

The Acting Assistant Administrator for Water, signed the following notice on September 22, 2009, and EPA is submitting it for publication in the Federal Register. While we have taken steps to ensure the accuracy of this pre-publication version, it is not the official version. Please refer to the official version in a forthcoming Federal Register publication, or on GPO's website at <http://www.gpoaccess.gov/fr/index.html>.

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OW-2007-1189 FRL- _____ - _____]

RIN 2040-AD99

Drinking Water Contaminant Candidate List 3– Final

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The US Environmental Protection Agency is publishing the third Contaminant Candidate List (CCL 3) since the Safe Drinking Water Act (SDWA) amendments of 1996. The CCL 3 is a list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations, that are known or anticipated to occur in public water systems, and which may require regulation under SDWA. Today's final CCL 3 includes 104 chemicals or chemical groups and 12 microbiological contaminants.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2007-1189. All documents in the docket are listed on <http://www.regulations.gov>. Although listed in the index, some information is not publicly available. For example, confidential business information or other information whose disclosure is restricted by statute is not publicly available. Certain other material, such as copyrighted material, is not placed on the Internet and is only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the Water Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open

from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the EPA Docket Center is (202) 566-2426.

FOR FURTHER INFORMATION CONTACT: For information on chemical contaminants contact Thomas Carpenter, Office of Ground Water and Drinking Water, Standards and Risk Management Division, at (202) 564-4885 or e-mail carpenter.thomas@epa.gov. For information on microbial contaminants contact Tracy Bone, Office of Ground Water and Drinking Water, at (202)564-5257 or e-mail bone.tracy@epa.gov. For general information contact the EPA Safe Drinking Water Hotline at (800) 426-4791 or e-mail: hotline-sdwa@epa.gov.

Abbreviations and Acronyms

CASRN – Chemical Abstract Services Registry Number

CDC – Centers for Disease Control and Prevention

CCL – Contaminant Candidate List

CCL 1 – EPA’s First Contaminant Candidate List

CCL 2 – EPA’s Second Contaminant Candidate List

CCL 3 – EPA’s Third Contaminant Candidate List

CERCLA – Comprehensive Environmental Response, Compensation, and Liability Act

CFR – *Code of Federal Regulations*

CSF – Cancer Slope Factor

DBP – disinfection byproduct

EPA – United States Environmental Protection Agency

ESA – ethanesulfonic acid

FDA – United States Food and Drug Administration

FIFRA – Federal Insecticide, Fungicide, and Rodenticide Act

FR – Federal Register

HRL – Health Reference Level

ICR – Information Collection Request

IUR – Inventory Update Rule

MCL – maximum contaminant level

MCLG – maximum contaminant level goal

NCFAP – National Center for Food and Agricultural Policy

NDWAC – National Drinking Water Advisory Council

NDMA – N-nitrosodimethylamine

NIRS – National Inorganic Radiological Survey

NRC – National Academies of Science’s National Research Council

NPDWR – national primary drinking water regulation

OPP – Office of Pesticide Programs

PCCL – Preliminary CCL

PFOA – perfluorooctanoic acid

PFOS – perfluorooctane sulfonic acid

PWS – public water system

RAISHE – Risk Assessment Information System, Health Effects

RDX– Cyclotrimethylenetrinitramine

RfD – reference dose

RTECS – Registry of Toxic Effects for Chemical Substances

SAB – EPA Science Advisory Board

SDWA – Safe Drinking Water Act

TRI – Toxics Release Inventory

TNT – 2, 4, 6-trinitrotoluene

UCMR – Unregulated Contaminant Monitoring Regulation

UCMR 1 – First Unregulated Contaminant Monitoring Regulation

UCMR 2 – Second Unregulated Contaminant Monitoring Regulation

UCM R1/2 – Unregulated Contaminant Monitoring Round 1/2

US – United States of America

USGS – United States Geological Survey

WBDO – waterborne disease outbreak

WHO – World Health Organization

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SUPPLEMENTARY INFORMATION

I. General Information

A. Does this Action Impose Any Requirements on My Public Water System?

The final Contaminant Candidate List 3 (CCL 3) will not impose any requirements on anyone. Instead, this action notifies interested parties of the availability of US EPA's final CCL 3, and provides information on the Agency's next steps to evaluate these contaminants.

B. What is the Purpose of This Action?

The purpose of this action is to present the final CCL 3, a summary of the comments received on the draft CCL 3, and a description of the Agency's process for identifying contaminants to be placed on the list. Pursuant to section 1412(b)(1)(B)(i) of SDWA, as amended in 1996, EPA is required to publish a list of contaminants (1) that are currently unregulated, (2) that are known or anticipated to occur in public water systems, and (3) which may require regulations under the Safe Drinking Water Act (SDWA). This section briefly

summarizes the statutory requirements for CCL 3, and related activities surrounding the contaminants included on the final CCL 3.

C. SDWA Risk Management Provisions

1. Contaminant Candidate List 3

SDWA section 1412(b)(1) requires that in the development of the CCL, EPA consider specific data sources and include the scientific community. EPA must evaluate 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). SDWA also requires the Agency to consider the National Contaminant Occurrence Database established under section 1445(g) of SDWA. SDWA directs the Agency to consult with the scientific community, including the Science Advisory Board (SAB). In addition it directs the Agency to consider the health effects and occurrence information for unregulated contaminants to identify those contaminants that present the greatest public health concern related to exposure from drinking water.

EPA interprets the criterion that contaminants are known or anticipated to occur in public water systems broadly. In evaluating this criterion, EPA considers not only public water system monitoring data, but also data on ambient concentrations in surface and ground waters, and releases to the environment (e.g., Toxics Release Inventory). While such data may not establish conclusively that contaminants are known to occur in public water systems, EPA believes these data are sufficient to anticipate that contaminants may occur in public water systems and to place them on the CCL. Once contaminants have been placed on the CCL, EPA identifies if there are any additional data needs, including gaps in occurrence data.

In selecting contaminants for the CCL 3, each of the above requirements was met. The Agency considered adverse health effects that may pose a greater risk to life stages and other sensitive groups which represent a meaningful portion of the population. Adverse health effects associated with infants, children, pregnant women, the elderly, and individuals with a history of serious illness were evaluated for both chemicals and microbes.

2. Regulatory Determinations

SDWA section 1412(b)(1) requires EPA to determine whether to regulate at least five contaminants from the CCL every five years. SDWA specifies that EPA shall regulate a contaminant if the Administrator determines that:

- 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.

EPA interprets these criteria as more rigorous than what is used to place contaminants on the CCL. Section IV of this notice presents the current data needs for regulatory determination for the CCL 3 contaminants.

If EPA makes a determination that a national primary drinking water regulation is needed, then the Agency has 24 months to publish a proposed Maximum Contaminant Level

Goal (MCLG)¹ and a proposed National Primary Drinking Water Rule (NPDWR)². After the proposal, the Agency has 18 months to publish a final MCLG and promulgate a final NPDWR (SDWA 1412(b)(1)(E)).³

3. Unregulated Contaminant Monitoring

SDWA provides EPA with the authority to require all large and a subset of small systems to monitor for up to 30 unregulated contaminants every five years under the Unregulated Contaminant Monitoring Regulation (UCMR). The second unregulated contaminant monitoring rule (UCMR 2), which was promulgated on January 4, 2007 (72 *FR* 367; USEPA, 2007a), requires monitoring for several pesticides and pesticide degradates, five polybrominated diphenyl ether (PBDE) flame retardants, a group of nitrosamines, and two munitions (TNT and RDX). All of the chemicals on UCMR 2 were included among the contaminants evaluated for CCL 3.

Data collected under the UCMR are an important source of occurrence information for both the CCL and Regulatory Determination processes. There is an additional discussion of the relationship between CCL and UCMR in Section III. D of this *Federal Register (FR)* notice.

¹ An MCLG is the "maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and which allows an adequate margin of safety. Maximum contaminant level goals are non-enforceable health goals" (40 CFR 141.2).

² An NPDWR is a legally enforceable standard that applies to public water systems. An NPDWR sets a legal limit (called a maximum contaminant level or MCL) or specifies a certain treatment technique (TT) for public water systems for a specific contaminant or group of contaminants.

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

II. What is on EPA's Drinking Water Contaminant Candidate List 3?

The draft CCL 3 was published on February 21, 2008 (73 *FR* 9628; USEPA 2008a), and included 93 chemicals or chemical groups and 11 microbiological contaminants. EPA provided information and sought comment on its efforts to expand and strengthen the underlying CCL listing process, the draft list, and EPA's efforts to improve the contaminant selection process for future CCLs.

In developing the draft CCL 3, EPA implemented a new process from that used for CCL 1 and CCL 2. This new process builds on evaluations from previous CCLs, and was based on substantial expert input and recommendations from various groups, including the National Academy of Science's National Research Council (NRC) and the National Drinking Water Advisory Council (NDWAC). This process is summarized in the draft CCL 3 *FR* notice.

In general, the criteria for including a contaminant on the CCL consisted of determining whether the occurrence or anticipated occurrence of a contaminant was likely at levels of concern to human health. The draft CCL 3 notice solicited input from the public, and specifically requested comments on (1) the approach EPA used to create the list; (2) contaminants on the list; and (3) on specific contaminants such as pharmaceuticals, perfluorinated compounds, and microbes.

The final CCL 3 includes 104 chemicals or chemical groups and 12 microbiological contaminants (Exhibit 1). The list includes, among others, pesticides, biological toxins, disinfection byproducts, chemicals used in commerce, and waterborne pathogens. The Agency considered the best available data and information on health effects and occurrence to evaluate 7,500 unregulated contaminants and selected 116 candidates for the final CCL 3, which have the potential to present health risks through drinking water exposure.

Exhibit 1. Final Contaminant Candidate List 3:

Chemical Contaminants

CASRN	Common Name - Registry Name
630206	1,1,1,2-Tetrachloroethane
75343	1,1-Dichloroethane
96184	1,2,3-Trichloropropane
106990	1,3-Butadiene
99650	1,3-Dinitrobenzene
123911	1,4-Dioxane
57910	17 alpha-Estradiol
71363	1-Butanol
109864	2-Methoxyethanol
107186	2-Propen-1-ol
16655826	3-Hydroxycarbofuran
101779	4,4'-Methylenedianiline
30560191	Acephate
75070	Acetaldehyde
60355	Acetamide
34256821	Acetochlor
187022113	Acetochlor ethanesulfonic acid (ESA)
184992444	Acetochlor oxanilic acid (OA)
107028	Acrolein
142363539	Alachlor ethanesulfonic acid (ESA)
171262172	Alachlor oxanilic acid (OA)
319846	alpha-Hexachlorocyclohexane
62533	Aniline
741582	Bensulide
100447	Benzyl chloride
25013165	Butylated hydroxyanisole
133062	Captan
14866683	Chlorate
74873	Chloromethane (Methyl chloride)
110429624	Clethodim
7440484	Cobalt
80159	Cumene hydroperoxide
NA	Cyanotoxins
141662	Diclotophos
55290647	Dimethipin
60515	Dimethoate
298044	Disulfoton
330541	Diuron
517099	Equilenin

474862	Equilin
114078	Erythromycin
50282	Estradiol (17-beta estradiol)
50271	Estriol
53167	Estrone
57636	Ethinyl Estradiol (17-alpha Ethynyl Estradiol)
13194484	Ethoprop
107211	Ethylene glycol
75218	Ethylene oxide
96457	Ethylene thiourea
22224926	Fenamiphos
50000	Formaldehyde
7440564	Germanium
74975	Halon 1011 (bromochloromethane)
75456	HCFC-22
110543	Hexane
302012	Hydrazine
72333	Mestranol
10265926	Methamidophos
67561	Methanol
74839	Methyl bromide (Bromomethane)
1634044	Methyl tert-butyl ether
51218452	Metolachlor
171118095	Metolachlor ethanesulfonic acid (ESA)
152019733	Metolachlor oxanilic acid (OA)
2212671	Molinate
7439987	Molybdenum
98953	Nitrobenzene
55630	Nitroglycerin
872504	N-Methyl-2-pyrrolidone
55185	N-Nitrosodiethylamine (NDEA)
62759	N-nitrosodimethylamine (NDMA)
621647	N-Nitroso-di-n-propylamine (NDPA)
86306	N-Nitrosodiphenylamine
930552	N-nitrosopyrrolidine (NPYR)
68224	Norethindrone (19-Norethisterone)
103651	n-Propylbenzene
95534	o-Toluidine
75569	Oxirane, methyl-
301122	Oxydemeton-methyl
42874033	Oxyfluorfen
14797730	Perchlorate
1763231	Perfluorooctane sulfonic acid (PFOS)

335671	Perfluorooctanoic acid (PFOA)
52645531	Permethrin
41198087	Profenofos
91225	Quinoline
121824	RDX
135988	sec-Butylbenzene
7440246	Strontium
107534963	Tebuconazole
112410238	Tebufenozide
13494809	Tellurium
13071799	Terbufos
56070167	Terbufos sulfone
59669260	Thiodicarb
23564058	Thiophanate-methyl
26471625	Toluene diisocyanate
78488	Tribufos
121448	Triethylamine
76879	Triphenyltin hydroxide (TPTH)
51796	Urethane
7440622	Vanadium
50471448	Vinclozolin
137304	Ziram

Microbial Contaminants

Adenovirus
Caliciviruses
<i>Campylobacter jejuni</i>
Enterovirus
<i>Escherichia coli</i> (O157)
<i>Helicobacter pylori</i>
Hepatitis A virus
<i>Legionella pneumophila</i>
<i>Mycobacterium avium</i>
<i>Naegleria fowleri</i>
<i>Salmonella enterica</i>
<i>Shigella sonnei</i>

III. What Comments did EPA Receive on the Draft CCL 3 and How did the Agency Respond?

EPA received comments from 177 individuals or organizations on the draft CCL 3. Commenters identified several issues on the draft CCL 3 and the process used to select

contaminants for the list. Many commenters noted the substantial effort, overall improvement, improved scientific rigor, and increased stakeholder involvement employed by EPA to develop the draft CCL 3. Commenters also provided information and recommendations for the Agency to consider as it finalized the CCL 3. The Agency has provided responses to individual comments in the “Final Comment Response Document for the Third Drinking Water Contaminant Candidate List 3 (Categorized Public Comments)” document that is available in the docket (USEPA 2009c).

A. Advisory from the EPA Science Advisory Board

The EPA SAB and its Drinking Water Committee reviewed the draft CCL 3 during 2008, and provided an advisory to the Administrator on January 29, 2009. EPA staff met with the SAB to provide an overview of the draft CCL 3, to answer questions from the Drinking Water Committee, and to clarify questions from the full SAB. The Agency also participated in teleconferences with SAB during the development of the “SAB Advisory on EPA's Draft Third Drinking Water Contaminant Candidate List (CCL 3)” (USEPA 2009d). SAB comments on the overall CCL 3 process and documentation are summarized in the following paragraphs.

The SAB noted that the process used to develop the draft CCL 3 represents a major improvement over the previous CCL processes and recognized the adaptive management strategies employed by EPA as an appropriate approach that should continue to be used in future CCLs. However, the SAB also believes the documentation of the process used to develop the draft CCL 3 lacks transparency. For example, one suggestion stated that EPA should document and justify why each of the contaminants from previous CCL lists were excluded from the draft CCL 3.

The SAB also stated that the current list may be too large for chemicals; and it may include too few pathogens. The SAB acknowledged that the CCL 3 has dual goals of developing regulatory determinations and identifying longer-term research needs. They also recommended that EPA prioritize the list to better identify regulatory priorities, research needs, and longer term needs for the next CCL.

EPA Response to SAB Recommendations:

The Agency has updated the technical support documents for the CCL 3 to increase the transparency of the process that was used to determine which contaminants to include on the final CCL 3. Several specific suggestions to improve the transparency of the process are addressed in the supporting documents and identified in Section III of this notice. Documents describing the process and tables that identify the data used to select contaminants can be found on EPA's Web site at: <http://www.epa.gov/safewater/ccl/index.html>. More detailed information on the contaminants, such as the "Final CCL 3 Contaminant Information Sheets.", (USEPA, 2009e) and the "Final Contaminant Candidate List 3 Microbes: PCCL to CCL Process" can be found in the docket (USEPA, 2009g) and on EPA's Web site.

In Section IV of this *FR* notice, the Agency has also identified which contaminants will need additional data and information on their occurrence, health effects, and analytical methods. As the Agency continues to evaluate contaminants on the CCL 3, we will work with EPA and non-EPA scientists to develop and collect the best available science to support decision making for future regulatory determinations.

B. Chemical Contaminants

EPA evaluated data and information on chemical contaminants provided by commenters and collected by the Agency after the draft CCL 3 was published. EPA used the same process described in the draft CCL 3 *FR* notice (73 *FR* 9628, USEPA 2008a) to evaluate contaminants for which data became available after the publication of the draft CCL 3. Based on these analyses, EPA is taking the following actions on chemical contaminants: EPA is removing two pesticides from the CCL 3 that are no longer used in the United States, and the Agency is adding 13 chemical contaminants to the final CCL 3. EPA concluded that one antibiotic (erythromycin), nine hormones (17 alpha-estradiol, 17 beta-estradiol, equilenin, equilin, estriol, estrone, ethinyl estradiol, mestranol, and norethindrone), two potential disinfection byproducts (DBP) (Halon 1011 (bromochloromethane) and chlorate), and one perfluorinated compound (Perfluorooctanoic sulfonic acid (PFOS)) should be included on the CCL 3 based on their potential adverse health effects and potential for occurrence in public water systems. The Agency has summarized the comments and information used to evaluate these contaminants in this section of the *FR* notice. The specific data used to evaluate these contaminants can be found in the response to comment document (USEPA, 2009c) and the “Final CCL 3 Contaminant Information Sheets” in the docket (USEPA, 2009e).

1. Pesticides and Degradates

EPA received more than 65 public comments on pesticides and their related degradates. Some commenters were concerned about the number of pesticides listed on the draft CCL 3. One commenter states, “...in the process of narrowing the universe of 7,500 unregulated chemicals down to 93...EPA selected nearly half (42 out of 93) to be pesticides or pesticide degradates.” This and other commenters viewed the listing of pesticides as a selection bias and noted that EPA has not clearly demonstrated, in the process used to derive the draft CCL 3, that these 42

pesticides and degradates pose the greatest public health concern. In addition, this commenter believed that the inclusion and proportional share of pesticides and their degradates on the draft CCL 3 should take into account the Agency's regulatory determination findings where none of the pesticides or degradates evaluated were ultimately determined to provide a meaningful opportunity to provide public health protection. In contrast, some commenters were in agreement with the pesticides included on the draft CCL 3, and in some cases, commenters suggested placing additional pesticides on the final CCL 3.

EPA Response:

EPA does not agree with the commenter's statement that there is a selection bias for pesticides. The CCL 3 process was developed to evaluate contaminants from a broad universe of chemicals in accordance with the NRC and NDWAC recommendations. The chemicals are subject to consistent screening and evaluation based on chemical specific factors such as physical properties, health effects data, and their potential to occur in public water systems. SDWA requires EPA to evaluate substances registered as pesticides under FIFRA. All pesticides identified in the universe of chemicals were evaluated by EPA using the same process as other chemicals. Previous regulatory determinations not to develop a NPDWR for 10 pesticides or degradates in Regulatory Determinations 1 and 2 are irrelevant to other pesticides on the CCL 3. The regulatory determination process, like the CCL process, is data driven. To make a regulatory determination, EPA evaluates the available occurrence and health effects data for that contaminant against the criteria in SDWA Section 1412 (b)(1)(a). The Agency has responded to comments on specific pesticides in the response to comment document (USEPA, 2009c).

2. Cancelled Pesticides Registrations

SAB and other public commenters suggested that specific pesticide active ingredients (Nitrofen and Ethion) should be removed from the CCL 3 because they are no longer used in registered pesticides. The SAB also commented that EPA should consider removing pesticides from the CCL 3 that are no longer registered products or are in the process of being phased out of use. The pesticides identified by the commenters, Nitrofen and Ethion, are not included on the final CCL 3. The evaluation of these two pesticides is summarized in the following paragraphs.

a. Nitrofen

EPA received comment from the public and the SAB that Nitrofen should not be included on the final CCL 3. Commenters noted that the available information on use, release, and potential environmental occurrence of Nitrofen indicate that it should not be anticipated to occur in public water systems (PWS).

EPA Response:

EPA agrees with the commenters that Nitrofen should be removed from the CCL 3. It is no longer manufactured or sold in the United States. Its inclusion on the draft list was based on a reported TRI release which, when investigated, indicated that Nitrofen stocks were recently found in a warehouse and properly disposed of in accordance with the Resource Conservation and Recovery Act Subtitle C landfill regulations. TRI requires that information on landfill releases, even releases in compliance with regulations, be reported; therefore, the Nitrofen release was incorporated in the total TRI data used in the CCL process. Based on this

information, Nitrofen is not anticipated to occur in PWSs, and the Agency has not included Nitrofen on the final CCL 3.

b. Ethion

Commenters noted that the registration for Ethion was cancelled and therefore EPA should not include Ethion on the final CCL 3.

EPA Response:

EPA agrees with the commenters and has not included Ethion on the final CCL 3. On March 22, 2002, EPA published a cancellation order discontinuing the manufacture of Ethion containing products as of October 1, 2003, and prohibiting the use of existing stocks after December 31, 2004 (67 *FR* 13328; USEPA, 2002). A July 23, 2004 action revoked the remaining Ethion tolerances, as of October 1, 2008 (69 *FR* 43918; USEPA, 2004). EPA notes that SDWA criteria consider whether a contaminant is known or anticipated to occur in PWSs and may have an adverse effect. It is possible for a contaminant to occur in a PWS even after its uses are canceled if it is very persistent in the environment. Ethion is moderately persistent in the environment, but is not likely to contaminate surface water through dissolved runoff. Based on laboratory and field data, including monitoring data compiled in EPA's Pesticides in Ground Water Database, EPA does not expect that Ethion will contaminate ground water (USEPA, 2001). Based on Ethion's discontinued registration status, prohibited use of stocks, and moderate persistence, the Agency does not anticipate that it will occur in PWSs; therefore, it is not included on the final CCL 3.

3. Perfluorinated Compounds

In the draft CCL 3 *FR* notice, EPA sought comments on its proposed decisions to include perfluorooctanoic acid (PFOA) and not to include PFOS on the draft CCL 3 (73 *FR* 9652, USEPA 2008a). The majority of commenters agreed with the inclusion of PFOA on the CCL 3. Commenters pointed out that PFOA warrants inclusion on the CCL due to its known occurrence in drinking water supplies and systems and its potential adverse health effects. A number of these commenters also wrote in support of regulating PFOA under SDWA. The SAB also stated that PFOA should be a high priority for consideration by the Agency for the CCL 3. One commenter argued that EPA did not use the most relevant information in the CCL 3 process to characterize PFOA's health effects and occurrence. Some of the commenters who were in support of including PFOA on the CCL also recommended adding PFOS and other perfluorinated compounds to the list. The SAB noted that perfluorochemicals may be a class of contaminants that the Agency should consider as a group based on their similar structures and chemical makeup.

EPA Response:

The Agency agrees with commenters that potential health effects based on animal studies and the occurrence of PFOA in drinking water supplies warrant its inclusion on the CCL 3. The Agency used the best available science and information to evaluate and list drinking water contaminant candidates. PFOA has been detected in a number of drinking water supplies and ambient waters. It is also highly persistent in the environment and has been shown to be toxic in animal studies. Based on these potential adverse health effects and occurrence information, EPA concludes that PFOA is known or anticipated to occur in public water systems and may require regulation. Therefore EPA has included PFOA on the final CCL 3.

PFOS was not included on the draft CCL 3, but has been included on the final CCL 3. A major factor in EPA's decision to not include PFOS on the draft CCL 3 was the voluntary phase-out of production of PFOS in the US between 2000 and 2002 (*FR* 73 9652; USEPA 2008a). However, EPA has evaluated new information from the October 9, 2007, significant new use rule (SNUR) that shows there are ongoing uses of PFOS that could lead to its occurrence in water (*FR* 72 57222-57235; USEPA 2007b). The Agency concluded, based upon this potential to occur in PWSs, existing data on environmental persistence, and toxicity in animal studies, that PFOS is known or anticipated to occur in public water systems and may require regulation. Therefore, EPA has included this compound on the final CCL 3.

The Agency continues to analyze the data and information related to the possible adverse health effects associated with PFOA and PFOS. As noted in the draft CCL 3 *FR* notice, the SAB completed a review of a draft PFOA risk assessment in 2006 and made recommendations for the further development of the risk assessment (USEPA, 2006a). A number of important studies are underway, and the Agency continues to participate in research regarding the toxicity of related perfluorochemicals, as well as research to help identify routes of human exposure. EPA is evaluating additional research and has not made any definitive conclusions on the risk assessment at this time. The Agency also issued "Provisional Health Advisories for PFOA and PFOS" (USEPA 2009f) to provide technical information to State and local officials, and PWSs for consideration in addressing local contamination of drinking water to protect public health. This information has been included in the docket and the "Final CCL 3 Contaminant Information Sheets" for PFOA and PFOS (USEPA, 2009e).

While the Agency did not specifically seek comment on other perfluorinated compounds in the draft CCL 3 *FR* notice, some of these compounds were included in the CCL 3 Universe.

However, the Agency had only limited data on the potential occurrence of these compounds and potential adverse health effects. Commenters did not provide additional occurrence or health effects data than those already evaluated by the Agency; therefore, they are not listed on the CCL at this time. The Agency will continue to evaluate perfluorinated compounds to ascertain whether they possess similar toxicological properties and if they are anticipated or known to occur in public water systems.

4. Pharmaceuticals

In the draft CCL 3 *FR* notice (73 *FR* 9652; USEPA, 2008a), EPA explained how pharmaceuticals were evaluated in the CCL 3 process, and sought additional data and information on the concentrations of pharmaceuticals in finished or ambient water. EPA also requested comment on how pharmaceuticals have been considered in the CCL 3 process. In addition, EPA sent a letter to State public health and environmental departments requesting information on the States' activities and initiatives involving pharmaceuticals. The Agency specifically requested information on pharmaceuticals in the areas of occurrence, human health effects research, analytical methods development, and stewardship. EPA received a number of comments on pharmaceuticals and the CCL 3. Commenters pointed out that additional research is needed to address the health effects and occurrence of pharmaceuticals in drinking water. Commenters also noted that the contaminants were detected at low levels. Commenters differed on whether pharmaceuticals should be included on the CCL 3. Some commenters provided references from the published literature on the occurrence of pharmaceuticals in water and on the health effects of pharmaceuticals. In its comments, the SAB noted that pharmaceuticals may be a class of contaminants that need special attention when considering them for CCL 3 or future CCLs, and recommended that EPA use additional data on occurrence of pharmaceuticals in

water from the United States Geological Survey (USGS), or studies in the peer-reviewed literature (USEPA, 2009d).

EPA Response:

EPA is actively working to evaluate the potential risks to human health and aquatic life posed by trace amounts of pharmaceuticals and personal care products in water, and to identify measures to minimize their occurrence. The Agency has a number of activities underway and will continue to add activities as appropriate. All of these activities are described in further detail on our Web site located at www.epa.gov/waterscience/ppcp. Additional information on the Agency's research related to pharmaceuticals can be found at www.epa.gov/ppcp.

In the CCL 3 process, EPA evaluated the potential adverse health effects of pharmaceuticals and their occurrence in public drinking water systems to determine if pharmaceuticals should be added to the list. Since the draft CCL 3 was published, several publications have focused on the occurrence of pharmaceuticals in ambient water and drinking water. In response to comments, EPA has conducted additional data collection efforts to comprehensively review recent published information from USGS and other sources, including those cited by commenters, to identify the best available occurrence information for pharmaceuticals. EPA identified new occurrence data for 81 contaminants from 22 sources. The Agency also conducted additional literature reviews to identify the best available health effects information and identified data from sources including: EPA Office of Pesticide Programs, the Food and Drug Administration (FDA) Center for Veterinary Medicine, the Joint Food and Agriculture Organization/World Health Organization (WHO) Expert Committee on Food Additives, and the European Medicines Agency, and the FDA Center for Drug Evaluation and

Research. EPA used the new data in the same process that was described in the draft CCL 3 *FR* notice to further evaluate pharmaceutical contaminants.

Based upon this re-evaluation with new data, EPA concluded that one antibiotic (erythromycin) and nine hormones (17 alpha-estradiol, 17 beta-estradiol, equilenin, equilin, estriol, estrone, ethinyl estradiol, mestranol, and norethindrone), should be included on the CCL 3 because these contaminants are known or anticipated to occur in public water systems and may require regulation. The specific data used to evaluate these contaminants can be found in the “Final CCL 3 Contaminant Information Sheets” (USEPA, 2009e).

5. Perchlorate

EPA received several comments on perchlorate in response to the draft CCL 3. Commenters noted that perchlorate should be included on the final CCL 3 and provided occurrence and health effects data. Commenters also identified potential sources of perchlorate in the environment.

EPA Response:

EPA included perchlorate on the first CCL in 1998 and on the second CCL in 2005. EPA is including perchlorate on CCL 3 while the Agency continues to evaluate scientific information related to a regulatory determination.

EPA published a preliminary regulatory determination for perchlorate in the *FR* on October 10, 2008 (73 *FR* 60262; USEPA, 2008b). In this notice, EPA solicited public comment on its preliminary determination not to regulate perchlorate. The Agency issued an interim health

advisory for perchlorate to provide technical information to State and local officials and PWSs for consideration in addressing local contamination of drinking water (USEPA, 2008c).

EPA received more than 32,000 comments on the preliminary regulatory determination (73 *FR* 60262; USEPA 2008b). The majority of comments were submitted by individuals opposed to the decision. There were also unique comments that recommended further scientific evaluation of the information EPA used to make the preliminary determination. These commenters included EPA's NDWAC, SAB, and Children's Health Protection Advisory Committee. All of the comments received on the preliminary regulatory determination *FR* notice can be reviewed on www.regulations.gov. Refer to docket number EPA-HQ-OW-2008-0692.

6. Disinfection Byproducts (DBP)

EPA received several comments on unregulated disinfection byproducts. Most comments supported the inclusion of N-nitrosodimethylamine (NDMA) and the other N-nitrosamines (N-nitrosodiethylamine, N-nitroso-di-n-propylamine, N-nitrosodiphenylamine, N-nitrosopyrrolidine) on CCL 3, citing the evidence for their carcinogenicity and the overarching need to evaluate this risk. The SAB advised EPA to consider N-nitrosamines as a group because of their similar toxicities and likelihood to occur together. One commenter expressed concern that two N-nitrosamines: N-nitroso-di-n-butylamine and N-nitroso-methylethylamine (which are included in UCMR 2) are not listed on the draft CCL 3. Several commenters expressed concern about the overall lack of DBPs on the draft CCL 3, citing their assumed presence as a result of drinking water disinfection. One commenter requested that the remaining halo-acetic acids not covered under the current DBP regulation (bromochloroacetic acid, dibromochloroacetic acid, bromodichloroacetic acid, and tribromoacetic acid) be added to the CCL 3. Several commenters

mentioned groups of chemicals, such as halo-nitriles, halo-aldehydes, halo-nitromethanes, and other nitrogenous DBPs that they believed should be included on the CCL 3.

EPA Response:

The CCL 3 process took into consideration the potential formation of DBPs in disinfected and treated drinking water. Potential DBPs with available health information were added to the CCL Chemical Universe even if they did not have measured occurrence data. This is because DBPs were considered to have “default” occurrence for the Universe since they are potentially formed in treated drinking water supplies (USEPA 2009a). In screening chemicals from the Universe to the Preliminary CCL (PCCL), EPA added DBPs to the PCCL that lacked quantitative occurrence data but were in the Toxicity Category 1 or Toxicity Category 2 groupings because of their potential presence in disinfected and treated drinking water (USEPA 2009b). EPA attempted to identify additional health effects and occurrence data for these DBPs to determine whether to include them on the CCL 3. Quantitative occurrence data were needed in order for DBPs to be evaluated for inclusion on the CCL 3. The Agency sought comment on the approach and the data used to select contaminants in the draft CCL 3.

EPA evaluated 85 chemicals in the groups of potential DBPs mentioned by the commenters, but the available data showed that most DBPs had limited or low levels of occurrence, or lacked health effects data. For example, the two UCMR 2 nitrosamines that are not on CCL 3 lacked sufficient occurrence information for inclusion on the list. There is additional discussion of the interrelationship between the CCL and UCMR in Section III.D of this *FR* notice.

Several commenters mentioned chemicals that were not included in the Universe data compilation, but they did not submit the health effects and/or occurrence information that would be necessary to support their inclusion on the final CCL 3.

In addition to the data used by the Agency in the draft CCL 3, such as the May 14, 1996, DBP Information Collection Rule (ICR) (61 *FR* 24354, USEPA 1996), EPA used drinking water occurrence data from the State of California Department of Health Services ICR and studies cited by commenters (Krasner et al., 2006) to evaluate the occurrence of DBPs. The Agency also sought and identified new health effects information. A study EPA requested during the development of the Stage 2 Rule on chlorate was completed (NTP 2008) and occurrence information on bromochloromethane (Halon 1011) was also identified. EPA concluded that chlorate and bromochloromethane are known or anticipated to occur in PWSs and may require regulation. Therefore the Agency added these two contaminants to the CCL 3.

EPA continues to participate in research concerning the toxicity, occurrence, exposure, and treatment of unregulated disinfection byproducts. This research will inform the development of future CCLs and the regulatory determination process, as well as future reviews of existing drinking water regulations.

C. Microbial Contaminants

EPA is including twelve pathogens on the final CCL 3, one more than the eleven pathogens on the draft CCL 3. The Agency is adding Adenovirus, Enterovirus, and *Mycobacterium avium* to the final CCL 3, and is removing *Vibrio cholerae* and *Entamoeba histolytica* from the final CCL 3.

The protocol EPA used to select the microbial contaminants for the CCL 3 is described in detail in the draft CCL 3, notice (73 *FR* 9631, 9644; USEPA, 2008a). Except for a minor change discussed in Section III.C.1, the protocol for selecting pathogens for the final CCL 3 remains the same as the protocol for the draft CCL 3; EPA selected the pathogens based on their health effects and occurrence in drinking water.

Based on public comment, EPA modified the waterborne disease outbreak (WBDO) protocol. The Agency removed older, Center for Disease Control (CDC) reported WBDOs (prior to 1990) from the occurrence analysis to account for the impact of drinking water regulations that have been implemented since 1990. This change in the WBDO protocol resulted in the exclusion of *Vibrio cholerae* and *Entamoeba histolytica* from the final CCL 3 and the inclusion of Adenovirus and Enterovirus to the final CCL 3.

Based on public comment, EPA reviewed the health score for *Mycobacterium avium*. After re-evaluating the health effects information, EPA determined that a higher health effects score was appropriate for this pathogen.

1. Using the CDC WBDO's as a Scoring Criterion

A commenter recommended the use of outbreak data tied to the implementation of the SDWA and its amendments (i.e., after 1990). The commenter, as well as SAB, also encouraged EPA to develop its own occurrence database instead of relying on CDC reported WBDOs. A few commenters noted that, in general, the information on occurrence of pathogens in drinking water is limited, and that EPA should develop more occurrence information.

EPA Response:

EPA agrees in part with this recommendation, and recognizes that after implementation of SDWA and its amendments, PWSs should have changed their practices resulting in fewer outbreaks. Therefore, early outbreaks (i.e., before 1990) may not represent the current situation and controls at PWSs operating under these regulations. EPA removed CDC WBDOs prior to 1990 from the occurrence analysis. This change resulted in the exclusion of *Vibrio cholerae* and *Entamoeba histolytica* from the final CCL 3 because their WBDO scores were reduced due to the removal of older documented WBDOs from consideration (USEPA, 2009e).

EPA disagrees with abandoning the CDC database and continues to use the CDC documented WBDOs in the CCL 3 pathogen scoring process. CDC collects statistical data on WBDOs every year (since 1920). CDC has consistently applied a definition for WBDO as well as consistently investigated and verified epidemiological information related to illnesses. This consistency in definitions and methods allows EPA to consistently compare the WBDO data. In contrast, individual research studies on isolated outbreaks may have different methods and goals, and therefore disparate study designs, making evaluation of the results difficult from a national perspective. No other national database on drinking-water related illnesses exists.

EPA contributes and collaborates with CDC on the *Morbidity and Mortality Weekly Report's* annual surveillance summary, and is confident of the quality of the information in the report. EPA agrees with the commenter that there is a need for more information on occurrence of pathogens in drinking water; however, EPA believes that the CDC WBDO data is the best available information at this time.

2. *Mycobacterium Avium*

EPA received more than a dozen comments requesting that EPA re-examine the health effects score for *Mycobacterium avium* and to include the pathogen on the final CCL 3. Commenters pointed to the long treatment duration and the severity of the disease particularly for the elderly population. Commenters also cited the increased incidence of disease, particularly amongst the elderly.

EPA Response:

EPA re-evaluated *Mycobacterium avium*'s health effects information and increased the health effects score for one of the sensitive life stages, or populations; specifically, the elderly. The Agency agrees with commenters that the potential health effects on the elderly and the occurrence of *Mycobacterium avium* in drinking water supplies warrant its inclusion on the CCL 3. The health effects score was increased based on the severity and treatment duration on the elderly as described in Murray 2007 (USEPA, 2009g). Based on this information, EPA anticipates that *Mycobacterium avium* may occur in PWSs and require regulation. Therefore the Agency has included *Mycobacterium avium* on the final CCL 3.

3. *Vibrio cholerae* and *Entamoeba histolytica*

EPA received a few comments recommending the exclusion of both *Vibrio cholerae* and *Entamoeba histolytica* from the final CCL 3. Commenters recommended that EPA not include these pathogens because cholera and amebiasis are currently rare in the United States, even though they are still common in other countries. Also, commenters felt that current treatment practices (i.e., disinfection) will provide sufficient protection against *Vibrio cholerae*. However,

one commenter supported keeping *Vibrio cholerae* because its occurrence is likely to increase and expand as climate change continues.

EPA Response:

Based on public comment discussed earlier, EPA changed the WBDO protocol. The Agency removed older, CDC reported WBDOs (prior to 1990) from the occurrence analysis to account for recently implemented regulations (e.g., Surface Water Treatment Rule, Total Coliform Rule). This change in the WBDO protocol resulted in the reduction of the WBDO score for both *Vibrio cholerae* and *Entamoeba histolytica*, and their exclusion from the final CCL 3. However, EPA did not consider treatment as one of the parameters for inclusion or exclusion of a pathogen onto the CCL 3 because many public water systems are not required to treat, as discussed in the draft CCL 3 *FR* notice (73 *FR* 9648; USEPA, 2008a). Further, EPA acknowledges the potential impact climate change may have on water quality; however, at this time EPA does not have enough information to assess the risk.

D. Other comments

1. Data Sources for Contaminant Candidate Lists

Several commenters noted that EPA used occurrence data sources that could only identify a contaminant's potential to occur in PWSs. These included data from the TRI, National Center for Food and Agricultural Policy (NCFAP), modeled occurrence data for pesticides, and chemical production data. While some commenters urged EPA to rely on this type of data, other commenters suggested that production data should only be used to identify chemicals for initial consideration (i.e., inclusion on the CCL 3 Universe) and more rigorous data should be used to screen or include chemicals on the CCL.

EPA response:

The Agency used data from the TRI and modeled occurrence data for pesticides developed by the Office of Pesticide Programs (OPP) to support the inclusion of contaminants on the CCL 3, but EPA did not rely on the Chemical Update System (CUS) and the Inventory Update Rule (IUR) data (i.e., production volume).

In developing the CCL, SDWA requires that EPA consider unregulated contaminants that are known or anticipated to occur in PWSs and may require regulation. EPA believes that the TRI and the OPP data are sufficient for it to anticipate that a contaminant that is released into the environment may occur in a PWS. The Agency coupled these data with health effects information to evaluate contaminants. The NRC (2001) and NDWAC (2004) reports included specific recommendations on data and information that the Agency could use to anticipate the occurrence of contaminants in PWSs. Both of these panels cited the importance of identifying contaminants that did not yet have occurrence information indicating detections in source waters or drinking water. NDWAC recognized that the Agency could apply a hierarchy to the use of detected occurrence over potential occurrence, but also noted that the use of these types of data enables the Agency to be proactive in protecting public health.

EPA also conducted several reviews of the data sources and information used to develop the CCL 3. EPA sought contaminants for the Agency to consider in its *FR* notice, seeking nominations (71 *FR* 65573, USEPA 2006b). The Agency published a list of data sources including the TRI, CUSIUR, and NCFAP. Many of the nominated contaminants are chemicals included solely on those lists. The Agency also conducted several expert panels to review the types of data and information it used to evaluate contaminants. While these panels provided

recommendation to qualify these types of data, which the Agency implemented, the panels did not recommend excluding these data sources. Based on this input from stakeholders and expert reviews, the Agency included 51 contaminants with TRI and/or modeled occurrence data for pesticides to support inclusion on the CCL 3 because EPA anticipates that these contaminants may occur in PWSs and may require regulation.

2. Contaminant Candidate List and Unregulated Contaminant Monitoring Regulation

Several commenters requested clarification on the interrelationship between the UCMR and the CCL. Commenters wanted to know whether the CCL draws from chemicals on the UCMR, or the UCMR draws from chemicals on the CCL to develop the respective lists. One commenter encouraged EPA to “improve correlation between the CCL and the UCMR.”

EPA response:

The 1996 amendments to SDWA instituted the CCL and UCMR programs to provide information EPA needs to determine which drinking water contaminants have the greatest potential to present a meaningful opportunity to reduce health risk through a NPWDR. The CCL is the primary mechanism for the identification of contaminants that may require regulation, while UCMR provides EPA with the data necessary to determine if a contaminant occurs at a frequency and at levels of public health concern. The CCL and UCMR are parts of the risk management process, and they support and inform each other.

The UCMR sampling program was designed to consider the technical difficulty and expense of analyzing up to 30 contaminants as well as their potential to occur in treated drinking water at levels of public health concern. The UCMR approach includes three different sampling design options, with the determination of the appropriate option for each contaminant based

primarily on the difficulty and expense of the analytical methods used, and the associated issue of laboratory capacity. The sampling designs described below are discussed in detail in the proposed UCMR 2 (70 *FR* 49094; USEPA 2005). Assessment monitoring is the most extensive, and is used when the technology of the analytical methods is in common use in drinking water laboratories. Screening monitoring relies more on identifying a statistically valid representation of the universe of PWSs in order to reduce the number of utilities impacted by the monitoring. It is designed to assure the necessary laboratory capacity in those cases where the analytical technology is more complex and/or expensive. The pre-screening monitoring option detailed in the UCMR program is based on assessing the vulnerability of selected PWSs and may be used when the analytical techniques are so complex that commercial laboratory capacity is severely limited; this option has not been exercised to date.

EPA promulgated UCMR 2 on January 4, 2007 (72 *FR* 367; USEPA 2007a). The UCMR program was developed in coordination with the development of the CCL. Both programs consider the adverse health effects a contaminant may pose through drinking water exposures.

Sixteen contaminants on the UCMR 2 monitoring list are also on the final CCL 3. The final CCL 3 includes acetochlor and its degradates, alachlor degradates, dimethoate, 1,3-dinitrobenzene, metolachlor and its degradates, RDX, terbufos sulfone, and four of the nitrosamines that are a part of UCMR 2. In addition to the health effects data and potential occurrence, the UCMR 2 also considers analytical method availability and cost, availability of analytical standards, and laboratory capacity to support a nationwide monitoring program in selecting contaminants.

The UCMR 2 includes nine contaminants that are not on the final CCL 3. The five polybrominated flame retardants can be measured by the same analytical method used for terbufos sulfone. The polybrominated flame retardants are listed on UCMR 2 because of concern that these have become more widespread environmental contaminants (Darnerud et al., 2001). The polybrominated flame retardants lacked sufficient occurrence information to be listed on final CCL 3 (73 *FR* 9628; USEPA 2008a). This UCMR 2 monitoring data will provide information for future CCLs. Similarly, 2,4,6-trinitrotoluene (TNT) and two of the nitrosamines not on CCL 3 are also measured by an analytical method in the UCMR 2. Alachor was listed on UCMR 2 for monitoring along with its degradates to allow for the measurement of concurrence between the parent compound and its degradates. It was removed from consideration for CCL 3 because it is currently regulated. The Agency will use the results from UCMR 2 as a source of occurrence information during the development of CCL 4, as well as for CCL 3 regulatory determinations.

IV. Data Needs for CCL 3 Contaminants

After the listing process, the CCL 3 contaminants are evaluated further to determine if a contaminant has sufficient data to meet the regulatory determination criteria set forth in SDWA section 1412(b)(1) and previously outlined in Section I.C of this notice. If the data are sufficient, a regulatory determination may be made. EPA must make regulatory determinations on at least five CCL 3 contaminants every five years.

The SAB and other commenters have indicated that the CCL 3 may be too large and recommended additional priority ranking of contaminants to focus resources. EPA acknowledges that many contaminants on the CCL 3 have substantial data and information needs that will have to be met before the Agency can make a regulatory determination in accordance with SDWA

1412 (b)(1)(A). Currently, several of the CCL 3 contaminants have data or information needs. These are described in the following section.

A. Chemical Contaminants

EPA assessed the data and information gathered on the CCL 3 chemical contaminants and generated a table (Exhibit 2) to help identify data/information needs for further regulatory determination evaluations. In general, EPA characterized each chemical contaminant included on the final CCL 3 for their data needs in three categories; health effects, occurrence, and analytical methods. The data needs were characterized as no data needs, specific data needs, or substantial data needs. The health effects, occurrence, and analytical methods data/information used to classify data needs are featured in the supporting documentation and in the “Final CCL 3 Contaminant Information Sheets” in the docket (USEPA, 2009e). Blank cells in Exhibit 2 generally indicate that there is no data need for that contaminant in that category. Cells with a “2” indicate that the data are under evaluation by EPA and the contaminant has a specific need. Cells with a “1” indicate that there is a data need for that contaminant, and that need may be substantial. The following sections describe the types of data or information gaps outlined in Exhibit 2 and provide examples.

1. Health Effects

EPA categorized the health effects data needs for Exhibit 2 using the following set of assumptions. Any chemical that had an existing EPA quantitative assessment (Reference Dose (RfD) or Cancer Slope Factor (CSF)) for the oral route of exposure is identified on the table as not having a health effect data need based on the assumption that EPA will be able to use the

existing data along with more recent studies to develop a quantitative health effects assessment. These chemicals are designated with a blank cell in the health effects column. There may well be opportunities to further elucidate mode of action or to reduce uncertainty for the analyses associated with these contaminants, but such data would not be necessary to develop an assessment. Similarly, any chemical that has an assessment being developed by EPA is not identified on the table as having a data need, and is represented by a blank cell because that work is currently ongoing.

The next category of chemicals with health effects data needs have quantitative assessments conducted by other government agencies such as WHO, and Agency for Toxic Substances and Disease Registry. These chemicals are designated with a “2” in the health effects column on the table, signifying that an EPA assessment is needed and sufficient information may be available to initiate the assessment. These data apply to oral exposures that can be used to support a quantitative assessment of risk; however, EPA has not yet thoroughly evaluated the existing risk assessment to determine if it and the supporting data meet EPA data quality guidelines and is compatible with EPA risk assessment policies. For example, at times there may be an RfD-equivalent for oral exposures based on inhalation data (i.e., California EPA), which is an approach EPA does not typically use unless there is a physiologically-based pharmacokinetic model that supports the cross route extrapolation. The Agency is currently evaluating whether this type of model information and results are available. For a few chemicals marked with the “2” designation in the health effects column, there is no assessment by another agency, but EPA identified a critical study suitable for quantification of likely cancer risk during the development of the CCL 3 process. In these cases, an assessment is needed based on the data identified.

The final group of chemicals on Exhibit 2 is designated with a “1” in the health effects column of the table. For these chemicals, the CCL process used data from a small group of studies identified through the Registry of Toxic Effects for Chemical Substances (RTECS), a provisional Risk Assessment Information System Health Effects assessment, and/or a limited literature search for the health effects component of the CCL 3 evaluation. These chemicals have the most substantial health effects data gaps and information collection needs.

2. Occurrence

EPA categorized the occurrence data needs for Exhibit 2, after evaluating data availability from UCMR 1 and 2, Unregulated Contaminant Monitoring Round 1 and 2 (UCM R1/2), National Inorganic Radiological Survey (NIRS), NAWQA, TRI, NCFAP, and other supplemental data sources.

Chemicals with finished water occurrence data from UCMR 1, UCMR 2, or UCM R1/2 were generally characterized as not having an occurrence data gap because these data are considered nationally representative; therefore, they have sufficient occurrence data to be further evaluated if it is consistent with the health effects information. These chemicals are designated with a blank cell in the occurrence column of Exhibit 2.

Contaminants from data sources with limited PWS monitoring data (i.e., ground water systems only), spatial or geographical data limitations, and/or a small sample size were identified as having a data gap because additional monitoring data may be needed for further evaluation as part of the regulatory determinations process. These were given a “2” in the occurrence column of Exhibit 2, and examples of data sources with this type of data include the UCMR screening survey, NIRS, DBP ICR data, and others.

Chemicals from occurrence data sources with ambient monitoring data, environmental release data, or modeled data were given a “1” in the occurrence column because there are substantial additional data needs to be considered and evaluated as part of the regulatory determinations process. Examples of data sources with this type of data include USGS’s NAWQA, National Reconnaissance of Emerging Contaminants, TRI, and others with similar data.

3. Analytical Methods

To conduct nationally representative drinking water occurrence studies, and support a regulatory determination, EPA must have an analytical method that is suitable for the drinking water matrix and is robust enough to be used by many laboratories to conduct national studies and/or compliance monitoring. The analytical method should be sensitive enough to allow for quantitation of the chemical at a concentration below the HRL, or as close to the HRL as practically feasible.

EPA categorized available analytical methods for the CCL chemicals to define the data needs presented in Exhibit 2. EPA reviewed the methods to assess if they had been developed for drinking water and then evaluated estimated reporting levels for the chemical by that method. When available, method-specific reporting levels, lowest concentration minimum reporting levels, and promulgated minimum reporting levels were also used to measure method sensitivity. When this was not possible, EPA used a value of five times the method detection limit or detection limit; this approach has been used in the past.

Chemicals with blanks in the analytical methods column of Exhibit 2 are generally those chemicals for which EPA has an established drinking water method, with estimated reporting

levels that are adequate for analysis relative to the HRL. However, in some cases, a blank may also signify that EPA is currently in the process of developing a method that it believes will have adequate reporting levels. Chemicals with a "2" in the analytical method column of Exhibit 2 have a drinking water method that is under development by EPA. EPA has evaluated the available methods for each of these chemicals and determined that the reporting level does not allow for quantitation of the chemical at a concentration below the HRL or as close to the HRL as practical. Therefore, EPA has designated that these methods require further development to increase their sensitivity and lower the estimated method reporting level or method detection level. Those chemicals listed as a "1" in the methods column do not have an established method for drinking water or a method that is suitable for a national drinking water occurrence study.

Key to Exhibit 2.

The following key is a reference guide to reading Exhibit 2 and interpreting the data presented in the table.

Note: Categories are based on the extent of available data for each contaminant.

1. Health Effects:

1 = Substantial data needs (RTECS, RAISHE, and other small study data); *2* = Assessments exist from other government agencies. Sufficient information may exist to conduct an EPA assessment; *Blank* = Existing or ongoing EPA quantitative assessment (e.g., IRIS)

2. Occurrence:

1 = No comprehensive drinking water occurrence data (e.g., often only environmental release data such as TRI, or ambient water data), *2* = Limited available drinking water monitoring data; however, data may be limited by scope and sample size (e.g., UCMR 1 Screening Survey, NIRS); *Blank* = EPA has more extensive national drinking water monitoring data (e.g., UCMR, UCM R1/2)

3. Analytical Method:

1 = No analytical method suitable for national drinking water occurrence studies; 2 = Drinking water method in development or being re-evaluated for comparison with new health effects information; *Blank* = EPA has a method or is in the process of developing a method that could be used for national drinking water monitoring.

Exhibit 2. Regulatory Determination Data/Information Needs for CCL 3 Chemicals				
CASRN	Common Name	Health Effects	Occurrence	Analytical Methods
630206	1,1,1,2-Tetrachloroethane			
75343	1,1-Dichloroethane	1		2
96184	1,2,3-Trichloropropane			
106990	1,3-Butadiene	1	1	2
99650	1,3-Dinitrobenzene			
123911	1,4-Dioxane		1	
71363	1-Butanol		1	1
109864	2-Methoxyethanol	2	1	1
107186	2-Propen-1-ol		1	1
16655826	3-Hydroxycarbofuran	2		
101779	4,4'-Methylenedianiline	2	1	1
30560191	Acephate		1	2
75070	Acetaldehyde		2	
60355	Acetamide	2	1	1
34256821	Acetochlor			
187022113	Acetochlor ethanesulfonic acid (ESA)	2		
184992444	Acetochlor oxanilic acid (OA)	2		
107028	Acrolein		1	1
142363539	Alachlor ethanesulfonic acid (ESA)	2		
171262172	Alachlor oxanilic acid (OA)	2		
319846	alpha-Hexachlorocyclohexane		1	2
64285069	Anatoxin-a		1	2
62533	Aniline	2	1	1
741582	Bensulide		1	1
100447	Benzyl chloride		1	1
25013165	Butylated hydroxyanisole	2	1	2
133062	Captan		1	2
14866683	Chlorate		2	
74873	Chloromethane (Methyl chloride)	2		
110429624	Clethodim		1	2
7440484	Cobalt		2	
80159	Cumene hydroperoxide	1	1	1
143545908	Cylindrospermopsin		1	2
141662	Dicrotophos		1	2

Exhibit 2. Regulatory Determination Data/Information Needs for CCL 3 Chemicals				
CASRN	Common Name	Health Effects	Occurrence	Analytical Methods
55290647	Dimethipin		1	2
60515	Dimethoate			
298044	Disulfoton		2	
330541	Diuron		2	
114078	Erythromycin	2	1	1
13194484	Ethoprop		1	2
107211	Ethylene glycol		1	1
75218	Ethylene oxide	1	1	1
96457	Ethylene thiourea		1	2
22224926	Fenamiphos		1	2
50000	Formaldehyde		2	
7440564	Germanium	1	2	2
74975	Halon 1011 (bromochloromethane)	1		2
75456	HCFC-22	1	1	2
110543	Hexane	1	1	1
302012	Hydrazine		1	1
10265926	Methamidophos		1	2
67561	Methanol		1	1
74839	Methyl bromide (Bromomethane)			
1634044	Methyl tert-butyl ether			
51218452	Metolachlor			
171118095	Metolachlor ethanesulfonic acid (ESA)	2		
152019733	Metolachlor oxanilic acid (OA)	2		
101043372	Microcystin-LR		1	2
2212671	Molinate			
7439987	Molybdenum		2	
98953	Nitrobenzene			
55630	Nitroglycerin	2	1	1
872504	N-Methyl-2-pyrrolidone	2	1	1
55185	N-Nitrosodiethylamine (NDEA)			
62759	N-nitrosodimethylamine (NDMA)			
621647	N-Nitroso-di-n-propylamine (NDPA)			
86306	N-Nitrosodiphenylamine		1	1
930552	N-nitrosopyrrolidine (NPYR)			
103651	n-Propylbenzene	1		2
95534	o-Toluidine	2	1	2
75569	Oxirane, methyl-		1	1
301122	Oxydemeton-methyl		1	2
42874033	Oxyfluorfen		1	2

Exhibit 2. Regulatory Determination Data/Information Needs for CCL 3 Chemicals				
CASRN	Common Name	Health Effects	Occurrence	Analytical Methods
14797730	Perchlorate			
1763231	Perfluorooctane sulfonic acid (PFOS)	2	1	
335671	Perfluorooctanoic acid (PFOA)	2	1	
52645531	Permethrin		1	2
41198087	Profenofos		1	2
91225	Quinoline		1	2
121824	RDX			
135988	sec-Butylbenzene	1		2
7440246	Strontium		2	
107534963	Tebuconazole		1	2
112410238	Tebufenozide		1	1
13494809	Tellurium	1	2	2
13071799	Terbufos		2	
56070167	Terbufos sulfone	2		
59669260	Thiodicarb		1	2
23564058	Thiophanate-methyl		1	2
26471625	Toluene diisocyanate	2	1	1
78488	Tribufos		1	2
121448	Triethylamine	1	1	1
76879	Triphenyltin hydroxide (TPTH)		1	1
51796	Urethane	2	1	1
7440622	Vanadium	2	2	
50471448	Vinclozolin		1	2
137304	Ziram		1	1
57910	17alpha-estradiol	1	1	1
517099	equilenin	1	1	1
474862	equilin	1	1	1
50282	Estradiol (17-beta estradiol)	2	1	
50271	estriol	1	1	2
53167	estrone	1	1	2
57636	Ethinyl Estradiol (17-alpha ethynyl estradiol)	1	1	2
72333	Mestranol	1	1	1
68224	Norethindrone (19-Norethisterone)	1	1	1

B. Microbial Contaminants

EPA intends to look at the over-arching risk posed by pathogens in drinking water. To this end, EPA is planning to evaluate the CCL 3 pathogens in the context of the existing drinking water regulatory program to determine the sufficiency of the barriers that help to prevent exposure.

Commenters noted a need for information on the national occurrence of pathogens in drinking water. Development of such data would aid EPA in determining the likelihood that pathogens will occur in public water systems and thus clarify the extent to which they represent a significant public health threat. One aspect of determining the occurrence of any contaminant is the availability of a method to monitor for that contaminant. While there are many methods for monitoring the CCL 3 pathogens available from scientific papers and consensus organizations, not all of them may be appropriate for use in drinking water or for a national monitoring effort. Of the CCL 3 pathogens, only enterovirus has an EPA-approved method for drinking water. EPA is working on developing and approving drinking water methods for some of the pathogens, and is considering the need for additional occurrence information. In addition, EPA is evaluating the suitability of current microbial indicators as well as the reliability of other indicators for CCL pathogens.

Furthermore, the Agency is actively working with stakeholders on additional information on distribution system issues needed to inform national risk management actions such as regulations and guidance. Based on currently available information, EPA and other stakeholders have identified the following issues as being the most relevant to protecting public health and maintaining the integrity of drinking water distribution systems for future consideration: cross connections and backflow of contaminated water; storage facility design, operation, or maintenance; main installation, repair or rehabilitation practices; intrusion due to pressure

conditions; significance and control of biofilm and microbial growth; nitrification issues; and accumulation and release of contaminants from distribution system scales and sediments. These issues may be applicable to chemicals as well as microbial contaminants.

V. Next Steps / Future Candidate Contaminant Lists

The CCL process is a critical input to shaping the future direction of the drinking water program. The Agency will continue to gather information and evaluate contaminants on the CCL 3 to make a regulatory determination for at least five contaminants by 2013. The Agency will also continue to refine the CCL process and gather more data to identify contaminants for the fourth CCL by 2014. EPA will also continue to work to prioritize contaminants on the CCL 3, both for regulatory determination and for additional research and data collection.

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