agreed that they could not determine whether these chemicals were likely to present the greatest public health concern through drinking water exposure and therefore should not advance further in the CCL 5 process. However, some were evaluated for possible research needs (see Chapter 5 of the Chemical Technical Support Document; USEPA, 2021c). More detailed information about how nominated chemicals were considered for the Draft CCL 5 can be found in Section 3.6 of the Chemical Technical Support Document (USEPA, 2021c).

Four publicly nominated chemicals were included on the Draft CCL 5 as a result of evaluation team listing decisions, including 1,4-dioxane, chlorpyrifos, manganese, and

molybdenum. In addition, 43 nominated chemicals consisting of 7 cyanotoxins, 18 DBPs, and 18 PFAS chemicals were included in the three chemical groups listed on the Draft CCL 5 (e.g., the cyanotoxin, DBP, and PFAS groups). The PFAS group is inclusive of any PFAS, except for PFOA and PFOS. Although PFOA and PFOS were nominated, EPA has made a positive final regulatory determination for these two chemicals; and therefore, did not include them in the PFAS group.

3. Listing Outcomes for the Nominated Microbial Contaminants

All the microbes nominated for the CCL 5, with the exception of *Salmonella enterica,* and *Aeromonas hydrophila,* and Hepatitis A*,* are listed on the Draft CCL 5. *Salmonella enterica*, *Aeromonas hydrophila* and Hepatitis A did not produce sufficient composite scores to place them on the Draft CCL 5. Although *Salmonella enterica* and Hepatitis A have numerous WBDOs, the route of exposure was not explicitly waterborne. Non-tuberculous Mycobacterium (NTM) and Mycobacterium (species broadly found in drinking water) were nominated for the CCL 5 and are not listed on the Draft CCL 5 as a group; instead, they were listed as *Mycobacterium avium* and *Mycobacterium abscessus*, two species of NTM that are found in drinking water.

D. *Data Availability Assessment for the Draft CCL 5 Chemicals*

In an effort to provide the current data availability of the Draft CCL 5 contaminants with respect to occurrence, health effects, and analytical methods data, EPA provides a summary table (Exhibit 14) depicting chemicals categorized into six groups depending upon the availability of their occurrence data and health assessment. EPA did not assess data availability for individual chemicals of the cyanotoxins, DBPs and PFAS groups because the availability of health effects and occurrence data varies with individual chemicals in each group. The agency is addressing these groups broadly in drinking water based on a subset of chemicals in these groups that are known to occur in public water systems and may cause adverse health effects.

Exhibit 14—Data Availability/Information for the Draft CCL 5 Contaminants

CASRN	DTXSID	Common name	Best Available Occurrence Data	Is a Health Assessment Available?	Is an Analytical Method Available?
A. Contaminants with Nationally Representative Finished Water Occurrence Data and Qualifying Health Assessments					
96-18-4	DTXSID9021390	1,2,3-Trichloropropane	National Finished Water	Yes	Yes
123-91-1	DTXSID4020533	1,4-dioxane	National Finished Water	Yes	Yes
319-84-6	DTXSID2020684	alpha-Hexachlorocyclohexane	National Finished Water	Yes	Yes
7440-42-8	DTXSID3023922	Boron	National Finished Water	Yes	Yes
63-25-2	DTXSID9020247	Carbaryl	National Finished Water	Yes	Yes
2921-88-2	DTXSID4020458	Chlorpyrifos	National Finished Water	Yes	Yes
7440-48-4	DTXSID1031040	Cobalt	National Finished Water	Yes	Yes
60-57-1	DTXSID9020453	Dieldrin	National Finished Water	Yes	Yes
330-54-2	DTXSID0020446	Diuron	National Finished Water	Yes	Yes
13194-84-4	DTXSID4032611	Ethoprop	National Finished Water	Yes	Yes
7439-93-2	DTXSID5036761	Lithium	National Finished Water	Yes	Yes
7439-96-5	DTXSID2024169	Manganese	National Finished Water	Yes	Yes
7439-98-7	DTXSID1024207	Molybdenum	National Finished Water	Yes	Yes
42874-03-3	DTXSID7024241	Oxyfluorfen	National Finished Water	Yes	Yes
52645-53-1	DTXSID8022292	Permethrin	National Finished Water	Yes	Yes
41198-08-7	DTXSID3032464	Profenofos	National Finished Water	Yes	Yes
1918-16-7	DTXSID4024274	Propachlor	National Finished Water	Yes	Yes
91-22-5	DTXSID1021798	Quinoline	National Finished Water	Yes	Yes
107534-96-3	DTXSID9032113	Tebuconazole	National Finished Water	Yes	Yes
78-48-8	DTXSID1024174	Tribufos	National Finished Water	Yes	Yes
7440-62-2	DTXSID2040282	Vanadium	National Finished Water	Yes	Yes
95-53-4	DTXSID1026164	2-Aminotoluene	National Finished Water	Yes	Yes

CASRN	DTXSID	Common name	Best Available Occurrence Data	Is a Health Assessment Available?	Is an Analytical Method Available?
51-28-5	DTXSID0020523	2,4-Dinitrophenol	National Finished Water	Yes	Yes
B. Contaminants with Non-Nationally Representative Finished Water Occurrence Data and Qualifying Health Assessments					
2163-68-0	DTXSID6037807	2-Hydroxyatrazine	Non-National Finished Water	Yes	No
120068-37-3	DTXSID4034609	Fipronil	Non-National Finished Water	Yes	No
121-74-5	DTXSID4020791	Malathion	Non-National Finished Water	Yes	Yes
36734-19-7	DTXSID3024154	Iprodione	Non-National Finished Water	Yes	No
298-02-2	DTXSID4032459	Phorate	Non-National Finished Water	Yes	Yes
27314-13	DTXSID8024234	Norflurazon	Non-National Finished Water	Yes	Yes
2303-17-5	DTXSID5024344	Tri-allate	Non-National Finished Water	Yes	No
139-40-2	DTXSID3021196	Propazine	Non-National Finished Water	Yes	Yes
1689-84-5	DTXSID3022162	Bromoxynil	Non-National Finished Water	Yes	No
2312-35-8	DTXSID4024276	Propargite	Non-National Finished Water	Yes	No
141-66-2	DTXSID9023914	Dicrotophos	Non-National Finished Water	Yes	Yes
709-98-8	DTXSID8022111	Propanil	Non-National Finished Water	Yes	Yes
153719-23-4	DTXSID2034962	Thiamethoxam	Non-National Finished Water	Yes	No
10605-21-7	DTXSID4024729	Carbendazim (MBC)	Non-National Finished Water	Yes	No
55283-68	DTXSID8032386	Ethalfluralin	Non-National Finished Water	Yes	No
3397624	DTXSID1037806	Diaminochlorotriazine (DACT)	Non-National Finished Water	Yes	No
96182535	DTXSID1032482	Tebupirimfos	Non-National Finished Water	Yes	Yes
114261	DTXSID7021948	Propoxur	Non-National Finished Water	Yes	Yes
732116	DTXSID5024261	Phosmet	Non-National Finished Water	Yes	Yes
2164-17-2	DTXSID8020628	Fluometuron	Non-National Finished Water	Yes	Yes
C. Contaminant with Nationally Representative Finished Water Occurrence Data Lacking Qualifying Health Assessments					

CASRN	DTXSID	Common name	Best Available Occurrence Data	Is a Health Assessment Available?	Is an Analytical Method Available?
1634-04-4	DTXSID3020833	Methyl tert-butyl ether (MTBE)	National Finished Water	No	Yes
D. Contaminants with Qualifying Health Assessments Lacking Finished Water Occurrence Data					
3397-62-4	DTXSID1037806	6-Chloro-1,3,5-triazine-2,4-diamine	National Ambient Water	Yes	Yes
30560-19-1	DTXSID8023846	Acephate	National Ambient Water	Yes	Yes
84-65-1	DTXSID3020095	Anthraquinone	National Ambient Water	Yes	No
6190-65-4	DTXSID5037494	Deethylatrazine	National Ambient Water	Yes	No
3397-62-4	DTXSID0037495	Desisopropyl atrazine	National Ambient Water	Yes	Yes
333-41-5	DTXSID9020407	Diazinon	National Ambient Water	Yes	Yes
60-51-5	DTXSID7020479	Dimethoate	National Ambient Water	Yes	Yes
142459-58-3	DTXSID2032552	Flufenacet (Thiaflumide)	National Ambient Water	Yes	No
22967-92-6	DTXSID9024198	Methylmercury	National Ambient Water	Yes	No
13071-79-9	DTXSID2022254	Terbufos	National Ambient Water	Yes	Yes
126-73-8	DTXSID3021986	Tributyl phosphate (TNBP)	National Ambient Water	Yes	No
103476-24-0	DTXSID5021411	Tris(2-chloroethyl) phosphate (TCEP)	National Ambient Water	Yes	No
7440-33-7	DTXSID8052481	Tungsten	National Ambient Water	Yes	No
107-02-8	DTXSID5020023	Acrolein	National Ambient Water	Yes	Yes
95-63-6	DTXSID6021402	Trimethylbenzene (1,2,4-)	National Ambient Water	Yes	Yes
80-05-7	DTXSID7020182	Bisphenol A	National Ambient Water	Yes	No
143-50-0	DTXSID1020770	Chlordecone (Kepone)[2]	Non-national Ambient Water	Yes	Yes
741-58-2	DTXSID9032329	Bensulide	Non-national Ambient Water	Yes	Yes
16752-77-5	DTXSID1022267	Methomyl	Non-National Finished Water	Yes	Yes
E. Contaminants Lacking Nationally Representative Finished Water Occurrence Data and Qualifying Health Assessments					

CASRN	DTXSID	Common name	Best Available Occurrence Data	Is a Health Assessment Available?	Is an Analytical Method Available?
104-40-5	DTXSID3021857	4-Nonylphenol (all isomers)	Non-National Finished Water	No	Method in review
86386-73-4	DTXSID3020627	Fluconazole	Non-National Finished Water	No	No
93413628	DTXSID40869118	Desvenlafaxine	Non-National Finished Water	No	No

Key to Exhibit
National = Occurrence data that are nationally representative are available
Non-National = Occurrence data that are not nationally representative are available
Note: Data availability was not assessed for cyanotoxins, DBPs and PFAS.

Contaminants in Group A have nationally representative finished drinking water occurrence data and qualifying health assessments. Contaminants in Group B have finished drinking water occurrence data that is not nationally representative and qualifying health assessments. Contaminants in groups C, D, and E lack either a qualifying health assessment or finished water occurrence data and have more substantial data needs.

In addition, EPA assessed the data availability of the PCCL 5 chemicals that are not included on the Draft CCL 5. For more information on EPA methodology to identify data availability and summary tables, see Section 5.3 of the Chemical Technical Support Document (USEPA, 2021c).

IV. Request for Comments

The purpose of this document is to present the Draft CCL 5. EPA seeks comments on the following:

A. Contaminants selected for the Draft CCL 5, including any supporting data that can be used in developing the Final CCL 5.

B. Data that EPA obtained and evaluated for developing the Draft CCL 5 may be found in the Chemical Technical Support Document and Microbial Technical Support Document located in the docket for this document.

C. The improvements EPA implemented in the CCL 5 process.

EPA will take these comments into consideration when developing future CCLs. EPA will consider all information and comments received in determining the Final CCL 5, in the development of future CCLs, and in the agency's efforts to set drinking water priorities in the future.

V. EPA's Next Steps

Between now and the publication of the Final CCL 5, EPA will evaluate comments received during the public comment period for this document, consult with EPA's Science Advisory Board, and prepare the Final CCL 5 considering this input.

VI. References

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