

EPA Assistant Administrator for the Office of Water, Radhika Fox, signed the following notice on 10/28/2022, and EPA is submitting it for publication in the Federal Register (FR). While we have taken steps to ensure the accuracy of this Internet version, it is not the official version of the notice. Please refer to the official version in a forthcoming FR publication, which will appear on the Government Printing Office's FDsys website (<https://www.gpo.gov/fdsys/>). It will also appear on Regulations.gov (<https://www.regulations.gov/>) in Docket No. EPA-HQ-OW-2018-0594. Once the official version of the notice is published in the FR, the version shown here will be removed from the Internet and replaced with a link to the official version.

6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 141

[EPA-HQ-OW-2018-0594; FRL-7251-02-OW]

Drinking Water Contaminant Candidate List 5—Final

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is issuing the Contaminant Candidate List (CCL) which is a list of contaminants in drinking water that are currently not subject to any proposed or promulgated national primary drinking water regulations. In addition, these contaminants are known or anticipated to occur in public water systems and may require regulation under the Safe Drinking Water Act (SDWA). This list is the Fifth Contaminant Candidate List (CCL 5) published by the agency since the SDWA amendments of 1996. CCL 5 includes 66 chemicals, 3 chemical groups (cyanotoxins, disinfection byproducts (DBPs), and per- and polyfluoroalkyl substances (PFAS)), and 12 microbial contaminants.

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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 Contaminant Candidate List 5 (CCL 5) does not impose any requirements on regulated entities.

B. How can I get copies of this document and other related information?

1. Docket. EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2018-0594. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available electronically through www.regulations.gov or in hard copy at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Ave., NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m. to 4:30 p.m., Monday through Friday (except Federal Holidays). For further information on the EPA Docket Center services and the current status, see: <https://www.epa.gov/dockets>.

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2. Electronic Access. You may access this *Federal Register* document electronically from <https://www.federalregister.gov/documents/current>.

C. What is the purpose of this action?

The Safe Drinking Water Act (SDWA), as amended in 1996, requires EPA to publish a list every five years of currently unregulated contaminants that may pose risks for drinking water (referred to as the Contaminant Candidate List, or CCL). This list is subsequently used to make regulatory determinations on whether or not to regulate at least five contaminants from the CCL with national primary drinking water regulations (NPDWRs) ((SDWA section 1412(b)(1)). The purpose of this action is to publish the CCL 5, a summary of the major comments received on the draft CCL 5, and a summary of EPA's responses to those comments. Today's action only addresses the CCL 5. The Regulatory Determination (RD) process for contaminants on the CCL is a separate agency action.

D. Background and Statutory Requirements for CCL, Regulatory Determination and Unregulated Contaminant Monitoring Rule

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

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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 statute requires EPA to consult with the scientific community, including the Science Advisory Board (SAB) and to provide notice and opportunity for public comment. 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 (USEPA, 2021a).

2. Regulatory Determination

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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 (with a possible extension of 9 months).

3. Unregulated Contaminant Monitoring Rule

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.

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SDWA section 1445(a)(2), as amended in 1996, requires that once every five years, beginning in 1999, EPA issue a new list of no more than 30 unregulated contaminants to be monitored in drinking water by PWSs. This is known as the Unregulated Contaminant Monitoring Rule (UCMR). Monitoring is required by all PWSs serving more than 10,000 persons. The America's Water Infrastructure Act of 2018 expanded the requirements of the UCMR 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 and non-regulatory public health protection actions for emerging contaminants in drinking water. EPA has issued five UCMRs; UCMR 1 was published on September 17, 1999 (64 FR 50556, USEPA, 1999), UCMR 2 was published on January 4, 2007 (72 FR 368, USEPA, 2007), UCMR 3 was published on May 2, 2012 (77 FR 26072, USEPA, 2012), UCMR 4 was published on December 20, 2016 (81 FR 92666, USEPA, 2016a), and UCMR 5 on December 27, 2021 (86 FR 73131, USEPA, 2021b). UCMR 5 requires monitoring for 30 chemical contaminants between 2023 and 2025 using analytical methods developed by EPA or consensus

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organizations. Consistent with EPA's PFAS Strategic Roadmap (USEPA, 2021c), UCMR 5 will provide new data to improve the agency's understanding of the concentrations and the frequencies that 29 per- and polyfluoroalkyl substances (PFAS) and lithium occur in the nation's PWS; PFAS (as a group) and lithium are included on CCL 5.

E. Interrelationship between CCL, Regulatory Determination, and Unregulated Contaminant Monitoring Rule

The CCL is the first step in the SDWA regulatory framework for screening and evaluating a subset of contaminants that may require future regulation. The CCL serves as the initial screening of potential contaminants for consideration under EPA's Regulatory Determination (RD) process. However, inclusion on the CCL does not mean that any particular contaminant will necessarily be regulated in the future. A decision to exclude a contaminant from a CCL may be reconsidered during future CCL cycles and that contaminant could potentially be listed if new information indicates that the contaminant meets the SDWA requirements for listing.

The UCMR provides a mechanism to obtain nationally representative occurrence data for contaminants in drinking water. Traditionally, unregulated contaminants chosen by EPA for monitoring have been selected from the most current 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

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laboratory capacity to support a nationwide monitoring program. The contaminant occurrence data collected under 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 Regulatory Determination or UCMR.

F. Summary of Previous CCLs and Regulatory Determinations

1. The First Contaminant Candidate List

The First Contaminant Candidate List (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

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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 Second Contaminant Candidate List (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-

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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 Third Contaminant Candidate List (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

EPA published a positive 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 February 11, 2011 (76 FR 7762, USEPA, 2011). EPA published final determinations not to regulate four additional CCL 3 contaminants—dimethoate, 1,3-dinitrobenzene, terbufos and terbufos sulfone on

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January 4, 2016 (81 FR 13, USEPA, 2016b). EPA published a proposed rulemaking for perchlorate on June 26, 2019 (85 FR 43990, USEPA, 2019a), and sought public input on regulatory alternatives for perchlorate, including withdrawal of the previous positive regulatory determination. Based on the evaluation of public comments, and review of the updated scientific data, EPA withdrew the 2011 positive regulatory determination and made a final determination not to regulate perchlorate on July 21, 2020 (85 FR 43990, USEPA, 2020). EPA has since completed a review for the final determination for perchlorate in accordance with President Biden’s Executive Order 13990 “Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis” (86 FR 7037, Executive Office of the President, 2021). On March 21, 2022, the agency concluded that the 2020 decision not to regulate perchlorate is supported by the best available peer reviewed science. Additionally, EPA announced multiple integrated actions to ensure that public health is protected from perchlorate in drinking water.

7. The Fourth Contaminant Candidate List

EPA published the Fourth Candidate List (CCL 4) on November 17, 2016 (81 FR 81099, USEPA, 2016c). CCL 4 contained 97 chemicals or chemical groups and 12 microbial contaminants. All contaminants listed on 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.

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8. The Regulatory Determinations for CCL 4 Contaminants

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

II. What is on EPA’s Drinking Water Contaminant Candidate List 5?

CCL 5 includes 81 contaminants or contaminant groups (Exhibits 1a, 1b, and 1c). The list is comprised of 69 chemicals or chemical groups which include 66 chemicals, one group of cyanotoxins, one group of disinfection byproducts (DBPs), and one group of PFAS chemicals. The list also includes 12 microbes; specifically eight bacteria, three viruses, and one protozoa.

A. Chemical Contaminants

Exhibit 1a—Chemical Contaminants on 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
6-Chloro-1,3,5-triazine-2,4-diamine	3397-62-4	DTXSID1037806
Acephate	30560-19-1	DTXSID8023846

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Chemical Name	CASRN¹	DTXSID²
Acrolein	107-02-8	DTXSID5020023
alpha-Hexachlorocyclohexane	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
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
Ethalfuralin	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

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Chemical Name	CASRN ¹	DTXSID ²
Nonylphenol	25154-52-3	DTXSID3021857
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
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, separated 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.

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⁴ This group includes 23 unregulated DBPs as shown in Exhibit 1b.

⁵ For the purpose of CCL 5, the structural definition of per- and polyfluoroalkyl substances (PFAS) includes chemicals that contain at least one of these three structures (except for PFOA and PFOS which are already in the regulatory process):

1. R-(CF₂)-CF(R')R'', where both the CF₂ and CF moieties are saturated carbons, and none of the R groups can be hydrogen
2. R-CF₂OCF₂-R', where both the CF₂ moieties are saturated carbons, and none of the R groups can be hydrogen
3. CF₃C(CF₃)RR', where all the carbons are saturated, and none of the R groups can be hydrogen

Exhibit 1b—Unregulated DBPs in the DBP Group on 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)	5278-95-5	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)	76-06-2	DTXSID0020315
Dibromochloronitromethane (DBCNM)	1184-89-0	DTXSID00152114
Iodinated Trihalomethanes		
Bromochloroiodomethane (BCIM)	34970-00-8	DTXSID9021502
Bromodiiodomethane (BDIM)	557-95-9	DTXSID70204235
Chlorodiiodomethane (CDIM)	638-73-3	DTXSID20213251
Dibromoiodomethane (DBIM)	593-94-2	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

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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

B. Microbial Contaminants

Exhibit 1c—Microbial Contaminants on CCL 5

Microorganism	Type of Microorganism
Adenovirus	Virus
Caliciviruses	Virus
<i>Campylobacter jejuni</i>	Bacteria
<i>Escherichia coli (O157)</i>	Bacteria
Enteroviruses	Virus
<i>Helicobacter pylori</i>	Bacteria
<i>Legionella pneumophila</i>	Bacteria
<i>Mycobacterium abscessus</i>	Bacteria
<i>Mycobacterium avium</i>	Bacteria
<i>Naegleria fowleri</i>	Protozoa
<i>Pseudomonas aeruginosa</i>	Bacteria
<i>Shigella sonnei</i>	Bacteria

III. Summary of the Approach Used to Identify and Select Candidates for the CCL 5

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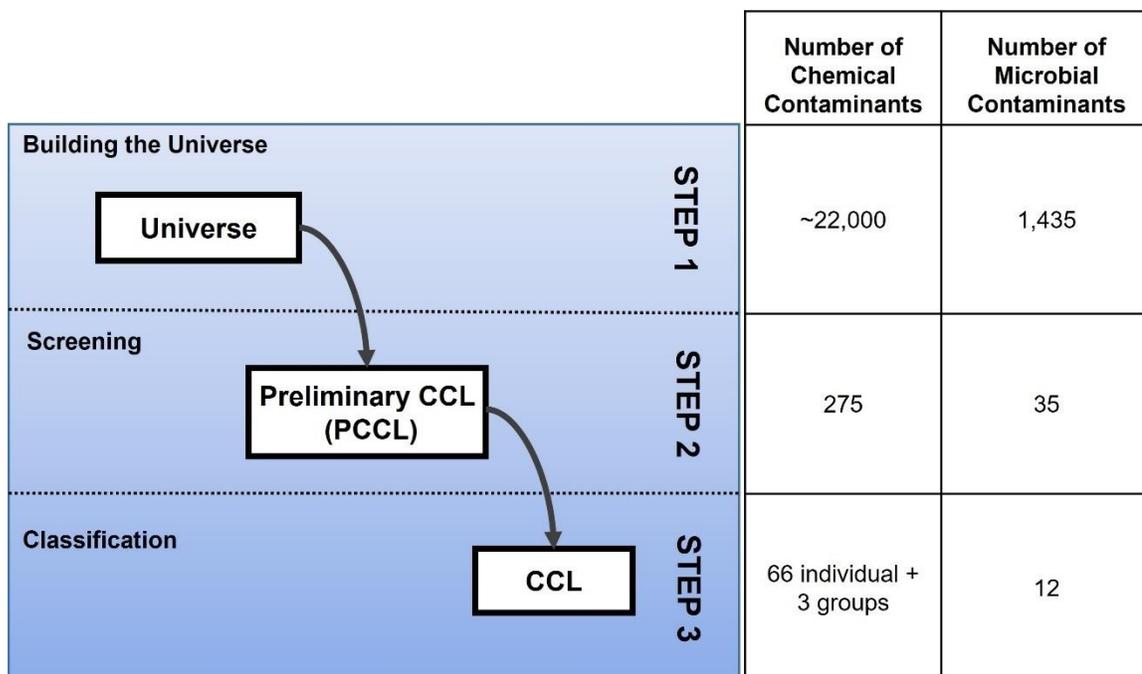
A. Overview of the Three-Step Development Process

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 public and the SAB. Therefore, in developing the 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 2 illustrates a generalized 3-step process EPA applied to both chemical and microbial contaminants for the CCL 5. The agency began with a large Universe of contaminants, screened it down to a Preliminary CCL 5 (PCCL 5), selected the Draft CCL 5, then published for public comment. The specific execution of particular steps differed in detail for the chemical and microbial contaminants. Each step of the CCL 5 process and associated number of chemical and microbial contaminants are described in the remainder of Section III of this document.

Exhibit 2—Generalized CCL 5 Development Process and Contaminant Counts

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1. Chemical Contaminants

EPA followed the three-step process illustrated in Exhibit 2 to identify chemicals for inclusion on the 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

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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. Classification of PCCL 5 chemicals to select the 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 CCL 5.

A detailed description of the processes used to develop the CCL 5 of chemicals using these steps can be found in the Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5) - Chemical Contaminants (USEPA, 2022a), referred to hereafter as the Final CCL 5 Chemical Technical Support Document.

2. Microbial Contaminants

EPA also followed the three-step process illustrated in Exhibit 2 to identify microbes for inclusion on the 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.

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- Step 3. Selecting the 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 a CCL 4 SAB recommendation. EPA re-examined all 12 microbial exclusionary screening criteria used in previous CCLs and modified one criterion for the CCL 5. A detailed description of these steps used to select microbes for the CCL 5 can be found in the Technical Support Document for the Final Fifth Candidate List (CCL 5) – Microbial Contaminants (USEPA, 2022b), referred to hereafter as the Final CCL 5 Microbial Technical Support Document.

B. Summary of Nominated Candidates for the CCL 5

EPA sought public nominations in a *Federal Register* notice (FRN) 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). EPA received nominations for 89 unique contaminants from 29 different organizations and/or individuals for the CCL 5, including 73 chemicals and 16 microbes. EPA compiled and reviewed the information from the nominations process to identify the nominated contaminants and any sources of supporting data submitted that could be used to supplement the data gathered by EPA to inform selection of the CCL 5. Nominated contaminants included chemicals used in commerce, pesticides, disinfection byproducts, pharmaceuticals, naturally occurring

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elements, biological toxins, and waterborne pathogens. Contaminants nominated for consideration for the CCL 5 are shown in Exhibits 3a and 3b. 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 Final CCL 5 Chemical Technical Support Document (USEPA, 2022a) and in Section 2.1 of the Final CCL 5 Microbial Technical Support Document (USEPA, 2022b).

Exhibit 3a—Chemical Contaminants Nominated for Consideration on CCL 5

Chemical Name	CASRN	DTXSID
1,1-Dichloroethane	75-34-3	DTXSID1020437
1,4-Dioxane	123-91-1	DTXSID4020533
1-Phenylacetone ²	103-79-7	DTXSID1059280
2-(N-Methylperfluorooctane sulfonamido)acetic acid (Me-PFOA-AcOH)	2355-31-9	DTXSID10624392
2-(N-Ethyl perfluorooctane sulfonamido) acetic acid (Et-PFOA-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 ²	29593-26-8	DTXSID30183774
4,8-Dioxa-3H-perfluorononanoic acid (ADONA)	919005-14-4	DTXSID40881350
6-Monoacetylmorphine ²	2784-73-8	DTXSID60182154
Ammonium perfluoro-2-methyl-3-oxahexanoate	62037-80-3	DTXSID40108559
Anatoxin A	64285-06-9	DTXSID50867064

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Chemical Name	CASRN	DTXSID
Azinphos-methyl	86-50-0	DTXSID3020122
Benzoic acid ²	65-85-0	DTXSID6020143
Benzoic acid glucuronide ²	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
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
Dibromochloroacetic acid (DBCAA)	5278-95-5	DTXSID3031151
Dibromochloronitromethane (DBCNM)	1184-89-0	DTXSID00152114
Dibromiodomethane (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
Hippuric acid ²	495-69-2	DTXSID9046073
Hydromorphone ²	466-99-9	DTXSID8023133
Hydromorphone-3-glucuronide ²	No CASRN	NO_DTXSID
Hydroxyamphetamine ²	103-86-6	DTXSID3023134
Isodrin (Pholedrine, 4-Hydroxymethamphetamine) ²	465-73-6	DTXSID7042065

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Chemical Name	CASRN	DTXSID
Manganese	7439-96-5	DTXSID2024169
Methamphetamine ²	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 ²	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

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Chemical Name	CASRN	DTXSID
Perfluorononanoic acid (PFNA)	375-95-1	DTXSID8031863
Perfluorooctanesulfonamide (PFOSA)	754-91-6	DTXSID3038939
Perfluorooctane sulfonic acid (PFOS)	1763-23-1	DTXSID3031864
Perfluorooctanoic acid (PFOA)	335-67-1	DTXSID8031865
Perfluorotetradecanoic acid (PFTA) ¹	376-06-7	DTXSID3059921
Perfluorotridecanoic acid (PFTrDA) ¹	72629-94-8	DTXSID90868151
Perfluoroundecanoic acid (PFUA/PFU _n A)	2058-94-8	DTXSID8047553
Phenylpropanolamine ²	37577-28-9	DTXSID4023466
Strontium	7440-24-6	DTXSID3024312
Tribromoacetic acid (TBAA)	75-96-7	DTXSID6021668
Triiodomethane (TIM)	75-47-8	DTXSID4020743

¹Other acronyms that may be used: Perfluorotetradecanoic acid (PFTetDA) and Perfluorotridecanoic acid (PFTriDA).

²Thirteen 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 CCL 5. See Section 4.2.1.1 of the Final CCL 5 Chemical Technical Support Document for more information.

Exhibit 3b—Microbial Contaminants Nominated for Consideration on CCL 5

Microorganism
Adenovirus
<i>Aeromonas hydrophila</i>
Caliciviruses
<i>Campylobacter jejuni</i>
Enterovirus
<i>Escherichia coli</i> (O157)
<i>Helicobacter pylori</i>
Hepatitis A virus

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Microorganism
<i>Legionella pneumophila</i>
<i>Mycobacterium species predominantly found in drinking water</i>
<i>Mycobacterium avium</i>
<i>Naegleria fowleri</i>
Non-tuberculous Mycobacterium (NTM)
<i>Pseudomonas aeruginosa</i>
<i>Salmonella enterica</i>
<i>Shigella sonnei</i>

1. Chemical Nominations and Listing Outcomes

EPA reviewed the 73 publicly nominated chemical contaminants and included 47 out of the 73 on the CCL 5. Four publicly nominated chemicals were included on the 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 CCL 5 (i.e., the cyanotoxin, DBP, and PFAS groups).

To evaluate the chemical nominations, EPA first compared the publicly nominated chemical contaminants with the top 250th scored chemicals and identified 19 chemicals which were already included in the top 250 chemicals of the scored CCL 5 Chemical Universe and not subject to proposed or promulgated NPDWRs. If a nominated chemical was part of the top 250 chemicals, then EPA had already identified and

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extracted health effects and occurrence data on this chemical from primary data sources in Step 1, Building the Chemical Universe. Some nominated chemicals were not included in the CCL 5 Chemical Universe; they would require further data collection to be evaluated for listing on the CCL 5. To identify additional data for these nominated chemicals, EPA assessed data sources cited with public nominations using the CCL-specific assessment factors (described in Section 2.2 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a)) 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. EPA also conducted literature searches to identify additional health effects and occurrence data; more information on the literature searches can be found in Section 4.2 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a).

EPA could not identify occurrence data for 13 nominated chemicals (noted in Exhibit 3a) 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 EPA should not advance

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these chemicals further in the CCL 5 process. However, four of these nominated chemicals were evaluated for possible research needs (see Chapter 5 of the Final CCL 5 Chemical Technical Support Document; USEPA, 2022a). More detailed information about how nominated chemicals were considered for CCL 5 can be found in Section 3.6 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a).

2. Microbial Nominations and Listing Outcomes

EPA reviewed the nominated microbial contaminants to determine if the microorganisms nominated were already included as a part of the CCL 5 Microbial Universe. EPA also collected additional data, when available, for the nominated microbial contaminants from data sources 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 developed for the CCL 3. A more detailed description of the data sources used to evaluate microbial contaminants for the CCL 5 can be found in the Final CCL 5 Microbial Technical Support Document (USEPA, 2022b).

All microbes nominated for the CCL 5, except for *Salmonella enterica*, *Aeromonas hydrophila*, Hepatitis A, and Non-tuberculous Mycobacterium (NTM) as a group are listed on the CCL 5. *Salmonella enterica*, *Aeromonas hydrophila* and Hepatitis A did not produce sufficient composite scores to place them on the CCL 5. Although *Salmonella enterica* and Hepatitis A have numerous outbreaks reported in Centers of

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Disease Control (CDC) National Outbreak Reporting System (NORS), the route of exposure was not reported as waterborne in NORS. Non-tuberculous Mycobacterium (NTM) and *Mycobacterium* (species broadly found in drinking water) were nominated for the CCL 5 and are not listed on the CCL 5 as a group; instead, two species of NTM that are found in drinking water, *Mycobacterium avium* and *Mycobacterium abscessus*, are listed.

C. Chemical Groups on the CCL 5

In addition to the 66 individual chemicals listed on the CCL 5, EPA is listing cyanotoxins, DBPs, and PFAS as chemical groups instead of listing them as individual chemicals. One of the primary goals of the CCL process is to identify priority contaminants for further evaluation under the regulatory determination process and/or additional research and data collection. These chemical groups meet the CCL SDWA requirements and were also identified as agency priorities and contaminants of concern for drinking water under other EPA actions. Therefore, EPA is listing these three groups on CCL 5. EPA's approach to listing cyanotoxins, DBPs, and PFAS as groups on CCL 5 as opposed to listing them as individual contaminants limits duplication of agency efforts, such as data gathering, analyses and evaluations. Listing these three chemical groups on the 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

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determinations. When making a determination to regulate a group, subgroup, or individual contaminants in the group, EPA must evaluate the group, subgroup, or individual contaminants under the three criteria in SDWA Section 1412(b)(1)(A).

Addressing the public health concerns of cyanotoxins in drinking water remains an agency 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”). Cyanotoxins were included on CCL 4 as an aggregate group in order to encompass all toxins produced by cyanobacteria (including, but not limited to, microcystins, cylindrospermopsin, anatoxin-a and saxitoxins). The reason for this decision, and as stated in CCL 4, is the similar sources of cyanotoxins (i.e., cyanobacteria) indicate their management may be similar. EPA listed cyanotoxins as a group on the CCL 5, identical to the CCL 4 listing.

From 2018 to 2021 under EPA’s Fourth Unregulated Contaminant Monitoring Rule (UCMR 4) Program, EPA coordinated with public water systems on the collection and reporting of nationally-representative finished drinking water cyanotoxin occurrence data for 10 cyanotoxins/cyanotoxin congeners. The final UCMR 4 data were published on February 18, 2022. UCMR 4 resulted in a low percentage of detections above the reference concentration and/or the national drinking water health advisory levels for the cyanotoxins monitored under UCMR 4. However, there are cyanotoxins that were not

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monitored as a part of UCMR 4. Also, significant health effects data and/or occurrence data are lacking for many of them (e.g., euglenophycin and saxitoxins). The prevalence, duration and frequency of HABs in freshwater is expanding in the U.S. and HABs continue to present a challenge for many state and local drinking water programs. Therefore, cyanotoxins continue to pose a potential public health risk and remain listed as a group on CCL 5.

EPA is also listing 23 unregulated DBPs (as shown in Exhibit 2b) as a group on the CCL 5; either these DBPs were publicly nominated, among the top 250 chemicals, or both. DBPs are formed when disinfectants react with naturally occurring materials in water. Under the Six-Year Review 3 (SYR 3), EPA identified 10 regulated DBPs (all but bromate) as “candidates for revision” (USEPA, 2017). EPA is conducting analyses to further evaluate the candidates for potential regulatory revisions identified under SYR 3 known as the Microbial Disinfection Byproducts (MDBP) Rule Revisions. Additionally, under the MDBP rule revisions effort, EPA is also evaluating information on unregulated DBPs.

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 may have been manufactured and used in a variety of industries worldwide since the 1940s (USEPA,

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2019b). Additionally, chemical intermediates, degradates, processing aids, and by-products of PFAS manufacturing may also meet one or more of the structural definitions of PFAS making the listing of PFAS individually on the CCL 5 difficult and challenging. Listing PFAS as a group is responsive to public nominations which stated that EPA should “include PFAS chemicals as a class on CCL 5,” and was supported by many public commenters and the SAB. EPA is listing PFAS as a group inclusive of any PFAS that fit the revised CCL 5 structural definition (except for PFOA and PFOS which have a proposed national primary drinking water regulation planned for late 2022). For the purposes of CCL 5, the structural definition of per- and polyfluoroalkyl substances (PFAS) includes chemicals that contain at least one of these three structures:

- 1) $R-(CF_2)-CF(R')R''$, where both the CF_2 and CF moieties are saturated carbons, and none of the R groups can be hydrogen
- 2) $R-CF_2OCF_2-R'$, where both the CF_2 moieties are saturated carbons, and none of the R groups can be hydrogen
- 3) $CF_3C(CF_3)RR'$, where all the carbons are saturated, and none of the R groups can be hydrogen.

EPA is also providing a list of PFAS that meet the CCL 5 structural definition (WATER|EPA: Chemical Contaminants - CCL 5 PFAS subset) on its CompTox dashboard (<https://comptox.epa.gov/dashboard/chemical-lists>).

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Listing PFAS as a group on CCL 5 supports the agency's commitment to better understand and ultimately reduce the potential risks caused by this broad class of chemicals. It also demonstrates the agency's commitment to prioritizing and building a strong foundation of science on PFAS while working to harmonize multiple statutory authorities to address the impacts of PFAS on public health and the environment.

EPA is also aware there may be emerging contaminants such as fluorinated organic substances that may be used in or are a result of the PFAS manufacturing process (e.g., starting materials, intermediates, processing aids, by-products and/or degradates) that do not meet the structural definition. Those emerging PFAS contaminants or contaminant groups may be known to occur or are anticipated to occur in public water systems, and which may require regulation. If emerging PFAS contaminants or contaminant groups are identified, EPA may consider moving directly to the regulatory determination process or consider listing those contaminants for future CCL cycles. EPA will continue to be proactive in considering evolving occurrence and health effects data of these emerging contaminants.

IV. What Comments Did EPA Receive on the Draft CCL 5 and How Did the Agency Respond?

A. Public comments

With publication of the Draft CCL 5 in a *Federal Register* notice on July 19, 2021 (86 FR 37948, USEPA, 2021e), EPA sought public comment on the following topics:

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1. Contaminants that EPA selected for the Draft CCL 5, and any supporting data that could assist with developing the Final CCL 5.
2. Existing data that EPA obtained and evaluated for developing the Draft CCL 5.
3. Improvements that EPA implemented for developing the Draft CCL 5.

The agency received a total of 54 unique comment letters from the public within the allotted 60-day comment period. EPA considered all public comments, data and information provided by commenters related to finalizing the CCL 5. EPA prepared responses to all public comments and included them in the “Comment Response Document for the Draft Fifth Drinking Water Contaminant Candidate List (CCL 5) - Categorized Public Comment),” which is available in the docket for this action (USEPA, 2022d). A summary of the public’s comments for the Draft CCL 5, along with EPA’s responses, are provided in this section.

1. General Comments

EPA received many general comments related to the Draft Fifth Contaminant Candidate List (CCL 5), including comments supporting EPA’s mission of protecting human health by continuing to regulate contaminants in drinking water and identifying drinking water contaminants that may require regulation. EPA also received multiple comments supporting the CCL purpose and process.

2. Chemical Process and Chemical Contaminants

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EPA received multiple comments in support of continued improvements to CCL documentation, with several commenters recommending specific steps to facilitate transparency and clear communication of the CCL process. Two commenters requested that EPA expand on contaminants that appeared on CCL 4 but were not listed on CCL 5. In response to this comment EPA has provided a table in Appendix O of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a).

a. Chemical Data/Data Sources

EPA received two comments related to chemical data and data sources used in developing the CCL 5. This included a comment supporting the agency's use of preliminary Fourth Unregulated Contaminant Monitoring Rule (UCMR 4) data to develop the CCL 5 and the agency's "decision to no longer exclude chemicals that could pose a public health risk through drinking water exposure from the CCL universe solely because they lack health or occurrence data." EPA also received a recommendation for the agency to expand the use wastewater data and data collected under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). EPA will consider expanding its uses of wastewater data and data collected under FIFRA and TSCA for future CCL cycles.

EPA received comments requesting clarification on EPA's effort to combine the health data from multiple forms of some chemical contaminants when constructing the CCL 5 Chemical Universe. Another commenter had specific concerns about the chemical

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information sheets (CIS) for cypermethrin which included data for multiple isomers of the contaminant. In response to these comments, EPA has updated the Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) - Contaminant Information Sheet (USEPA, 2022c) for five contaminants to clarify which data entries are associated with which forms of the contaminant; these include cypermethrin, lithium, manganese, propiconazole, and vanadium.

b. Chemical Groups

EPA received many comments related to the inclusion of three contaminant groups on the CCL 5: cyanotoxins, disinfection byproducts (DBPs), and per- and polyfluoroalkyl substances (PFAS). Many commenters expressed support for listing these three groups on the CCL 5, while many were opposed or expressed concerns with the ways the groups were defined.

i. Cyanotoxins

EPA received comments supporting listing cyanotoxins as a group on the CCL 5. Supportive commenters noted the increase in frequency in harmful algal blooms (HABs) in drinking water sources, the widespread occurrence of cyanotoxins and often in complex mixtures, the harmful effects to humans and animals, and the challenges state drinking water treatment facilities face with water quality changes from HABs and removing cyanotoxins in a safe yet cost-effective way.

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In contrast, EPA received a comment suggesting that EPA explain the rationale for retaining cyanotoxins on the CCL 5. The commenter pointed to the low occurrence results of the cyanotoxins monitored under UCMR 4. For EPA's rationale, see section III.C of this document.

ii. DBPs

EPA received comments supporting listing unregulated DBPs on CCL 5. One commenter specifically supported listing bromochloroacetic acids (BCAA) as one of the unregulated DBPs in the group, noting the contaminant causes abnormalities in laboratory animals and is commonly found in drinking water. Another supporting commenter of listing unregulated DBPs also recommends that EPA work to fill research gaps for these contaminants, because few DBPs have been quantitatively assessed for their occurrence and health effects. The commenter further states that occurrence and health effects as well as additional data on the accuracy and reliability of analytical methods for detecting unregulated DBPs would be beneficial as EPA considers revisions to the MDBP rule regulations.

A commenter asked the agency to provide justification on the lack of health effects and occurrence information for the DBPs listed on the CCL 5 and on the selection of the 23 DBPs from hundreds of known DBPs. The commenter also stated that EPA should present the supporting data for including DBPs as a group in the CCL, since there are marked differences in occurrence and health effects information among these DBPs.

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The commenter did agree with EPA's stated intent of evaluating DBPs in a coordinated manner to assure adequate disinfection. Many commenters supported EPA's decision that DBPs should be listed as a group and suggested DBPs should be considered for regulatory determination and/or under the efforts of the Microbial Disinfection Byproducts Rule revisions.

For CCL 5, the group of 23 unregulated DBPs includes the DBPs that were publicly nominated and/or in the top 250 scored CCL 5 Universe chemicals (outlined in Appendix P of the Final CCL 5 Chemical Technical Support Document). These DBPs bypassed the evaluation teams' review due to the ongoing EPA actions to consider revisions to five microbial and disinfection byproduct (MDBP) drinking water regulations in which EPA is also evaluating information on unregulated DBPs. Under the third Six-Year Review (SYR 3), EPA identified eight National Primary Drinking Water Regulations (NPDWRs) covered by five Microbial and Disinfection Byproducts (MDBP) rules as "candidates for revision" (USEPA, 2017). EPA is currently conducting analyses and consulting with the NDWAC to further evaluate these candidates and several unregulated DBPs for regulation under the potential revisions to the Microbial Disinfection Byproducts (MDBP) Rules. Additional information on the group of 23 unregulated DBPs on CCL 5 is included in Section 4.7 of the Final CCL 5 Chemical Technical Support Document.

iii. PFAS

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Some comments supported listing chemicals as groups on the CCL 5 and in particular listing PFAS as a group. However, EPA received extensive comments opposing the Draft CCL 5 PFAS structural definition for being too narrow and excluding PFAS such as perfluoro-2-methoxyacetic acid (PFMOAA), detected in the Cape Fear River source water and drinking water. For the CCL 5, EPA maintains its decision that the PFAS group meets the criteria for listing, which is that they are not yet subject to drinking water regulation, are known or “anticipated” to occur in drinking water systems and may require drinking water regulation. EPA’s decision to retain the group of PFAS on CCL 5 also aligns with the agency’s commitment to address PFAS, which was laid out in its October 2021 PFAS Strategic Roadmap (USEPA, 2021c).

EPA agrees with the commenters who recommended expanding the CCL 5 PFAS definition and in response, EPA is expanding the CCL 5 PFAS structural definition. For the CCL 5’s PFAS structural definition, see section III.C of this document.

EPA’s revised CCL 5 PFAS definition captures PFAS known to occur in drinking water and/or source water. Many of these were mentioned in the public comments, such as perfluoro-2-methoxyacetic acid (PFMOAA) and perfluoro-2-methoxy propanoic acid (PMPA). The revised definition maintains the draft CCL 5 PFAS structural definition but augments it to include additional PFAS substructures such as PFAS that are ethers or highly branched, persistent in water, and known to occur in drinking water and/or source water. This revised definition is only for the purposes of CCL 5. It is not meant to

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represent an agency-wide definition. The definition could be revised for future cycles as more information is gathered on PFAS. EPA includes additional language in this notice acknowledging emerging PFAS contaminants that EPA may consider moving directly to the regulatory determination process or consider listing those contaminants for future CCLs. The FRN also references EPA's Comptox Database which includes a CCL 5 PFAS list of over 10,000 PFAS substances that meet the Final CCL 5 PFAS definition.

c. Individual Chemical Contaminants

EPA received comments from multiple commenters regarding the listing status or information collected for individual contaminants listed on the Draft CCL 5. Some commenters expressed support for the listing of specific contaminants while others disagreed with EPA's evaluation and requested EPA reconsider listing specific contaminants on the Final CCL 5. EPA received comments pertaining to 1,4-dioxane, chlorpyrifos, cobalt, manganese, molybdenum, tungsten, and vanadium.

EPA received comments supporting the listing of 1,4-dioxane, chlorpyrifos, and manganese. Commenters cite the need for updated health assessments, concerns about new or existing health effects, occurrence, and use data, and potential benefits of Federal regulations for states as reasons for supporting the listing decision made by EPA.

EPA received comments requesting reevaluations of the listing decisions for cobalt, manganese, molybdenum, tungsten, and vanadium. Some commenters provided resources and analyses that they recommended EPA consider when listing a contaminant

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of interest. The recommendations provided by commenters frequently conflicted with established protocols and hierarchies that EPA applied uniformly across all chemical contaminants during the Classification step of CCL 5 described in Chapter 4 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a). However, EPA will consider these recommendations and comments on the protocol's strengths and weaknesses when reviewing potential modifications for future CCL cycles. Additionally, some recommendations, though outside the scope of the CCL process, may be useful during the Regulatory Determination process.

EPA maintained the listing of 1,4-dioxane, chlorpyrifos, cobalt, manganese, molybdenum, tungsten, and vanadium on the Final CCL 5 because they are known or anticipated to occur in public water systems, may require drinking water regulations, and therefore meet the SDWA requirements for listing on the CCL. EPA has provided individual responses to each comment received for individual contaminants in the *Response to Comments Document on the Draft Fifth Contaminant Candidate List (CCL 5)* document.

3. The Microbial Process and Microbial Contaminants

EPA received a comment that neither the Draft CCL 5 FRN nor the CCL 5 Microbial Technical Support Document (*Technical Support Document of the Draft Fifth Contaminant Candidate List-Microbial Contaminants*) described the weight-of-evidence approach used when applying the modification made to the exclusionary screening

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criteria applied to screen the microbial universe to the PCCL. The modification expanded Criterion 9 of the screening criteria to include nosocomial pathogens where drinking water-related infections were implicated. The comment also stated that if EPA finalizes CCL 5 retaining the incorporation of this modified criterion, it must more clearly describe its approach to implementing the revised criterion given that nosocomial infections occur under a unique combination of exposure scenarios and involve individuals that are very susceptible to infection. EPA addresses this comment by clarifying in the Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5) - Microbial Contaminants, the approach to implementing the revised criterion.

a. Comments on Individual Microbial Contaminants

EPA received comments on listing *Legionella pneumophila* and *Mycobacterium*. Two of the three commenters expressed support for listing the pathogen *Legionella pneumophila* on CCL 5, stating the burden *Legionella pneumophila* has on state drinking water programs. The third commenter recommended EPA address how the CCL 5 and MDBP rule revisions processes will interplay given the inclusion of the same contaminants, *Legionella pneumophila*, other pathogens, and DBPs being listed on CCL 5 as well as being considered in the MDBP rule revisions. EPA has listed *Legionella pneumophila* on CCL 5. The MDBP potential revisions are a separate agency action from CCL.

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EPA received one comment supporting the inclusion of *Mycobacterium avium* and *Mycobacterium abscessus* on CCL 5 and supports not listing Non-tuberculous Mycobacteria (NTM) as a group on the CCL. EPA has listed speciated *Mycobacterium* on the CCL 5, versus as a group.

4. Contaminants Not on CCL 5

EPA received one comment to include two microbial contaminants, Hepatitis A and *Salmonella enterica*, on CCL 5. Hepatitis A and *Salmonella enterica* are not listed for CCL 5. Although both contaminants were listed on past CCLs, nominated for CCL 5, and still pose public health concerns, the outbreak data from CDC's NORS indicate that the route of exposure is not waterborne for the majority of infections.

5. Suggestions to Improve Future CCLs

EPA received a comment to consider presenting CCL 5, and future CCLs, as an organized list that illustrates relative levels of potential risk and the gaps in information needed to craft risk management decisions. EPA does not organize CCLs based on "relative levels of potential risk" or "gaps needed to craft risk management decisions" because both of these actions require analysis and evaluation that is outside the scope of SDWA requirements for the CCL and align with the regulatory determinations and rule development process. However, EPA provides a table (Exhibit 4) in the FRN that shows the best available occurrence and health effects data for contaminants listed on CCL 5. Another commenter recommends that future CCLs be reviewed by an external expert

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panel in advance of the proposal. The commenter noted EPA prepared the Draft CCL 5 *Federal Register* notice without seeking external expert review as was recommended by NDWAC and has been past practice (e.g., CCLs 1 and 3). EPA will consider the use of an external expert panel for future CCLs.

The commenter notes the technical support documents do not describe any internal process control measures, making the role of an independent third-party review even more important. EPA includes a description of the data management and quality assurance steps taken for the chemical CCL 5 process in Chapter 6 of the CCL 5 Final Chemical Technical Support Document (USEPA, 2022a).

B. Recommendations from the EPA Science Advisory Board

On January 11, 2022, EPA held the first of five public meetings with the Science Advisory Board (SAB) Drinking Water Committee (DWC) Augmented for the CCL 5 review. During this initial meeting, EPA provided an overview of the process used to develop the Draft CCL 5 and answered questions from the Committee. EPA then requested Committee members to review the Draft CCL 5 materials and address the following charge questions:

1. Please comment on whether the *Federal Register* notice and associated support documents are clear and transparent in presenting the approach used to list contaminants on the Draft CCL 5. If not, please provide suggestions on

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how EPA could improve the clarity and transparency of the FRN and the support documents.

2. Please comment on the process used to derive the Draft CCL 5, including but not limited to, the CCL 5 improvements to assess potential drinking water exposure, consider sensitive populations, and prioritize contaminants that represent the greatest potential public health concern.

3. Based on your expertise and experience, are there any contaminants currently on the Draft CCL 5 that should not be listed? Please provide peer-reviewed information or data to support your conclusion.

4. Based on your expertise and experience, are there any contaminants which are currently not on the Draft CCL 5 that should be listed? Please provide peer-reviewed information or data to support your conclusion.

On February 16 and February 18, 2022, EPA reconvened with the SAB DWC to discuss preliminary responses to the charge questions and answer remaining questions. The Committee met again on June 6, 2022 to discuss a draft of the final report, and again on July 18, 2022 to discuss their recommendations for CCL 5 with the Chartered SAB. The SAB's final recommendations were provided in their report "Review of the EPA's Draft Fifth Drinking Water Contaminant Candidate List (CCL 5)" (USEPA, 2022e) to the EPA Administrator on August 19, 2022.

1. Overall SAB Recommendations

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The SAB commended EPA on the level of effort in developing the Draft CCL 5 and support documents. Overall, the SAB found the CCL 5 development process and documentation clear and transparent. The SAB provided many recommendations in response to EPA’s charge questions and emphasized the following “key” recommendations for CCL 5 and future CCLs to the Administrator.

- The SAB recommended that the EPA clarify the types of occurrence data that were included or rejected for consideration in development of the Draft CCL 5. In particular, clarifying how the literature review of the chemical contaminants in the Preliminary Contaminant Candidate List (PCCL) was conducted and used. Specifically, the SAB recommended providing an explicit list of the criteria used to screen chemical contaminants from the initial universe to form the PCCL before the point-based scoring is applied. The SAB suggested EPA explain the rationale for setting the threshold for the number of chemicals to be included on the Draft CCL 5 at 250.

EPA response: In response to SAB’s recommendation, the agency added clarification of how the occurrence literature review was conducted for the chemical process is described in Appendix E, Protocol of the Literature, of the Final CCL 5 Chemical Technical Support Document (2022a). The occurrence data that was considered for chemical contaminants can be found in the Appendix N, Data Management for CCL 5, of the Final CCL 5 Chemical Technical Support Document (2022a). Appendix N details the primary

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data sources that were considered for chemical contaminants. The information identified through the literature search was used to fill data gaps and provide additional information most relevant to drinking water exposure. This information was provided on the chemical CIS for the evaluators to consider when making their listing recommendations.

For past CCLs, EPA has received many comments about CCLs consisting of too many contaminants. With over 20,000 chemicals in the CCL 5 Universe and in response to past feedback, EPA used the screening scores to select and advance the top 250th scored chemicals for evaluation teams to review for potential inclusion on the CCL 5. Limiting the PCCL 5 to the top 250th scored chemicals, plus 53 nominated chemicals that were not already included in the top scored chemicals, focuses EPA's resources on those contaminants with sufficient data to evaluate whether they are known, or anticipated to occur in public water systems and those that pose the greatest potential public health concern. EPA conducted statistical analyses and developed a logistic regression model to validate selection of the top 250th scored chemicals for the PCCL 5. The results of those analyses are in Section 4.6 of the Final CCL 5 Chemical Technical Support document (USEPA, 2022a).

- The SAB supported the use of contaminant groups being listed on the CCL, but recommended transparency about the reasoning for listing contaminants as a group, and clarifying whether individual contaminants or subgroups within the groups should be prioritized. SAB also recommended EPA provide information

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on the criteria for grouping individual per- and polyfluoroalkyl substances (PFAS) and disinfection byproducts (DBPs) within the CCL 5. The SAB also recommended clarifying the justification for inclusion of cyanotoxins as a group despite relatively low occurrence data in the UCMR 4. In addition, the SAB recommended EPA elaborate on how listing contaminants as groups impacts the regulatory process.

EPA response: In response to SAB's recommendations, EPA has provided additional rationale for listing contaminants as groups on CCL 5 in Section III.C of this document. The objective of CCL is to identify priority contaminants for potential regulation. As described in Section III.C. of this document and also described in Section 4.7 of the Final CCL 5 Chemical Technical Support Document, cyanotoxins, DBPs, and PFAS are chemical groups that have already been identified as agency priorities and contaminants of concern for drinking water under other agency actions, including the 2015 Algal Toxin Risk Assessment and Management Strategic Plan for Drinking Water, EPA's decision to identify a number of microbial and disinfection byproducts (MDBPs) drinking water regulations as candidates for revision in the third Six-Year Review (SYR 3) of the NPDWRs, and the 2021 PFAS Strategic Roadmap.

EPA is listing cyanotoxins on CCL 5 as an aggregate group in order to encompass all toxins produced by cyanobacteria. For EPA's rationale see section III.C of this document.

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As information is available, EPA will evaluate the scientific data on the listed groups, including evaluating subgroups and/or individual contaminants within the groups to inform any regulatory determinations for the group, subgroup, or individual contaminants in the group.

- The SAB suggested that EPA elaborate on how sensitive populations were evaluated for chemical contaminant risks, clarify why immunosuppressed individuals are not considered sensitive populations and specify terminology regarding chronic disease and serious illness as risk factors when assessing microbial contaminant risks.

EPA response: As described in Final CCL 5 Chemical Technical Support Document section 4.3.1, sensitive populations were evaluated based on calculating health concentrations. For carcinogens, the health concentration is the one-in-a-million (10^{-6}) cancer risk expressed as a drinking water concentration. EPA applied age-dependent adjustment factors (ADAFs) to chemicals identified as having a mutagenic mode of action to account for risks associated with early life exposure to mutagenic carcinogens. For non-carcinogens, the toxicity value (RfD or equivalent) was divided by an exposure factor (i.e., body weight-adjusted drinking water intake; USEPA, 2019) relevant to the target population and critical effect and multiplied by a 20% relative source contribution (USEPA, 2000b). Target populations considered for CCL 5 include sensitive subpopulations such as bottle-fed infants, pregnant women, and lactating women. If a

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chemical has toxicity values based on both cancer and non-cancer data, EPA selected the endpoint that resulted in the most health protective value as the final health concentration.

As described in the FRN for the Draft CCL 5, EPA states “The SDWA refers to several categories of sensitive populations including children and infants, elderly, pregnant women, and persons with a history of serious illness.” Additionally, in the FRN for Draft CCL 5, EPA states “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.” EPA clarifies that the Agency does view immunocompromised individuals as a sensitive population, and immunocompromised populations are considered regardless of marked suppression of immune system and/or quality of health care when weighing health risks and when scoring the microbes’ severity for CCL. See the Final CCL 5 Microbial Technical Support Document CIS sheets for supporting information. EPA has clarified

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the terms “chronic disease” and “serious illness” in the Final CCL 5 Microbial Technical Support Document (USEPA, 2022b).

- The SAB recommended EPA provide clarification of the difference in approach used by the chemical and microbial processes in regard to weighing expert opinion on contaminants to be included on the CCL 5.

EPA response: For CCL 5, the microbial process relied on expert opinion for inclusion of contaminants on the CCL 5 due to the composite scores of the microbial PCCL 5 contaminants varying slightly (i.e., 0.1 difference) of each other and having no natural break in scores, as was the case with CCL 3 and CCL 4. To ensure CCL 5 was capturing the microbial contaminants with the greatest public health risk, EPA consulted with CDC microbial experts. For the CCL 5 chemical process, EPA relied on two evaluation teams, internal subject matter experts, to evaluate 214 PCCL 5 chemicals and provide listing recommendations for CCL 5.

- The SAB recommended expanding the CCL 5 definition of PFAS to be more inclusive of a broad range of compounds of potential health risk, recommending a definition that captures all relevant fluorinated compounds and degradates in commercial use or entering the environment.

EPA response: EPA revised the CCL 5 PFAS definition to be more inclusive. This revised definition maintains the Draft CCL 5 structural definition but is augmented to include additional PFAS substructures to address PFAS known to occur in drinking water

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and/or source water, such as Perfluoro-2-methoxyacetic acid (PFMOAA) and Perfluoro-2-methoxy propanoic acid (PMPA). This revised definition is only for the purposes of CCL 5. It is not meant to represent an agency-wide definition. The definition could be revised for future cycles as more information is gathered on PFAS. For more information on the CCL 5 PFAS group and structural definition, see Section IV.A.2.b.iii of this document.

- The SAB suggested that the definition and discussion of waterborne disease outbreaks (WBDO) as a criterion for microbial contaminant selection be expanded and relocated to earlier in the final FRN. The SAB further clarified that the discussion about WBDOs should include a clear outline of the definition, the limitations associated with the underlying data, how the data were used in the selection process, and how sensitive populations were considered. The SAB also recommended renaming “health effects” to “health risks” throughout the CCL 5 documents for both microbial and chemical contaminants.

EPA response: In the Final CCL 5 Microbial Technical Support Document, EPA defines WBDOs, and further clarifies how WBDO data are used in the selection process, and how sensitive populations were considered for microbial contaminants. EPA acknowledges there are limitations to the use of WBDO outbreak data and has expanded the discussion of WBDO criteria to include the limitations associated with WBDO data in the Final CCL 5 Microbial Technical Support Document (USEPA, 2022b).

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EPA agrees that the term “health risk” rather than “health effects” is a more appropriate term to use in some instances. EPA considers risk to be the chance of harmful effects to human health or to ecological systems resulting from exposure to an environmental stressor (USEPA, 2022f). An endpoint may be associated with a risk of a disease which is determined after evaluating the health effects, occurrence, and potential exposure data. There are instances in the CCL 5 process when EPA identifies an adverse health endpoint (or effect) from a health assessment but does not go further to analyze the risk of disease in humans and therefore the term “health effects” is appropriate. EPA has reviewed the use of the terms throughout the CCL 5 documents and made the appropriate changes.

- The SAB recommended including additional bisphenols, bisphenol F (BPF) and bisphenol S (BPS) on the Final CCL 5. In addition to saxitoxin (STX), the EPA should include other saxitoxins including neo-STX and dc-STX on the Final CCL.

EPA response: EPA reviewed the references provided by the SAB to support their recommendations for including Bisphenol S and F on CCL 5. However, there are still substantial health effects and occurrence data gaps for Bisphenol S and Bisphenol F to determine whether they are known, or anticipated to occur in public water systems and pose the greatest potential public health concern. Therefore, EPA is not listing them at this time. EPA will consider additional Bisphenols for future CCLs.

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Cyanotoxins is listed as a group on CCL 5. The group of cyanotoxins on CCL 5 includes, but is not limited to: Anatoxin-a, cylindrospermopsin, microcystins, and saxitoxin. As information is available, EPA will evaluate scientific data on the listed groups, subgroups, and/or individual contaminants included in the group to inform any regulatory determinations for the group, subgroup, or individual contaminants in the group.

- The SAB questioned how microbial organisms covered under existing regulations were listed on the CCL, for example *Legionella* and viruses covered by the Surface Water Treatment Rules (SWTRs) and Ground Water Rule (GWR). The SAB recommended that the EPA provide greater clarity on the process used to establish the list of microbial contaminants, as well as a rationale for carrying over most of the microbial contaminants from prior CCLs.

EPA response: Despite the MCLGs for *Legionella* and for viruses, these contaminants have limitations as a class under the SWTRs and GWR, and therefore lack contaminant-specific monitoring and filtration or treatment requirements. Because *Legionella* and viruses have known public health risks associated in water systems and do not have specific regulatory requirements, EPA believes it is appropriate to list these as unregulated contaminants for purposes of inclusion on the CCL.

For clarification, the microbial contaminants listed on CCL 5 that were listed on prior CCLs were not “carried-over”; these contaminants did not receive positive

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determinations through the regulatory determination process, and therefore are placed back into the microbial universe. After evaluating these contaminants through the CCL microbial process, their composite scores consisting of health effects and occurrence data supported listing them for CCL 5. EPA has provided additional clarity on the process and justification for each microbial contaminant included on the Final CCL 5 Microbial Technical Support Document (USEPA, 2022b).

- The SAB suggested providing a table containing the considered PFAS, similar to the table for DBPs.

EPA response: EPA is providing a list of PFAS chemicals included in the CCL 5 PFAS group (WATER|EPA: Chemical Contaminants - CCL 5 PFAS subset) on the EPA's CompTox Dashboard website under List of Chemicals (<https://comptox.epa.gov/dashboard/chemical-lists>).

- The SAB suggested that EPA consider grouping other compounds, such as organophosphate esters and triazines.

EPA response: EPA will take this recommendation into consideration for future CCLs.

- The SAB advised EPA to ensure that the CCL 5 microbial process incorporates the most up-to-date version of the Control of Communicable Diseases Manual.

EPA response: EPA used the most up-to-date version of the Manual of Clinical Microbiology (MCM) and where the Control of Communicable Disease Manual is cited, a newer citation from either the MCM or CDC is also cited. EPA will ensure the most up-

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to-date version of the Control of Communicable Diseases Manual be used in future CCLs.

- The SAB proposed that EPA clarify the process of selecting contaminants for monitoring under the UCMR when contaminants had *only* health effects or occurrence data.

EPA response: For each UCMR cycle, the UCMR program coordinates with the CCL program in establishing the list of contaminants for monitoring. UCMR considers contaminants listed on the CCL, other priority contaminants, and the opportunity to use multi-contaminant methods to collect occurrence data in an efficient, cost-effective manner.

EPA evaluates candidate UCMR contaminants using a multi-step prioritization process. The first step includes identifying contaminants that: (1) were not monitored under prior UCMR cycles; (2) may occur in drinking water; and (3) are expected to have a completed, validated drinking water analytical method in time for rule proposal. The next step considers the following: availability of health assessments or other health-effects information (e.g., critical health endpoints suggesting carcinogenicity); public interest (e.g., PFAS); active use (e.g., pesticides that are registered for use); and availability of occurrence data. EPA also considers stakeholder input; looks at the cost-effectiveness of the potential monitoring approaches; considers implementation factors

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(e.g., laboratory capacity); and further evaluates health effects, occurrence, and persistence/mobility data.

- The SAB recommended that EPA further describe the validity of the health effects linear scoring system for microbial contaminants.

EPA response: When the CCL microbial process was developed, it was recognized that pathogens may produce a range of illnesses, from asymptomatic infection to fulminate illness progressing rapidly to death. The health effect protocol scores are representative of common clinical presentation for specific pathogens for the population category under consideration. EPA believes the linear scoring system enables the reproducibility of the scores for health risks.

- The SAB suggested clarifying the reasons for calculating the Pathogen Total Score for microbial contaminants.

EPA response: EPA uses the composite pathogen score, which factors in the microbe's three attribute scoring protocols for occurrence, waterborne disease outbreaks, and health effects to score and the rank contaminants on the PCCL. The composite score normalizes the health effects (for the general population and for sensitive populations) and occurrence because the agency believes they are of equal importance. This scoring system also prioritizes and restricts the number of pathogens on the CCL to those that are strongly associated with water-related diseases.

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- SAB recommended EPA clarify the reason for using a 10-year timeframe for the supplemental literature review for the chemical contaminants' occurrence data.

EPA response: For CCL 5, EPA's goal was to conduct a targeted occurrence literature search for the chemical contaminants to identify supplemental data that would be more recent or provide more information on potential exposure from drinking water than information from primary data sources used to compile the CCL 5 Universe. For future CCLs, EPA will consider expanding the timeframe for occurrence literature searches for chemical contaminants.

- The SAB suggested that EPA compare the CCL 5 list to the European-based data to identify overlooked compounds of high concern.

EPA response: For CCL 5, EPA incorporated the use of several European data sources in the CCL 5 process. Appendix B of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a) list those data sources that were used as supplemental sources for CCL 5. For example, EPA searched for toxicity values such as derived no effect levels (DNELs) from European Chemicals Agency (ECHA) Registration Dossiers to derive CCL Screening Levels for chemicals of interest.

- The SAB recommended that EPA incorporate speciation information into the scoring system to aid in the justification for inclusion or exclusion of Vanadium in the Final CCL.

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EPA response: Based upon the data collected for CCL 5, including occurrence data collected for UCMR 3 and the available health assessments, EPA concludes that vanadium is known or anticipated to occur in public water systems and may require drinking water regulation and therefore meets the criteria for listing under the SDWA. EPA recognizes the value of data on vanadium speciation, both in terms of potential differences in health effects resulting from oral exposures and occurrence in water from public systems. EPA is aware that the National Toxicology Program (NTP) is currently conducting toxicity studies on vanadyl sulfate (+4) and sodium metavanadate (+5) to fill data gaps. When NTP publishes their subchronic study results, it will contribute to the vanadium health effects database to be considered for the Regulatory Determination Process and/or future CCL cycles.

- The SAB recommended removing *Shigella sonnei*, *Campylobacter* and *Helicobacter pylori* from the Final CCL 5. In addition, before finalizing CCL 5, the SAB also suggested that EPA conduct further evaluation of caliciviruses and provide further justification for including enteroviruses and Human Adenovirus on CCL 5.

EPA response: *Shigella sonnei*, *Campylobacter jejuni*, caliciviruses, enteroviruses, and adenovirus remain a concern for vulnerable water systems such as undisinfected (i.e., undisinfected ground water systems) or inadequately disinfected systems. EPA has

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provided additional supporting evidence and justification of inclusion of each microbial organism on the CCL 5 in the Final CCL 5 Microbial Technical Support Document.

- The SAB recommended that EPA clearly communicate the relative levels of potential risk and gaps in information needed to craft risk management decisions for PFAS.

EPA response: The SDWA requires EPA to follow a process to identify unregulated contaminants for potential regulation. The CCL is one of the many integral components of EPA's coordinated risk management process. The objective of CCL is to identify contaminants of concern in drinking water to inform and assist in priority-setting efforts for potential regulatory determination. The process of Regulatory Determination examines in depth if there is sufficient data for EPA to make a decision on whether EPA should initiate a rulemaking process to develop an NPDWR for a specific contaminant.

2. Recommendations for Future CCLs

For future CCLs, the SAB suggested that EPA bring the processes for selecting the chemical contaminants and the microbial contaminants into better alignment with each other, noting that currently the two processes differ in detail and technique. EPA recognizes the differences between the chemical and microbial processes due to differing metrics and data availability for contaminant assessment. Although the chemical and microbial processes differ, the overarching steps of the CCL process of building the universe, screening, and classification of contaminants are followed in parallel. However,

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for future CCLs, EPA will re-examine both the chemical and microbial processes to determine if there are benefits to aligning the two processes.

Specifically, for the CCL chemical process, the SAB recommended future CCLs consider evaluating contaminants such as: shorter lived pesticides that transform into longer-lived metabolites or degradates, urban runoff occurrence data in parallel with wastewater occurrence data, assess data gathered in Europe during the implementation of the REACH system, the NORMAN network, and IP-CHEM databases to assess contaminants in surface or drinking water, identify and assess by-products, impurities, and transformation products (including metabolites and degradates), persistent and mobile organic compounds (PMOCs), antimicrobials, microplastics, nanoparticles, and weigh whether to include manganese and tungsten on future CCLs.

To improve the CCL chemical processes, the SAB suggested the following for future CCLs: consider employing machine learning to identify whether there may be other compounds of concern within the baseline of compounds, report the range and median method detection limit and reporting limit for each occurrence dataset listed in the CIS and using this information to inform the prevalence score for chemical contaminants, ensure that data cited in secondary sources are from qualifying primary sources, observe anticipated speciation of metals in drinking water and potential source waters including groundwater. In addition, the SAB recommended that EPA develop a

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strategy to address the gap in occurrence data that will arise when the U.S. Geological Survey (USGS) discontinues its contaminants monitoring program.

For future CCLs EPA will consider evaluating the data sources that the SAB referenced for the groups of contaminants in their CCL 5 recommendations, including additional European-based data sources, to determine if those sources are appropriate to use as primary data sources when developing the chemical universe or supplemental data sources when filling data gaps for future CCLs. EPA will also consider evaluating the contaminants SAB has referenced. In addition, EPA will reconsider the use of machine learning in the future rounds of CCL. Also, EPA intends to continue to use the USGS compiled for CCL 5 for future CCLs but will consider other strategies to address the gap in occurrence data that will arise when the USGS ends its contaminant monitoring program.

For the microbial process, the SAB suggested future CCLs consider adding a group of pathogenic mycobacteria to focus research and public health protection on a more identifiable and actionable group of opportunistic pathogens in comparison to the nondescript NTM designation. EPA will take this recommendation into consideration for future CCLs.

3. EPA's Overall Response to SAB Recommendations

EPA has considered all SAB's comments and incorporated recommendations, where applicable, for the Final CCL 5 to increase the scientific concepts, clarity, and

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transparency of the decisions relative to the contaminants included on CCL 5. These updates/changes are reflected in the Final CCL 5 Chemical and Microbial Technical Support Documents (USEPA, 2022a and USEPA, 2022b, respectively). Other recommendations made by SAB in their final report (2022e) will be considered for future CCLs.

V. Data Availability for CCL 5 Contaminants

In an effort to provide current data availability of the CCL 5 contaminants with respect to occurrence and health effects data and EPA approved analytical methods, EPA has provided a summary table in Exhibit 4, depicting the CCL 5 chemicals categorized into five groups depending upon the availability of their occurrence data and peer-reviewed health assessment(s) containing oral toxicity values at the time of the Draft CCL 5 publication. The status of health effects data availability for the CCL chemical contaminants, as of the date by which each chemical was evaluated for placement on the Draft CCL 5 (February to July 2020) and for analytical methods (September 2020) is presented in Exhibit 4.

For individual chemicals of the cyanotoxins, DBPs and PFAS groups, the availability of health effects and occurrence data varies with individual chemicals in each group. The agency is addressing these groups broadly, instead of individually, 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.

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Exhibit 4—Data Availability/Information for the 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
95-53-4	DTXSID1026164	2-Aminotoluene	National Finished Water	Yes	Yes
51-28-5	DTXSID0020523	2,4-Dinitrophenol	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

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CASRN	DTXSID	Common name	Best Available Occurrence Data	Is a Health Assessment Available?	Is an Analytical Method Available?
7439-98-7	DTXSID1024207	Molybdenum	National Finished Water	Yes	Yes
42874-03-3	DTXSID7024241	Oxyfluorfen	National Finished Water	Yes	No
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
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
1689-84-5	DTXSID3022162	Bromoxynil	Non-National Finished Water	Yes	No
10605-21-7	DTXSID4024729	Carbendazim (MBC)	Non-National Finished Water	Yes	No
141-66-2	DTXSID9023914	Dicrotophos	Non-National Finished Water	Yes	Yes
55283-68	DTXSID8032386	Ethalfuralin	Non-National Finished Water	Yes	No
120068-37-3	DTXSID4034609	Fipronil	Non-National Finished Water	Yes	No
2164-17-2	DTXSID8020628	Fluometuron	Non-National Finished Water	Yes	Yes

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CASRN	DTXSID	Common name	Best Available Occurrence Data	Is a Health Assessment Available?	Is an Analytical Method Available?
36734-19-7	DTXSID3024154	Iprodione	Non-National Finished Water	Yes	No
121-74-5	DTXSID4020791	Malathion	Non-National Finished Water	Yes	Yes
27314-13	DTXSID8024234	Norflurazon	Non-National Finished Water	Yes	Yes
298-02-2	DTXSID4032459	Phorate	Non-National Finished Water	Yes	Yes
732-11-6	DTXSID5024261	Phosmet	Non-National Finished Water	Yes	No
709-98-8	DTXSID8022111	Propanil	Non-National Finished Water	Yes	Yes
2312-35-8	DTXSID4024276	Propargite	Non-National Finished Water	Yes	No
139-40-2	DTXSID3021196	Propazine	Non-National Finished Water	Yes	Yes
114-26-1	DTXSID7021948	Propoxur	Non-National Finished Water	Yes	Yes
96182-53-5	DTXSID1032482	Tebupirimfos	Non-National Finished Water	Yes	No
153719-23-4	DTXSID2034962	Thiamethoxam	Non-National Finished Water	Yes	No
2303-17-5	DTXSID5024344	Tri-allate	Non-National Finished Water	Yes	No
C. Contaminant with Nationally Representative Finished Water Occurrence Data Lacking Qualifying Health Assessments					
57-63-6	DTXSID5020576	17-alpha ethynyl estradiol	National Finished Water	No	Yes
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

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CASRN	DTXSID	Common name	Best Available Occurrence Data	Is a Health Assessment Available?	Is an Analytical Method Available?
30560-19-1	DTXSID8023846	Acephate	National Ambient Water	Yes	Yes
107-02-8	DTXSID5020023	Acrolein	National Ambient Water	Yes	No
84-65-1	DTXSID3020095	Anthraquinone	National Ambient Water	Yes	No
741-58-2	DTXSID9032329	Bensulide	Non-national Ambient Water	Yes	Yes
80-05-7	DTXSID7020182	Bisphenol A	National Ambient Water	Yes	No
143-50-0	DTXSID1020770	Chlordecone (Kepone)	Non-national Ambient Water	Yes	Yes
6190-65-4	DTXSID5037494	Deethylatrazine	National Ambient Water	Yes	No
1007-28-9	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
16752-77-5	DTXSID1022267	Methomyl	Non-National Finished Water	Yes	Yes
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	National Ambient Water	Yes	No
95-63-6	DTXSID6021402	Trimethylbenzene (1,2,4-)	National Ambient Water	Yes	Yes
115-96-8	DTXSID5021411	Tris(2-chloroethyl) phosphate (TCEP)	National Ambient Water	Yes	No

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CASRN	DTXSID	Common name	Best Available Occurrence Data	Is a Health Assessment Available?	Is an Analytical Method Available?
7440-33-7	DTXSID8052481	Tungsten	National Ambient Water	Yes	No
E. Contaminants Lacking Nationally Representative Finished Water Occurrence Data and Qualifying Health Assessments					
93413-62-8	DTXSID40869118	Desvenlafaxine	Non-National Finished Water	No	No
86386-73-4	DTXSID3020627	Fluconazole	Non-National Finished Water	No	No
104-40-5	DTXSID3021857	Nonylphenol	Non-National Finished Water	No	Method in review

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.

As shown in Exhibit 4, Group A are contaminants that have nationally representative finished drinking water data and a peer reviewed health assessment deriving an oral toxicity value and are likely to have sufficient data available to be placed on a short list for further assessment under RD 5. The contaminants in Group B have finished drinking water data that is not nationally representative and peer reviewed health assessments. Group B contaminants may have sufficient data to be placed on a short list for further assessment under RD 5, particularly if the non-nationally representative occurrence data shows detections at levels of public health concern. Contaminants in groups C, D, and E of Exhibit 4 are those that lack either a peer reviewed health assessment or finished water data have more substantial data needs and are unlikely to have sufficient information to allow further assessment under RD 5. For Groups C, D,

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and E, EPA plans to identify them as research priorities and work to fill their research needs such as evaluating the potential for monitoring under the UCMR program or identifying those contaminants as priorities for health effects research. In addition, EPA assessed the data availability of the PCCL 5 chemicals that are not included on CCL 5. For more information on EPA methodology to identify data availability and summary tables, see Chapter 5 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a).

The SAB and other commenters have recommended additional prioritization of the CCL 5 contaminants to communicate research needs, help focus efforts for researchers, and inform future regulatory decision-making. EPA acknowledges that multiple contaminants on the CCL 5 have substantial data and information needs to fulfill in order for the agency to make a regulatory determination in accordance with SDWA 1412 (b)(1)(A). By identifying those contaminants that need additional research and information, EPA is communicating to stakeholders both research priorities and gaps for these contaminants.

VI. Next Steps and Future Contaminant Candidate Lists

The CCL process is critical to shaping the future direction of drinking water regulations. The agency will continue to examine relevant research studies and gather additional data to prioritize CCL 5 contaminants to make regulatory determinations on at least five contaminants for Regulatory Determination 5. The agency will also continue to

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refine the CCL process, gather and examine the best available data, and identify contaminants for the CCL 6. EPA expects to complete the CCL 6 in late 2026.

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Radhika Fox,
Assistant Administrator.

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