Response to Comments Document on the Draft Fifth Contaminant Candidate List (CCL 5)

Office of Water (4607M)
EPA 815-R-22-001
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www.epa.gov/safewater

Table of Contents

Abbreviations and Acronyms

ATSDR	Agency for Toxic Substances and Disease Registry
AMWA	Association of Metropolitan Water Agencies
ASDWA	Association of State Drinking Water Administrators
AWWA	American Water Works Association
CASRN	Chemical Abstracts Service Registry Number
CCL	Contaminant Candidate List
CCL 1	EPA's First Contaminant Candidate List
CCL 2	EPA's Second Contaminant Candidate List
CCL 3	EPA's Third Contaminant Candidate List
CCL 4	EPA's Fourth Contaminant Candidate List
CCL 5	EPA's Fifth Contaminant Candidate List
CDC	Centers for Disease Control
CDR	Chemical Data Reporting
CI	Cobalt Institute
CISs	Contaminant Information Sheets
CFR	Code of Federal Regulations
cPAD	Chronic Population-Adjusted Dose
CWA	Clean Water Act
CWS	Community Water System
DBP	Disinfection Byproduct
D/DBPR	Disinfectants and Disinfection Byproducts Rule
DRI	Dietary Reference Intake
DTXSID	Distributed Structure-Searchable Toxicity Database Substance Identifier
EDCs	Endocrine Disruptors
EDSP	Endocrine Screening Program
EPA	United States Environmental Protection Agency
FR	Federal Register
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
HA	Health Advisory
HRL	Health Reference Level
HHBP	Human Health Benchmarks for Pesticides
IMOA	International Molybdenum Association
IOM	Institute of Medicine
IRIS	Integrated Risk Information System
ITIA	International Tungsten Industry Association
LD50	Median Lethal Dose
LOAEL	Lowest Observed Adverse Effect Level
MCLG	Maximum Contaminant Level Goal
MIG	Manganese Interest Group
MTBE	Methyl tertiary butyl ether

NAB	National Advisory Board
NAWQA	National Ambient Water Quality Assessment
NDWAC	National Drinking Water Advisory Council
MDBP	Microbial and Disinfection Byproduct
MDL	Method Detection Limit
NOAEL	No Observed Adverse Effect Level
NPDES	National Pollutant Discharge Elimination System
NPDWR	National Primary Drinking Water Regulation
NRC	National Research Council
NTP	National Toxicology Program
OCSPP	Office of Chemical Safety and Pollution Prevention
OPP	Office of Pesticide Programs
OPPT	Office of Pollution Prevention and Toxics
ORD	Office of Research and Development
OW	Office of Water
PCCL	Preliminary-CCL
PCCL 3	EPA's Third Preliminary-CCL
PCCL 4	EPA's Fourth Preliminary-CCL
OGWDW	Office of Ground Water and Drinking Water
PBPK	Physiologically-Based Pharmacokinetic
PFAS	Per- and Polyfluoroalkyl Substances
PFBA	Perfluorobutanoic Acid
PFBS	Perfluorobutanesulfonic Acid
PFDA	Perfluorodecanoic Acid
PFDoA	Perfluorododecanoic Acid
PFEESA	Perfluoro (2-ethoxyethane) Sulfonic Acid
PFHpA	Perfluoroheptanoic Acid
PFHpS	Perfluoroheptanesulfonic Acid
PFHxA	Perfluorohexanoic Acid
PFHxS	Perfluorohexanesulfonic Acid
PFMBA	Perfluoro-4-methoxybutanoic Acid
PFMPA	Perfluoro-3-methoxypropanoic Acid
PFNA	Perfluorononanoic Acid
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctanesulfonic Acid
PFPeA	Perfluoropentanoic Acid
PFPeS	Perfluoropentanesulfonic Acid
PFTA	Perfluorotetradecanoic Acid
PFTrDA	Perfluorotridecanoic Acid
PFUnA	Perfluoroundecanoic Acid
PPCPs	Pharmaceuticals and Personal Care Products
PPRTV	Provisional Peer-Reviewed Toxicity Values
PWS	Public Water System
RfD	Reference Dose

SAB	Science Advisory Board
SDWA	Safe Drinking Water Act
SMCL	Secondary Maximum Contaminant Level
SRMD	Standards and Risk Management Division
SWTR	Surface Water Treatment Rule
SYR	Six Year Review
TOF	Total Organic Fluorine
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
UCMR	Unregulated Contaminant Monitoring Rule
UCMR 1	First Unregulated Contaminant Monitoring Rule
UCMR 2	Second Unregulated Contaminant Monitoring Rule
UCMR 3	Third Unregulated Contaminant Monitoring Rule
UCMR 4	Fourth Unregulated Contaminant Monitoring Rule
U.S.	United States
USGS	United States Geological Survey
USEPA	United States Environmental Protection Agency
WHO	World Health Organization

1. Introduction and Overview

Background

The Safe Drinking Water Act (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 National Primary Drinking Water Regulations (NPDWRs), are known, or anticipated to occur in public water systems (PWSs) and may require regulation under the SDWA. EPA uses this list of unregulated contaminants to help identify priority contaminants for regulatory decision making and to prioritize research and data collection efforts. SDWA also requires the agency to consult with the scientific community, including the Science Advisory Board (SAB), and provide notice and opportunity for public comment prior to the publication of the final CCL. In addition, SDWA directs the agency to consider the health effects and occurrence information for unregulated contaminants to identify those contaminants that present the greatest public health concern related to exposure from drinking water.

EPA implemented an improved CCL process and published the Draft CCL 5 on July 19, 2021 (86 FR 37948) which included 81 contaminants or groups. The list is comprised of 69 chemicals or chemical groups which include 66 chemicals recommended for listing by evaluation teams, one group of cyanotoxins, one group of disinfection by products (DBPs), and one group of PFAS chemicals. The list also included 12 microbes; specifically, 8 bacteria, 3 viruses, and 1 protozoa that were recommended for listing based on the scores for waterborne outbreaks, occurrence and health effects, and recommendations from various experts. EPA requested comments on the contaminants included on the Draft CCL 5 and on improvements to the CCL 5 process. The public comment period closed on September 17, 2021.

EPA specifically sought public comment on the following: contaminants selected for the Draft CCL 5; data that EPA obtained and evaluated for developing the draft CCL 5; and improvements EPA implemented in the CCL process. After considering comments, EPA developed the Final CCL 5 and provided rationale and clarification to the CCL 5 process.

Who Submitted Comments

A total of 54 unique comments were received from the public via postings to www.regulations.gov, under docket ID No. EPA-HQ-OW-2018-0594. There was one letter issued from a mass mailing campaign from the Environmental Working Group containing over 9,000 signatures and another over 2,000 identical comments from private citizens urging EPA to reverse the decision not to regulate perchlorate. All comments received that were related to CCL are included and addressed in this response to comment document. Referenced supporting documents can be found in the CCL 5 public dockets at https://www.regulations.gov along with any comment submitted on the draft CCL5, which can be read as it appears within the commenter's original letter, email or posting.

Exhibit 1. Categorizes comments by organization type.	
Organization Type	**Count of Comments**
Anonymous/Private Citizens	33
Drinking Water Organization	4
Environmental Groups	4
Industry Representatives	10
Non-Profit Organization	1
State Agency (1 letter representing 14 states and District of Columbia)	2
Total	**54**

Science Advisory Board

In addition to public comment, a Science Advisory Board (SAB) Drinking Water Committee (DWC) was augmented and conducted a review of EPA's fifth Drinking Water Contaminants Candidate List (CCL 5). The SAB reviewed EPA's Draft Fifth Drinking Water Contaminant Candidate List (CCL 5) (86 FR 37948) and three associated support documents: (1) Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) – Contaminant Information Sheets; (2) Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) – Chemical Contaminants; and (3) Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) – Microbial Contaminants.

The SAB's subject matter experts provided comments and recommendations in response to EPA's charge questions in a Report "Review of the EPA's Draft Fifth Contaminant Candidate List (CCL 5)" issued on August 19, 2022 (USEPA, 2022d).

Comment Organization

Each set of public comments was assigned a unique Document ID in the CCL 5 public docket. The Document ID is the CCL 5 Docket ID No. (EPA-HQ-OW-2018-0594) with an additional four-digit identifier. For example, comment number 51 has the Document ID EPA-HQ-OW-2018-0594-0051. Prior to receiving any comments via the public docket, EPA posted 50 documents to support the Draft CCL. Thus, the first public comment received is number 51, the second is 52, etc. Exhibit 2 provides the Document ID, corresponding comment number, and submitter information for all comments received. Clicking the blue hyperlinked Document ID for each comment in Exhibit 2 will take the reader to the original comment submission in the public docket, where additional information can be viewed, such as tables, figures, attachments, and references that may have been included within the context of the original submission. If such additional information was included with a comment, EPA has provided a note within the comment text (presented in Section 2 of this document) and the Document ID link. If footnotes were used, they are provided within the comment text as [FN#:]. The original comment

submissions can also be accessed by searching for the associated Document ID on https://www.regulations.gov/ under Docket ID No. EPA-HQ-OW-2018-0594.

EPA's Categorization of Public Comments and Document Organization

Each set of comments were read by EPA and assigned a topic code, as appropriate. Comment excerpts from different stakeholders that addressed similar subjects were then grouped under the corresponding topic.

Section 2 of this document presents the public comments and EPA responses by topic. EPA developed an Agency Topic Discussion to collectively address the comments received on each topic, which appears at the beginning and summarizes each topic section. Throughout this document, the Agency Topic Discussions have a green header and background. Following the Agency Topic Discussion are comment excerpts assigned to the topic, organized numerically by comment number. No grammatical or spelling edits were made to the text of the comments received; they are presented in this document verbatim. The comment excerpts for each topic and their corresponding responses are presented under a blue header and have a white background. Clicking on the blue hyperlinked comment number appearing at the beginning of each excerpt will take the reader to Exhibit 2, which presents the full Document ID, submitter name, and organization. Exhibit 2 should be referenced for the full list of commenters and a link to the original comment submission in the CCL 5 public docket. Each comment excerpt is followed by an Individual Response from EPA, which directs the reader to the associated Agency Topic Discussion(s) and, where appropriate, provides supplemental comment-specific responses that may not be addressed in the Agency Topic Discussion. Clicking on the blue hyperlinked topic(s) in the Individual Response will digitally direct the reader to the corresponding Agency Topic Discussion(s) in this document.

Cross Referencing of Responses

Comment excerpts that addressed multiple topics within a sentence or paragraph could not practically be divided. For these excerpts, EPA has identified and digitally cross referenced all associated *Agency Topic Discussions* in the *Individual Responses* to provide clarity, avoid redundancy, and ensure consistency. If a response for a comment excerpt cross references multiple discussions, the excerpt is only presented under one of those topics (i.e., the most relevant topic). This is to improve readability and ensure that all comments are included in entirety only once in this document. It is important to note that while most *Agency Topic Discussions* address multiple comments, not all related excerpts are presented thereafter; related excerpts in other sections throughout the document instead digitally cross reference that specific discussion in their Individual Response.

Exhibit 2: List of Public Commenters

Comment Information		**Submitter Information**		
Commenter Number	**Document ID**	**First Name**	**Last Name**	**Organization Name**
51	EPA-HQ-OW-2018-0594-0051			The Ranger Leadership and Policy Center
52	EPA-HQ-OW-2018-0594-0052	Alicia	Johnston	Private Citizen
53	EPA-HQ-OW-2018-0594-0053			Anonymous

Exhibit 2: List of Public Commenters				
Comment Information		**Submitter Information**		
Commenter Number	**Document ID**	**First Name**	**Last Name**	**Organization Name**
54	EPA-HQ-OW-2018-0594-0054			Anonymous
55	EPA-HQ-OW-2018-0594-0055			Anonymous
56	EPA-HQ-OW-2018-0594-0056	Brian	Callahan	Private Citizen
57	EPA-HQ-OW-2018-0594-0057	W.L.	Leow	Private Citizen
58	EPA-HQ-OW-2018-0594-0058			Anonymous
59	EPA-HQ-OW-2018-0594-0059			Anonymous
60	EPA-HQ-OW-2018-0594-0060	Khemmarin	Ortez	Private Citizen
61	EPA-HQ-OW-2018-0594-0061	Kexin	Yu	Private Citizen
62	EPA-HQ-OW-2018-0594-0062	Karen	Benavente	Private Citizen
63	EPA-HQ-OW-2018-0594-0063	Michael	Vicars	Private Citizen
64	EPA-HQ-OW-2018-0594-0064	Elizabeth	Rice	Private Citizen
65	EPA-HQ-OW-2018-0594-0065			Anonymous
66	EPA-HQ-OW-2018-0594-0066	Angela	Pesquiera	Private Citizen
67	EPA-HQ-OW-2018-0594-0067	Justin	Prendergast	Private Citizen
68	EPA-HQ-OW-2018-0594-0068			International Tungsten Industry Association (ITIA)
69	EPA-HQ-OW-2018-0594-0069	Jason	Lowery	Private Citizen
70	EPA-HQ-OW-2018-0594-0070			National Ground Water Association (NGWA)
71	EPA-HQ-OW-2018-0594-0071	Diane	VanDe Hei	Association of Metropolitan Water Agencies (AMWA)
72	EPA-HQ-OW-2018-0594-0072			Arkema, Inc.
73	EPA-HQ-OW-2018-0594-0073	Stephen	Risotto	American Chemistry Council (ACC)
74	EPA-HQ-OW-2018-0594-0074			Cobalt Institute (CI)
75	EPA-HQ-OW-2018-0594-0075	J. Alan	Roberson	Association of State Drinking Water Administrators (ASDWA)
76	EPA-HQ-OW-2018-0594-0076			Attorneys General of the States of Connecticut, Delaware, Iowa, Maine, Maryland, Massachusetts, Minnesota, New

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Comment Information		**Submitter Information**		
Commenter Number	**Document ID**	**First Name**	**Last Name**	**Organization Name**
				Jersey, New Mexico, New York, Oregon, Pennsylvania, Virginia, and Wisconsin, and the District of Columbia
77	EPA-HQ-OW-2018-0594-0077	G. Tracy	Mehan	American Water Works Association (AWWA)
78	EPA-HQ-OW-2018-0594-0078			3M Company
79	EPA-HQ-OW-2018-0594-0079	Paul	Nyffeler	Private Citizen
80	EPA-HQ-OW-2018-0594-0080	Terrence	Thrweatt Jr.	Private Citizen
81	EPA-HQ-OW-2018-0594-0081			Louisiana Chemical Association (LCA)
82	EPA-HQ-OW-2018-0594-0082			Manganese Interest Group (MIG)
83	EPA-HQ-OW-2018-0594-0083	David	Andrews	Earthjustice
84	EPA-HQ-OW-2018-0594-0084	D. Lee	Currey	Maryland Department of the Environment
85	EPA-HQ-OW-2018-0594-0085	Stephen	Wilhelm	Chloropicrin Manufacturers' Task Force (CMTF)
86	EPA-HQ-OW-2018-0594-0086	John	Hilbert	Vanadium Producers and Reclaimers Association (VPRA)
87	EPA-HQ-OW-2018-0594-0087	Daniel	Estrin	Waterkeeper Alliance
88	EPA-HQ-OW-2018-0594-0088			Silent Spring Institute
89	EPA-HQ-OW-2018-0594-0089			Natural Resources Defense Council (NRDC)
90	EPA-HQ-OW-2018-0594-0090	Bill	Isler Simmons	Private Citizen
91	EPA-HQ-OW-2018-0594-0091	Carter	Phillips	Private Citizen
92	EPA-HQ-OW-2018-0594-0092			Anonymous
93	EPA-HQ-OW-2018-0594-0093	Michelle	Garrigan	Private Citizen
94	EPA-HQ-OW-2018-0594-0094	Rebecca	Potvin	Private Citizen
95	EPA-HQ-OW-2018-0594-0095	Adam	Nelson	Private Citizen
96	EPA-HQ-OW-2018-0594-0096	Ned	Rollins	Private Citizen
97	EPA-HQ-OW-2018-0594-0097	Josephine	Scipione	Private Citizen
98	EPA-HQ-OW-2018-0594-0098			Anonymous

Exhibit 2: List of Public Commenters				
Comment Information		**Submitter Information**		
Commenter Number	**Document ID**	**First Name**	**Last Name**	**Organization Name**
99	EPA-HQ-OW-2018-0594-0099			Anonymous
100	EPA-HQ-OW-2018-0594-0100	Dan	Man	Private Citizen
101	EPA-HQ-OW-2018-0594-0101			Mass comment campaign – unknown sponsoring organization
102	EPA-HQ-OW-2018-0594-0102			Mass comment campaign – Environmental Working Group (EWG)
103	EPA-HQ-OW-2018-0594-0103	Princess	Eterna	Private Citizen
104	EPA-HQ-OW-2018-0594-0104			International Molybdenum Association (IMOA)

2. Comments and EPA Responses by Topic

General Comments

Agency Discussion on General Comments

Agency Topic Discussion:

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. The Agency agrees that protecting the quality of drinking water is an important part of protecting public health and appreciates the commenters' support for the Contaminant Candidate List (CCL) process and the drinking water program.

A couple of commenters refer to CCL as a regulation. The CCL is not a regulation or a proposed regulation. It has no binding effect and is not enforceable. Section 1412(b)(1) of the Safe Drinking Water Act (SDWA), 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 National Primary Drinking Water Regulations (NPDWRs), are known or anticipated to occur in public water systems (PWSs) and may require regulation under the SDWA. The SDWA also 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. EPA uses the CCL to help identify priority contaminants for regulatory decision making and to prioritize research and data collection efforts. On a five-year cycle, under a separate action, known as the regulatory determination process, the SDWA requires EPA to make decisions on whether it should initiate a process to develop an NPDWR for no fewer than five contaminants on the CCL. Under Section 1412 (b)(1)(a) of SDWA, EPA makes a determination to regulate a contaminant in drinking water if the Administrator determines that it meet the three following criteria:

1. The contaminants may have an adverse effect on the health of persons;
2. The contaminant is known to occur or there is substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern and;
3. In the sole judgement of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

If EPA determines that these three statutory criteria are met and makes a final determination to regulate a contaminant, the Agency must publish a proposed Maximum Contaminant Level Goal (MCLG) and NPDWR within 24 months. After proposal, the Agency must publish the final MCLG and promulgate final NPDWR (SDWA section 1412 (b)(1)(E) within 18 months. (These deadlines may be extended by 9 months.)

Comments related to regulated contaminants in drinking water, such as lead, and developing new regulations for contaminants are outside the scope of the CCL. EPA continues to value and encourage partnerships that benefit local water systems and foster strong partnerships with other federal agencies, tribes, local governments, and states. EPA's regional offices play a significant role in supporting states in implementing NPDWRs.

One comment suggest that EPA make a more easily digestible document for the public. The Agency has developed a Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5) –

Agency Discussion on General Comments

Chemical Contaminants (USEPA, 2022a); Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5) – Contaminant Information Sheets (USEPA, 2022b); and Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5) – Microbial Contaminants (USEPA, 2022c) that outlines in detail with diagrams, figures and exhibits that assist with explaining various parts of the CCL 5 process. Between the Draft CCL 5 and the Final CCL 5, the Agency took steps, where possible, to increase clarity and transparency of these technical support documents based on public comments and SAB recommendations. EPA will continue to work to improve materials and information to make the process clearer and more concise with each CCL cycle.

In addition, as described in the Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5) - Microbial Contaminants, the Agency considers a broad range of microbes, known as the CCL microbial universe, to identify those pathogens that present the greatest public health concern related to health risks and occurrence in drinking water to list on the CCL. The Human Coronavirus (SARS-COV-2), the virus that causes COVID, was included in the CCL 5 Microbial Universe and processed through the microbial screening process. Using the exclusionary screening criteria developed for CCL microbial pathogens, SARS-CoV-2 was screened out using Criterion 6: Pathogens transmitted solely by respiratory secretions. The World Health Organization (WHO) has stated that the "presence of the COVID-19 virus has not been detected in drinking-water supplies and based on current evidence the risk to water supplies is low" (WHO, 2020). As mutations of the Human Coronavirus may occur over time, EPA will continue to research species that could potentially be found in drinking water. During each CCL process, which occurs every five years, there is an effort to evaluate any new information/data on contaminants and identify any new contaminants for evaluation through the CCL process for listing and/or as a potential as a research priority. For more details about Coronavirus and Drinking Water please see EPA's Coronavirus and Drinking Water and Wastewater webpage: https://www.epa.gov/coronavirus/coronavirus-and-drinking-water-and-wastewater.

Comments Received on General Comments

Comment Excerpt from Commenter 52

The population in the United States relies on the EPA to continue to regulate the water that they use for drinking, cooking, bathing, and even watering their own gardens that they use to grow their own foods. The general public is unaware of the many different types of contaminants that could negatively effect the health of themselves and their families and relies on the experience of the scientists that make the CCL to identify the contaminants that could be harmful to their health and to continue to regulate the previously identified contaminants and identify contaminants that requires regulation.

Individual Response: Please see Discussion on General Comments.

Comments Received on General Comments

Comment Excerpt from Commenter 54

The Draft CCL 5 includes an additional 81 contaminants or groups. The list is comprised of 69 chemicals or chemical groups and 12 microbes. Since 1998, the CCL listing has been revised to include the contaminants that pose the greatest public health concern. In this recent draft I would ask if there was research indicative of contaminants that may have come about due to the recent coronavirus global pandemic. The pandemic has caused a rise in unemployment and a review of this data may be important to ascertain if we have enough or appropriate number of resources still reviewing or monitoring the data sources. Also, the recent changes in climate could have also taken a toll on our drinking water exposure.

Individual Response: Please see Discussion on General Comments.

EPA compiled data sources identified from CCL 3 and CCL 4, along with data sources recommended by the CCL 5 workgroup and subject matter experts. As a result of this effort, EPA identified 134 potential data sources and further assessed their potential use for the CCL 5 development process. More information on Assessing and Identifying Data Sources can be found in section 2.2 of the Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5) - Chemical Contaminants (USEPA, 2022a).

EPA agrees that changes in climate may affect drinking water quality as a result of an increase in the frequency and intensity of storms and warmer air temperatures. More frequent storms and floods may cause overflows from sewage systems and treatment plants into freshwater sources for drinking water. This may lead to an increase in the prevalence of waterborne parasites, such as *Cryptosporidium* and *Giardia.* Additionally, higher air temperatures, and the corresponding increase in water temperatures, can also promote increased growth of algae and cyanobacteria in some waterbodies causing harmful algal blooms (HABs). An increase in HABs can threaten availability of source water, impact drinking water quality and increase the need for drinking water treatment.

Comment Excerpt from Commenter 58

As a consumer and a private citizen, I do not know many things about chemical compounds and what good or bad they can do for my body. However, I know that many contaminants can naturally occur in the water and also could happen as a chemical byproduct. I am really glad that this agency is adding more chemical groups and contaminants, that are currently not subject to any regulations to this proposed CCL 5 regulation.

It is really important to recognize contaminants because the adverse effects of those contaminants are not known to the health of the person. This regulation would be a good opportunity for reducing health risks for persons served by public water systems.

Individual Response: Please see Discussion on General Comments and Contaminant Groups.

Comment Excerpt from Commenter 59

Re: Document Citation 86 FR 37948

To whom it may concern:

Thank you for the opportunity to comment on document citation 86 FR 37948. As a PhD scientist with a Masters in Public Health, I appreciate the efforts of the EPA and support the continuation of your

Comments Received on General Comments
three step process of (1) building a broad universe of contaminants and microbes; (2) screening this universe to identify those that need more scrutiny, and (3) selecting what makes the list based on human health effects. I also appreciate the utilization of subject matter experts from the NAB, NRC, NDWAC and the public in the continuous identification of contaminants and determination of future regulatory actions on these contaminants. The general public depends on these subject matter experts to identify contaminants that may negatively affect their health. **Individual Response:** Please see Discussion on General Comments.
Comment Excerpt from Commenter 60 As a regular user of water, like many other Americans, it is imperative that the EPA continue to generate the Containment Candidate List (CCL) which the Safe Drinking Water Act (SDWA) mandates is published every five years. After reviewing the lists of different contaminants in our water, the EPA has done a thorough job of listing and also providing explanations to the public of what these contaminants are so it is easier for the public to understand. The list can be intimidating to some and also has the ability to put fear of drinking water into others. Though I understand that simplifying most of the list for the general public is difficult, there should be a way to provide a more general breakdown of the list to everyone. Unfortunately, in the U.S. there are areas where water contamination is terrible, thankfully this is not the norm. I appreciate the publishing of this list since 1996 and hope the EPA continues to do so, in hopes that efforts are made to continue to make our water safer for everyone. I propose the EPA make a more easily digestible document for the public, maybe one with pictures and explanations so all can learn from it and have any fears set aside. Thank you. **Individual Response:** Please see Discussion on General Comments.
Comment Excerpt from Commenter 61 The proposed rule that regulates 66 chemicals, 3 chemical groups (per-and polyfluoroalkyl substances (PFAS), cyanotoxins, and disinfection byproducts) and 12 microbial contaminants. I fully support the regulation of chemicals in drinking water which might affect human health . I understand EPA has followed 3 three-step processes to classify and select the Draft CCL5 chemicals. The last step was to select contaminants based on occurrence in drinking water. Based on the ERA previous announcement, tap water is still safe to drink during Covid-19 pandemic. It has raised my concern that the select contaminants are based on the occurrence or score in drinking water. For viruses like SARS, Coronavirus, and its mutations, they are very contiguous and it may have a huge effect on human health, but may not be found in the drinking water now. It raises the question if we have enough resources and techniques to analyze and monitor the data. **Individual Response:** Please see Discussion on General Comments and Suggestions to Improve the Process for Future CCLs.
Comment Excerpt from Commenter 65 The current coronavirus pandemic is resulting in significant impacts worldwide in many aspects. It has been causing major drawbacks in terms of environmental protection policies around the global. For example, with the fear of COVID-19 transmission, people increased use of single-us plastic, disinfecting products and related chemicals - hand sanitizers, sanitizing wipes, toilet papers, cleaning products and tissue, therefore, it caused increased environmental water pollution concerns. One of the main routes of human exposure to pollutants is through our drinking water. It is important for

Comments Received on General Comments

EPA to focus on and add certain pollutants considered major contaminants in drinking water which are expected to show increased levels during and after the COVI-19 pandemic and result in adverse effects to human's immune system into the list of regulated chemicals.

Individual Response: Please see Discussion on General Comments.

Comment Excerpt from Commenter 77

The American Water Works Association (AWWA) appreciates the opportunity to provide comments on the Environmental Protection Agency's (EPA's) draft of the Drinking Water Contaminant Candidate List 5 (CCL 5). AWWA has a continuing interest in EPA's Safe Drinking Water Act (SDWA) program and has been an active participant in, and facilitator of, technical dialogues and stakeholder engagement around the drinking water regulatory process since its inception.

The CCL is the element of the nation's drinking water program that helps EPA identify contaminants that represent public health risks that can be reduced through drinking water treatment / control. As such it provides the starting point for identifying regulatory and research / information collection priorities for EPA, the federal government, and the sector. Consequently, it is important to recognize:

1. The work of the involved EPA staff and peer-reviewers on the CCL is vitally important and should be recognized by EPA management.

2. For the CCL to be an effective tool it must be a short, preferably prioritized, list. Given EPA's available resources, the draft CCL 5 is not yet sufficiently focused.

3. The Final CCL 5 Federal Register notice will be a key opportunity to present research and information needs to advance EPA's drinking water regulatory program.

4. CCL 5 and subsequent CCLs should be used to inform coordination with other EPA programs (e.g., the Toxic Substances Control Act program [TSCA]) in order to prevent contamination of the nation's water supply.

5. The draft CCL 5 technical support document suggests that there are significant gaps in data that should be available from the TSCA program and the Clean Water Act National Pollutant Discharge Elimination System. EPA should take steps now to address these gaps – action may be needed by the TSCA and Office of Enforcement and Compliance program offices to facilitate development of future CCLs.

6. The CCL process should be an ongoing effort rather than the current prepare-pause-regenerate preparation model and that ongoing effort should be in concert with external expert input.

7. The Draft CCL 5 Federal Register notice and technical support documents should be supplemented to better communicate the effect of influential decisions in CCL preparatory process, especially the identification of named groups rather than individual contaminants.

8. The CCL is an important and underutilized tool in EPA's risk communication efforts. A clearly described and supported prioritized list of contaminants would provide a framework for EPA communication about its efforts to protect the public from contaminants in drinking water

Comments Received on General Comments

AWWA hopes that the following comments will assist EPA to utilize this important element of SDWA effectively. If you have any questions regarding this correspondence, please contact me or Chris Moodyat 202.326.6127 or cmoody@awwa.org.

FOR THE AMERICAN WATER WORKS ASSOCATION.

G. Tracy Mehan, III

Executive Director – Government Affairs

American Water Works Association

Attachment (1)

cc: Michal Freedhoff, EPA/OCSPP

Andrew Sawyers, EPA/OW/OWM

Jennifer McLain, EPA/OW/OGWDW

Randy Hill, EPA/OECA/ETDD

Madeline Beal, EPA/OPA

Kesha Forrest, EPA/OW/OGWDW

Who is AWWA

The American Water Works Association (AWWA) is an international, nonprofit, scientific and educational society dedicated to providing total water solutions assuring the effective management of water. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our membership includes more than 4,500 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation’s wastewater. Our 50,000-plus total membership represents the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water, our most important resource. AWWA unites the diverse water community to advance public health, safety, the economy, and the environment.

ATTACHMENT A

Comments prepared by the

American Water Works Association

on the

U.S. Environmental Protection Agency’s

Drinking Water Contaminant Candidate List 5-Draft

(86 Federal Register 37948, Docket ID: EPA-HQ-OW-2018-0594)

Prepared

September 17, 2021

Contents

Comments Received on General Comments

Comments

Prepared by the American Water Works Association on

EPA's Drinking Water Contaminant Candidate List 5-Draft

(86 Federal Register 37948, Docket ID: EPA-HQ-OW-2018-0594)

Introduction

AWWA has commented extensively on prior contaminant candidate lists (CCLs) and their development. [FN1: AWWA, 2009, Comment submitted on Drinking Water Contaminant Candidate List 3 – Draft, EPA-HQ-OW-2007-1189-0100.] [FN2: AWWA, 2012. AWWA Response to Contaminant Candidate list 4 Request for Nominations, Docket ID No. EPA-HQ-OW-2012-0217. https://www.regulations.gov/comment/EPA-HQ-OW-2012-0217-0059] In its Draft CCL 5 Federal Register notice EPA solicited comments on the following:

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

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

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

The following comments are focused on these areas.

AWWA appreciates that EPA's approach in developing the draft CCL 5 and implementing recommendations from the National Drinking Water Advisory Council (NDWAC), AWWA, and others.

Comments Received on General Comments

The process described in the proposal is thorough and provided for consideration of large universe of potential candidate contaminants. The Agency clearly recognizes that the development of the CCL should be a comprehensive and methodical process. The CCL process is an important component of the Agency's Safe Drinking Water Act (SDWA) work plan and is essential to moving beyond regulating the "contaminant du jour". A well-crafted CCL is essential to informing future risk management actions that effectively utilize scarce resources to best protect public health.

Structuring a More Effective CCL 5

As described by the SDWA, the CCL is the first step of the regulatory process for drinking water contaminants and is intended to represent the contaminants that "present the greatest public concern". To be an effective tool, the CCL must provide adequate focus to drinking water research needs. When effectively developed and structured, the CCL guides EPA and external stakeholders to conduct research important to addressing risks associated with drinking water risks, and thus informing action under SDWA when needed.

The CCL should also facilitate clear communication with consumers and engaged stakeholders on research gaps limiting further regulatory action, the scope of the necessary research projects (short-, mid-, and long-term), and the relative levels of priority that contaminants present as a public health risk. The CCL is revised on a five-year cycle so that the list reflects changes in available science and the relative risks presented by unregulated contaminants. For example, the national occurrence of a listed contaminant may decrease due to management efforts under the Toxic Substances Control Act (TSCA), state regulatory actions, or changes in manufacturing and use trends. Alternatively, contaminants not previously on the CCL due to a limited availability of data may be added to the CCL due to new data that show the contaminant presents a greater public concern.

Individual Response: Please see Discussion on General Comments, Length of CCL 5, Other Drinking Water Programs, Other EPA Programs, Chemical Data/Data Sources, and Contaminant Groups.

Comment Excerpt from Commenter 95

I appreciate the ability to comment on this upcoming regulation. I feel like this is a great thing to be doing, as it notifies the public of these 66 new chemicals. I noticed that none of these 66 chemicals are being regulated by the EPA in any way, and am curious if the EPA tests these chemicals to see if they are a danger to human health? I noticed that there are specific effects listed for the bacterial contaminants and pathogens listed in the regulation, however I am curious what the EPA is doing to attempt to combat these rising new bacteria that are found in our drinking water.

Individual Response: Please see Discussion on General Comments and Draft CCL 5-Microbes. EPA respectfully disagrees with the commenter's statement that "none of the 66 chemicals are being regulated by the EPA in any way". The 66 individually listed chemicals on the CCL 5 are currently not regulated under the SDWA with a National Primary Drinking Water Regulation (NPDWR); however, some of the chemicals listed on the CCL 5 are regulated under other EPA regulatory programs. For example, EPA regulates 2,4-dinitrophenol under the Clean Water Act's national permitting program and regulates all pesticides listed on CCL 5, such as diazinon and dicrotophos, under the Federal Insecticide, Fungicide, and Rodenticide Act.

Regarding the question on human health, almost all except for four contaminants (4- Methyl tert-butyl ether (MTBE), Nonylphenol (all isomers), Desvenlafaxine, and Fluconazole) of the CCL 5 listings

Comments Received on General Comments
have available health effects information or qualifying health assessments developed by EPA or other health agencies. Further, EPA works to prioritize research on CCL contaminants. EPA conducts research including toxicity testing, computational toxicology approaches, and the development of new approach methods to fill data gaps in support of Agency regulatory needs. EPA also conducts research on microbial contaminants including exposure, dose-response, and treatment studies. Results from this research can help inform future decisions on CCL 5 listed contaminants. For additional information on data availability, please see the Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5) - Chemical Contaminants, Table 26.
Comment Excerpt from Commenter 99 As an Environmental Policy student, I agree with the EPA's mission of protecting human health and the American public. Through this improvement of the draft list within the Safe Drinking Water Act (SDWA), the agency is placing a greater priority on the health and safety of Americans. As the chemical manufacturing industry grows and mitigation of chemicals in the landscape becomes more difficult, this type of Contaminant Candidate List is ever more pertinent. The continuation and update to this program are needed more than ever to protect people, especially those who live in agricultural and manufacturing adjacent communities. **Individual Response:** Please see Discussion on General Comments.
Comment Excerpt from Commenter 100 This is a good reason why people should be safe, not even water is considered safe, especially if its contaminated, it could seriously get someone hurt. **Individual Response:** Please see Discussion on General Comments.
Comment Excerpt from Commenter 101 Thank you for this opportunity to comment on EPA's draft Fifth Contaminant Candidate List (Draft CCL 5) under the Safe Drinking Water Act (SDWA). I support EPA regulating all of the dangerous contaminants on the SDWA candidate list. It is especially important that EPA include and set safe drinking water limits on groups of extremely hazardous chemicals like cyanotoxins, disinfection byproducts, and PFAS. Accessing safe drinking water has been a concern of mine for many years. When my children were preschoolers and tested high for lead, I became very aware of the importance of being vigilant about the quality of the water we were drinking. We should be able to depend on the quality of water coming out of our taps. We need agencies like the EPA to work with our local governments to provide strong guidelines for safety. We need EPA to ensure our drinking water is safe from all of the toxic and hazardous chemicals that are being released into the environment. To do that, EPA must increase staffing and speed up the process for reviewing the contaminants and setting legal limits on how much can be in our drinking water. **Individual Response:** Please see Discussion on General Comments, Chemical Groups, PFAS, DBPs, and Cyanotoxins.
Comment Excerpt from Commenter 102

Comments Received on General Comments

The undersigned 9,292 supporters of the Environmental Working Group, or EWG, add their voices to EWG's comments calling for regulating hazardous drinking water contaminants.

9,292 supporters signed EWG's petition stating:

Clean up our water! Chemicals linked to cancer, hormone disruption and infertility should not be allowed in our water. It's time for the EPA to do its job and regulate hazardous drinking water contaminants like PFAS, pesticides and disinfection byproducts.

EWG and our supporters urge you to take steps to clean up our drinking water.

Individual Response: Please see Discussion on General Comments, PFAS, and DBPs.

Length of CCL 5

Agency Discussion on Length of CCL 5

Agency Topic Discussion:
Section 1412(b)(1) of the Safe Drinking Water Act (SDWA), as amended in 1996, does not impose a limit to the number of drinking water contaminants that may or should be included on a given CCL.

EPA's Science Advisory Board (SAB) report on the Third Contaminant Candidate List (CCL 3) noted, however, that the process used for CCL 3 had "not whittled the Universe sufficiently to be efficient or effective," with 104 contaminants identified for that iteration. The SAB report further noted that larger CCLs could "not clearly communicate to the [drinking water community], other specific interested parties, and/or the general public which contaminants might – or might not – be considered for a meaningful regulatory determination" (USEPA, 2009b).

Based on SAB's feedback for CCL 3, EPA worked to deliver a shorter CCL 5 compared to its predecessor. When considering that the improved CCL 5 process generated the broadest and most comprehensive chemical universe of health and occurrence information to date (with approximately 22,000 chemicals and 1,435 microbes in the CCL 5 Universe compared to approximately 6,000 chemicals and 1,415 microbes in the CCL 3 Universe), EPA views the resulting list of 66 chemicals, three chemical groups and 12 microbial contaminants as having been more effectively narrowed for the purposes of identifying priority contaminants for both future regulatory decisions and for prioritizing research and data collection efforts.

Comments Received on Length of CCL 5

Comment Excerpt from Commenter 71

The Association of Metropolitan Water Agencies (AMWA) is an organization representing the largest publicly owned drinking water utilities in the United States. AMWA appreciates the opportunity to comment on the Environmental Protection Agency's (EPA) draft Drinking Water Contaminant Candidate List 5 (CCL 5). AMWA has continually supported the scientific and data-driven process under the Safe Drinking Water Act (SDWA). The association believes following the process outlined in the SDWA remains the best way to prioritize the agency's limited resources by focusing on those contaminants most likely to present human health risks through drinking water while also being conscious of the finite resources available to public water systems across the country. The CCL process remains an essential first step for the agency to determine which contaminants should move further through the SDWA process.

As AMWA has stressed in previous comments to the agency, the association believes that EPA should focus the CCL in a way that will best utilize the agency's limited resources and optimize its resource budget. AMWA maintains the need for EPA to reduce the number of substances included in each CCL. The association believes that restricting the CCL to a more manageable number will better accomplish the agency's goal of accurate and meaningful regulatory determinations for currently unregulated substances.

The SDWA states that the Administrator shall regulate contaminants that will provide a "meaningful opportunity for health risk reduction for persons served by public water systems" (§1412 (b)(1)(A)(iii)). EPA has maintained in (or throughout) previous statements that the SDWA does not limit the number of contaminants that may be included in the CCL.

Although AMWA agrees with EPA's assessment that the SDWA does not limit to the size of the CCL, it remains unclear how the agency can best prioritize these contaminants when the list grows exponentially, yet EPA's budget to study emerging contaminants does not. For example, the number of contaminants included more than doubled between CCL 2 and CCL 4, with 51 contaminants on the list for CCL 2 and 109 contaminants on CCL 4. It appears that EPA has acknowledged this issue and reduced the number of substances on this most recent CCL by not automatically carrying over all chemicals from CCL 4 to CCL 5, but instead revisiting the available information for each contaminant before including it again. AMWA encourages the agency to continue this procedure when creating future CCLs to keep the list more manageable.

Individual Response: Please see Discussion on Length of CCL 5.

Comment Excerpt from Commenter 77

AWWA offers the following recommendations for EPA to consider as the CCL 5 is finalized and in the development of future CCLs.

Short, Manageable List is Needed

The EPA Science Advisory Board observed that CCL 3, which included 116 contaminants was a list too large to "achieve the stated objectives of the CCL process." [FN3: SAB. 2009. SAB Advisory on EPA's Draft Third Drinking Water Contaminant Candidate List (CCL3).] As proposed, the Draft CCL 5 is comprised of more than 1,400 individual contaminants. It is difficult, if not impossible, for stakeholders and consumers to effectively understand the EPA's priorities moving forward with such an extensive CCL. AWWA and other stakeholders have previously emphasized the need for a short,

Comments Received on Length of CCL 5

manageable CCL to facilitate the efficient advancement of research activities and to clearly communicate potential contaminants that present opportunities for meaningful public health protection. EPA should consider reducing the size of the CCL 5 such that only drinking water contaminants presenting the "greatest public concern" are included on the list and that the list's scope is commensurate with the funding available for EPA to deploy to advance SDWA decision-making processes. Moreover, it's completely infeasible to meaningfully consider regulation for 1,400+ contaminants. This dilutes the impact of the CCL and suggests that listing doesn't truly have any substantive significance to EPA's regulatory decision-making.

Individual Response: Please see Discussion on Length of CCL 5.

Other Drinking Water Programs

Agency Discussion on Other Drinking Water Programs

Agency Topic Discussion:

EPA received many comments related to the Unregulated Contaminant Monitoring Rule (UCMR) and the Regulatory Determination process. The CCL, UCMR, and Regulatory Determinations are three separate, but interrelated, steps in the drinking water regulatory process authorized under SDWA. The selection of contaminants for previous or upcoming UCMR monitoring and prioritizing contaminants on the CCL for regulatory determinations are both outside the scope of CCL 5.

The CCL is not a regulation and therefore there are no drinking water enforcement actions under SDWA with respect to contaminants on the list. The statute does not authorize banning of contaminants. EPA uses the CCL to identify priority contaminants for regulatory decision making and information collection.

For contaminants that have sufficient information available, the Agency can proceed through the regulatory determination process. Under that process, EPA determines whether the three statutory criteria for regulation of a new drinking water contaminant are met for any contaminant not yet regulated, the Agency may decide to develop a Health Advisory (HA), which provides non-regulatory and non-enforceable concentration values for drinking water contaminants at which adverse health effects are not anticipated to occur over specific exposure durations (one-day, ten-days, several years, and a lifetime). HAs serve as informal technical guidance to assist Federal, State, and local officials, and managers of public or community water systems (CWSs) in protecting public health, such as when emergency spills or contamination situations occur.

UCMR

EPA received many comments related to previous and upcoming UCMR monitoring cycles. SDWA section 1445(a)(2)(B)(i) requires that every five years EPA issue a new list of no more than 30 unregulated contaminants to be monitored by public water systems (PWSs).
In establishing the list of contaminants for each UCMR cycle, EPA considers the CCL and other priority contaminants. This national occurrence study is one of the primary sources of occurrence data in drinking water that the Agency uses to develop regulatory decisions for contaminants in the public drinking water supply.

Agency Discussion on Other Drinking Water Programs

EPA selected UCMR contaminants using a multi-step prioritization process. The first step identified contaminants that were not monitored under previous UCMR cycles; may have significant occurrence nationally; and have a completed, validated drinking water analytical method. The next step focused on contaminants associated with one or more of the following considerations: an available health assessment to facilitate regulatory determinations; high public concern; critical health endpoints (for example, a likely or suggestive carcinogen); active use (for example, pesticides); and/or an occurrence data gap. Then EPA considered stakeholder input; looked at cost-effectiveness of analytical methods (single methods that address multiple contaminants of interest); considered implementation factors (such as laboratory capacity); and further considered available health data (e.g., children), occurrence data, and persistence/mobility data.

Regulatory Determination

EPA also received many comments regarding the initiation of new drinking water regulations as a result of the Regulatory Determination process. SDWA section 1412(b)(1)(B)(ii) directs EPA to determine, after public notice and an opportunity to comment, whether to regulate at least five contaminants from the CCL every five years. Prior to making regulatory determinations, EPA will compile additional available data on all the CCL 5 contaminants to prioritize which contaminants have sufficient information to be evaluated against the three criteria for regulation of a new drinking water contaminant.

Under section 1412(b)(1)(A) of SDWA, EPA makes a determination to regulate a contaminant in drinking water if the Administrator determines that:

> i) the contaminant may have an adverse effect on human health;
> ii) 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
> iii) 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 comments on a preliminary determination, the Agency makes a final determination to regulate a contaminant, EPA will initiate the process to propose and promulgate a National Primary Drinking Water Regulation (NPDWR). NPDWR are legally enforceable drinking water standards expressed as maximum contaminant levels (MCLs) or treatment technique requirements that apply to public water systems. In that case, the statutory time frame provides for agency 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).

Six Year Review (SYR)

SDWA requires EPA to review each NPDWR at least once every six years and revise them, if appropriate. Under SYR, EPA evaluates any newly available data, information and technologies to determine if any regulatory revisions are needed to maintain or strengthen public health protection. For EPA's third SYR, EPA concluded that eight NPDWRs are candidates for regulatory revision. EPA is currently conducting analyses to further evaluate theses eight NPDWRs for potential regulatory revisions under EPA's Microbial and Disinfection Byproducts (MDBP) Rule Revisions efforts.

Microbial and Disinfection Byproducts (MDBP) Rule Revisions

Agency Discussion on Other Drinking Water Programs

EPA is currently conducting analyses to further evaluate eight MDBP NPDWRs for potential regulatory revisions. The eight contaminants: Chlorite, Cryptosporidium, Haloacetic acids, Heterotrophic bacteria, Giardia lamblia, *Legionella*, Total Trihalomethanes, and viruses were identified as candidates for revision in the agency's third SYR and are included in the following MDBP rules: Stage 1 and Stage 2 Disinfectants and Disinfection Byproducts Rules, Surface Water Treatment Rule, Interim Enhanced Surface Water Treatment Rule, and Long-Term 1 Enhanced Surface Water Treatment Rule.

EPA has initiated the MDBP rule revision process and plans to meet the schedule in the 2020 Waterkeepers Alliance v. EPA settlement agreement of proposing to revise the NPDWRs for the MDBP contaminants by July 2024, and publish a notice of final action on that proposal by September 2027. For more a copy of the WaterKeepers settlement agreement, please see: https://www.regulations.gov/document/EPA-HQ-OGC-2020-0140-0002.

Comments Received on Other Drinking Water Programs

Comment Excerpt from Commenter 63

The typical US resident is not equipped to comment on a draft list of contaminants that may be subject to regulation. However, the typical US resident does rely on the FDA for protection against harmful contaminants in our drinking water. I was struck that this is required only once every five year and is limited to 30 contaminants and don't understand why either is in place. Beyond what is added to the list, an explanation of the contaminants, their prevalence and coordination in mitigating risk with local municipalities would be helpful.

Individual Response: Please see Discussion on Other Drinking Water Programs and Chemical Technical Support Documents. The EPA regulates public drinking water (tap water) under SDWA, while the Food and Drug Administration (FDA) regulates bottled water under the Federal Food, Drug, and Cosmetic Act. SDWA, as established by Congress, requires EPA, once every five years, to publish a list of no more than 30 unregulated contaminants to be monitored by public water systems, which is known as the Unregulated Contaminant Monitoring Rule (UCMR). The UCMR is a separate action from the CCL.

An explanation of each chemical evaluated on the Fifth Preliminary Contaminant Candidate List (PCCL 5) and the CCL 5 is provided in the Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5) - Contaminant Information Sheets, along with the occurrence and health effects data for those contaminants (USEPA, 2022b). Information on the microbial contaminants health risks and occurrence can be found in the Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5) Microbial Contaminants (USEPA, 2022c).

If it is determined that a contaminant from the Final CCL 5 warrants regulation on under SDWA, risk mitigation would be determined as part of the rule development process to establish a NPDWR. EPA, in partnership with states, tribes, and local municipalities, implement NPDWRs.

Comment Excerpt from Commenter 67

I support the Contaminant Candidate List (CCL) 5 Proposed Rule to regulate the "66 individual chemicals, 12 microbes, and three chemical groups - per- and polyfluoroalkyl substances (PFAS), cyanotoxins, and disinfection byproducts (DBPs)" (EPA 2021). If the EPA has determined that these

Comments Received on Other Drinking Water Programs

substances meet the criteria they set forth, then I believe the decision is sound. The criteria are as follows:

"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 2021, II, B, 2).

The EPA should approach regulating these substances with the precautionary principle in mind. An overabundance of caution will help to prevent potentially harmful side effects from consuming contaminated drinking water such as cancer, infertility, organ failure, or compromising ones immune system. If a substance has been nominated for the CCL 5, its use should be suspended from any action that could result in its introduction to drinking water or navigable waterways or other sources of water that are covered by the Safe Drinking Water Act (SDWA). The process of reviewing potentially harmful substances, as mentioned, is sound, but the enforcement of the list should take greater precedence.

All substances under review are submitted via public comment either with the scientific assumption or knowledge that those substances could potentially cause harm to humans or the environment. The review process is thorough and substantive in its research on the nominated substances, but the review process is time consuming in a way that could leave compromised individuals susceptible to harm.

My recommendation, as previously suggested, would be to generate the list of substances for review. This includes filtering out redundant entries and substances that might not meet the criteria for review. Once organized, the substances on the list should be suspended from use in all processes that could result in those substances ending up in consumable drinking water. Once these substances have been reviewed and the CCL 5 is proposed, those substances listed would become more permanently banned and fully regulated.

In the existing process of review, the extent to which some substances affect people is estimated using models and other predictive methods. Since not all of these substances new or old can be consistently or safely tested on people to determine the range of symptoms, they should be suspended from use until the entire review is conducted and a more accurate result is determined.

Individual Response: Please see Discussion on Other Drinking Water Programs, General Comments, and Other EPA programs.

Comment Excerpt from Commenter 75
September 17, 2021

Ms. Radhika Fox,

Assistant Administrator, Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Ave., NW

Washington, DC 20460

Comments Received on Other Drinking Water Programs

Subject: Proposed Rule - Drinking Water Contaminant Candidate List 5-Draft [Docket # EPA-HQ-OW2018-0594]

Dear Ms. Fox:

In response to the notice in the Federal Register of July 19, 2021 (Volume 86, Number 135) the Association of State Drinking Water Administrators (ASDWA) would like to offer comments on the draft fifth Contaminant Candidate List (CCL 5). ASDWA supports and represents the collective interests of the states, territories, and the Navajo Nation in their administration of national drinking water program requirements within their states or territories including regulatory development and the CCL. ASDWA appreciates the opportunity to provide the perspective of states on this important phase of the regulatory process. It should be noted, however, that these comments do not necessarily represent the specific views and concerns of individual states or consensus from all states. We encourage EPA to consider individual state's comments, in addition to ASDWA's, to gain further perspective.

The CCL Process

ASDWA strongly supports the regulatory development process outlined in the 1996 Safe Drinking Water Act (SDWA) amendments, including the CCL, the Unregulated Contaminant Monitoring Rule (UCMR), Regulatory Determination, and Six Year Review. Through this process, EPA can assess health risks and assemble occurrence data needed to determine whether or not contaminants warrant national regulations and, if so, at what levels. The regulatory determination process is designed to capture the contaminants that pose the greatest potential public health threat, based on health effects, occurrence and the potential regulatory opportunity for health risk reduction. This process, supported with best available, peer-reviewed data, is vastly preferable to regulating based on arbitrary target numbers or focusing on contaminants with high media profiles -- but where there may not be reliable data to support regulation. The CCL is the critical first step in the regulatory consideration and development process. As such, the link between the CCL and UCMR is critical. ASDWA is concerned with the Agency's approach for UCMR 5, specifically that the final UCMR 5 did not include many contaminants identified in CCL 4 where national occurrence data is needed. ASDWA recommends that EPA take steps to optimize the connection between the CCL and UCMRs. Future UCMRs should be designed to generate robust national occurrence data to fill data gaps for contaminants listed on the most recent CCL.

Individual Response: Please see Discussion on Other Drinking Water Programs, and General Comments. EPA considered all public comments received on the Draft CCL 5, including comments received from individual states. The Agency took steps to coordinate the development of the draft CCL 5 and UCMR 5. For example, in the development of UCMR 5, EPA evaluated the contaminants nominated by the public for potential inclusion in CCL 5 (83 FR 50364, USEPA, 2018; 86 FR 13846 USEPA, 2021c). All contaminants on the final UCMR 5 are on CCL 5. For more information on the selection of contaminants for UCMR 5, please see the Information Compendium for Candidate Contaminants for the Proposed Unregulated Contaminant Monitoring Rule (UCMR 5).

Comments Received on Other Drinking Water Programs

Comment Excerpt from Commenter 75

Moving Forward with Regulatory Determinations

ASDWA recommends that EPA act on CCL contaminants with sufficient data to make a Regulatory Determination. The CCL is not intended to be a permanent home for contaminants, yet eight contaminants that have been on all five CCLs: Diuron, Methyl tert-butyl ether (MTBE), Vanadium, Adenoviruses, Caliciviruses, Cyanobacteria/toxins, Helicobacter pylori, and Mycobacterium avium-intracellular (MAC). EPA first identified these contaminants as concerning in 1998 and, from ASDWA's perspective, no progress in regulatory-decision making has been made in over 20 years for these eight.

Additionally, the draft CCL 5 lists 23 contaminants that have nationally representative finished water occurrence data and qualifying health assessments. ASDWA recommends that EPA make regulatory decisions on these contaminants in Fifth Regulatory Determination. While the law requires EPA to make regulatory determinations for at least five contaminants from the most recent CCL within five years after the completion of the previous round of regulatory determinations, ASDWA encourages EPA to make a regulatory determination for any CCL contaminants with adequate data – specifically, these 23 contaminants. Once adequate data is available to support a decision to regulate or not to regulate, those contaminants should be removed so the focus can shift to other contaminants where more information is needed.

Individual Response: Please see Discussion on Other Drinking Water Programs. Based on the best available data, the eight contaminants mentioned by ASDWA as listed on previous CCLs remain appropriate for listing on the CCL 5. The CCL process and the Regulatory Determination process involve different statutory requirements as described in General Comments and Other Drinking Water Programs. Contaminants that lack sufficient information for Regulatory Determination criteria will not move forward in the regulatory determination process. For example, Diuron did not proceed from Phase 1 to Phase 2 in the Fourth Regulatory Determination because it did not have nationally representative finished water data and also did not have any documented occurrence in finished water at or near levels of health concern (specifically, no documented occurrence at levels > ½ HRL).

Comment Excerpt from Commenter 87

Waterkeeper Alliance thanks you for this opportunity to comment on EPA's draft Fifth Contaminant Candidate List (Draft CCL 5). We fully support EPA's inclusion of the robust list of dangerous contaminants that EPA is considering for regulation under the Safe Drinking Water Act (SDWA), and we applaud EPA's inclusion of three dangerous chemical groups (cyanotoxins, DBPs, and PFAS) rather than listing subsets of individual chemicals. We strongly urge you to ensure that these groups of hazardous chemicals remain on the CCL 5 when it is finalized.

We remain concerned, however, about the slow pace of EPA's administration of the SDWA over many years with respect to review of unregulated contaminants, determining which contaminants require listing on a CCL for further review, affirmatively determining which contaminants require regulation, and then setting legally enforceable limits for those dangerous contaminants. We are also aware that over the past several years EPA fell behind in meeting its statutory requirements, which resulted in our organization and others filing a 2019 citizen suit which led to a settlement agreement pursuant to which EPA is required to get back on track and catch up with the regulatory schedule mandated by Congress.1 1 Waterkeeper Alliance, Inc., et al. v. U.S. EPA, No. 19-Civ.-899 (LJL)(S.D.N.Y.). A true and

Comments Received on Other Drinking Water Programs
correct copy of this settlement agreement is available at https://waterkeeper.org/wp-content/uploads/2020/06/ Settlement-Agreement.pdf, and is also submitted herewith as an exhibit and incorporated by reference herein. In light of this history and these concerns, we urge you to do everything in your power to increase the capacity of EPA staff assigned, and program resources allocated, to administer the SDWA, and to dramatically enhance the agency's ability to expedite these lengthy, drawn-out, multi-year regulatory processes. We further urge you to ensure that the precautionary principle is fully incorporated into EPA's decision making with respect to the issuance of a Final CCL 5 and the development of final national drinking water regulations for all of the dangerous chemicals on the draft list. Meeting the bare minimum requirements set by Congress is simply not enough. The health of our nation, and particularly of our children and underserved communities, depends upon EPA ensuring that the nearly 300 million people across the United States who rely on public water systems won't unknowingly poison themselves by drinking their tap water. There are simply too many dangerous contaminants that remain unregulated, and when it comes to drinking water safety, what we don't know most certainly can hurt us. **Individual Response:** Please see Discussion on Other Drinking Water Programs and General Comments. The development of final national drinking water regulations is outside the scope of the CCL 5 process.
Comment Excerpt from Commenter 89 Overview On behalf of the millions of members and activists of the Natural Resources Defense Council, we submit these comments on EPA's Draft Contaminant Candidate List 5 (CCL 5), proposed at 86 Fed.Reg. 37948 (July 19, 2021). As discussed in these comments, we urge that EPA take expedited regulatory action on PFAS (as redefined consistent with our recommendations below), unregulated DBPs and pathogens, cyanotoxins, 1,4-dioxane, and chlorpyrifos. If the agency does not initiate immediate regulatory steps, it should include all 66 individual chemicals and 12 microbes proposed for the CCL 5, including the redefined PFAS class. **Individual Response:** Please see Discussion on Other Drinking Water Programs, PFAS, DBPs, Draft CCL 5-Microbes, Cyanotoxins, and 1,4-Dioxane.
Comment Excerpt from Commenter 89 In sum, we recommend that EPA immediately move forward with positive regulatory determinations for priority chemical contaminants including: (1) PFAS as a class (if the agency does not initiate an urgent threat to health rulemaking); (2) cyanotoxins; (3) DBPs as a class (and include them in the MDBP rulemaking); (4) 1,4-dioxane; and (5) chlorpyrifos. **Individual Response:** Please see Discussion on Other Drinking Water Programs, PFAS, Cyanotoxins, DBPs, and 1,4-Dioxane.

Comments Received on Other Drinking Water Programs

Comment Excerpt from Commenter 89

III. EPA SHOULD INCLUDE ALL OF THE INDIVIDUAL PROPOSED CHEMICALS & PATHOGENS IN CCL5, AND IMMEDIATELY INITIATE REGULATORY ACTION FOR KEY CONTAMINANTS

As discussed extensively in the Federal Register notice proposing listing 66 individual chemicals and 12 microbes, and as documented in the agency's background documents and record, there is ample evidence to justify listing all of these proposed contaminants. They are "known or anticipated to be found in public water systems and may require regulation." [FN29: Ibid.] All may pose public health hazards. We believe that several of these contaminants are of particularly high priority because of their known widespread occurrence and health impacts, such as 1,4-dioxane and chlorpyrifos.

Individual Response: Please see Discussion on Other Drinking Water Programs and 1,4-Dioxane.

Comment Excerpt from Commenter 89

IV. CONCLUSION

We appreciate the opportunity to comment. We support EPA's treatment of PFAS as a class but urge that the agency use the scientifically more soundly OECD definition rather than the overly narrow proposed definition, The agency should immediately initiate urgent threat to health rulemaking for the PFAS class rather than delaying by going through the CCL and complete multi-year unregulated contaminant process that to date has not produced in a single new drinking water standard the quarter century since 1996. We also urge that EPA consider the unregulated DBPs and microbes proposed for the CCL for immediate controls through the upcoming MDBP rulemaking. While of course PFAS, DBPs and the microbes all clearly qualify for the CCL5, more prompt action is required.

Similarly, with respect to cyanotoxins, we support their treatment as a class, but urge that a prompt positive regulatory determination be made for them as well. And because of the ample database showing the threats from 1,4-dioxane and chlorpyrifos, we urge that they too be subject to an immediate positive regulatory determination. Clearly, all of these contaminants qualify for inclusion on CCL5, but swifter action is needed.
Finally, with respect to all of the proposed chemical and microbial contaminants, they qualify for inclusion on CCL5 and should be listed if EPA fails to initiate more immediate regulatory action for them.

Individual Response: Please see Discussion on Other Drinking Water Programs, PFAS, DBPs, Draft CCL 5-Microbes, and 1,4-Dioxane.

Comment Excerpt from Commenter 96

Thank you for this opportunity to comment on EPA's draft Fifth Contaminant Candidate List (Draft CCL5) under the Safe Drinking Water Act (SDWA). I support EPA regulating all of the dangerous contaminants on the SDWA candidate list.
Do the right thing.
Water is Life

Individual Response: Please see Discussion on Other Drinking Water Programs.

Comment Excerpt from Commenter 97

Thank you for this opportunity to comment on EPA's draft Fifth Contaminant Candidate List (Draft

Comments Received on Other Drinking Water Programs

CCL5) under the Safe Drinking Water Act (SDWA). I support EPA regulating all of the dangerous contaminants on the SDWA candidate list. It is especially important that EPA include and set safe drinking water limits on groups of extremely hazardous chemicals like cyanotoxins, disinfection byproducts, and PFAS.

Individual Response: Please see Discussion on Other Drinking Water Programs, Cyanotoxins, DBPs, and PFAS.

Comment Excerpt from Commenter 101

Because the public's health and safety is threatened by so many new contaminants, I am asking you to set strict standards on the most dangerous chemicals and err on the side of protecting the public when data is limited. The health of our nation, and particularly children and underserved communities, depends on it.

Individual Response: Please see Discussion on Other Drinking Water Programs.

Other EPA Programs

Agency Discussion on Other EPA Programs

Agency Topic Discussion:

EPA received multiple comments related to other EPA programs including comments that Office of Groundwater and Drinking Water (OGWDW) and Office of Research and Development (ORD) should align efforts and that EPA should develop a stronger and more visible connection between CCL and the Agency's research plans. Another commenter mentioned the need for CCL to inform risk management efforts beyond the scope of the SDWA (e.g., Toxic Substance Control Act). EPA's Office of Water coordinates its efforts with other EPA offices, including ORD and TSCA.

ORD

Office of Water's OGWDW engages with ORD throughout the CCL process, specifically obtaining input and review of published research on current and proposed CCL chemicals and microbes. Data gaps are identified for each CCL chemical as part of this process. EPA categorized chemical contaminants with respect to the available occurrence, health effects and analytical methods data in the Data Availability Assessment table (Exhibit 4), located in the Drinking Water CCL 5 - Final *Federal Register* notice. EPA will continue to evaluate data needs through the regulatory determination process and will continue to work with internal and external researchers to discuss research needs and priorities.

Additionally, ORD is currently in the next Strategic Research Action Plan (StRAP) development phase. ORD works with other EPA Program Offices and Regions, states, and tribes to identify research gaps as part of this process. OW provides input related to data gaps for CCL contaminants to ORD as part of StRAP development. For the current planning cycle, research gaps include analytical methods, occurrence/exposure, and toxicity for some CCL 5 contaminants. ORD remains flexible during research plan implementation to adjust to changing OW priorities if they occur, enabling ORD to incorporate CCL related research projects such as analytical methods, health effects, and treatment into ORD research planning as needed. Existing StRAP documents for each of ORD's 6 National Research Programs are publicly available at https://www.epa.gov/research/strategic-research-action-plans-

Agency Discussion on Other EPA Programs

2019-2022. Once finalized the updated ORD StRAPs will be available to the public.

Toxic Substance Control Act (TSCA)

OW also coordinates with OCSPP on actions under TSCA. Under the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA evaluates potential risks from new and existing chemicals and acts to address any unreasonable risks those chemicals present to human health and the environment. Pursuant to relevant TSCA authorities, EPA may restrict the production, importation, processing, use, and/or disposal of specific chemical substances in order to address unreasonable risks. For example, under TSCA section 6(a), EPA may regulate (including restricting or banning) the manufacture, processing, distribution in commerce, commercial use, and/or disposal of any chemical substance that EPA determined through a risk evaluation presents an unreasonable risk of injury to human health or the environment. For more information, see EPA's webpage on the Regulation of Chemicals under Section 6(a) of the Toxic Substances Control Act. In addition, under TSCA section 9, EPA may coordinate certain actions on chemical substances under TSCA with actions taken under other federal laws, including those administered by other federal agencies as well as other laws administered by EPA. For more information, see EPA's webpage on TSCA Section 9 Relationship to Other Federal Laws. TSCA also gives EPA the authority to require reporting, record-keeping, and testing relating to chemical substances and mixtures. For additional information, please visit: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/regulation-chemicals-under-section-6a-toxic-substances and https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/tsca-section-9-relationship-other-federal-laws.

Comments Received on Other EPA Programs

Comment Excerpt from Commenter 71

AMWA encourages EPA to continue to align efforts between the Office of Ground Water and Drinking Water (OGWDW) and the Office of Research and Development (ORD). It is vital that the work included in ORD's multiyear strategic research action plan be in concert with the current CCL to best prioritize research needs and utilize the agency's resources. OGWDW relies on ORD to perform the research needed to support its mission. AMWA encourages ORD to clearly identify how it intends to support the CCL process. Listing contaminants on the CCL should enable all offices in EPA responsible for supporting regulatory determinations with the ability to focus precious research dollars on those chemical and microbial contaminants that are a potential health risk to drinking water consumers.

Thank you for the opportunity to provide comments on EPA's CCL 5. If you have any questions about these comments, please contact Stephanie Hayes Schlea, AMWA's Director of Regulatory and Scientific Affairs, at schlea@amwa.net.

Sincerely,

Diane VanDe Hei
Chief Executive Officer

cc: Jennifer McLain, Director, Office of Ground Water and Drinking Water Eric Burneson, Director, Standards and Risk Management Division

Comments Received on Other EPA Programs

Individual Response: Please see Discussion on Other EPA programs.

Comment Excerpt from Commenter 75
Connecting the CCL with EPA Research

ASDWA recommends that EPA develop a stronger and more visible connection between the CCL and the Agency's research plans. The vast amount of work to chronicle research gaps for these contaminants listed on the CCL should serve as a springboard for federal and federally funded research over the following five years. EPA research should aim to fill gaps in health effects data, treatment information, and occurrence data. Contaminants listed in the CCL that do not have approved analytical methods, for example, should be EPA's focus for analytical method development over the next five years. If EPA already uses the CCL as the foundation for its research, ASDWA recommends that the Agency make this connection clearer for stakeholders in the final CCL 5.

Individual Response: Please see Discussion on Other EPA Programs and Other Drinking Water Programs. EPA has provided a table in the Final FR notice that categorizes the CCL 5 contaminants based on the data available for each contaminant during the development of the Draft CCL 5. The CCL is used to inform priorities for internal and external research communities.

Comment Excerpt from Commenter 77
[AWWA offers the following recommendations for EPA to consider as the CCL 5 is finalized and in the development of future CCLs.]

Using CCL to Advance Source Water Protection

The CCL should inform risk management efforts beyond the scope of SDWA. This is especially important for contaminants like PFAS, where the source of the contamination is beyond the authorities of SDWA. In developing and presenting the CCL, EPA should consider how it can leverage this information to inform discussion about chemicals that may pose a risk to the nation's drinking water supply. For example, PFAS are a group of contaminants most appropriately addressed through the Toxic Substances Control Act, CWA, and Resource Conservation and Recovery Act. There are opportunities for federal agencies other than EPA to fund relevant research, employ policies and procedures that reduce the use of PFAS substances (e.g., Department of Defense, General Services Administration, etc.).

For other contaminants, other federal agencies may be most relevant to exposure reduction (e.g., Food and Drug Administration, U.S. Department of Agriculture, etc.). In order for EPA to effectively leverage CCL 5 to reduce contaminant occurrence, the final Federal Register notice must provide a sense of priority for (1) which contaminants appear to pose the greatest priority for action and (2) research and data development needs to inform decision-making.

The CCL development process occurs over a five-year cycle. There are frequently stated concerns that the SDWA regulatory process is too slow. The CCL is an opportunity for EPA to step beyond that critique and move instead to timely initiation of action not only to inform risk in drinking water but contamination of the nation's waters.

Individual Response: Please see Discussion on Other EPA Programs and PFAS. Actions to reduce the occurrence of contaminants are outside the scope of the CCL process. In regard to the commenters

Comments Received on Other EPA Programs

statement that EPA "must provide a sense of priority" for CCL, EPA has provided a table in the Final FR notice that categorizes the CCL 5 contaminants based on the data available for each contaminant during the development of the Draft CCL 5. As part of the Regulatory Determination process, EPA will further prioritize CCL 5 contaminants of the greatest public health concern.

Comments Related to Process – Chemicals

Agency Discussion on Comments Related to Process – Chemicals

Agency Topic Discussion:

The CCL 5 process maintained, but improved upon, the three-step framework that was establish for CCL 3 based on recommendation by the National Academy of Sciences' (NAS) National Research Council and further endorsed by the National Drinking Water Advisory Council (NDWAC). The three steps include:

(1) Building a broad universe – EPA identified and assessed a broadly defined ''universe'' of potential drinking water contaminants based on occurrence and health effects data.
(2) Screening the universe to select a Preliminary CCL (PCCL) – EPA reduced the "universe" to a preliminary CCL (PCCL) using simple screening criteria.
(3) Classifying the PCCL chemicals to select a draft CCL – Following literature searches to collect supplemental data available for the PCCL chemicals, EPA scientist, referred to as chemical evaluators, classified chemicals on the PCCL for listing on the draft CCL 5 based on all of the available health effects and occurrence data for each PCCL 5 chemical.

The CCL 5 process used to select chemical contaminant has been described in detail in Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5) - Chemical Contaminants (USEPA, 2022a).

EPA received one comment related to CCL 5 screening process (Step 2) used to reduce the Universe to a PCCL 5.

Comments Received Related to Process - Chemicals

Comment Excerpt from Commenter 77

If one were to focus exclusively on the 176 contaminants that were reviewed by chemical evaluators for inclusion in the Draft CCL 5. The scoring process retained 38% of the contaminants that were subjected to a full evaluation. Alternatively, if one were to look at the total list of provisional contaminant candidate list (PCCL) chemicals that were listed on the Draft CCL 5 as individual contaminants, the Draft CCL 5 chemical list would total 114 chemicals (a 44% retention rate). EPA should consider whether the current scoring process is providing enough discrimination of high priority contaminants or alternatively if the challenge EPA faces in refining the CCL to an actionable length is institutional.

Individual Response: Please see Discussion on Comments Related to Process – Chemicals. Step 2 of the CCL 5 process involves screening the Universe (~22,000 chemicals) and public nominations to a subset of chemicals known as the preliminary CCL (PCCL), that warrant further in-depth review due to

Comments Received Related to Process - Chemicals

their potential to occur in public water systems and pose a risk to public health.

The CCL 5 evaluation teams reviewed 214 chemicals on the PCCL and listed 66 chemicals. The screening scores were used as a tool specifically to prioritize chemicals within the Universe and identify a PCCL which was a subset of chemicals that required additional data gathering and evaluation. The outcome of the screening process and screening scores were not designed to select a CCL. The screening scores were also not meant to reflect EPA's regulatory priorities, nor reflect a ranked list of high-priority chemicals. The screening score is a singular parameter that represents both the relative wealth of occurrence or health data available from primary data sources and one supplemental data source (CompTox Dashboard), and relative toxicity or occurrence for each chemical.

As part of the classification step, EPA manually extracted additional information from supplemental sources for PCCL chemicals, conducted in-depth reviews, and leverage the knowledge of the expert reviewers. Because the screening score is a singular parameter that only incorporates data from primary data sources, it is reasonable to assume and expect there will be a slight disconnect between the screening scores and the listing decisions of the expert evaluators. The CCL process is complex; therefore, a single parameter, screening score, cannot capture every contributing factor that influenced listing decisions.

EPA conducted statistical tests to measure the discriminatory performance of screening scores as a predictor of listing decisions. We found that screening scores were a moderate predictor of listing and therefore were an appropriate tool for screening the Universe. In CCL 6, we will consider fine-tuning the scoring rubric or adjusting the screening system to improve the screening scores' predictive power.

Chemical Data/Data Sources

Agency Discussion on Chemical Data/Data Sources

Agency Topic Discussion:

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." Another comment provided recommendations for EPA to consider with regards to using data to develop the Final CCL 5 and future CCLs, particularly the agency's use of wastewater data as well as data collected under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA).

The SDWA directs the agency to consider 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. In identifying these contaminants, the SDWA requires that, when developing the CCL, EPA considers the National Contaminant Occurrence Database established under Section 1445(g) of the SDWA. EPA must consider substances identified in Section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and substances registered as pesticides under the FIFRA as well as other relevant data sources.

Agency Discussion on Chemical Data/Data Sources

EPA used a variety of data sources throughout the CCL 5 development process. In Step 1 of the CCL 5 process, EPA compiled health and occurrence data sources to identify chemicals that would form a broad CCL 5 Chemical Universe. Primary data sources used to build the CCL 5 Chemical Universe met four assessment factors: relevance, completeness, redundancy, and retrievability. These assessment factors were developed during the CCL 3 process in response to the National Drinking Water Advisory Council's (NDWAC) Report (2004) recommendations and are described in Section 2.2 of the Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5) – Chemical Contaminants, hereafter referred to as the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a).

In Step 2 of the CCL 5 process, EPA applied a data-driven screening points system and screened chemicals to a Preliminary CCL (PCCL) by evaluating the health effects and occurrence information provided in the data sources used to compile the CCL 5 Universe. Specifically, EPA developed screening scores for universe chemicals based on the health effects and occurrence data and advanced the top scoring chemicals as well as publicly nominated chemicals to the PCCL for further evaluation.

In Step 3 of the CCL 5 process, EPA conducted literature searches to identify supplemental health and occurrence data for the PCCL chemicals. EPA summarized the data from primary and supplemental data sources collected throughout the CCL 5 process in a standardized document called a Contaminant Information Sheet (CIS) for each chemical. Chemical evaluators reviewed the data provided in CISs, along with any available supplemental data and qualifying studies encountered during the additional data collection for PCCL chemicals, to assess chemicals' potential public health risk and make listing decision recommendations for the CCL 5.

Comments Received on Chemical Data/Data Sources

Comment Excerpt from Commenter 71

The association also greatly supports the agency's use of preliminary UCMR 4 data, as was suggested by the SAB. This occurrence data comes directly from drinking water utilities and should be used to inform any initiatives under the SDWA. The association agrees with EPA's assessment that it "is important to use more recent occurrence data in the screening process to ensure that new and potentially relevant information is not disregarded and that potentially hazardous chemicals are not discounted."

AMWA also supports EPA'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. This change to the CCL development process resulted in the compilation of the most chemical and data-rich CCL universe to date. The association believes that the CCL process should start by capturing all data on possible contaminants of note before moving to later steps where qualifiers like occurrence and health effects data can be used to reduce the list to a more manageable length for inclusion in the final CCL.

Individual Response: Please see Discussion on Chemical Data/Data Sources.

Comment Excerpt from Commenter 77

[AWWA offers the following recommendations for EPA to consider as the CCL 5 is finalized and in the development of future CCLs.]

Comments Received on Chemical Data/Data Sources

Lack of Information Characterizing Wastewater Discharges.

A cursory review of the information data sheets illustrates that the Agency has a limited pool of datasets to characterize pollutant levels in wastewater discharges. The CCL 5 factsheets rely almost exclusively on two very limited research papers. [FN5: Scott, T. M., Phillips, P. J., Kolpin, D. W., Colella, K. M., Furlong, E. T., Foreman, W. T., & Gray, J. L. (2018). Pharmaceutical manufacturing facility discharges can substantially increase the pharmaceutical load to US wastewaters. Science of the Total Environment, 636, 69-79.] [FN6: Kostich MS, et al. 2014 Concentrations of prioritized pharmaceuticals in effluents from 50 large wastewater treatment plants in the US and implications for risk estimation. Environ Pollut. 2014 Jan;184:354-9. doi: 10.1016/j.envpol.2013.09.013. Epub 2013 Oct 3. PMID: 24095705.] Currently, permittees in the Clean Water Act (CWA) National Pollutant Discharge Elimination System (NPDES) submit compliance monitoring data that provides discharge location, analyte concentration, and discharge flow information. That data is submitted electronically and should be readily available to inform the CCL process. Analytes for which monitoring is required have specified analytical methods of known resolution and robustness. EPA's CWA analytical methods include a number of contaminants included in the CCL 5 PCCL and it is possible that the use of this occurrence data could inform the list of contaminants for which EPA seeks out health effects information. [FN7: EPA, Accessed August 31, 2021. Approved CWA Chemical Test Methods.] Utilizing data available through the CWA would be consistent with the NDWAC Report on the CCL Classification Process and the National Research Council report that preceded the NDWAC recommendations. [FN8: NDWAC. 2004. National Drinking Water Advisory Council Report on the CCL Classification Process.] [FN9: NRC. 2001. Classifying Drinking Water Contaminants for Regulatory Consideration.]

Individual Response: Please see Discussion on Chemical Data/Data Sources. EPA agrees that there is a "limited pool of datasets to characterize pollutants levels in wastewater discharges" and that the Clean Water Act (CWA) National Pollutant Discharge Elimination System (NPDES) compliance monitoring data "should be readily available to inform the CCL process." EPA will consider using this data in developing future CCLs. However, given the current CCL 5 process, EPA disagrees with the commenter's statement that the use of this wastewater data "could inform the list of contaminants for which EPA seeks out health effects information" for CCL 5.

To screen the Universe chemicals to a Preliminary CCL 5 (PCCL 5) and identify chemicals with the greatest potential for public health concern, EPA developed a screening system that prioritized data elements most relevant to drinking water exposure. Wastewater effluent data was not assigned screening points in the CCL 5 screening system because wastewater data was considered less relevant to drinking water exposure and less relevant than the other occurrence data elements assigned points in the CCL 5 screening phase. EPA screened chemicals to the PCCL 5 by developing screening scores based on the health effects and occurrence information provided in the data sources used to compile the CCL 5 Universe. To form the PCCL 5, EPA selected the top scoring universe chemicals and publicly nominated chemicals which were advanced for further evaluation, including conducting literature searches to identify additional health and occurrence data.

Thirteen of the publicly nominated chemicals added to the PCCL 5 did not have available water occurrence data, even after a targeted occurrence literature search was conducted, and therefore

Comments Received on Chemical Data/Data Sources

they were not included in the health effects rapid systematic review and were not evaluated by chemical evaluators for listing on the Draft CCL 5. These chemicals were instead highlighted as having substantial data gaps. These included 1-phenylacetone, 3-monoacetylmorphine, 6-monoacetylmorphine, benzoic acid, benzoic acid glucuronide, hippuric acid, hydromorphone, hydromorphone-3-glucuronide, hydroxyamphetamide, isodrin, methamphetamine, morphine-6-glucuronide, and phenylpropanolamine. Without available data regarding measured occurrence in water or relevant data provided by the nominators, the two evaluation teams agreed that they could not determine whether these chemicals were likely to present the greatest public health concern through drinking water exposure and therefore should not advance further in the CCL 5 process.

Searching for wastewater data was not part of the occurrence literature search protocol which was targeted towards identifying finished and ambient water data. If identifying wastewater data had been part of the occurrence literature search protocol, and wastewater data on these 13 chemicals had been identified through NPDES or other sources, then it is possible that the use of this occurrence data could have informed the list of contaminants for which EPA sought out health effects information as the commenter stated. EPA may consider including wastewater data in the targeted occurrence literature search for future CCLs. The data elements used for point assignments in the CCL 5 screening system and the occurrence literature search protocol are provided in Table 4 and Appendix E, respectively, of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a).

Comment Excerpt from Commenter 77

[In reviewing the CCL 5 process as described by the Agency, AWWA found:]

3. In constructing the CCL Universe, EPA combined the health effects data from multiple forms of some chemical contaminants. [FN22: EPA. 2021. Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) Chemical Contaminants. EPA 815-R-21-005.] This approach is described in the docket, and there are compounds for which this would be a sound approach. Unfortunately, the Draft CCL 5 documentation only provides a handful of examples. The docket does not summarize the list of CCL or PCCL chemicals for which this approach was influenced by the availability of data. Consequently, the public does not have a clear notion of which contaminants are, in fact, included in the CCL based on data regarding the health-effects posed by contaminants likely to be present in water.

Individual Response: Please see discussion on Chemical Technical Support Document. The commenter describes that "In constructing the CCL Universe, EPA combined the health effects data from multiple forms of some chemical contaminants." It is unclear what the commenter is referring to; however, in this response, EPA assumes the commenter is referring to the grouping of several chemicals, such as lithium and lithium salts, under a single Distributed Structure-Searchable Toxicity Database Substance Identifier (DTXSID). For additional examples of chemicals grouped under a single DTXSID, please see Section 2.4.2 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a). The commenter is correct that the "Draft CCL 5 documentation only provides a handful of examples." EPA's efforts to group DTXSIDs in this way focused on identifying chemicals with ionized and/or salt forms (e.g., inorganic ions). EPA recognizes that communication of this approach has not been clear and is considering ways to make it more transparent in future CCLs.

EPA has updated the Contaminant Information Sheets (CISs) for five contaminants to clarify which data entries are associated with other forms of the contaminant; these include cypermethrin, lithium,

Comments Received on Chemical Data/Data Sources

manganese, propiconazole, and vanadium (please see Technical Support Document for the Final Fifth Contaminant List (CCL 5) – Contaminant Information Sheets, hereafter referred to as the Final CCL 5 CIS Technical Support Document (USEPA, 2022b).

Comment Excerpt from Commenter 77

[In reviewing the CCL 5 process as described by the Agency, AWWA found:]

4. EPA describes, in limited detail, a new presumption of contaminant occurrence used during CCL 5 screening. [FN23: EPA. 2021. Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) Chemical Contaminants. EPA 815-R-21-005.] Specifically, EPA occurrence metrics were calculated where non-detects were set equal to one-half the method detection level when data sources provided a method detection level (MDL). EPA does not describe how this presumption impacts the composition of the CCL 5 list in comparison with alternative valid approaches (e.g., setting non-detects equal to "0" or the MDL). Occurrence is a critical data element in the CCL development process. No doubt EPA analyzed such a substantial change on CCL contaminant scores. While this assumption of occurrence should generally be avoided for analyses such as construction of the CCL, by failing to show its work the Agency prevents commenters from understanding how influential this assumption is in the CCL 5 process. EPA makes similar assumptions elsewhere (e.g., chemical production data). Taken individually such assumptions can be influential; when applied regularly to multiple data elements, the compounding conservatism can distort the occurrence data elements that underpin the CCL process.

Individual Response: Please see Discussion on Chemical Data/Data Sources. EPA acknowledges the commenter's concern of how EPA calculated certain occurrence metrics for CCL 5 screening. In this response, EPA assumes the comment specifically refers to how EPA imputed or temporarily substituted the following occurrence metrics in the screening step of CCL 5: 1) maximum concentrations values for non-detected chemicals in finished or ambient waters when the study or survey provided detection limits, and 2) chemical production volume categories for determining point assignments.

EPA's decision to substitute a maximum concentration value for non-detected chemicals in ambient and finished waters and chemical production values at the CCL 5 screening step is a conservative and health-protective approach. In CCL 5 classification, chemical concentrations in water were based on analytical detections only and production volumes were the same values as reported by the Chemical Data Reporting (CDR) rule.

EPA disagrees with the commenter that substituting concentration values for non-detected chemicals in finished and ambient waters in CCL screening should be avoided. Non-detections do not necessarily indicate that the chemical is absent, and risk of exposure is zero, but rather indicate that the amount of chemical present is below a level that could be detected or quantified. There is potential risk for exposure when a chemical is reported as a non-detect; therefore, imputing maximum concentrations for chemicals in ambient and finished waters where the study or survey provides detection limit information is a health-protective approach. EPA did not test out alternative approaches for imputing or substituting these occurrence metrics in the screening step for CCL 5. Therefore, EPA did not assess the impact that these presumptions had on the screening scores or the composition of the CCL 5.

A chemical's maximum concentration in finished water is a data element used to derive a chemical's

Comments Received on Chemical Data/Data Sources

screening Hazard Quotient (sHQ). The sHQ is the ratio of the maximum concentration of the chemical in finished drinking water to the most health-protective health screening level for a chemical. The sHQ is the highest tiered occurrence data element in the scoring rubric in CCL 5 screening and most applicable to potential hazards through drinking water. The sHQ requires a chemical to have a maximum concentration in finished water value in order to be calculated. If the maximum concentrations in finished water were not imputed for non-detected chemicals where the study or survey provided detection limit information and relied solely on analytical detections, the sHQ could not be calculated for those chemicals. Non-detections in finished water do not mean the concentration of the chemical is zero. Therefore, not imputing maximum concentration in finished water for non-detected chemicals may have resulted in an underestimation of potential drinking water exposure at the screening step.

Production volume data required special data processing steps to be incorporated into the CCL 5 screening rubric. Chemical production volumes were reported as categories (i.e., a range of values such as 100,000 – 500,000 lb.) or inequalities (e.g., < 25,000 lb.) and needed to be converted to single numerical values so that distributions and quantiles could be calculated. These quantiles were subsequently used to establish relative point assignments for the production volume data element. EPA's method of converting production volumes to single numerical values was driven by how the data was originally reported by CDR. EPA analyzed the variations of production volume categories and determined that using the minimum value for the category ranges and temporarily substituting ½ for the lowest production volume was the appropriate approach.

The lowest two production volume categories available for chemicals in the CCL 5 Universe were "< 25000 lb" (e.g. less than 25,000 lb.) and "25000 - 100000 lb" (e.g. between 25,000 lb. and 100,000 lb.). EPA determined that these two production volumes should not be assigned the same numerical value (25,000 lb.) because CDR reports the production volumes as two distinct categories. Therefore, EPA temporarily substituted "12,500 lb" for "<25000 lb" and used the minimum values for the other production volume categories for point assignments.

Similarly, the highest two production volume categories available for chemicals in the CCL 5 Universe were "> 200,000,000,000 lb" (e.g. greater than 200 billion lb.) and "190,000,000,000 – 200,000,000,000 lb" (e.g. between 190 billion lb. and 200 billion lb.). EPA determined that these two production volume categories should not be assigned the same numerical value (200 billion lb.) because CDR reports the production volumes as two distinct categories. Therefore, EPA substituted "190,000,000,000 lb" for the "190,000,000,000 – 200,000,000,000 lb" category and "200,000,000,000 lb" to the "> 200,000,000,000 lb" category specifically for calculating quantiles and relative point assignments.

Additionally, the statistical ranges, the differences between the largest and smallest values, of production volume categories were not equal. Therefore, EPA determined that using the average value of production volume categories was inappropriate for establishing relative point assignments in CCL 5 screening.

EPA agrees with the commenter that contaminant occurrence is a critical element of the CCL development process. EPA agrees with the commentor that the action of imputing or substituting occurrence metric values individually and when applied regularly to multiple occurrence metrics can

Comments Received on Chemical Data/Data Sources

be influential to the CCL process. EPA may consider alternative approaches for imputing or substituting these occurrence metrics and assess cumulative impact these assumptions have on the CCL process in future rounds of CCL.

Comment Excerpt from Commenter 77

[In reviewing the CCL 5 process as described by the Agency, AWWA found:]

6. EPA notes the use of FIFRA modelled pesticide concentrations to estimate exposure in developing the Draft CCL 5. The FIFRA drinking water exposure models are deliberately conservative, which generate exposure estimates that are typically substantially higher than observed occurrence. The chemical information sheets for three Draft CCL 5 contaminants (i.e., Bensulide, Propanil, and Thiamethoxam) include the modelled estimates. It is not clear from the docket how influential the FIFRA pesticide modelling estimates are as part of the CCL 5 decision-making process. FIFRA risk assessments did not emphasize drinking water risks for Propanil or Thiamethoxam.

7. The Draft CCL 5 is inconsistent in its treatment of pesticide degradates. CCL 5 considered risk analysis of individual pesticides conducted under the Federal Insecticide Fungicide Rodenticide Act. CCL 5 Contaminant Information Sheets reference at least 12 FIFRA re-registration dockets that note the role of pesticide degradates including degradates created during drinking water treatment in estimating associated risks. Yet, the Draft CCL 5 includes four triazine degradates without explanation of why these four degradates warrant specific inclusion and the degradates of other pesticides in the Draft CCL 5 do not. The relative accessibility of information from available sources is not a rational explanation for this inconsistency given the extensive referencing of FIFRA work products in the Draft CCL 5 Federal Register notice docket.

Individual Response: Please see Discussion on Chemical Data/Data Sources and the Final CCL 5 Chemical Technical Support Document. EPA's Office of Pesticide Programs (OPP) risk assessments were an important supplemental source of health and occurrence data for the CCL 5. EPA agrees with the commenter that modeled estimates from the OPP risk assessments may overestimate actual environmental concentrations as they are often based on maximum use and application rates; the chemical evaluators were made aware of this when they were presented the data to evaluate contaminants for listing on the CCL 5.

The commenter stated that "It is not clear from the docket how influential the FIFRA pesticide modelling estimates are as part of the CCL 5 decision-making process." As explained in Section 4.2.1.2 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a), EPA manually extracted modeled concentration data, known as estimated environmental concentrations (EECs) or estimated drinking water concentrations (EDWCs), from OPP risk assessments only for pesticides on the PCCL 5 that lacked nationally representative finished and/or nationally representative ambient water data. As shown in the protocol in Appendix H of the Final CCL 5 Chemical Technical Support Document, EPA prioritized the use of nationally representative finished water data to derive the final hazard quotient (fHQ) for chemicals, followed by nationally representative ambient water data. EPA used modeled water data developed by OPP only when no measured nationally representative water data was available for calculating the fHQ. The fHQ is a calculated data element intended to indicate a chemical's potential for public health risk related to exposure from drinking water by capturing the relationship between a chemical's relative potency and the concentrations at which it may be found

Comments Received on Chemical Data/Data Sources

in water. The fHQ is one of many data elements that inform the CCL 5 listing process. Chemical evaluators reviewed all relevant health effects and occurrence data provided on the CISs and any available supplemental data and qualifying studies encountered during the additional data collection for PCCL chemicals in order to provide listing decision recommendations for the CCL 5. For an idea of how influential different variables may be during the listing decision process, please see Section 4.6.3.1 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a) which provides the results of the simple logistic regression model EPA conducted.

In particular, the commenter noted that the "FIFRA risk assessments did not emphasize drinking water risks for Propanil or Thiamethoxam." Fourteen pesticides on the PCCL 5 lacked nationally representative finished and/or nationally representative ambient water data and 3 of these pesticides were included on the CCL 5: Bensulide, Propanil, and Thiamethoxam. For these pesticides, the EECs were used to calculate the fHQ which was only one data point that chemical evaluators considered when making listing decisions. For example, regarding Propanil and Thiamethoxam, the OPP risk assessments were also provided to the chemical evaluators to review as part of the evaluation process. EPA acknowledges that these two pesticides have a data gap; however, based on a review of all of the data provided on the CISs and the risk assessments, EPA is listing these two pesticides on the CCL 5.

EPA disagrees with the commenter's statement that the "Draft CCL 5 is inconsistent in its treatment of pesticide degradates." In particular, the commenter expressed confusion with the inclusion of four triazine degradates on the Draft CCL 5 while other pesticide degradates in "FIFRA re-registration dockets" were not included. Pesticide degradates went through the CCL 5 process the same way as every other chemical contaminant, passing through three steps: Building the Chemical Universe, Screening Chemicals to a PCCL, and Classification of PCCL Chemicals to Select the CCL. At the end of this process, contaminants found to be known or anticipated to occur in public water systems and not subject to proposed or promulgated NPDWRs were listed on the CCL 5. If a pesticide registered with FIFRA or pesticide degradate was not listed on the CCL 5, this means it either did not have enough screening points to be included in the PCCL 5 and was not further evaluated for listing, or the chemical evaluators did not recommend it for listing on the CCL 5 based on the evaluated data. All evaluated data are provided in the Final CCL 5 CIS Technical Support Document.

Comment Excerpt from Commenter 77

[In reviewing the CCL 5 process as described by the Agency, AWWA found:]

9. There are more than 1,300 pesticide constituents regulated under FIFRA and 86,000 chemicals in the TSCA inventory. The Draft CCL 5 includes 39 pesticides and 5 pesticide degradates. Pesticide-related contaminants make up over half of the individually named chemical contaminants in the Draft CCL. FIFRA maintains an active and thorough registration / re-registration process providing data in public-facing documents that do not exist for the thousands of industrial chemicals managed under TSCA. Both FIFRA and TSCA regulated chemicals are in the CCL 5 Universe. It is not clear from the docket whether the Draft CCL 5 process is being biased by the data-rich and transparent implementation of FIFRA re-registration practice. It appears that the FIFRA program is more capable of informing the CCL 5 process compared to the much less transparent TSCA process. In finalizing CCL 5, EPA should evaluate the impact of data accessibility and completeness between these two programs and for their potential to influence the CCL process. Such an analysis could inform not only EPA's SDWA processes but those implemented under TSCA.

Comments Received on Chemical Data/Data Sources

10. The FIFRA program evaluations of pesticide chemistry, actual use, and conservative modelling of use patterns indicate that aggregate dietary exposure including drinking water exposure is unlikely to reach a level of concern for roughly half of the pesticides listed in the Draft CCL 5. For several pesticides, drinking water exposure was a significant, if not dominant, route of exposure in FIFRA exposure assessments, but only in a few instances were levels of concern exceeded under modelled high-risk pesticide use conditions. Even after review of FIFRA dockets (updated since the end of data collection for the Draft CCL docket), it is not apparent how EPA is reconciling inclusion of all listed pesticides in the Draft CCL 5 with available information from FIFRA. In finalizing Draft CCL 5 EPA should clearly describe how this evaluation, which is largely reliant on the same data as available to the FIFRA pesticide re-registration, is reaching different conclusions regarding the potential risk to drinking water and why this is appropriate.

Individual Response: Please see Discussion on Chemical Data/Data Sources. The commenter noted that "Pesticide-related contaminants make up over half of the individually named chemical contaminants in the Draft CCL" and expressed concern about the greater accessibility of FIFRA data compared to TSCA data and how this may bias what contaminants are listed on the Draft CCL 5. SDWA section 1412(b)(1)(B)(i), as amended in 1996, specifies that the unregulated contaminants considered for listing on CCL shall include, among others, substances registered as pesticides under FIFRA. For this reason, FIFRA registered pesticide and pesticide ingredients represent a significant source of chemicals for consideration in CCL. With regards to data collected under TSCA, EPA used production volume information collected by EPA under the Chemical Data Reporting (CDR) rule requirements pursuant to section 8 of TSCA as a primary data source to build the CCL 5 Universe of chemicals. Data collected under TSCA also served as a source of supplemental data in the CCL 5 development process; if available, EPA extracted health data from the agency's Risk Evaluations conducted under TSCA to derive health concentrations for chemicals evaluated for listing on the CCL 5. Some TSCA data includes confidential business information (CBI) and therefore was not included in the CCL 5 process. EPA notes that primary data sources used to build the CCL 5 Chemical Universe must meet four assessment factors: relevance, completeness, redundancy, and retrievability (see Section 2.2 of Final CCL 5 Chemical Technical Support Document (USEPA, 2022a)). To be retrievable, the data must be formatted for automated retrieval (e.g., data are stored tabular format) and publicly accessible. These assessment factors were developed during the CCL 3 process in response to the National Drinking Water Advisory Council's (NDWAC) 2004 recommendations. For more information on the FIFRA and TSCA programs, please see Discussion on Other EPA Programs.

The commenter stated that "FIFRA program evaluations […] indicate that aggregate dietary exposure including drinking water exposure is unlikely to reach a level of concern for roughly half of the pesticides listed in the Draft CCL 5." EPA notes that OPP risk assessments are one of many sources of data evaluated during the CCL 5 listing decision process. Chemical evaluators reviewed all relevant health effects and occurrence data provided on the CISs and any available supplemental data and qualifying studies encountered during the additional data collection for PCCL chemicals in order to provide listing decision recommendations for the CCL 5. All of the data that informed the evaluation process is provided in the Final CCL 5 CIS Technical Support Document. EPA disagrees with the commenter's statement that the Draft CCL 5 evaluation "is reaching different conclusions regarding the potential risk to drinking water" than the FIFRA pesticide assessments. OPP assessment and the CCL are two different processes. Under the SDWA, the CCL is a list of contaminants not subject to any

Comments Received on Chemical Data/Data Sources

proposed or promulgated NPDWR which are known or anticipated to occur in public water systems and may require regulation under SDWA. EPA's approach to the CCL utilizes the best available data to characterize the occurrence and adverse health risks a chemical may pose from potential drinking water exposure. Based on all of the available data and the SDWA requirements for listing, EPA identified the CCL 5.

Additionally, EPA manually extracted modeled concentration data from OPP risk assessments for pesticides on the PCCL 5 that lacked nationally representative finished and/or nationally representative ambient water data. While EPA did not manually extract the conclusions, the full risk assessments were provided to the chemical evaluators to review as part of the evaluation process. These data were not in a retrievable format that could be efficiently extracted for all CCL 5 Chemical Universe pesticides; however, EPA will consider manually extracting the modeled concentration data and conclusions from the risk assessments for all pesticides evaluated during the classification step and including them on CISs in future CCLs.

Regarding the commenter's concern about the transparency of the TSCA process, that is outside the scope of the CCL; please see Discussion on Other EPA Programs.

Contaminant Groups

Agency Discussion on Contaminant Groups

Agency Topic Discussion:

EPA received many comments related to the inclusion of contaminant groups on the CCL 5. The CCL 5 includes three contaminant groups: 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. Please see Discussions on Cyanotoxins, DBPs, and PFAS for responses to comments on these particular groups.

Multiple commenters expressed support for EPA considering contaminants as groups in the CCL process or listing contaminant groups on the CCL. However, a couple commenters raised concerns about the way EPA applied this grouping approach to certain contaminants while listing some other contaminants, such as pesticides with a similar mode of action, individually. As described in Section 4.7 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a), PFAS, cyanotoxins, and DBPs are chemical groups that have been identified as agency priorities and contaminants of concern for drinking water under other agency actions, including the 2021 PFAS Strategic Roadmap, the 2015 Algal Toxin Risk Assessment and Management Strategic Plan for Drinking Water, and EPA's decision identifying a number of microbial and disinfection byproducts (MDBPs) drinking water regulations as candidates for revision in the Six-Year Review 3 (SYR 3) of NPDWRs. As a couple of commenters pointed out, some of the pesticides evaluated for the CCL 5, such as pyrethroids and organophosphates, share a common mechanism and are grouped under other agency actions including the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). While EPA evaluated and listed contaminants in these groups individually, the agency provided chemical evaluators with the Office of Pesticide Programs (OPP) cumulative risk assessments for these groups to consider when evaluating these contaminants for listing on the CCL 5. EPA may consider listing these and other contaminants as groups in future CCLs.

A couple of commenters requested more information on how EPA plans to prioritize contaminants within the groups on the CCL 5 (cyanotoxins, DBPs, PFAS), specifically related to EPA's research priorities. For information on research priorities, please see Discussion on Other EPA Programs. One commenter inquired about how groups of contaminants will be treated for Regulatory Determinations and UCMR selection. As stated in Section 4.7 of the Final CCL 5 Chemical Technical Support Document, listing contaminant groups on the CCL 5 does not necessarily mean EPA will make subsequent regulatory decisions for the entire group. EPA will evaluate scientific data on the listed groups, subgroups, and individual contaminants to inform any regulatory determinations for the group, subgroup, or individual contaminants in the group. For more information on Regulatory Determination and UCMR, please see Discussion on Other Drinking Water Programs.

Comments Received on Contaminant Groups

Comment Excerpt from Commenter 55

I'm concerned about the data here being misleading, particularly where functional groups are assessed separately or where data are under-represented due to isomerism.

First, to address functional groups: one group that comes up often in the PCCL but not frequently in the Draft CCL are pyrethroids. In this category, only permethrin was listed on the draft CCL. Some of

Comments Received on Contaminant Groups

the others on the PCCL include: cypermethrin, cyfluthrin, bifenthrin, cyhalothrin, fenpropathrin, lambda-cyhalothrin, and tefluthrin. There seems to be plenty of data across the board between these pyrethroids, but it doesn't seem like the health effects data are compared. Given that they are functional analogs and would have similar modes of action, I would encourage these to be considered jointly or more serious consideration given to the fact that many of these will have similar modes of action.

Individual Response: Please see Discussion on Contaminant Groups.

Comment Excerpt from Commenter 64

EPA's Contaminant Candidate List 5 (CCL 5) will have a significant impact on drinking water regulation. EPA is tasked with implementing the Safe Drinking Water Act. As such, long-term regulatory planning can empower EPA to make a positive contribution in building safe and healthy communities.

The draft CCL5 lists 66 unique chemicals, twelve individual microbes, and three groups of chemicals (namely, polyfluoroalkyl substances (PFAS), disinfection byproducts (DBPs), and cyanotoxins). I recommend PFAS be listed as a group, or class, in the final CCL5, rather than retaining only PFOA and PFOS, which were listed in the Final CCL4. Adopting precautionary approach in environmental regulation is essential in ensuring ecosystem and human health and safety. For too long new or poorly understood chemicals were released into our water and soil with minimal or no regulation. In the case of PFAS, communities have been, and will continue to be for generations, paying the price for that lack of regulation in absorbing the costs of cancer, high infant and child mortality rates, and other disastrous health outcomes.

Past CCLs have generally focused on listing unique substances, instead of groups. By restricting regulation to just a handful of chemicals in an overall harmful class, EPA limits its effectiveness in administering the SWDA. For example, the Association of Safe Drinking Water Agencies shared in its response to the draft CCL5 that PFHxS, GenX, and PFBA (unique chemicals in the PFAS group) "will not necessarily be removed by treatment installed for PFOA and PFOS." Regulating individual substances in a group is akin to playing the classic game "Whack-A-Mole," where the player, using a mallet, attempts to hit mechanical moles that pop up out of a grid of holes at random. As the game continues, ever more moles pop up ever faster, and the player almost always loses eventually. Because there are thousands of known unique chemicals in the PFAS group, and more may be found or created as time goes on, the EPA will eventually lose its game of Whack-A-Mole, with deadly consequences for communities. In contrast, by regulating PFAS as a class, water quality agencies can more holistically address water contamination caused by these substances.

There is precedent for listing a group of chemicals. One notable example, cyanotoxins, comes from 2016's final CCL4 (83 FR 81099). Cyanotoxins are most well-known for contributing to algal blooms and hypoxia in bodies of water, as well as harming humans and animals. Listing groups of contaminants permits EPA and lower-level regulatory agencies flexibility in managing their water quality programs, while also reducing the burden of regulation. I commend EPA for its commitment to "working collaboratively with states, tribes, water systems, and local communities that have been impacted by PFAS," as stated in an EPA press release dated February 22, 2021. By including PFAS as a group, rather than focusing on individual chemicals, EPA can make good on its commitment to support affected communities. Moreover, by investing in drinking water safety - a critical component in public infrastructure - EPA can support the current Presidential administration's objectives, thereby

Comments Received on Contaminant Groups
not only earning a modicum of political clout but also positioning itself to make immense positive changes in U.S. communities. **Individual Response:** Please see Discussion on Contaminant Groups, Other Drinking Water Programs, and PFAS. EPA agrees with the commenter's recommendation for "PFAS be listed as a group, or class, in the final CCL5, rather than retaining only PFOA and PFOS, which were listed in the Final CCL4." Including the broad group of PFAS on the CCL 5 is responsive to the many public nominations EPA received and the agency's commitment to better understand and ultimately reduce the potential risks caused by this broad class of chemicals. EPA notes that PFOA and PFOS are not considered under CCL 5 as the agency made final regulatory determinations to regulate these two chemicals. 3.1 PFAS The commenter notes the importance of "Adopting a precautionary approach in environmental regulation" and recommends "regulating PFAS as a class." EPA notes that regulation is outside of the scope of the CCL 5.
Comment Excerpt from Commenter 71 AMWA appreciates EPA's clarification that including a set of substances as a group, such as per- and polyfluoroalkyl substances (PFAS), cyanotoxins, and disinfection byproducts, does not necessarily mean it will be moved further through the SDWA process as a group. AMWA believes this is appropriate but asks EPA to include more information as to how the agency plans to prioritize substances within these groups, specifically related to EPA's research priorities. **Individual Response:** Please see Discussion on Contaminant Groups and Other EPA Programs.
Comment Excerpt from Commenter 75 Contaminant Groups ASDWA generally supports EPA's use of groups on the CCL, however, the agency should provide clarification on how groups of contaminants will be treated for Regulatory Determinations and UCMR selection as well as how contaminants within the groups will be prioritized for research. **Individual Response:** Please see Discussion on Contaminant Groups, Other Drinking Water Programs, and Other EPA Programs.
Comment Excerpt from Commenter 77 Organizing the CCL so that it clearly communicates the strength of available information and the Agency's concern based on that data would also clarify inclusion of contaminants as part of a group in the CCL. The Draft CCL 5 also includes groups of contaminants for which there is a wide variety of available information with respect to individual chemicals in the group (e.g., levels of toxicity, occurrence (or a risk of occurrence)). For example, the Draft CCL 5 includes more than 1,350 per- and polyfluoroalkyl substances (PFAS) and notes that listing all PFAS individually would be both "difficult and challenging." Rather than choosing between the extremes (e.g., listing all PFAS as a group or listing 1,000's of PFAS) the Agency could reflect groups of PFAS compounds based on the relevant and applicable data at hand. This approach is not dissimilar to the implied prioritization of certain groups of DBPs in the Draft CCL 5 Federal Register notice, though the docket underlying the notice regarding DBPs is lacking. [FN4: 4 86 FR 37954] **Individual Response:** Please see Discussion on Contaminant Groups, PFAS, and DBPs. The commenter states that "Organizing the CCL so that it clearly communicates the strength of available information and the Agency's concern based on that data would also clarify inclusion of contaminants as part of a

Comments Received on Contaminant Groups
group in the CCL." EPA notes that the contaminants included on the CCL 5 as part of a group have been identified as agency priorities and contaminants of concern for drinking water under other EPA actions. The CCL is not intended to be organized in a way to communicate the "strength of available information;" the CCL is a list of contaminants, not currently subject to any proposed or promulgated NPDWR that are known or anticipated to occur in public water systems and may require regulation under SDWA. For information on the available information for CCL 5 contaminants, EPA recommends the commenter view the Contaminant Information Sheets (CISs) which display health effects, occurrence, and other data on CCL 5 contaminants (see Final CCL 5 CIS Technical Support Document (USEPA, 2022b)). In addition, EPA has provided a table summarizing the data availability for CCL 5 chemicals (please see Chapter 5 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a)).
Comment Excerpt from Commenter 77 [In reviewing the CCL 5 process as described by the Agency, AWWA found:] 8. The Draft CCL 5 includes three groups of contaminants (i.e., cyanotoxins, disinfection byproducts, and per- and polyfluoroalkyl substances). These groups contain contaminants that do not share known common mechanisms of toxicity and are known to occur in water under different conditions and timescales. Conversely, the Draft CCL 5 includes groups of pesticides that are already managed under FIFRA because such similarities exist, yet the docket does not address what distinguishes one "group" from another in the CCL decision-making process (i.e., why are some contaminants listed as individuals and others in groups). The description of EPA's area-under-the-curve receiver operating characteristics model is the only point in the docket that the Agency notes that orthophosphate pesticides (OPs) are highly selected by the Draft CCL 5 process when 12 of the Draft CCL contaminants are OPs. [FN25: EPA. 2021. Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) Chemical Contaminants. EPA 815-R-21-005.] **Individual Response:** Please see Discussion on Contaminant Groups and Pesticides. The commenter stated that "The description of EPA's area-under-the-curve receiver operating characteristics model is the only point in the docket that the Agency notes that orthophosphate pesticides (OPs) are highly selected by the Draft CCL 5 process." In this response, EPA assumes the commenter is referring to organophosphates. As described in Section 4.6.3 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a), the chemical evaluators evaluated 19 organophosphates. Of these 19, they recommended 14 for listing on the Draft CCL 5. To explore what factors may have influenced listing decisions for the CCL 5, EPA conducted post-evaluation statistical analyses. This included the use of an area under the curve-receiver operating characteristics (AUC-ROC) curve to assess how well various models predict listing decisions. EPA does not state that organophosphates are "highly selected by the Draft CCL 5 process;" however, according to one of the models assessed by the AUC-ROC curve, chemical evaluators were more likely to recommend for listing on the Draft CCL 5 those PCCL 5 chemicals they evaluated that had high prevalence, screening scores, or fHQs (deciles), or that were organophosphates. Please see Section 4.6.3 of the Final CCL 5 Chemical Technical Support Document for more information. Such post-evaluation analyses help to identify what variables may be associated with positive listing decisions and could be used to inform how the agency addresses groups in future CCLs.

Cyanotoxins

Agency Discussion on Cyanotoxins

Agency Topic Discussion:
Cyanobacteria, formerly referred to as blue-green algae, are found naturally in lakes, rivers, ponds and other surface waters. When certain conditions exist, such as in warm water containing an abundance of nutrients, they can rapidly form harmful algal blooms (HABs). Some HABs are capable of producing toxins, called cyanotoxins, which can pose health risks to humans and animals through drinking water and recreational water exposure.

Conventional water treatment can generally remove intact cyanobacterial cells and low levels of cyanotoxins from source waters. However, water systems may face challenges and/or increased costs in providing cyanotoxin-free drinking water during a severe bloom event when there are high levels of cyanobacteria and cyanotoxins in source waters. 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 drinking water programs. For this reason, cyanotoxins remain an agency priority as stated in EPA's Algal Toxin Risk Assessment and Management Strategic Plan for Drinking Water (USEPA, 2015). Cyanotoxins are one of the three chemical groups EPA listed as a group instead of individually 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.

Comments Received on Cyanotoxins

Comment Excerpt from Commenter 64
There is precedent for listing a group of chemicals. One notable example, cyanotoxins, comes from 2016's final CCL4 (83 FR 81099). Cyanotoxins are most well-known for contributing to algal blooms and hypoxia in bodies of water, as well as harming humans and animals. Listing groups of contaminants permits EPA and lower-level regulatory agencies flexibility in managing their water quality programs, while also reducing the burden of regulation.

Individual Response: Please see Discussion on Cyanotoxins.

Comment Excerpt from Commenter 75
ASDWA supports the inclusion of cyanotoxins on CCL 5, as cyanotoxins from harmful algal blooms (HABs) are occurring with increasing frequency in drinking water sources and negatively impacting drinking water treatment facilities throughout the US. State drinking water programs play a key role in helping water systems monitor for and treat cyanotoxins and respond to HAB events. Multiple states have been adversely affected by cyanotoxins, including those along the Ohio River, in Toledo, Ohio and in Salem, Oregon where the water systems had to issue "do not drink" notices to their customers. These drinking water treatment facilities face a difficult task of not only addressing water quality changes from HABs and removing cyanotoxins but doing so in a safe and cost-effective way to protect public health.

Many states have taken action to address cyanotoxins, such as Oregon and Ohio, who have developed state regulations for cyanotoxin monitoring. Oregon requires that drinking water systems using

Comments Received on Cyanotoxins

surface water sources susceptible to harmful algae blooms routinely test for Total Microcystins and Cylindrospermopsin and notify the public about the test results. Ohio has also developed HAB monitoring and reporting rule requirements for public water systems with a surface water source. Additionally, Wisconsin, Indiana, Massachusetts, New York, Oregon, and Ohio have developed algae websites that provide information, fact sheets, and resources for the public about possible high levels of blue-green algae and the potential health effects of cyanotoxins.

Individual Response: Please see Discussion on Cyanotoxins. EPA agrees that cyanotoxins remain a public health concern for many state drinking water programs.

Comment Excerpt from Commenter 77

Cyanotoxins

Cyanotoxins are a group of toxins naturally produced and released by some specifies of cyanobacteria. Several cyanotoxins were listed on the Third and Fourth CCL as part of a group. AWWA has recommended their inclusion in both the CCL and as part of the Unregulated Contaminant Monitoring Rule sampling. UCMR 4 included several Microcystins: nodularin, cylindrospermopsin, and anatoxin-a. As EPA summarizes, the UCMR is a nationally representative dataset providing sufficient data to support rulemaking decisions. In EPA's most recent data summary from UCMR 4 (July 2021) microcystins were only detected in finished water sample points at 0.2% of all participating systems and cylindrospermopsin was only detected in less than 0.4% of participating systems. Despite the extremely low occurrence of these cyanotoxins, the Draft CCL 5 includes these contaminants.

The role of CCL is to identify priority contaminants for potential drinking water regulation. Contaminants listed in the CCL should represent contaminants that present a public health risk and an opportunity for effective risk-reduction based on a chemical's occurrence and toxicity and its removal through drinking water treatment. Given that several cyanotoxins (e.g., total microcystins and cylindrospermopsin) were generally not detected in drinking water as part of the UCMR 4 monitoring program, it is unclear why these contaminants are included in the Draft CCL 5. The substantiation provided by the Agency in the docket to-date, is that inclusion is consistent with a risk assessment and plan created in 2015 that has not been subsequently updated. [FN41: EPA. 2015. Algal Toxin Risk Assessment and Management Strategic Plan for Drinking Water.] [FN42: EPA. 2021. Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) Chemical Contaminants. EPA 815-R-21-005.] If retained in the Final CCL 5 Federal Register notice, EPA must provide additional information to demonstrate the value and objectives in retaining the several cyanotoxins for which EPA has occurrence data from UCMR 4. At present, EPA summarizes its bases for inclusion of the cyanotoxins as:

1. Not based on an assessment of data availability for individual cyanotoxin occurrence or health effects data

2. Reflecting model cyanotoxin health effects and the presumption that all cyanotoxins will have similar effects

3. Based on an assumption that since some cyanotoxins are present, occurrence of all in the group are likely and present at a level of concern [FN43: 86 FR 37970]

Comments Received on Cyanotoxins

The UCMR 4 data should give EPA pause, and the Agency should reconsider whether its assumptions regarding inclusion of this group are sound. If retained in the Final CCL 5, EPA should more clearly articulate a rationale for the cyanotoxins included.

Conclusion

AWWA greatly appreciates the Agency's efforts to bring the best available information to bear on identifying contaminants of concern in drinking water. The staff involved in developing the Draft CCL 5 should be commended.

EPA is often criticized for not regulating drinking water contaminants quickly. Managing the CCL as an ongoing component of the Agency's SDWA program rather than a cyclical statutory duty and aligning research and communication priorities, based on prioritized needs tied to the CCL, would be an important step toward addressing such critics. A more focused and prioritized CCL would great improve the Agency's success in advancing a clear and consistent regulatory agenda, which would benefit public health, the Agency's day-to -day work, and the sector more broadly.

Individual Response: Please see Discussion on Cyanotoxins, General Comments, and Other Drinking Water Programs. Under UCMR 4, public water systems monitored for 10 cyanotoxins during a 4-consecutive month period from March 2018 through November 2020. At the time when the Draft CCL 5 was published, the UCMR 4 data set was not finalized. The final UCMR 4 data set was published on February 18, 2022. The next step would be for EPA to consider the cyanotoxins as part of the regulatory determinations process. The full UCMR 4 data set will be considered as part of that process. Cyanotoxins continue to be listed on CCL 5 as an aggregate group in order to encompass all toxins produced by cyanobacteria. Not all cyanotoxins were monitored as part of UCMR 4 and significant health effects data is not available for many cyanotoxins. Significant information gaps still exist on the health impacts and/or occurrence for many cyanotoxins (e.g., euglenophycin and saxitoxins). Therefore, cyanotoxins still pose a potential public health risk and EPA retained listing cyanotoxins as a group on CCL 5.

Comment Excerpt from Commenter 89

We also support listing cyanotoxins as a group instead of listing them as individual chemicals.

Individual Response: Please see Discussion on Cyanotoxins.

Comment Excerpt from Commenter 89

EPA SHOULD ADDRESS CYANOTOXINS AND DBPs AS CLASSES

As discussed extensively in EPA's CCL5 proposal and the record and background documents, the class of cyanotoxins (including but not limited to anatoxin-a, cylindrospermopsin, microcystins, and saxitoxin) are widespread, often found in complex mixtures, known or anticipated to occur in public water systems and pose substantial public health threats. They clearly meet the criteria under the Safe Drinking Water Act (SDWA) for listing [FN28: See SDWA §1412(b)(1)(B)(i)(I).] as well as for a positive regulatory determination.

Individual Response: Please see Discussion on Cyanotoxins and Other Drinking Water Programs. EPA agrees that cyanotoxins are appropriate to be included on CCL 5 as a group. However, an evaluation as part of the regulatory determination process is necessary to determine whether EPA

Comments Received on Cyanotoxins

will consider regulatory action. The regulatory determination process is outside the scope of CCL process. A contaminant must be evaluated under the regulatory determination process to determine whether EPA will make a positive regulatory determination and initiate regulatory action.

Disinfection Byproducts (DBPs)

Agency Discussion on Disinfection Byproducts (DBPs)

Agency Topic Discussion:
Disinfection Byproducts (DBPs) are formed when disinfectants react with naturally occurring organic materials in water. EPA is listing 23 unregulated DBPs as a group on the CCL 5, along with cyanotoxins and PFAS, which all having been identified as agency priorities and contaminants of concern for drinking water under other EPA actions. The group of 23 unregulated DBPs listed for CCL 5 were either publicly nominated, or among the 250 top-scoring chemicals included on the PCCL 5. EPA acknowledges there are differences in occurrence and health effects information among DBPs in the group. The CCL is not intended to be organized in a way to communicate the "strength of available information;" the CCL is a list of contaminants, not currently subject to any proposed or promulgated NPDWR that are known or anticipated to occur in public water systems and may require regulation under SDWA. The 23 unregulated DBPs listed on CCL 5 can be found in Table 25 in the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a).

Under the Stage 2 Disinfectants and Disinfection Byproducts Rule, there are currently 11 regulated DBPs from three subgroups that include four trihalomethanes, five haloacetic acids, and two inorganic compounds (bromate and chlorite). Under the third Six-Year Review (SYR 3), EPA identified eight National Primary Drinking Water Regulations (NPDWRs) covered by the Microbial and Disinfection Byproducts (MDBP) rules as "candidates for revision" (USEPA, 2017).

Currently, 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.

Comments Received on DBPs

Comment Excerpt from Commenter 62
B) HAA6br: Brominated Haloacetic Acids, particularly Bromochloracetic acids (BCAA) which are added to the drinking water supply to purify it against contaminants. Most water supplies abide by the first 5 regulated halo acetic acids (HAA5), but leave out BCAA, as it is it not necessary to detect it. BCAA causes abnormalities in laboratory animals and is quite commonly found in drinking water. Some harmful effects include: sore throat, vomiting and diarrhea
[FN20: Delaware Health and Social Services. Division of Public Health. "Haloacetic Acids". https://dhss.delaware.gov/dhss/dph/files/haloaceacfaq.pdf]

Individual Response: Please see Discussion on DBPs. Disinfection byproducts are formed when an oxidant, like chlorine or chloramine, disinfectants, are added to water and interact with organic matter. Bromochloroacetic acid is not added to drinking water but may form in drinking water when

Comments Received on DBPs
bromide is present. EPA agrees with the commenter that brominated haloacetic acids are of concern and therefore EPA listed brominated haloacetic acids as one of the 23 DBPs listed as a group on the CCL 5. The reference that the commenter has provided will be taken into consideration.
Comment Excerpt from Commenter 75 The following comments provide additional detail on contaminants listed on the Draft CCL 5 that are a particular concern for state drinking water programs. Unregulated Disinfection Byproducts (DBPs) ASDWA supports the continued inclusion of unregulated DBPs on CCL 5. According to EPA research, "Since 1976, more than 600 DBPs have been reported, but only a few of them have been quantitatively assessed for their occurrence and health effects." States are concerned about the lack of information for many DBPs. As EPA considers changes to the Microbial and DBP regulations, health effects data and additional data on the accuracy and reliability of analytical methods for detecting unregulated DBPs at low concentrations is critical. ASDWA recommends that EPA work to fill research gaps for these contaminants, particularly the nine species of haloacetic acids (HAA9), nitrosamines, brominated and iodinated DBPs. This research effort should also include developing further information, including treatment, on precursors (e.g., bromide) for these currently unregulated contaminants and the means to protect sources of drinking water. **Individual Response:** Please see Discussion on DBPs. EPA agrees that unregulated DBPs are a public health concern and recognizes the information gaps and needs for additional research.
Comment Excerpt from Commenter 77 [In reviewing the CCL 5 process as described by the Agency, AWWA found:] 2. With the ongoing M/DBP effort, it is not clear why EPA was not able to include information on the health effects and occurrence of DBPs in the Draft CCL 5 Federal Register notice support documents. EPA must have information not otherwise included in the support documents to justify selecting 23 DBPs from the hundreds of known DBPs. At present, EPA cites the inclusion of 23 DBPs in the CCL 5 solely on the basis that it is contemplating revising existing M/DBP regulations. [FN21: EPA. 2021. Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) Chemical Contaminants. EPA 815-R-21-005.] In finalizing CCL 5, EPA should present the supporting data for including DBPs as a group in the CCL, since EPA is aware that there are marked differences in both DBP occurrence and health effects. AWWA agrees with EPA's stated intent of evaluating DBPs in a cohesive manner while assuring adequate disinfection. **Individual Response:** Please see Discussion on DBPs and Other Drinking Water Programs. The MDBP rule revisions effort is outside the scope of CCL 5.
Comment Excerpt from Commenter 85 September 17, 2021 Via Regulations.gov U.S. Environmental Protection Agency EPA Docket Center, Water Docket Environmental Protection Agency

Comments Received on DBPs

Mail Code: 28221T
1200 Pennsylvania Ave, NW.
Washington, DC 20460

ATTN: Kesha Forrest
Office Ground Water and Drinking Water
Standards and Risk Management Division

Re: EPA-HQ-OW-2018-0594

Dear Ms. Forrest:
The Chloropicrin Manufacturers' Task Force (CMTF) [FN1: The CMTF represents all U.S. manufacturing-use registrants and many end-use registrants of chloropicrin.] appreciates the opportunity to comment on the draft Drinking Water Contaminant Candidate List 5 (CCL 5). The CMTF's comments specifically address the proposal to include chloropicrin on the CCL 5. Chloropicrin has been proposed for the list as part of 23 unregulated Disinfection Byproducts (DBP). [FN2: 86 Fed. Reg. 37,948 (July 19, 2021). In addition, chloropicrin was publicly nominated as a DBP. Id. at 37,968. Chloropicrin is also a registered pesticide; however, EPA's Office of Pesticide Programs concluded as part of the Re-Registration of chloropicrin that "the Agency does not expect the pesticidal uses of chloropicrin to adversely impact ground water or surface water." EPA Memo re Chloropicrin Third Revision of the HED Human Health Risk Assessment, p. 76 (April 30, 2009) (hereinafter EPA 2009).] However, as explained below chloropicrin does not meet the Safe Drinking Water Act (SDWA) criteria for listing.

Halogenated organic compounds like chloropicrin can form during the chlorination process of natural water containing nitrates and dissolved organic substances. The use of ozone in the water treatment process followed by chlorination may increase the amount of chloropicrin in the water. [FN3: EPA Memo re Chloropicrin Final Revised HED Human Health Risk Assessment for the Reregistration of Chloropicrin, p. 73 (June 18, 2008) (hereinafter EPA 2008); see also, EPA 2009, p. 19.] Reported concentrations of chloropicrin in the treated water were less than 1.00 µg/L. [FN4: EPA 2008, p. 73.] EPA's Office of Pesticide Programs concluded that "the concentrations of chloropicrin detected in potable water are below the concentrations of HED's level of concern." [FN5: Id.]

EPA must consider three statutory criteria when identifying contaminants for potential regulation: (1) the contaminant may have an adverse effect on the health of persons; (2) the contaminant is known 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, (3) the regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems. [FN6: 42 U.S.C. § 300g-1(b)(1)(A).]

As explained above, there is not a substantial likelihood that chloropicrin will occur at levels of public health concern. Regulation of the contaminant does not present a meaningful opportunity for health risk reduction for persons served by public water systems. Therefore, the criteria for listing are not met.

If you have any questions, please contact the Task Force's manager, Sara Beth Watson at 202-429-

Comments Received on DBPs
6460 or swatson@steptoe.com. Regards, Stephen Wilhelm Chairman Chloropicrin Manufacturers' Task Force cc: Sara Beth Watson **Individual Response:** Please see Discussion on DBPs, General Comments, and Other Drinking Water Programs. EPA disagrees with the comment that chloropicrin "does not meet the Safe Drinking Water Act (SDWA) criteria for listing". The SDWA requirements for listing a contaminant on the CCL are that it is unregulated, known or anticipated to occur in public water systems, and may require regulation under SDWA. The three criteria that the commenter references are the criteria for the regulatory determinations process and are required for determining whether a CCL contaminant may require regulation under SDWA. The regulatory determinations process is a separate process from the CCL listing process.
Comment Excerpt from Commenter 89 With respect to the 23 unregulated disinfection byproducts EPA has proposed, we urge that they be considered as part of the upcoming MDBP regulations, which we have under separate cover (with AWWA, AMWA and CWA) urged be conducted through a regulatory negotiation. These DBPs also clearly qualify as a class for inclusion in the CCL5. **Individual Response:** Please see Discussion on DBPs and Other Drinking Water Programs. EPA agrees that DBPs are appropriate to be added to CCL 5 as a group. EPA's MDBP rule revisions are outside the scope of CCL 5.
Comment Excerpt from Commenter 89 [II. EPA SHOULD ADDRESS CYANOTOXINS AND DBPs AS CLASSES] Similarly, the 23 unregulated disinfection byproducts EPA has listed in the proposal (four haloacetic acids, two haloacetonitriles, three halonitromethanes, six iodinated trihalomethanes, six nitrosamines, chlorate and formaldehyde) are known or anticipated to be of substantial health concern and to widely occur in drinking water. They also should be considered as a class under the upcoming MDBP rulemaking, and EPA clearly can and should make a positive regulatory determination for them. Moreover, it is manifest that they qualify for inclusion in the CCL 5 as a class for the reasons noted in the Federal Register notice for the proposal, supporting documents cited therein, and in the record. **Individual Response:** Please see Discussion on DBPs, Cyanotoxins, and Other Drinking Water Programs. EPA agrees that DBPs are appropriate to be added to CCL 5 as a group. EPA's MDBP rule revisions and the regulatory determination process are outside the scope of CCL 5.

Comments Received on DBPs

Comment Excerpt from Commenter 89
With respect to the 23 unregulated disinfection byproducts EPA has proposed, we urge that they be considered as part of the upcoming MDBP regulations, which we have under separate cover (with AWWA, AMWA and CWA) urged be conducted through a regulatory negotiation.

Individual Response: Please see Discussion on DBPs and Other Drinking Water Programs.
EPA's MDBP rule revisions and the regulatory determination process are outside the scope of CCL 5.

Per- and Polyfluoroalkyl substances (PFAS)

Agency Discussion on Per- and Polyfluoroalkyl substances (PFAS)

Agency Topic Discussion:
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. PFAS have been detected in water (finished and source water), air, fish, and soil at locations across the nation. These widely used and persistent chemicals have also been found in blood samples of humans (CDC, 2019). EPA is committed to addressing per- and polyfluoroalkyl substances (PFAS) in drinking water and the environment in general. In October 2021, EPA announced a comprehensive PFAS Strategic Roadmap which outlined an integrated approach for tackling PFAS challenges in the environment (USEPA, 2021b). This strategic roadmap lays out EPA's whole-of-agency approach to addressing PFAS. The strategic roadmap builds on and accelerates implementation of policy actions identified in the Agency's 2019 action plan and commits to bolder new policies to safeguard public health, protect the environment, and hold polluters accountable.

EPA's integrated approach to PFAS is focused on three central directives:
• **Research**. Invest in research, development, and innovation to increase understanding of PFAS exposures and toxicities, human health and ecological effects, and effective interventions that incorporate the best available science.
• **Restrict**. Pursue a comprehensive approach to proactively prevent PFAS from entering air, land, and water at levels that can adversely impact human health and the environment.
• **Remediate**. Broaden and accelerate the cleanup of PFAS contamination to protect human health and ecological systems.

EPA's approach is shaped by the unique challenges to addressing PFAS contamination. EPA cannot solve the problem of "forever chemicals" by tackling one route of exposure or one use at a time. EPA will continue to pursue a rigorous scientific agenda to better characterize toxicities, understand exposure pathways, and identify new methods to avert and remediate PFAS pollution. As EPA learns more about the family of PFAS chemicals, the Agency can do more to protect public health and the environment.

In regard to addressing PFAS in drinking water, the roadmap specifically lays out its plans to undertake national PFAS monitoring under UCMR 5 and establish drinking water regulations for PFOA and PFOS. The roadmap also states that as part of the PFOA and PFOS regulation, EPA will also evaluate additional PFAS and consider regulatory actions to address groups of PFAS. Including PFAS as

Agency Discussion on Per- and Polyfluoroalkyl substances (PFAS)

a group on the CCL 5, aligns with EPA's commitment to better understand PFAS and ultimately reduce the potential risk caused by this broad class of chemicals.

When initiating the CCL 5 process, EPA sought public nominations for unregulated contaminants to be considered for inclusion on the CCL 5. EPA compiled and reviewed the information from the nominations process to assist in identifying contaminants for listing. Among the chemicals nominated, PFAS chemicals received the most nominations. Listing a group of PFAS on CCL 5 is also responsive to public nominations which stated that EPA should "include PFAS chemicals as a class on CCL 5."
For the Draft CCL 5, EPA proposed to list PFAS as a group inclusive of any PFAS (except for PFOA and PFOS). For the purposes of the Draft CCL 5, the structural definition of PFAS included per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R''. Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R'') can be hydrogen.

Listing PFAS as a group

EPA received many comments supporting EPA's decision to list PFAS as a group while multiple commenters opposed listing PFAS as a group. EPA agrees with commenters that support listing PFAS as a group and has retained a group of PFAS on the Final CCL 5, with the exception for PFOA and PFOS in which EPA has made final positive regulatory determinations under the fourth Regulatory Determinations process and is in the process of developing a National Primary Drinking Water Regulation. EPA maintains its decision that the CCL 5 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 will evaluate scientific data on the listed groups, subgroups, and individual contaminants included in the group to inform any regulatory determinations for the group, subgroup, or individual contaminants in the group.

PFAS definition

EPA received many comments related to expanding the Draft CCL 5 PFAS structural definition because it was too narrow and did not include PFAS that have been identified in drinking water and source water. Commenters also provided alternative PFAS definitions for EPA's consideration and these alternatives have been addressed in the "Individual Responses" below. 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 to state the following:

> 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.

This revised definition maintains the Draft CCL 5 structural definition but augments it to include additional PFAS substructures to address 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

Agency Discussion on Per- and Polyfluoroalkyl substances (PFAS)

(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. EPA is also including additional language in the Final CCL 5 FRN 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.
Several public commenters suggested EPA apply the Organisation for Economic Co-operation and Development (OECD) 2021 PFAS definition for CCL 5. The OECD definition states as follows:

> "PFASs are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e., with a few noted exceptions, any chemical with at least a perfluorinated methyl group (–CF3) or a perfluorinated methylene group (–CF2–) is a PFAS."

OECD acknowledges that this definition is expansive and describes the universe of chemicals with perfluorinated carbons, and that "working scope" definitions may be needed depending on programmatic needs. EPA is committed to addressing PFAS known to occur in drinking water and/or source water but the OECD 2021 definition would also include fluorinated chemicals that are unlikely to be found in source water based on chemical characteristics.

PFAS contamination in drinking water/environment

EPA also received many comments regarding the regulation of PFAS substances and their associated risk on the environment, especially in drinking water/environment. The regulation of PFAS substances and their associated risk on the environment is outside the scope of CCL 5. Please see Discussion on Other Drinking Water Programs and Other EPA Programs.

PFAS testing methods

EPA also received many comments regarding PFAS analytical testing methods. EPA has developed, validated, and published three methods to support the analysis of 29 PFAS in drinking water: Method 533 (2019), 537 (2009) and 537.1 (2020). EPA's methods were developed and validated for the analysis of finished drinking water (i.e., potable water) from both groundwater and surface water sources. Multiple commenters suggested or recommended that EPA limit the CCL 5 PFAS group to the 29 PFAS included on UCMR 5 with validated drinking water analytical methods. EPA disagrees with these suggests/recommendations. SDWA does not require validated drinking water analytical methods for a contaminant to be included on the CCL. EPA is continuing to develop testing methods to understand occurrence to support future regulatory decisions.

Comments Received on PFAS

Comment Excerpt from Commenter 56

Polyfluoroalkyl substances (PFAS) should be added to the fifth drinking water Contaminant Candidate List (CCL 5). Millions of public citizens have expressed their concern with PFAS and the associated risk imposed on safe drinking water. Therefore, regulating potentially toxic substances such as PFAS under the SDWA should be a top priority for the EPA on CCL 5.

PFAS are manufactured and used in a variety of industries around the world which has led to extensive studies on these types of chemicals. PFAS can be found in many things such as food packaging materials, commercial household products, or within workplace production facility equipment. In regard to CCL 5, PFAS in drinking water are typically found in a localized areas such as a landfill or wastewater treatment center but also have the ability to build up over time in living organisms (EPA 2021). PFAS do not easily breakdown and there is evidence that these chemicals can accumulate over time leading to adverse human health effects.

More than 3,000 synthetic compounds are classified as PFAS and if these chemicals are not regulated properly, they will continue to accumulate in drinking water as well as the environment. Numerous studies indicate that PFAS can have detrimental effects on the endocrine system in humans, including the thyroid function in particular (Coperchini 2021). According to the US National Library of Medicine, PFAS have been recognized as endocrine disrupters through in vitro studies and also on different types of subjects, including animal and human data. This is important because thyroid hormones are involved in many different biological processes including regulation of energy expenditure, neurodevelopment, growth, synaptogenesis, and metabolic processes well into adult life (Coperchini 2021). Recent reviews of thyroid disrupting effects on various biological pathways show that any step in the biosynthesis and secretion of thyroid hormones could be affected by PFAS exposure. These effects include impairment of iodine uptake by thyroid cells, interference in thyroglobulin synthesis, modification of Thyrperoxidase, and interference with feedback mechanisms (Coperchini 2021).

Thyroid disease is not the only concern associated with PFAS exposure. Recently, studies have also linked the possible relationship between PFAS exposure and thyroid dysfunction during pregnancy (Coperchini 2021). Elevated levels of thyroid-stimulating hormone (TSH) in early pregnancy is also associated with possible adverse maternal and fetal outcomes. From available morbidity studies, it is evident that PFAS definitely alters human thyroid hormone production and could potentially contribute to thyroid autoimmunity (Fenton 2020).

Current data indicates that 90% of US residents have detectable PFAS levels in their bloodstreams and there are many common PFAS associated with drinking water (Chowdhury 2020). Within those detectable levels of PFAS are long chain compounds that tend to be more resistant to degradation and decay, often persisting for 2-9 years within the human body. Table 1 below shows half-life estimates of various PFAS substances in rats, mice, monkeys, and humans (Fenton 2020).

Given that many epidemiological studies have extensively explored the relationship between PFAS exposure and potential human toxicity, PFAS should be nominated as a known contaminant within public water systems on the CCL 5 list. Granted, the adverse health effects within humans are dependent on an array of factors including magnitude, duration, and route of exposure to PFAS chemicals. It is important to note which studies provide the strongest evidence across different

Comments Received on PFAS

populations. It is evident that preliminary data from heavily exposed PFAS populations is also correlated to reproductive and development issues, kidney disease, kidney cancer, lipid and insulin dysregulation, liver disease and cancer, immune dysfunction, hepatic and metabolic toxicity (Fenton 2020).

Individual Response: Please see Discussion on PFAS, General Comments, and Other Drinking Water Program.

Comment Excerpt from Commenter 69

I have a question about your definition of PFAS in the CCL 5 proposed rule: "... includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R". Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R") can be hydrogen (USEPA, 2021f)." I'm particularly confused by the term "C(F)(R')R" and also just "R" and wondering what are some compounds that some people consider PFAS that may not be included. For example, some definitions of PFAS include anything with a fully fluorinated C atom (a single C2 or C3). It looks like this definition wouldn't include all these but I can't tell for sure.

Jason Lowery

Madison, WI

Individual Response: Please see Discussion on PFAS. Perfluoroalkyl substances are fully fluorinated (perfluoro-) alkane (carbon-chain) molecules. Their basic chemical structure is a chain of two or more carbon atoms (or the tail) with a charged functional group (the head) attached at one end. The functional groups commonly are carboxylates or sulfonates, but other forms are also detected in the environment. For perfluoroalkyl substances, fluorine atoms are attached to all possible bonding sites along the carbon chain of the tail, except for one bonding site on the last carbon where the functional group head is attached. "CnF2n+1" defines the length of the perfluoroalkyl chain tail, "n" is >2, and "R" represents the attached functional group head. Note that the functional group may contain 1 or more carbon atoms, which are included in the total number of carbons when naming the compound.

Comment Excerpt from Commenter 70

National Ground Water Association Comments on:

Environmental Protection Agency Drinking Water

Contaminant Candidate List 5-Draft

ACTION: Notice of availability; request for comments; Proposed Rule by the Environmental Protection Agency for Drinking Water Contaminant Candidate List 5

Publication Date: July 19, 2021

Document Citation: 86 FR 37948

Docket ID Number: EPA-HQ-OW-2018-0594

SUMMARY:

The U.S. Environmental Protection Agency (EPA) is publishing a draft list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations for public review and comment. These contaminants are known or anticipated to occur in public water

Comments Received on PFAS

systems and may require regulation under the Safe Drinking Water Act (SDWA). This draft list is the Fifth Contaminant Candidate List (CCL 5) published by the agency since the SDWA amendments of 1996. The Draft CCL 5 includes 66 chemicals, 3 chemical groups (16 per- and polyfluoroalkyl substances (PFAS), cyanotoxins, and disinfection byproducts) and 12 microbial contaminants. EPA seeks comment on the Draft CCL 5 and on improvements implemented in the CCL 5 process for consideration in developing future CCLs.

Electronic Link: https://www.federalregister.gov/documents/2021/07/19/202115121/drinking-water-contaminant-candidate-list-5-draft

Submission Due Date: September 17, 2021.

Date Submitted: September 7, 2021

COMMENTS OF THE NATIONAL GROUND WATER ASSOCIATION (NGWA) TO EPA

The NGWA supports the inclusion on the Contaminant Candidate List 5 (CCL 5) of the 16 per- and polyfluoroalkyl substances (PFAS) listed in the footnote below. [FN1: Perfluoro(2-((6-chlorohexyl)oxy)ethanesulfonic acid) (9Cl-PF3ONS), Perfluoro-2-methyl-3-oxahexanoic acid, Perfluorobutane sulfonic acid (PFBS), Perfluorobutyric acid (PFBA), Perfluorodecanoic acid (PFDeA/PFDA), Perfluorododecanoic acid (PFDoA), Perfluoroheptanoic acid (PFHpA), Perfluorohexane sulfonic acid (PFHxS), Perfluorohexanoic acid (PFHxA), Perfluorononononanoic acid (PFNA), Perfluorooctanesulfonamide (PFOSA), Perfluorooctane sulfonic acid (PFOS), Perfluorooctanoic acid (PFOA), Perfluorotetradecanoic acid (PFTA), Perfluorotridecanoic acid (PFTrDA), Perfluoroundecanoic acid (PFUA/PFUnA).]

The NGWA commented on and supported the establishment of the previous list of the Unregulated Contaminant Monitoring Rule 5 (UCMR5) monitoring program to establish the occurrence of the 29 PFAS among representative large and small water systems in order to determine exposure of the U.S. population to these chemical substances (publication date: March 11, 2021; document citation: 86 FR 13846; Agency/Docket Number EPA-HQ-OW-2018-0530).

NGWA has focused on concerns about PFAS prior to and since its report:

National Ground Water Association (NGWA). 2017 (and Updates). Groundwater and PFAS: State of Knowledge and Practice. NGWA Press, Westerville, Ohio.

This report documented treatment capability for PFOA and PFOS and cited concerns for other PFAS in groundwater.

In the letter to EPA of June 3, 2020, joined by NGWA and eight other prominent water associations, the associations asked that EPA (1) engage with outside experts to develop and review a public health risk assessment for PFAS, (2) with all key stakeholders establish the adequacy of analytical methods and capacity, effective risk communication, and sustainable treatment options, among other important factors, (3) accelerate research on water treatment, occurrence, and health effects to support future decision making and contaminant prioritization, and (4) leverage available regulatory tools in other statutes to gather occurrence and health risk assessment data and organize them to support research and decision making, using regulatory tools that include the Toxics Release Inventory, Sections 4 and 8 of the Toxic Substances Control Act, and the Unregulated Contaminant Monitoring Rule.

Comments Received on PFAS

NGWA appreciates EPA moving forward on regulating PFAS in drinking water with this action regarding CCL 5. The EPA PFAS program should be a comprehensive approach to protecting our nation's population from these chemicals in the future. NGWA also notes the following factors related to the need for regulating and monitoring of PFAS across the country:

The Centers for Disease Control and Prevention reports that PFAS chemicals are in the blood of virtually all Americans. [FN2: Centers for Disease Control and Prevention. 2017. Per- and Polyfluorinated Substances (PFAS) Factsheet. https://www.cdc.gov/biomonitoring/PFAS_FactSheet.html] Seventy-seven (77) percent (401 out of 524) of military installations across the nation have measured levels of PFAS contamination. The

Environmental Working Group (EWG) found that 90 more current and former Army and Army National Guard installations had levels of ground or drinking water contamination than previously reported. [FN3: Military.com. 2019. List of Bases Contaminated with PFAS Chemicals Expected to Grow, Pentagon Says. https://www.military.com/daily-news/2019/09/13/list-bases-contaminated-pfas-chemicals-expectedgrowpentagon-says.html]

NGWA is very concerned that Guelfo and Adamson (2018) [FN4: Guelfo, J.L. and D.T. Adamson. 2018. Evaluation of a national data set for insights into sources, composition, and concentrations of per- and polyfluoroalkyl substances (PFASs) in U.S. drinking water. Environmental Pollution vol. 236 (May), pp.505-513. Cited in U.S. Environmental Protection Agency, Regulatory Determination 4 Support Document; EPA 815-R-19-006, December 2019, p. 3-38.] examined PFAS results from UCMR 3 in detail and found that approximately 50 percent of samples with reportable levels of one or more PFAS detections contained at least two PFAS and 72 percent of detections occurred in groundwater. When detected, median total PFAS concentrations were higher in small PWSs serving 10,000 or fewer persons (0.12 µg/L) than in large PWSs (0.053 µg/L). This PFAS level in small water systems is nearly twice the current Health Reference Level of 70 ppt. This concern is highlighted by the fact that 75 percent (36,398) of all community water systems are primarily ground-supplied, and 96 percent of those groundwater-supplied systems are small water systems serving 10,000 or fewer people and have fewer resources to manage their water systems. Ninety-seven (97) percent (93,807) of nontransient and transient noncommunity water systems are groundwater-supplied. [FN5: U.S. Environmental Protection Agency. 2021. Drinking Water Government Performance Reporting Act Tool.

https://obipublic.epa.gov/analytics/saw.dll?PortalPages&PortalPath=/shared/SFDW/_portal/Public]

Guelfo and Adamson also reported that large water systems serving more than 10,000 persons were 5.6 times more likely than small PWSs to have PFAS detections. Many large systems have groundwater sources for supplementary or backup water supply.

Basis for the Interest of the National Ground Water Association (NGWA) in Regulation of PFAS in Drinking Water

NGWA, the largest trade association and professional society of groundwater professionals in the world, represents over 10,400 groundwater professionals within the United States and internationally. NGWA represents four key sectors: scientists and engineers, employed by private industry, by the consulting community, by academic institutions, and by local, state, and federal governments, to assess groundwater quality, availability, and sustainability; water-well contractors responsible for developing and constructing water-well infrastructure for residential, commercial, and agricultural use; and the manufacturers and the suppliers responsible for manufacturing and

Comments Received on PFAS

providing the equipment needed to make groundwater development possible. Over 41 million people in the United States rely on private wells and over 90 million people are served by groundwater from community water systems. NGWA's mission is to advocate for and support the responsible development, management, and use of groundwater. Control of potential and active sources of contamination should be a national objective, reducing the need for remediation of groundwater. Aquifers should be protected from degradation.

Thank you for the opportunity to comment on this proposed regulatory action.

For further follow up, please contact:

Charles Job, Regulatory Affairs Manager

National Ground Water Association

202-660-0060

cjob@ngwa.org

Individual Response: Please see Discussion on PFAS, General Comments, Other Drinking Water Programs, and Other EPA Programs.

Comment Excerpt from Commenter 71

While AMWA does not have initial concerns with EPA's inclusion of PFAS as a group on CCL 5, the association does have concerns with EPA's definition for PFAS included in the notice. EPA has defined PFAS as those chemicals containing the structure unit R-(CF2)-C(F)(R')R''. This definition for PFAS restricts this group to substances that contain a two-carbon chain, where one carbon is fully fluorinated and therefore captures far fewer PFAS than other more broad classifications. [FN1: Organization for Economic Co-operation and Development, 2018. Toward a New Comprehensive Global Database of Per- and Polyfluoroalkyl Substances (PFASs): Summary Report on Updating The OECD 2007 List of Per- and

Polyfluoroalkyl Substances (PFASs). https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENVJM-MONO(2018)7&doclanguage=en] AMWA is concerned that this restriction excludes PFAS that are already known to be found in drinking water. For example, perfluoro-2methoxyacetic acid (PFMOAA) is a perfluoro-ether carboxylic acid that has been found in the North Carolina Cape Fear River and within nearby drinking water supplies [FN2: North Carolina PFAS Testing Network, 2019. NC PFAST Quantitative Screening Results for Raw Drinking Water.] [FN3: Hopkins et al., 2018. Recently Detected Drinking Water Contaminants: GenX and other Per- and Polyfluoroalkyl Ether Acids. Journal AWWA. https://doi.org/10.1002/awwa.1073] but would not be included in the PFAS group under the definition contained in CCL 5. As a result, this definition is not in line with EPA's stated goal for the group to be "inclusive of any PFAS (except for PFOA and PFOS)." AMWA suggests that EPA use a broader definition that will capture all relevant PFAS.

Individual Response: Please see Discussion on PFAS.

Comment Excerpt from Commenter 72

Comments of Arkema Inc. on EPA's NPRM "Drinking Water Contaminant

Candidate List 5-Draft", EPA-HQ-OW-2018-0594

Comments Received on PFAS

Arkema is a global chemical manufacturing company with operations in 22 states and over 3,500 employees, producing innovative solutions for the technologies of the future. In particular, Arkema manufactures Kynar® PVDF fluoropolymers that are used in a variety of important applications, including lithium ion batteries, wire and cable jacketing, semiconductors, solar energy, water filtration, cool roofing and construction coatings that are critical to advancing sustainability. The lithium ion battery is a necessary component of any electric vehicle.

Arkema has been a pioneer in the reformulation of PVDF fluoropolymers to be produced entirely without the use of PFAS surfactants. This extraordinary technical innovation required many years of dedicated R&D efforts. These innovative grades are fully industrialized and commercialized.

As a general matter, we support the transition away from PFAS materials, but we believe the definition in this regard must be clear so that it does not include fluoropolymers made without the use of PFAS surfactants.

To that end, we propose to modify the draft definition in the NPRM to the one recently adopted by the state of Delaware: "PFAS means non-polymeric perfluoroalkyl and polyfluoroalkyl substances that are a group of man-made chemicals that contain at least 2 fully fluorinated carbon atoms, excluding gases and volatile liquids". We believe that this definition correctly captures the PFAS chemicals of concern while leaving out fluoropolymers that have completely different properties.

Fluoropolymers, such as Kynar® PVDF, that meet the OECD "polymer of low concern" criteria are non-toxic, bio-compatible, non-soluble and immobile molecules, and they are deemed as such to have insignificant environmental and human health impacts. The properties of these fluoropolymers enable a durable society as opposed to a disposable society.

Thank you for the opportunity to provide comments.

Sincerely,

Jean-Marie Cencetti

Senior Director Environment & Sustainable Development Arkema, Inc.

Individual Response: Please see Discussion on PFAS. EPA is aware of and considered that multiple states were developing their own PFAS definitions for statewide efforts, including Delaware. At this time, EPA is opting to use a more inclusive CCL 5 PFAS definition to represent those chemicals that are known or anticipated to occur in public water systems and is not prematurely excluding volatiles or fluoropolymers from further evaluation.

Comment Excerpt from Commenter 73
September 17, 2021

EPA-HQ-OW-2018-0594

EPA Docket Center – Water Docket

U.S. Environmental Protection Agency

Comments Received on PFAS

Mail Code 28221T

1200 Pennsylvania Avenue, NW

Washington, DC 20460

Re: Fifth Contaminant Candidate List under the Safe Drinking Water Act - notice of availability, request for comment (86 Federal Register 37948, July 19, 2021)

To Whom It May Concern:

The American Chemistry Council (ACC) submits the following comments on the draft list of contaminants for inclusion on the fifth Contaminant Candidate List (CCL 5) established under Section 1412(b)(1)(B)(i) of the Safe Drinking Water Act (SDWA). ACC supports the identification of individual per- and polyfluoroalkyl substances (PFAS) that meet the criteria for inclusion on the CCL established by the Agency, but strongly opposes the proposal to include the entire class of PFAS on the CCL 5. The draft proposal and supporting documentation have not provided evidence to support a finding that all PFAS "present the greatest public health concern" [FN1: 86 Federal Register 37950.] related to drinking water exposure or even that all members of the class are reasonably anticipated to occur in public water systems. Consequently, EPA cannot determine that most PFAS compounds meet the three criteria required for regulatory action under Section 1412(b)(1)(B)(ii) of the Act, as amended in 1996.

When finalized, the CCL 5 will serve as the primary basis for selecting contaminants to be evaluated for national primary drinking water regulations (NPDWRs) under the provisions of the SDWA. The Act 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. Section 1412(b)(1)(B)(ii) of the Act requires EPA to make determinations of whether to issue a NPDWR for no fewer than five contaminants from the CCL every 5 years, using the following criteria --

• 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.

As explained below, EPA has identified no scientific basis for considering that all PFAS are likely to meet these three criteria. Indeed, it is clear from the scientific evidence that all PFAS compounds do not meet these criteria.

According to EPA, there are more than 1,000 PFAS compounds listed on the TSCA inventory and at least 669 that have been active in commerce since 2006. [FN2: USEPA. TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances. Proposed Rule.

Comments Received on PFAS

86 Federal Register 33926 (June 28, 2021).] For most of these substances, EPA has little or no information on potential health and environmental effects and, therefore, the Agency cannot assess whether they present a public health concern. For example, EPA has established or proposed a chronic reference dose (RfD) for four PFAS. EPA cannot conclude based on those four assessments that all PFAS should be included on the CCL because all "may have an adverse effect on the health of humans." Indeed, substances in the broad category of PFAS identified as fluoropolymers satisfy the criteria for being polymers of low concern established by the Organization of Economic and Cooperative Development (OECD) criteria. According to the European Environmental Bureau, fluoropolymers "have negligible solubility, low mobility, large physical size, low biological uptake and, hence, lower (eco)toxicological concern." [FN3: European Environmental Bureau. PFASs – Avoiding the streetlight effect: An overview of the current situation in the EU (July 15, 2020), at 6. https://eeb.org/library/pfass-avoiding-the-streetlight-effect/] It is unlikely that a finding of health risk can be made for this group of PFAS compounds.

Regarding the likelihood that all PFAS are known, or likely, to be found in public water systems, EPA has identified just a few PFAS compounds in drinking water systems. While the number of PFAS that can reliably be measured in drinking water will likely continue to increase from the current list of 29, [FN4: All 29 PFAS are proposed for inclusion in the fifth Unregulated Contaminant Monitoring Rule (86 Federal Register 13846) per the requirements of National Defense Authorization Act (Public Law 116-92).] it is unlikely that all of the substances captured in the definition of PFAS will be found in drinking water or that the Agency will ever develop methods to measure all those PFAS that may be found. Moreover, unlike the two other chemical groups included in the CCL 5 proposal (i.e., cyanotoxins and unregulated disinfection byproducts), many PFAS would not be expected to be found in drinking water. Fluoropolymers, for example, are not water-soluble and will not be found in public water systems. In addition, many compounds that meet the proposed definition of PFAS are present as gases under environmental conditions and typically will not remain in drinking water supplies.

With regard to the third SDWA criteria that a drinking water regulation will result in a meaningful health risk reduction for persons served by a public water system, EPA cannot reach this conclusion for all PFAS compounds. EPA does not know the health risk, if any, of 99 percent of the PFAS present so it cannot now conclude that all PFAS compounds may cause adverse health effects. Moreover, until many more PFAS compounds are known to be in drinking water and can be measured in drinking water, EPA has no basis for concluding that regulation of them will provide a "meaningful opportunity for health risk reduction for persons served by public water systems."

The Technical Support Document (TSD) for the CCL 5 proposal outlines the following principles used to achieve the critical goals of the CCL established by the SDWA –

• Classification must consider chemicals for listing based on a consideration of their potential for occurrence in water and their potential for causing adverse health effects.

• Data supporting the decision to list or not list must be linked back to these criteria. The most relevant data used for the classification process are health data that indicate adverse effects associated with chronic oral exposure, and occurrence data that indicate the nature and spatial

Comments Received on PFAS

extent of potential occurrence in drinking water.

• The classification approach must be a transparent process that can be reviewed by external experts and the public. The attributes and data characterizing the contaminants should be easy to understand and the decision-making process to list or not list a particular chemical must be conveyed in a straightforward manner. [FN5: USEPA. Technical support document for the draft fifth Contaminant Candidate List (CCL 5) – chemical contaminants. EPA 815-R-21-005 (July 2021), at 43.]

The TSD asserts that EPA applied this scientific evaluation process to the chemicals it is proposing to add to the CCL 5, but offers no explanation of how this process was followed for PFAS. Nor does the document explain how PFAS were found to meet the science-based toxicity and occurrence criteria of the SDWA. [FN6: In fact, the TSD (page 41) indicates that only 18 individual PFAS were included on the preliminary CCL 5 list, or PCCL. There is no indication of how or why the Agency departed from this original plan to consider 18 PFAS for inclusion in CCL 5 to include 1000+ PFAS.] Rather, EPA reasons that listing several thousand PFAS individually on the CCL 5 would be "difficult and challenging." [FN7: 86 Fed. Reg. at 37962.] The challenge in evaluating a large group of substances is not an appropriate justification for listing more than a thousand as a class. Nor is it sufficient to suggest that listing is "responsive to public nominations" recommending inclusion of PFAS chemicals as a class. [FN8: However Appendix C of the TSD indicates that only 16 individual PFAS, not all PFAS, were nominated by a public commentator for inclusion on CCL 5.] As a final justification for proposing that all PFAS be included, EPA reasons that –

[i]ncluding the broad group of PFAS on the Draft CCL 5 demonstrates the agency's commitment to prioritizing and building a strong foundation of science on PFAS while working to harmonize multiple authorities to address the impacts of PFAS on public health and the environment. EPA is also committed to a flexible approach and working collaboratively with states, tribes, water systems, and local communities that have been impacted by PFAS. [FN9: 86 Federal Register 37962.]

However, including all PFAS on the CCL 5 runs counter to the Agency's attempts to identify and prioritize those members of the class that warrant further investigation and to building a scientific foundation for such prioritization. Rather than serve to harmonize efforts to address potential PFAS impacts, such an "all-in" approach is inconsistent with efforts elsewhere in the Agency to define the scope of the PFAS issue. Although flexibility is important in working with communities impacted by PFAS, the lack of a clear set of priorities and focus can only serve to confuse and alarm public water supply customers.

ACC recognizes that inclusion of contaminants on the CCL 5 is an early step in the regulatory evaluation process, and that EPA cannot legally establish maximum contaminant limits (MCLs) for contaminants on the CCL without finding in later stages of the regulatory process that a specific contaminant meets the statutory criteria of Section 1412(b)(1)(B)(ii) of the SDWA. Indeed, so as not to create exaggerated expectations, EPA should expressly confirm that contaminants added to the CCL may be candidates for further consideration as to whether their regulation in drinking water meets the three statutory criteria. Accordingly, ACC can support the inclusion on the CCL 5 (and on the UCMR 5) of those individual PFAS for which EPA has developed validated analytical methods.

Comments Received on PFAS

National survey data for the PFAS included in UCMR 5 will be collected between 2023 and 2025 and will provide the Agency with important information on which to evaluate potential drinking water exposures to PFAS. In the meantime, EPA is expected to develop validated methods for measuring additional PFAS in drinking water and to continue its efforts to prioritize those PFAS, or properly defined subclasses of PFAS, for priority consideration of potential public health concerns. As provided for by the SDWA, and as noted in the proposal, inclusion on the CCL is not a prerequisite for addition to the UCMR and is not required for the Agency to take future action on a substance found to be of concern in drinking water. [FN10: Section 1412 (b)(1)(B)(ii)(III)]

ACC urges EPA to abandon its proposal to add the class of PFAS to the CCL 5. Instead the Agency should limit listing to those specific PFAS included in the proposed UCMR 5 for which the Agency has developed analytical methods for drinking water. Thereafter, EPA should determine which, if any, PFAS to regulate based on whether the specific contaminant meets the statutory criteria of adverse health effects, presence in public water systems, and a meaningful opportunity for risk reduction. Please feel free to contact me at 202-249-6727 or at srisotto@amercanchemistry.com if you have questions about the information provided above.

Sincerely,

Stephen P. Risotto

Senior Director

Individual Response: Please see Discussion on PFAS, General Comments, and Other Drinking Water Programs. The commenter states that "EPA has identified no scientific basis for considering that all PFAS are likely to meet these three criteria." The three criteria mentioned in the comment are those SDWA requires for regulatory determinations and not for CCL.

The commenter recognizes that "flexibility is important in working with communities impacted by PFAS," and the agency agrees. On the other hand, the agency disagrees with the commenter's suggestions that a "lack of a clear set of priorities and focus can only serve to confuse and alarm public water supply customers". CCL is used to set priorities and prompt additional data gathering which will assist the agency in setting future regulatory priorities and address the public's already existing concerns about PFAS in drinking water.

Comment Excerpt from Commenter 75

Contaminant Groups

ASDWA generally supports EPA's use of groups on the CCL, however, the agency should provide clarification on how groups of contaminants will be treated for Regulatory Determinations and UCMR selection as well as how contaminants within the groups will be prioritized for research.

ASDWA specifically supports EPA placing the per- and polyfluoroalkyl substances (PFAS) group on the CCL, however there are some concerns regarding the definition of PFAS the Agency is using. In the proposed rule, EPA states the following regarding the definition of PFAS, "This group is inclusive of any PFAS (except for PFOA and PFOS). For the purposes of this document, the structural definition of PFAS includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R". Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R")

Comments Received on PFAS

can be hydrogen (USEPA, 2021f).” Using this definition limits the group of PFAS to substances that contain a two-carbon chain, where one carbon is fully fluorinated. This definition undoubtedly excludes many substances that could otherwise be considered PFAS, including those that have been found in drinking water and their sources, for example, this definition of PFAS would not include perfluoro-2-methoxyacetic acid (PFMOAA), a perfluoro-ether carboxylic acid which has been found in the North Carolina Cape Fear River and nearby drinking water supplies. ASDWA recommends that EPA reevaluate this definition to be appropriately inclusive of PFAS and should consider revising the structural definition for PFAS being used by the agency. EPA should consider the definitions used and developed by the Organization for Economic Co-operation and Development and the Interstate Technology Regulatory Council. EPA should also recognize that this classification groups together many substances that will have vastly different overall structures thereby calling into question both their fate and transport in the environment and the likelihood that they would cause similar adverse health outcomes. EPA should explain if and how grouping thousands of PFAS for inclusion on the final CCL 5 will impact the treatment of individual compounds throughout the regulatory determination process and clarify how and if screening and proxy methods such as the total organic fluorine (TOF) method will be used.

[Comments on Select Draft CCL 5 Contaminants

The following comments provide additional detail on contaminants listed on the Draft CCL 5 that are a particular concern for state drinking water programs.]

PFAS

ASDWA supports the inclusion of PFAS as a group on CCL 5. State and territorial drinking water programs have been confronted over the past several years with how to appropriately address PFAS challenges. In response to increasing discoveries of PFAS contamination in drinking water sources, and without a federal enforceable standard for PFAS in drinking water, states that have never developed drinking water standards in the past are now setting state-level MCLs for the first time. Six states have state-level MCLs for a subset of PFAS; another four states have set response or action levels. An additional five states are currently developing standards or guidelines.

Some states are also taking other non-regulatory approaches and actions to assess and address PFAS in drinking water and more broadly for other media. These approaches and actions include: developing multi-agency PFAS Action Plans and Response Teams; undertaking PFAS sampling programs for drinking water systems and surface water and groundwater sources of drinking water; conducting inventories of facilities that use, have used, or produced PFAS; responding to drinking water contamination throughout the state and across media (e.g., residuals, effluent discharges, landfill leachate, Superfund sites); banning use in products; and working with EPA and the Department of Defense (DoD) to address site specific PFAS contamination. At least 15 states have a prohibitive law or policy that prevents them from being stricter than federal water standards. PFAS remain a high priority drinking water contaminant and further research is needed on the thousands of compounds that make up this chemical class.

Individual Response: Please see Discussion on PFAS and Other Drinking Water Programs. EPA is

Comments Received on PFAS

aware of and considered the definitions used and developed by the Organization for Economic Co-operation and Development and the Interstate Technology Regulatory Council. At this time, EPA is opting to use a more restrictive CCL 5 PFAS definition that represents those chemicals that are known or anticipated to occur in public water systems and is not prematurely excluding volatiles or fluoropolymers from further evaluation.

Comment Excerpt from Commenter 76

The Attorneys General of the States of Connecticut, Delaware, Iowa, Maine, Maryland, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Oregon, Pennsylvania, Virginia, and Wisconsin, and the District of Columbia

September 17, 2021

Via Regulations.gov

Water Docket

EPA Docket Center

U.S. Environmental Protection Agency

Mail Code: 28221T

1200 Pennsylvania Ave. NW

Washington, D.C. 20460

Re: Comments on Drinking Water Contaminant Candidate List 5—Draft, 86 Fed. Reg. 37948 (July 19, 2021)

Docket ID No. EPA-HQ-OW-2018-0594

Dear Administrator Regan:

The Attorneys General of the States of Connecticut, Delaware, Iowa, Maine, Maryland, Massachusetts, Minnesota, New Jersey, New Mexico, New York, Oregon, Pennsylvania, Virginia, and Wisconsin, and the District of Columbia (collectively, the States) offer these comments in support of the U.S. Environmental Protection Agency's (EPA) Drinking Water Contaminant Candidate List 5—Draft (Draft CCL 5), 86 Fed. Reg. 37,948 (July 19, 2021). EPA's Draft CCL 5 lists 66 chemicals, 3 chemical groups (per- and polyfluoroalkyl substances (PFAS), cyanotoxins, and disinfection byproducts) and 12 microbial contaminants. [FN1: See Drinking Water Contaminant Candidate List 5—Draft (Draft CCL 5), 86 Fed. Reg. 37,948, 37,962 (July 19, 2021) (to be codified at 40 C.F.R. pt. 141). These comments address only the proposed listing of PFAS as a class]. In these comments, the States support EPA's proposal to include PFAS as a class of chemicals in CCL 5 as a first step in the process to consider whether to set drinking water standards for these substances. The States request, however, that EPA modify the definition of PFAS in the Draft CCL 5 to make it sufficiently comprehensive to include all of the PFAS identified by EPA and consistent with the definition of PFAS used by the federal government and states in other contexts.

Comments Received on PFAS

Background

The Safe Drinking Water Act (SDWA), [FN2: 42 U.S.C. §§ 300f et seq.] section 1412(b)(1)(B)(i), requires EPA to publish the Drinking Water Critical Contaminant List (CCL) every five years. "The SDWA specifies that the [CCL] must include contaminants that are not subject to any proposed or promulgated [national primary drinking water regulations (NPDWRs)], are known or anticipated to occur in public water systems (PWSs), and may require regulation under the SDWA." FN3: Id. at 37,949]. The CCL "serves as the initial screening of potential contaminants," and the listing "does not mean that any particular contaminant will necessarily be regulated in the future." [FN4: Id. at 37,950].EPA may select contaminants from the CCL for inclusion in the Unregulated Contaminant Monitoring Rule (UCMR), which requires public water systems to gather and report occurrence data for those contaminants. [FN5:Id].The occurrence data produced by the UCMR program may then provide the basis for EPA's regulatory determination FN6: Id]. The SDWA, section 1412(b)(1)(B)(ii), requires EPA to make regulatory determinations no less frequently than every five years for at least five contaminants from the CCL on whether to set NPDWRs for those contaminants.

As stated in the Draft CCL 5, "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 firefighting foam." [FN7: Id. at 37,962]. As EPA notes in the Draft CCL 5, there are "[o]ver 4,000 PFAS that have been manufactured and used globally since the 1940s [FN8: Id. at 37,962]. Although numerous studies have shown that exposures to PFAS negatively affect human health, there is currently no national requirement that public water systems test for and remove unsafe levels of PFAS in drinking water. [FN9: See Announcement of Final Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate, 86 Fed. Reg. 12,272, 12,278 (Mar. 3, 2021) (to be codified at 40 C.F.R. pt. 141)].

As EPA acknowledges, [FN10: 86 Fed. Reg. at 37,962.] the large number of chemical substances that are part of the PFAS class makes it difficult to list each of them on the CCL. As set forth below, the States endorse EPA's proposal to include PFAS as a class in the CCL 5 and make the following specific recommendations: (A) we urge EPA to define PFAS broadly to ensure that the entire class of PFAS is included in the CCL 5; and (B) in addition to including PFAS as a class in the CCL 5, we urge EPA to gather information to consider setting drinking water standards for PFAS as a class.

Discussion

A. The States urge EPA to define PFAS broadly and clearly to ensure that the entire universe of PFAS is included as a class of chemicals in CCL 5.

While the States support EPA's proposal to include PFAS as a class in CCL 5, we urge EPA to use a definition of PFAS that is broad enough to actually include the entire universe of PFAS as a class of chemicals on the CCL 5. [FN11: The States urge EPA to define PFAS broadly in the CCL 5 because it is a preliminary, investigatory step in the SDWA regulatory process. However, we do not take a position on how any regulations that may result should be structured or how PFAS as a class should be defined in later stages of the SDWA regulatory process]. EPA states that it is proposing "to list PFAS as a group inclusive of any PFAS." [FN12: 86 Fed. Reg. 37,962 (July 19, 2021). EPA is not including PFOA and PFOS in the proposed CCL 5 because EPA has already made final regulatory determinations for those two PFAS. 86 Fed. Reg. 37,969 (July 19, 2021)]. It acknowledges that "[o]ver 4,000 PFAS have been manufactured and used globally since the 1940s." [FN13: Id. at 37,962.] By proposing to list PFAS as a

Comments Received on PFAS

class inclusive of any PFAS, the States' expectation is that the definition of PFAS in the CCL 5 includes all PFAS formulations, both currently known PFAS and PFAS that may be created in the future. Unfortunately, however, the definition of PFAS proposed in the Draft CCL 5 may exclude some PFAS. The States urge EPA to analyze other definitions of PFAS and choose one that is broader and clearer than the definition proposed in the Draft CCL 5 to ensure that the entire universe of PFAS is included in the final CCL 5.

It is important that EPA include a broad definition of PFAS in the CCL 5 because future regulatory determinations will be made based on that definition. As EPA notes, "[t]he CCL is the first step in the SDWA regulatory framework for screening and evaluating the subset of contaminants that may require future regulation." [FN14: Id. at 37,950.] And, "[h]istorically, most unregulated contaminants chosen by EPA for monitoring" under the Unregulated Contaminant Monitoring Rule (UCMR) "have been selected from the CCL." FN15: Id.] While listing PFAS on the CCL 5 "does not necessarily mean that EPA will make subsequent regulatory decisions for the entire group," it does mean that "EPA will evaluate scientific data on the listed groups, subgroups, and individual contaminants included in the group to inform any regulatory determinations for the group, subgroup, or individual contaminants in the group." [FN16: Id. at 37,962.] Because future regulatory decisions may be made for the entire class of PFAS as defined in the CCL 5 or individual contaminants in the group, it is important that the definition of PFAS capture the entire universe of PFAS.

In the Draft CCL 5, EPA proposes the following definition of PFAS:

For the purposes of this document, the structural definition of PFAS includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R". Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R") can be hydrogen (USEPA, 2021f).[FN17: Id.]

This is the same definition of PFAS that EPA included in its recently proposed rule "TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances" (TSCA rule). [FN18: 86 Fed. Reg. 33,929 (June 28, 2021) ("For the purposes of this proposed action, the structural definition of PFAS includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R". Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R") can be hydrogen.")]. In that pending rulemaking, EPA acknowledged that this definition may only cover a subset—"at least 1,364 chemical substances and mixtures"—of the over 4,000 PFAS that have been manufactured and used [FN19:Id.].

The States are concerned that the definition of PFAS in the Draft CCL 5 may be too narrow to ensure that the entire universe of PFAS is included in the CCL 5. For example, the definition seems to exclude fluorinated compounds containing a spacer, such as CH2 or oxygen, between the CF2 and CF groups. Fluorinated chemicals containing these spacers have been found in environmental testing near PFAS manufacturing plants [FN20: Newton S, McMahen R, Stoeckel JA, Chislock M, Lindstrom A, Strynar M. Novel polyfluorinated compounds identified using high resolution mass spectrometry downstream of manufacturing facilities near Decatur, Alabama, USA. Environ Sci Technol. 2017 February 07; 51(3): 1544-1552. https://doi.org/10.1021/acs.est.6b05330; Zhang C, Hopkins ZR, McCord J, Strynar MJ, Knappe DRU. Fate of per- and polyfluoroalkyl ether acids in the total oxidizable precursor assay and implications for the analysis of impacted water. Environ Sci Technol Lett. 2019; 6(11): 662-668. https://doi.org/10.1021/acs.estlett.9b00525]. The definition also seems to exclude fluorinated compounds that contain only one CF3 group, such as some fluorinated gases, pesticides, pharmaceuticals, and dyes. The definition of PFAS should be modified to be broad enough to include chemicals containing spacers and a single CF3 group. The States are also concerned that the current

Comments Received on PFAS

definition may not be clear enough to accurately describe the entire universe of PFAS. In this regard, the Draft CCL 5 is not clear as to whether one of the R groups (R, R', or R") can be halogens other than fluorine or include one or more CH2 molecules and still be included in the definition of PFAS. Also, it is not clear why none of the R groups can be hydrogen—this requirement narrows the definition.

Recent State and Federal legislation have adopted definitions of PFAS that are simpler and may be broader and more inclusive than the Draft CCL 5 definition. For example, the 2021 National Defense Authorization Act (2021 NDAA) defines PFAS as "a perfluoroalkyl or polyfluoroalkyl substance with at least one fully fluorinated carbon atom, including the chemical GenX." FN21: William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Pub. L. No. 116-283, § 335(e)(2) (2021)]. Similarly, Vermont recently enacted a statute defining PFAS as "a class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." [FN22: Vt. Stat. Ann. tit. 18, § 1661(5) (effective July 1, 2022); 2021 Vt. Acts & Resolves 36, § 1.]

EPA should analyze these and other available definitions of PFAS against the proposed definition of PFAS in the Draft CCL 5 before issuing the final CCL 5. The States urge EPA to choose the broadest and clearest definition to ensure that, consistent with EPA's stated intent, the final CCL 5 includes the entire universe of PFAS as a class of chemicals on the CCL 5.

B. The States support EPA's proposal to include PFAS as a class in the CCL 5, and we urge EPA to gather information to consider setting drinking water standards for PFAS as a class.

The States support EPA's proposal to include PFAS as a class in the CCL 5. Clearly, PFAS meet the SDWA criteria for listing in the CCL.[FN23: 42 U.S.C. § 300g–1(b))(1)(B)(i)]. First, PFAS as a class are not currently regulated under the SDWA. [FN24: See Announcement of Final Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate, 86 Fed. Reg. 12,272, 12,278 (Mar. 3, 2021) (to be codified at 40 C.F.R. pt. 141)]. Second, PFAS are known or anticipated to occur in public water systems. [FN25: For a summary of occurrence data for PFAS other than PFOA and PFOS, see Attorneys General of Wisconsin et al., Comment Letter on the Preliminary Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List 12-18 (May 10, 2021), https://www.doj.state.wi.us/sites/default/files/news-media/6.10.20_PFAS_Letter.pdf]. Third, PFAS may require regulation under the SDWA due to their prevalence in drinking water supplies and public health impacts. This listing is a significant first step in EPA's consideration of whether to set drinking water standards under the SDWA for PFAS as a class. We urge EPA to move forward quickly to gather occurrence data on PFAS as a class in public water systems and to evaluate whether to set drinking water standards for PFAS as a class.

PFAS contamination detected in the environment is generally made up of mixtures of PFAS, which often contain PFOA or PFOS, two specific PFAS. [FN26: See, e.g., Bălan SA, Mathrani VC, Guo DF, Algazi AM. Regulating PFAS as a Chemical Class under the California Safer Consumer Products Program. Environ. Health Perspectives 2021 Feb 17;129(2). https://doi.org/10.1289/EHP7431.] This PFAS mixture results from multiple sources of PFAS present in an area, the use of PFAS as mixtures in single products (e.g., fire-fighting foam or aqueous film forming foam (AFFF)), and the changes in the types of PFAS that have been commonly used over time. Mixtures of PFAS may pose similar health risks to those associated with exposure to PFOA or PFOS alone, contaminants whose public health impact is well documented. [FN27: Id].

Comments Received on PFAS

A class-based approach may be the most effective way to regulate PFAS as it would provide increased protection to the public, decrease the burden on regulatory agencies, and provide greater certainty to the operators of public water systems. Indeed, regulation of specific PFAS in the past has led to their replacement with other PFAS with similar hazards. [FN28: Bălan SA, Mathrani VC, Guo DF, Algazi AM. Regulating PFAS as a Chemical Class under the California Safer Consumer Products Program. Environ. Health Perspectives 2021 Feb 17;129(2). https://doi.org/10.1289/EHP7431]. PFAS generally show similar indicia of toxicity, environmental persistence (hence, the common reference to PFAS as "forever" chemicals), bioaccumulation, and ubiquity in the environment. [FN29: Addition of Certain Per- and Polyfluoroalkyl Substances; Community Right-to-Know Toxic Chemical Release Reporting (ANPRM), 84 Fed. Reg. 66,369 (Dec. 4, 2019); USEPA. EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan. EPA 823R18004. U.S. Environmental Protection Agency, Washington, D.C. February 2019]. One of the most consistent features of the PFAS class is that, despite the diversity of PFAS substances, all PFAS are extremely resistant to environmental and metabolic degradation. [FN30: Cousins IT, DeWitt JC, Glüge J, Goldenman G, Herzke D, Lohmann R, Ng CA, Scheringer M, Wang Z. The high persistence of PFAS is sufficient for their management as a chemical class. Environ Sci Process Impacts. 2020 Dec 16;22(12):2307-2312. https://pubmed.ncbi.nlm.nih.gov/33230514/; Kwiatkowski CF, Andrews DQ, Birnbaum LS, Bruton TA, DeWitt JC, Knappe D, Maffini MV, Miller MF, Pelch KE, Reade A, Soehl A, Trier X, Venier M, Wagner CC, Wang Z, Blum A. Scientific Basis for Managing PFAS as a Chemical Class. Environ. Sci. Technol. Lett. 2020 Jun 30;7, 8:532-543. https://doi.org/10.1021/acs.estlett.0c00255].There is also a growing body of evidence that shorter-chained PFAS have similar toxicological effects to the well documented adverse effects of longer-chained PFAS such as PFOA and PFOS. [FN31: Kwiatkowski CF, Andrews DQ, Birnbaum LS, Bruton TA, DeWitt JC, Knappe D, Maffini MV, Miller MF, Pelch KE, Reade A, Soehl A, Trier X, Venier M, Wagner CC, Wang Z, Blum A. Scientific Basis for Managing PFAS as a Chemical Class. Environ. Sci. Technol. Lett. 2020 Jun 30;7, 8:532–543. https://doi.org/10.1021/acs.estlett.0c00255].

As EPA recognizes in its notice of this proposed action, listing the many individual PFAS in the CCL 5 would be challenging and impractical, while listing PFAS as a class squares with EPA's commitment to better understand and then reduce the potential risks caused by this broad class of chemicals. [FN32: 86 Fed. Reg. at 37,962] Similarly, it is neither practical nor desirable for EPA to regulate PFAS on an individual basis. Attempting to regulate the over 4,000 known PFAS individually, let alone the potentially never-ending succession of formulations that may regrettably emerge, is a recipe for failing adequately to protect the public. We acknowledge that there are also practical and technical challenges to regulating PFAS as a class in drinking water or other environmental media. These challenges are potentially different than those posed by regulating PFAS as a class in other settings, such as the regulation of consumer products. In these comments, we do not address the challenges to regulating PFAS as a class in drinking water. At this stage, we urge EPA to gather the information needed to consider regulating PFAS as a class in the future.

We also applaud EPA's recent actions to regulate individual PFAS and to gather data for other individual PFAS. On June 10, 2020, many of the undersigned States [FN33: The Attorneys General of the States of California, Colorado, Connecticut, Delaware, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Virginia, Washington, and Wisconsin, and the District of Columbia submitted joint comments in support of EPA's proposed decision to set drinking water standards for PFOS and PFOA.] submitted comments in support of EPA's proposed decision to set drinking water standards for two PFAS—perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA)—

Comments Received on PFAS

which EPA announced in its Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List [FN34: Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List (Preliminary Determination), 85 Fed. Reg. 14,098, 14,120 (Mar. 10, 2020)]. Some of the States [FN35: The Attorneys General of the States of California, Colorado, Connecticut, Delaware, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, New Mexico, Oregon, North Carolina, Pennsylvania, Rhode Island, Virginia, Washington, and Wisconsin, and the District of Columbia submitted joint comments in support of EPA's proposal to include 29 PFAS in the UCMR 5.] also recently submitted comments in support of EPA's proposal to include 29 PFAS in the UCMR 5. [FN36: Attorneys General of Wisconsin et al., Comment Letter on the Proposed Rule, Revisions to the Unregulated Contaminant Monitoring Rule (UCMR 5) (May 10, 2021), https://www.doj.state.wi.us/sites/default/files/news-media/510.21_PFAS_Comments.pdf.] Including these individual PFAS in the UCMR 5 will provide vital information about the occurrence of these contaminants in public water systems. However, to evaluate fully the public health protections needed with respect to PFAS in drinking water, we urge EPA to gather such data about PFAS as a class.

The States therefore urge EPA to gather occurrence data for PFAS as a class. One way to do so is through the UCMR program. Accordingly, in comments on the UCMR 5, some of the undersigned States urged EPA to include PFAS as a class so that important helpful data may expeditiously be gathered. [FN37: Attorneys General of Wisconsin et al., Comment Letter on the Proposed Rule, Revisions to the Unregulated Contaminant Monitoring Rule (UCMR 5) (May 10, 2021), https://www.doj.state.wi.us/sites/default/files/news-media/510.21_PFAS_Comments.pdf. .] Whether through the UCMR program or other means, gathering such data is an important step in setting appropriately protective drinking water standards for these groups of contaminants.

Conclusion

The States appreciate the opportunity to submit these comments on the Draft CCL 5 and fully support EPA's inclusion of PFAS as a class in the CCL 5. The States also urge EPA to define PFAS as a class broadly to ensure that the entire universe of PFAS is included in the CCL 5. In addition to including PFAS as a class in the CCL 5, we urge EPA to gather the information necessary to move forward expeditiously in considering setting drinking water standards for PFAS as a class.

Sincerely,

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Individual Response: Please see Discussion on PFAS, General Comments, and Other Drinking Water Programs.

Comment Excerpt from Commenter 77

[AWWA offers the following recommendations for EPA to consider as the CCL 5 is finalized and in the development of future CCLs.]

Using CCL to Advance Source Water Protection

The CCL should inform risk management efforts beyond the scope of SDWA. This is especially important for contaminants like PFAS, where the source of the contamination is beyond the authorities of SDWA. In developing and presenting the CCL, EPA should consider how it can leverage this information to inform discussion about chemicals that may pose a risk to the nation's drinking water supply. For example, PFAS are a group of contaminants most appropriately addressed through the Toxic Substances Control Act, CWA, and Resource Conservation and Recovery Act. There are opportunities for federal agencies other than EPA to fund relevant research, employ policies and procedures that reduce the use of PFAS substances (e.g., Department of Defense, General Services Administration, etc.).

For other contaminants, other federal agencies may be most relevant to exposure reduction (e.g., Food and Drug Administration, U.S. Department of Agriculture, etc.). In order for EPA to effectively leverage CCL 5 to reduce contaminant occurrence, the final Federal Register notice must provide a sense of priority for (1) which contaminants appear to pose the greatest priority for action and (2) research and data development needs to inform decision-making.

The CCL development process occurs over a five-year cycle. There are frequently stated concerns that

Comments Received on PFAS

the SDWA regulatory process is too slow. The CCL is an opportunity for EPA to step beyond that critique and move instead to timely initiation of action not only to inform risk in drinking water but contamination of the nation's waters.

Individual Response: Please see Discussion on PFAS, Other Drinking Water Programs, and Other EPA Programs.

Comment Excerpt from Commenter 77

Specific CCL5 Contaminants

Appropriately Define PFAS

The Draft CCL 5 includes PFAS as a group of chemical contaminants. EPA describes the structural definition as, intended to be, inclusive of all PFAS compounds. Specifically the EPA has defined PFAS as chemicals with the chemical structure R-(CF2)-C(F)(R')R" where the CF2 and CF moieties are saturated carbons and none of the R groups can be hydrogen. This definition is based on the definition of PFAS included in a recently proposed TSCA Rule. [FN26: EPA, 2021. TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances.] Under that rule, EPA indicated that approximately 1,346 PFAS meet this definition. This definition does not include all PFAS. The accepted definition of PFAS broadly is those substances containing at least one fluorinated carbon moiety. [FN27: Buck et al, 2011. Perfluoroalkyl and Polyfluoroalkyl Substances in the Environment: Terminology, Classification, and Origins. Integrated Environmental Assessment and Management. Doi: 10.1002/ieam.258.] [FN28: Organization for Economic Co-operation and Development, 2018. Toward a New Comprehensive Global Database of Per- and Polyfluoroalkyl Substances (PFASs): Summary Report on Updating The OECD 2007 List of Per- and Polyfluoroalkyl Substances (PFASs). https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV-JM-MONO(2018)7&doclanguage=en] [FN29: EPA, 2020. EPA: PFAS Structures in DSSTox (Update August 2020). https://comptox.epa.gov/dashboard/chemical_lists/PFASSTRUCTV3] According to the EPA CompTox PFAS Master List there are approximately 9,252 known PFAS chemicals, a much larger universe of PFAS compounds than what is included by the definition in the Draft CCL 5.

The Draft CCL 5 definition for PFAS excludes certain PFAS that have been found in drinking water and their sources from the proposed reporting requirements. For example, perfluoro-2-methoxyacetic acid (PFMOAA) does not meet the structural definition since this compound does not have a fluorinated tnwo-carbon chain. However, PFMOAA is a perfluoro-ether carboxylic acid that has been found in the North Carolina Cape Fear River and nearby drinking water supplies. [FN30: North Carolina PFAS Testing Network, 2019. NC PFAST Quantitative Screening Results for Raw Drinking Water. https://www.brunswickcountync.gov/wp-content/uploads/2019/08/NC-PFAST-Quantitative-Screening-Results-for-Raw-Drinking-Water-Brunswick-County-Drinking-Water-System.pdf] [FN31: Hopkins et al., 2018. Recently Detected Drinking Water Contaminants: GenX and other Per- and Polyfluoroalkyl Ether Acids. Journal AWWA. https://doi.org/10.1002/awwa.1073] PFMOAA is an example of a replacement PFAS being used as legacy PFAS compounds (e.g., PFOA and PFOS) are phased out. If EPA anticipates using an all-inclusive structural definition of PFAS, then the appropriate chemical structure would be R-CF(R')(R"), where R, R', and R" are not hydrogen.

If EPA includes PFAS as a group in the final CCL 5, then it should be intentional and transparent in its inclusion and the chemical structures it is including. The framing of the CCL is as important as the list itself. As EPA notes, the current inclusion of 1,346 PFAS compounds assumes a common level of toxicity that is not substantiated in the docket and a premise that would be even less credible if

Comments Received on PFAS

applied to 9,252 PFAS compounds. This is an instance where, if EPA were to more clearly communicate the relative levels of potential risk and gaps in information needed to craft risk management decisions, it could more readily incorporate a group (or groups) of PFAS on the Final CCL 5.

Individual Response: Please see Discussion on PFAS and Other EPA Programs.

Comment Excerpt from Commenter 78

Submitted electronically via the Federal eRulemaking portal at www.regulations.gov

September 17, 2021

EPA Docket Center, Water Docket

Environmental Protection Agency

Mail code: 28221T

1200 Pennsylvania Ave. NW

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Re: Drinking Water Contaminant Candidate List 5 – Draft: Proposed Rule Docket ID: EPA-HQ-OW-2018-0594

Dear Sir or Madam:

The 3M Company ("3M") appreciates the opportunity to comment on the proposed Drinking Water Contaminant Candidate List 5 ("CCL 5") published by the Environmental Protection Agency ("EPA") at 86 Fed. Reg. 37948 on July 19, 2021. As a science-based company, 3M appreciates the efforts EPA has made to take a science-based approach to the CCL 5. In particular, 3M supports EPA's approach to screening substances for potential inclusion on the CCL 5. It is important that EPA maintain this science-based approach with regard to its consideration of per- and polyfluoroalkyl substances ("PFAS"), particularly when considering broad regulatory actions, such as grouping PFAS with known variations in chemistries, and making decisions about application of the screening criteria to PFAS.

Today's PFAS compounds are used by a broad range of customers and industries worldwide that enable critical products such as life-saving medical devices and low-emission vehicles. Regulatory policy must take these important applications into account. While the science behind PFAS can be complex and continues to evolve, science must be at the forefront of providing answers and solutions. 3M encourages EPA to apply the same scientific standards consistently across all contaminant candidates and to consider the feasibility of the proposed CCL 5 listing. We look forward to continued engagement in these and other important discussions around PFAS.

I. Groupings Can be Useful, But EPA Should Not List PFAS as an Undifferentiated Chemical Group

PFAS refers to a broad category of compounds that encompasses thousands of materials with distinct and widely varying properties, profiles, and uses. As EPA has noted, "PFAS vary widely in chemical and physical properties, behavior, and potential risks to human health and the environment. Differences in the chemical structure, carbon chain length, degree of fluorination, and chemical functional

Comments Received on PFAS

group(s) of individual PFAS have implications for their mobility, fate, and degradation in the environment, as well as uptake, metabolism, clearance, and toxicity in humans, plants, and other animals." EPA Multi-Industry Per- and Polyfluoroalkyl Substances (PFAS) Study – 2021 Preliminary Report ("EPA PFAS Study") at 3-1 (September 2021). [FN1: EPA published the Multi-Industry PFAS Study – 2021 Preliminary Report on September 16, 2021, one day before the submission deadline for comments on the draft CCL 5. There is a significant amount of relevant information regarding the "family" of PFAS that 3M suggests EPA incorporate into its CCL 5 listing proposal.] As a result, treating all PFAS as a single group or class is not scientifically sound or appropriate. At the same time, we understand some parties' desire to reduce the volume of individual regulatory assessments through groupings or sub-groupings. We therefore support a rigorous, science based dialogue and review among regulators, academic researchers, manufacturers, and others to determine how these materials could be potentially be grouped in a scientifically sound way.

Consistent with sound environmental policy, such assessments must not only be based on the best available science, but also specific ways in which these substances may or may not impact human health and the environment. Such assessments should consider potential exposure routes and identified hazards, not simply structural similarities. Furthermore, to reach a positive outcome for the communities that regulators serve, these ongoing discussions must be measured and thoughtful to yield effective solutions for use in critical regulatory applications.

a. The Proposed Definition of PFAS is Not Scientifically Sound

In the draft CCL 5, EPA proposes to define PFAS as follows [FN2: EPA's proposed definition of PFAS is the same as what it proposes in the proposed TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 86 FR 33926, June 28, 2021] :

For the purposes of this document, the structural definition of PFAS includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)- C(F)(R')R". Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R") can be hydrogen (USEPA, 2021f).

This definition of PFAS presents significant problems. EPA has acknowledged that the proposed definition "is responsive to public nominations which stated that EPA should 'include PFAS chemicals as a class on CCL 5.'" 86 Fed. Reg. at 37962. For such broad groups of substances, it is critical that this definition is science-based and rooted in appropriate appreciation of the many implications that such a definition could hold.

First, this definition is inconsistent with other regulatory definitions and is not recognized by any other federal or international organization. Moreover, the definition includes substances that EPA specifically excluded from the proposed candidate contaminant list ("PCCL"). Specifically, EPA excluded PFOA and PFOS from the PCCL because it already made regulatory determinations for those substances. The proposed definition itself makes no such distinction. Given the importance of accurate regulatory definitions, 3M encourages EPA to ensure its proposal is as clear and scientifically sound as possible.

Second, EPA's PFAS definition as drafted is both over- and under-inclusive. The definition is over-inclusive because, as noted above and as EPA itself acknowledges, the range of substances encompassed by the definition includes substances with widely varying toxicity, fate and transport, and other characteristics. EPA acknowledges that data availability regarding health effects and occurrence varies significantly within the defined PFAS group, but nonetheless lists the entire group based on "a subset of chemicals" in the group that are known to occur and "may cause" adverse

Comments Received on PFAS

health effects. EPA states that it "did not assess data availability for the cyanotoxins, DBPs, and PFAS groups because the availability of health effects and occurrence data varies with individual chemicals in each group. EPA is addressing these groups broadly in drinking water based on a subset of chemicals in these groups that are known to occur in PWSs and may cause adverse health effects." Id. at 37970. EPA does not identify the "subset of chemicals" it is basing this determination on with respect to PFAS. This is particularly troubling given that EPA is excluding PFOA and PFOS from its listing (but not definition) of PFAS. Further, EPA has not cited any occurrence or health effects information indicating treatment of the defined PFAS as an undifferentiated group is appropriate. In fact, EPA has not identified any scientific basis to group thousands of substances without any distinction. 3M has not identified any precedent in EPA's prior regulatory actions for grouping thousands of chemicals with such widely varying characteristics.

At the same time, EPA also excluded components of significant groups of fluorinated substances from its PFAS definition. Hydrofluorocarbons (HFCs), hydrofluoroolefins (HFOs), and hydrochlorofluoroolefins (HCFOs) are all PFAS in that they contain at least one perfluoroalkyl moiety, yet EPA's proposed definition of PFAS excludes certain substances in these groups. For example, the definition excludes CF3CH2CF2CH3, which has CF3 and CF2 moieties but does not have adjacent fluorinated carbons. Likewise, although it has it two adjacent fluorinated carbons, CF3CFH2 is excluded from EPA's PFAS definition because it contains an H atom in an "R" position. Indeed, EPA's PFAS definition excludes nearly all commercially significant HFCs and HFOs/HCFOs used as solvents, refrigerants, foam blowing agents, etc., as well as a number of pharmaceuticals and anesthetics containing CF3 or CF2 groups because, in many cases, there are alternating moieties. EPA has not identified any scientific basis to exclude these or certain other HFCs, HFOs, and HCFOs from its PFAS definition.

It is vital that the proposed PFAS definition is fair and consistently applied to substances based on substances' environmental, health, and safety profiles. To the extent EPA has a scientific basis to exclude HFCs, HFOs, and HCFOs from the CCL 5 listing, it should also review the broad but incomplete group of PFAS included in its current definition. Many PFAS are included in EPA's definition despite there being little difference in the environmental, health, and safety properties from the compounds excluded. EPA should either propose more narrow definitions focused on appropriate science-based sub-groupings (based on similarity of characteristics), or it should expand the definition of PFAS to include the full array of fluorinated substances, including all HFCs, HFOs, and HCFOs.

b. Treating PFAS as an Undifferentiated Group is Inconsistent With EPA's Treatment of Chlorinated Organic Compounds

EPA's proposal to treat PFAS as a single undifferentiated group is inconsistent with EPA's approach to another class of organohalogens: chlorinated organic compounds. There are more than 2,000 chlorinated organic compounds. [FN3: See, e.g., https://www.eurochlor.org/term/organic-chlorinecompounds/#:~:text=Organic%20chlorine%20compounds%20constitute%20a,one%20or%20more%20chlorine%20 atoms.] Analytical test methods and approaches to assess human and environmental risk have been established for individual chlorinated organic compounds as well as sub-groups of those compounds. Chlorinated organic compounds are divided into several groups based primarily on chemical structure within those sub-groups and use. Examples of these sub-groups include:

- Polychlorinated Biphenyl's (PCBs)

Comments Received on PFAS

- Polychlorinated Dibenzodioxins and Furan (PCDDs/PCDFs)
- Chlorinated Solvents (i.e., dichloromethane, tetrachloroethylene)
- Chlorinated Pesticides (i.e., atrazine, metholachlor, DDT, hexachlorocyclohexanes (HcHs))
- Chlorinated hydrocarbons
- Chlorinated Phenols (i.e., 2, 4 Dicholorphenol)
- Chlorobenzenes
- Pharmaceuticals containing chlorine

In addition, EPA has developed and validated analytical test methods for nearly 500 individual chlorinated compounds within classes of chlorinated organic compounds in a variety of environmental matrices (i.e., air, water, and solid waste). [FN4: Such analytical methods include EPA Methods 505, 508, 515.1, 551, 508; Methods 608, 612, and 615; Methods 1613, 1653, and 1668; Methods 8081, 8082, 8121, 8151, 8280, and 8290; Methods TO-4a, TO-9a, and TO-10a; and Method 23. Individual chlorinated organic compounds are also included in the target analyte list of the following analytical methods: EPA Methods 601, 602, 604, 605, 608, 611, 612, 613, 615, 624, 625, 8021, 8081, 8082, 8121, 8151, 8260, 8270, and 8290.] Chlorinated organic compounds pose many of the same complexities in terms of volume and diversity of the class of chemistries that EPA suggests are raised by PFAS.

c. EPA Should Use a Scientifically Rigorous Approach to Listing PFAS

EPA should use a similarly scientifically rigorous approach to PFAS as it has for chlorinated organic compounds. EPA has acknowledged that there are differences between, for example, perfluorocarbons (PFCs) and PFAS generally. https://www.epa.gov/pfas/what-arepfcs-and-how-do-they-relate-and-polyfluoroalkyl-substances-pfass. Both PFCs and PFAS molecules contain fluorine and carbon atoms, but PFCs are "quite different from PFASs in significant respects…" Id. Despite these significant differences, PFCs are included in EPA's proposed PFAS definition.

On September 16, 2021, EPA published the Multi-Industry Per- and Polyfluoroalkyl Substances (PFAS) Study – 2021 Preliminary Report. That report included an entire section describing the many significant differences between various PFAS. See EPA PFAS Study at 3-1 – 3-11. As EPA notes, "[t]he thousands of chemicals that make up the PFAS family can be divided into two classes: nonpolymers and polymers. Each class may contain subclasses, groups, and subgroups." Id. at 3-1. Figure 1 of the EPA PFAS Study shows how EPA has divided the PFAS "family" into two classes (nonpolymers and polymers), five subclasses, five groups, and ten subgroups. Id. at 3-2. EPA then identifies specific substances that fall into each subclass, group, and subgroup, with a description of general chemical structure. Id. at 3-5 – 3-6. EPA should consider these and other differences within the broad PFAS group, just as it did with chlorinated organic compounds, and develop definitions based on environmental, health, and safety properties with proven causal effects against stated target metrics.

Finally, 3M recognizes EPA's statement that "listing these three chemical groups on the Draft CCL 5 does not necessarily mean that EPA will make subsequent regulatory decisions for the entire group. EPA will evaluate scientific data on the listed groups, subgroups, and individual contaminants included in the group to inform any regulatory determinations for the group, subgroup, or individual contaminants in the group." Id. at 37962. However, it is important for the scientific integrity of EPA's future actions to apply consistent groupings across the Agency's analysis now at a foundational level.

Comments Received on PFAS

II. EPA Should Not Evaluate PFAS Differently Than Other Contaminants

Although EPA used a scientific screening process to identify nearly all substances it recommends for inclusion on the draft CCL 5, PFAS are treated quite differently than other candidates considered. PFAS as a group was a public nomination that should have been vetted based on the same scientific standards EPA applied to screen for development of the PCCL. This includes EPA's application of the new screening system to PFAS, but because there is no contaminant information sheet (CIS) for PFAS provided in the supporting technical materials, it is unclear whether this important information was taken into consideration.

The Proposed Rule describes in detail the screening process it used to identify substances for inclusion on the PCCL:

EPA maintained the framework of screening chemicals to the PCCL based on their available toxicity properties and occurrence data (USEPA, 2009b). To screen chemicals for the CCL 5, EPA developed a transparent and reproducible scoring rubric and pointbased screening system. This pointbased screening system is an improvement over the Toxicity Categories and Occurrence Hierarchies developed for the CCL 3 (USEPA, 2009b) because it incorporates data from all the available data elements identified for use in screening rather than relying on an individual data element that indicates the highest toxicity or occurrence for a chemical.

Also:

There are also new data elements related to both health and occurrence endpoints that EPA included in the CCL 5 screening process that were not available in a retrievable format or not used in previous CCL cycles, including National Health and Nutrition Examination Survey (NHANES) biomonitoring data and results from EPA's ToxCast in vitro screening assays. EPA designed the CCL 5 screening process to accommodate quantitative, calculated, and descriptive types of data.

In addition to considering frequency of detections in drinking water, EPA assigned data elements to chemicals including Reference Dose, no observed adverse effect level (NOAEL), lowest observed adverse effect level (LOAEL), and LD50. EPA identified none of this information for PFAS, either individually or as a group. Indeed, this kind of information is not currently available for every PFAS and certainly not for the listed group as a whole.

For other substances, EPA's evaluation teams considered a range of data including occurrence in water and health effects data as part of the preliminary screening process. The Proposed Rule states that EPA "did not add publicly nominated groups like 'the top 200 most prescribed drugs in 2016 and their parents and metabolites' to the PCCL 5 because health effects and occurrence data must be linked to specific individual contaminants in order to be evaluated." Id. at 37969. EPA also states that "[w]ithout available data regarding measured occurrence in water or relevant data provided by the nominators, the two evaluation teams agreed that they could not determine whether these chemicals were likely to present the greatest public health concern through drinking water exposure and therefore should not advance further in the CCL 5 process." Id.

EPA did not apply this standard to PFAS. EPA did not link any health effects or occurrence data to specific PFAS included in the listed group. The only occurrence data EPA identified related to PFAS was specific to PFOA and PFOS, which are explicitly not included in the listing. Where occurrence data was not available for substances other than PFAS, the substance was removed from the draft CCL. EPA states "Data search efforts did not yield occurrence data for 13 publicly nominated chemicals that

Comments Received on PFAS

were lacking occurrence data in the CCL 5 Chemical Universe. As a result, these chemicals were not evaluated for listing on the Draft CCL 5." Id. at 37960.

These inconsistencies in the screening and selection process for the CCL jeopardize the scientific integrity of the tool. If EPA is proposing a risk-based program, as it appears to be based on the description of the screening process, the decision to list materials would be supported by data on these materials' potential risks. If the program is not risk-based but instead based on a precautionary approach or external pressures, it is still vital that there be some framework through which EPA will decide which chemicals to list. If the approach is precautionary, the potential costs and benefits of a proposed listing must be explicit. No such information was provided for listing PFAS. EPA has not identified any basis for treating PFAS differently other than there are many of them and therefore it is challenging to evaluate them.

PFAS should not be evaluated differently than other substances. Using different standards, applying screening criteria inconsistently, or requiring different or no technical support undermines the integrity of the process and is inconsistent with past practice. It also undermines the future precedential value of the process. EPA should identify a methodology for screening substances for inclusion on the CCL and apply it to all substances consistently.

III. The Proposed Rule Lacks Technical Support for Listing PFAS as a Group

EPA has included almost no technical support for its decision to include PFAS on the draft CCL 5. [FN5: One of the technical documents EPA lists as a document relied upon is not accessible on the www.regulations.gov docket site (Identification of Novel Perfluoroalkyl Ether Carboxylic Acids (PFECAs) and Sulfonic Acids (PFESAs) in Natural Waters Using Accurate Mass Time-of-Flight Mass Spectrometry (TOFMS).] There is no CIS for PFAS as a group, or any specific PFAS, included in the technical support information. EPA cites neither occurrence nor health effects information for PFAS in the proposal or the technical support documents. Moreover, EPA did not cite any qualifying health assessments for PFAS and there are no results for PFAS included in the Rapid Systemic Literature Review Results ("RSR"). To the extent it relies on technical support for its PFAS listing, EPA either uses surrogate indicators it ranked as least desirable in place of actual data for every category that it considered in the screening process or relies on information related to substances it specifically excluded from listing (PFOA and PFOS).

Although EPA explained that it did not conduct a health effects RSR for chemicals currently prioritized by other agency processes (e.g., PFAS), it also did not include reasonably sufficient information in the Federal Register notice or supporting documents to indicate the basis upon which it decided to list PFAS as a chemical group. Combining multiple PFAS as a sum for risk assessment and/or assuming equal potency for individual PFAS are not scientifically sound and there is no support for such a practice.

a. There is No Technical Support for Listing PFAS as a Group

Even among just a handful of the thousands of PFAS captured by EPA's proposed definition, these materials' distinct and widely varying properties mean there is no scientific basis for evaluating PFAS as a monolith. Scialli et al. (2007) and Peters and Gonzalez (2011) independently evaluated the scientific feasibility of combining perfluoroalkyl exposures for risk assessment based on the critical concept of Toxic Equivalency Factors (TEFs), which was developed for dioxin-like compounds. Scialli et al. (2007) reviewed similar same-species studies performed with different perfluoroalkyls and they found large discordance in endpoints measured for PFOS, PFOA, PFBS, and PFDA. Peters and Gonzalez

Comments Received on PFAS

(2011) also concluded that perfluoroalkyl exposure should not be combined for risk assessment purposes based on the following observations:

- lack of conclusive evidence demonstrating that a single receptor is required to mediate the toxicities of perfluoroalkyl chemicals;
- the potential influence of species differences in the response to PPARα ligands that would significantly limit this approach;
- inconsistent toxicities observed with different perfluoroalkyl chemicals; and
- a limited toxicological database for a number of perfluoroalkyls chemicals (e.g., perfluorinated sulfonamide polymers and perfluorinated sulfonamide-based phosphate fluorosurfactants).

Rigorous, reliable scientific evidence indicates there is not a sound basis to treat thousands of PFAS as a group. 3M welcomes the opportunity to continue to engage with EPA in rigorous, science-based dialogue to determine how these materials potentially could be grouped in a scientifically sound way. However, there is not currently any technical support in the Proposed Rule or supporting documents that justify listing PFAS as a single group.

b. Assuming Equal Properties Among Individual PFAS is Not Scientifically

Supported

Available data demonstrate that there is a large spectrum of differences in the biological responses observed in laboratory animals under toxicological study conditions for most perfluoroalkyls evaluated. For example, the European Food Safety Authority (EFSA) recently applied equal toxicity potencies to a group of selected PFAS (PFOA, PFOS, PFHxS, and PFNA). The actual data, however, are inconsistent with that application. Qualitatively, it is true that these four perfluoroalkyls do have longer serum elimination half-lives in humans, however, there are distinct quantitative differences for the reported half-lives as well as in the categorical effects with animal data. Specific effects, such as dose response outcomes included health conditions and mortality in toxicological animal studies, are observed at largely different quantitative levels depending on the compounds and doses. The proposed definition of PFAS includes gaseous, liquid, and solid compounds with variation in properties such as volatility and water solubility. Therefore, it is scientifically inappropriate to assume they all have the same effects.

IV. EPA Should Not Include Substances on the CCL 5 for Which There is Currently

No EPA Validated Testing Methodology

At this time, there is no testing methodology approved by EPA for the vast majority of substances included in EPA's listing definition for PFAS. EPA Methods 537.1 and 533, both for drinking water, are validated methods for 29 PFAS total. During the public comment period on the Proposed Rule, EPA published draft Method 1633, "a single-laboratory validated method to test for 40 PFAS compounds in wastewater, surface water, groundwater, soil, biosolids, landfill leachate, and fish tissue." [FN6: See https://www.epa.gov/cwa-methods/cwa-analytical-methods-and-polyfluorinated-alkyl-substances-pfas] Even the most current and innovative testing capabilities cannot test for more than approximately 70 PFAS. Given the variety among PFAS substances, any evaluation of their occurrence or potential health or environmental effects will vary depending on the specific PFAS under consideration. It is also not scientifically appropriate to rely on total organic fluorine levels in

Comments Received on PFAS

environmental sampling as a proxy for PFAS that do not currently have an approved testing methodology. EPA has appropriately recognized elsewhere that total organic fluorine "may not be sensitive or specific enough to support decision making…." 86 Fed. Reg. at 13855. As EPA has noted, total organic fluorine is broader even than PFAS and could capture other fluorine-containing compounds.

There is no practical reason to list substances on the CCL 5 that cannot be tested. EPA should focus on establishing testing methodology to understand occurrence, which can and should inform future regulatory decisions. In the meantime, it should only list substances on the CCL 5 for which it has validated testing methods. If EPA nonetheless proceeds with including substances on the CCL 5 that have no validated test methods, 3M suggests the use of performance-based criteria and that method validations be done for each PFAS in each environmental media (drinking water, wastewater, air, soil, etc.).

3M appreciates the opportunity to share our input on this important topic with EPA as we seek to work collaboratively to achieve our shared goal of regulations grounded in rigorous, reliable science. The proposed CCL 5 provides an opportunity for this important exchange of ideas, and we welcome the opportunity to engage further in this discussion.

Individual Response: Please see Discussion on PFAS, General Comments, Other Drinking Water Programs, and Other EPA Programs. EPA acknowledges that PFAS, along with other groups of contaminants listed on CCL 5, are priority contaminants and therefore were treated differently than the individually listed contaminants. In the PFAS Strategic Roadmap, EPA also acknowledges its need to evaluate a large number of PFAS for potential human health and ecological effects and that most PFAS have limited or no toxicity data. To address this data gap, EPA is developing a national PFAS testing strategy to deepen understanding of the impacts of categories of PFAS, including potential hazards to human health and the environment. EPA will use the testing strategy to identify important gaps in existing data and to select representative chemical(s) within identified categories as priorities for additional studies. For more information please refer to EPA's National PFAS Testing Strategy (USEPA, 2021a).

In response the commenters statement that EPA "should expand the definition of PFAS to include the full array of fluorinated substances, including all HFCs, HFOs, and HCFOs." At this time, EPA is not expanding the definition to include these substances. However, EPA is proposing its first rule under the American Innovation and Manufacturing (AIM) Act of 2020 to phase down the production and consumption of hydrofluorocarbons (HFCs), highly potent greenhouse gases commonly used in refrigerators, air conditioners, and many other applications. The AIM Act, which was included in the Consolidated Appropriations Act, 2021, provides EPA new authorities to address HFCs in three main areas: phasing down the production and consumption of listed HFCs, maximizing reclamation and minimizing releases (via air, water, or soil) of these HFCs and their substitutes in equipment (e.g., refrigerators and air conditioners), and facilitating the transition to next-generation technologies by restricting the use of HFCs in particular sectors or subsectors.

Comment Excerpt from Commenter 79
September 17, 2021

Submitted via www.regulations.gov

Comments Received on PFAS

Ms. Radhika Fox, Assistant Administrator

Office of Water, USEPA Headquarters William Jefferson Clinton Building 1200 Pennsylvania Avenue, N. W.

Mail Code: 4101M

Washington, DC 20460

Re: EPA's Draft 5th Drinking Water Contaminant Candidate List [EPA–HQ–OW–2018– 0594; FRL–7251–01–OW]

Dear Assistant Administrator Fox:

I appreciate the opportunity to comment on the EPA's Draft Fifth Drinking Water Contaminant Candidate List (CCL5). I support the EPA's stated intention to investigate and, if supported by good data and sound science, regulate the chemical class referred to as per- and polyfluoroalkyl substances (PFAS) in drinking water. However, as the EPA considers such regulation, it must keep in mind the ubiquity of PFAS chemicals in the environment and the inability to detect and quantify 99+% of the class's constituents in drinking water, coupled with the diversity of the class, the uncertainty as to their human toxicity, and the lack of data on the ability to remove all class members using existing technology.

PFAS have followed that unfortunate trajectory of being discovered as having unique, beneficial properties decades ago; used widely for numerous purposes without adequate consideration of potential harmful effects; discovered that their use is accompanied by detrimental environmental and health impacts; and attempting to address the problems long after the materials have been recklessly released into the environment. Polychlorobiphenyls (PCBs) are the classic example of such a group, yet PFAS has the potential for greater damage to public health and the environment. PFAS have no business being in the environment or in drinking water, but it must be recognized that neither drinking water consumers nor drinking water utilities put them there. Although I support efforts to keep these chemicals out of drinking water, addressing the chemicals at first instance by seeking to remove them from drinking water foists all costs on the innocent instead of those responsible for putting them there and fails to stop these contaminants at their source. This is not merely an environmental and public health issue, but also an environmental justice issue that must be addressed.

I also note that the description used to define membership in PFAS (using classic Markush language) is potentially ambiguous. As the notice states,

For the purposes of this document, the structural definition of PFAS includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)C(F)(R')R". Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R") can be hydrogen.

The potential ambiguity occurs when a given compound contains one portion that satisfies this structural requirement but also contains another portion that does not. For example, the compound commonly referred to as ADONA (Dodecafluoro-3H-4,8-dioxanonanoate, CAS Nos. 919005-14-4 or

Comments Received on PFAS

958445-44-8) has the chemical formula CF3OCF2CF2CF2OCHFCF2COOH (in protonated form). The portion of the formula highlighted here in green would satisfy the structural definition of PFAS provided by the EPA, but the portion in red would not. It would be helpful to clarify that the presence of a portion not meeting the structural requirement would exclude the compound from the PFAS class if one or more other portions do so.

Additionally, I believe that the definition being used is inadequate because it would omit several compounds from the PFAS class that nevertheless should be considered along with the members of that class. For example, this structural definition would not encompass the following compounds:

Acronym	Compound	Molecular Formula	CAS No.
PFMOAA	Perfluoro-2-methoxyacetic acid	CF3OCF2COOH	674-13-5
PMPA	Perfluoro-2-methoxypropanoic acid	CF3OCF(CF3)COOH	13140-29-9
PEPA	Perfluoro-2-ethoxypropanoic acid	C2F5OCF(CF3)COOH	267239-61-2
PFO2HxA	Perfluoro (3,5-dioxahexanoic) acid	CF3(OCF2)2COOH	39492-88-1
PFO3OA	Perfluoro(3,5,7-trioxaoctanoic) acid	CF3(OCF2)3COOH	39492-89-2
PFO4DA	Perfluoro(3,5,7,9-tetraoxadecanoic) acid	CF3(OCF2)4COOH	39492-90-5
PFO5DoDA	Perfluoro(3,5,7,9,11- pentaoxadodecanoic) acid	CF3(OCF2)5COOH	39492-91-6

As these compounds have been previously detected in the Cape Fear River in North Carolina, they should not escape the same regulatory fate as any other PFAS compound. Putative Markush descriptions to capture this group and other related compounds could be R-CF2-O-CF2-R' and RCF2-O-CHF-R', wherein both the CF2 and CHF moieties are saturated carbons and none of the R groups (R or R') can be hydrogen.

A more significant concern is the near impossibility of actually detecting and quantifying the occurrence of 99+% of the members of the putative PFAS class in raw and finished drinking water. The problem with not being able to detect virtually all members of the PFAS group is that no one would be able to say with any certainty that their drinking water contained an acceptable amount of PFAS unless it had testing data to back up such a claim. The problem can be explained using the notable example of the compound known as 6:2 fluorotelomer alcohol (6:2 FTOH, CAS # 64742-7). In 2020, the U.S. Food and Drug Administration (FDA) published findings from a postmarket scientific review and analysis of data from rodent studies on 6:2 FTOH, which raised questions about the potential human health risks from dietary exposure resulting from exposure to food-packaging material that contained 6:2 FTOH, which the FDA had authorized. Shortly thereafter, the FDA announced that it had convinced several manufacturers to voluntarily phase out some food-packaging materials that are referred to as side-chain polymers, where the side chains were 6:2 FTOH and had a tendency to escape the polymer and migrate to the food. See https://www.fda.gov/food/cfsan-constituent-updates/fda-announces-voluntary-phase-out-industry-certain-pfas-used-food-packaging. However, those materials were only one category of food-packaging materials that may contain 6:2 FTOH. Two

Comments Received on PFAS

other categories of food-packaging materials, polyfluoroalkyl phosphate monoesters (monoPAPs) and polyfluoroalkyl phosphate diesters (diPAPs), are widely used food contact materials that imbue water and oil repellency for surfaces to which they have been applied. See Birgit Geueke, Food Packaging Forum, July 2016, https://www.foodpackagingforum.org/fpf-2016/wp-content/uploads/2016/07/FPF_Dossier10_PFASs.pdf. Both monoPAPs and diPAPs are known to have been manufactured using 6:2 FTOH and would serve as potential sources of 6:2 FTOH in a similar manner as the side-chain polymers that FDA convinced some manufacturers to phase out. This background is provided because even though it is undisputed that 6:2 FTOH poses potential health risks to humans, there is no current EPA-approved analytical method available to test drinking water for 6:2 FTOH. In fact, there are no such approved analytical methods to test drinking water for monoPAPs, diPAPs, or even the 6:2 FTOH-containing side-chain polymers that FDA was quick to push to be phased out. Part of the reason that 6:2 FTOH is not included in drinking water methods is that the class of fluorotelomer alcohols are notoriously difficult to detect using the analytical technology and equipment employed in EPA-approved methods. See https://well-labs.com/docs/pfc_reference_handling_guide.pdf, page 14. Yet no such difficulty exists for detecting 6:2 FTOH-containing diPAPs. See Timothy L. Coggan et. al, "A single analytical method for the determination of 53 legacy and emerging per- and polyfluoroalkyl substances (PFAS) in aqueous matrices," Analytical and Bioanalytical Chemistry (2019) 411:3507–3520, https://doi.org/10.1007/s00216-019-01829-8.

Even if these compounds existed in drinking water, it is unclear how effective existing treatment technologies would be to remove them. To be sure, monoPAPs and diPAPs would likely be removed by granular activated carbon (GAC) and/or anionic ion exchange resins. But 6:2 FTOH will remain nonionic in drinking water, whether introduced on its own or shed from a captured polymer or PAP, and no one knows for how long GAC (or less likely ion exchange resins) will be effective in removing it from drinking water, assuming any efficacy at all.

I've described one single PFAS compound, well known and under current study, as well as two subcategories of PFAS that have been used for years in food packaging with the FDA's blessing, that drinking water suppliers would have no practical ability to detect in their water even if they wanted to. And there are thousands of other compounds in the PFAS family, none of which have a chance of being detected. This brings me to my greatest concern of all: any attempt to regulate PFAS as a uniform, monolithic group will inevitably lead to the creation of a false sense of security in the public, because no water provider can honestly say that PFAS in its drinking water does not exceed a given value when 99+% of PFAS compounds cannot be detected or quantified using existing analytical methods.

I wish dealing with PFAS compounds were as simple as EPA's proposal for treating them as a class sounds. Such an approach made sense for PCBs, which are highly similar in terms of structure and properties. But that it is not the case for PFAS compounds, which are extremely diverse in terms of structure, properties, occurrence, and risk to public health. PFAS compounds do pose risks to public health, and they must be studied and dealt with. But attempting to take shortcuts without putting in the time and effort to properly assess them is not the answer.

Comments Received on PFAS

For sure, some subgroups of PFAS can and should be assessed together, but even that has limits. For example, EPA developed chronic reference doses (RfDs) for perfluorooctanesulfonic acid (PFOS) and perfluorobutanesulfonic acid (PFBS), both of which are within the perfluoroalkanesulfonic acid (PFSA) subgroup. However, PFBS' RfD was 150% higher than PFOS' RfD, which reflected significant lower chronic toxicity. If EPA can extensively study two different compounds that are squarely within the PFAS family—and the PFSA subgroup—and decide that one requires regulation in drinking water and the other does not, how could it ever be reasonable to attempt to assess the entire PFAS class in gross? If the EPA decides to regulate all PFAS (except PFOA and PFOS, which it has excluded from consideration here) as a class, does that mean that the EPA erred in concluding that regulating PFBS was unnecessary?

Perhaps it may turn out that many or even most PFAS require regulation in drinking water. The EPA has already concluded that such regulation is unnecessary for PFBS, and others will not require regulation. But the EPA, Congress, and the citizens of the United States need to make this a priority and spend the time and money needed to reach the reasonable, defensible, and just conclusion for PFAS compounds. It should and must be done, but it must be done with hard work, not by taking the shortcut of lumping all PFAS compounds together because it is simpler or easier.

Thank you for considering my comments.

Very truly yours,

Paul T. Nyffeler, Ph.D.

Individual Response: Please see Discussion on PFAS, General Comments, and Other Drinking Water Programs. EPA agrees with the commenters statement that PFAS are a diverse group of chemicals. As EPA moves to the following stages of the SDWA framework, it will follow a robust process and will provide proper assessment to individual PFAS and PFAS as a group.

Comment Excerpt from Commenter 80
Terrence Thrweatt Jr.

University of Baltimore

September 17, 2021

Per- and Polyfluoroalkyl (PFAs) are Harmful and Should be Banned

I am writing this comment in support of adding the per- and polyfluoroalkyl (PFAs) to the Candidate Contaminant List (CCL) for Public Water Suppliers (PWS) to monitor and report any level of contamination, as well as to comply with any initiated regulations at the local or state level. PFAs are toxic by-products which are commonly used chemicals in the production process of non-stick materials. They have been used in non-stick cookware (i.e. pots and pans), food packaging items, and beauty and cosmetic items . The side effects of PFAS include low infant birth weights, adverse effects on the immune system, cancer (for PFOA), and thyroid hormone disruption (for PFOS). Unfortunately, PFAs remain on a product through its full production and even into the disposal. Today, due to its unescapable use in manufacturing and industrial supply chains, nearly every American can find

Comments Received on PFAS

evidence of PFAs in their bloodstream . Despite PFAs imposing a public health risk, little is being done by our law-making bodies to curb the consequences.

The CCL is a list of contaminants which currently can be found in rural, urban, and suburban water supply systems. The listed substances are known to be pervasive enough that at least trace amounts are expected to be found in even the most properly maintained public municipalities. Unmaintained or outdated water systems are at an equally, or increased, pronounced risk of testing positive for the impurities. In fact, a study of 300 military bases demonstrated that PFAs were prominent in the drinking water of the majority of the studied sites. This is unacceptable. Due to their level of toxicity and producible harm posed against humanity, I believe that PFAs have earned their place on the CCL list.

Currently, only one state, Maine, has banned products containing PFAS . The people of Maine took this necessary step to protect their citizens from PFAS-related harms. We must make this a national priority. There is already legislation before Congress to address this deadly compound. The EPA can take the first step. By acting within its power, it can advance PFAs on the CCL. This will lead to regulation of PFAs in drinking water. It is my profound hope that this product will be more strictly regulated to prevent further harm.

Individual Response: Please see Discussion on PFAS, General Comments, Other Drinking Water Programs, and Other EPA Programs.

Comment Excerpt from Commenter 81
Gregory M. Bowser, President & CEO

COMMENTS OF THE LOUISIANA CHEMICAL ASSOCIATION on EPA Draft Drinking Water Contaminant Candidate List—5 86 Federal Register 37948 July 19, 2021 (Proposed Rule) Docket ID Number EPA–HQ–OW-2018-0594

INTRODUCTION

The Louisiana Chemical Association (“LCA”) appreciates the opportunity to comment on the U.S. Environmental Protection Agency’s (“EPA”) Notice of Drinking Water Contaminant Candidate List 5 (“CCL 5”) Draft under the Safe Drinking Water Act (SDWA), Docket ID No. EPA–HQ–OW-2018-0594, published in the Federal Register on July 29, 2021, at 86 Federal Register 37948.

LCA is a nonprofit Louisiana corporation, composed of sixty-three (63) members with over one hundred (100) chemical manufacturing plant sites in Louisiana. LCA was formed in 1959 to promote a positive business climate for chemical manufacturing that ensures long-term economic growth for its member companies. LCA members are committed to excellence in safety, health, security and environmental performance, and to protecting our employees and surrounding communities.

LCA member companies have managed or have used per- and polyfluoroalkyl substances (“PFAS”) in a wide range of applications. PFAS are used in almost all industries and are found in many consumer products. LCA members are therefore directly affected by this Draft CCL 5, as it relates to the inclusion of PFAS as a chemical group. LCA supports the development of drinking water standards that protect public health and reflect the best available scientific evidence. However, LCA opposes

Comments Received on PFAS

regulating PFAS as a class and submits these comments on behalf of its affected members.

COMMENTS

1. Background

Section 1412(b)(1)(B)(i) of the Safe Drinking Water Act ("SDWA"), as amended in 1996, requires the EPA to publish every five years a list of drinking water contaminants which are not subject to any proposed or promulgated National Primary Drinking Water Regulations ("NPDWR"), are known or anticipated to occur in public water systems ("PWS"), and may require regulation under the SDWA. This list is known as the Contaminant Candidate List, or CCL.

The SDWA directs the EPA to consider health effects and occurrence information for unregulated contaminants to identify those that present the greatest public health concern related to exposure from drinking water. EPA uses this list of unregulated contaminants to help identify priority contaminants for regulatory decision making and to prioritize research and data collection efforts.

On July 19, 2021, EPA published the fifth candidate list. The Draft CCL 5 includes 66 chemicals, three chemical groups (PFAS, cyanotoxins, and disinfection byproducts) and 12 microbial contaminants. EPA requested comments on the Draft CCL 5 and on improvements implemented in the CCL 5 process for consideration in developing future CCLs. With these comments, LCA focuses on the inclusion of PFAS as a chemical group.

2. The diverse chemistries of PFAS chemicals make including them in the CCL 5 and regulating them as a group inappropriate.

According to the Draft CCL 5, "[o]ver 4,000 PFAS have been manufactured and used globally since the 1940s, which would make listing PFAS individually on the Draft CCL 5 difficult and challenging." [FN1: Draft CC 5, pg. 37962 (citations omitted).] Accordingly, EPA is proposing to list PFAS as a group inclusive of any PFAS, except the two that are already in the regulatory process – perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS).

PFAS as a class represent differing fundamental physical, chemical, and biological properties. According to the EPA, "approximately 600 PFAS are manufactured (including imported) and/or used in the United States." [FN2: Addition of Certain Per- and Polyfluoroalkyl Substances; Community Right-to-Know Toxic Chemical Release Reporting, 84 FR 66369 (Dec. 4, 2019).] Among these 600 are substances in the solid (e.g., fluoropolymers), liquid (e.g., fluorotelomer alcohols), and gaseous (e.g., hydrofluorocarbon refrigerants) forms. [FN3: American Chemistry Council, "PFAS Grouping: An Emerging Scientific Consensus" (collecting sources) (available at: https://www.americanchemistry.com/chemistry-in-america/chemistries/fluorotechnology-per-andpolyfluoroalkyl-substances-pfas/resources/pfas-grouping-an-emerging-scientific-consensus) (last visited Sept. 15, 2021).] These distinct physical and chemical properties demonstrate how varied PFAS are and why a simple grouping approach to risk is inadequate.

EPA's reasoning that the sheer number of PFAS makes classification on a chemical or sub-class basis impossible is a false premise. Rather, because the number of chemicals classified as PFAS is so great, and the chemistries vary so vastly, it is scientifically accurate and appropriate to not regulate them as

Comments Received on PFAS

a class. EPA has already proven the Agency is capable of analyzing PFAS on a chemical basis through its regulation of PFOA and PFOS. As such, EPA should not include PFAS as a class in the final CCL 5.

3. The inclusion of PFAS as a class without performing full screening or classification demonstrates the inadequacy of regulating PFAS as a single class.

EPA describes its decision process for including chemicals briefly in the Draft CCL 5 Notice and more fully in the Technical Support Document. [FN4: See Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) – Chemical Contaminants.] As noted in the Technical Support Document, EPA performs three steps: (1) assessing and identifying data sources; (2) screening; and (3) classification. Within each of those steps, EPA performs multiple layers of analysis. For example, during the screening step, EPA develops a scoring rubric and selects the top 250 chemicals before considering publicly nominated chemicals and chemicals that should be excluded. For CCL 5, this process identified 275 chemicals. [FN5: Notably, 13 individual PFAS were included in the identified 275 chemicals. But instead of analyzing these 13, EPA excluded them and opted for including PFAS as a class. Id. at pg. 42 of 101 and Appendix D.] The selected chemicals are then further classified using supplemental data, calculated data elements (such as health reference levels, screening levels, final hazard quotients, and attribute scores), and contaminant information sheets. Because EPA included PFAS as a collective group in response to public nominations, none of the PFAS chemicals were fully analyzed under EPA's CCL development framework for chemicals.

None of the individual PFAS chemicals were fully analyzed through the screening system or subject to the classification process. Rather, EPA included PFAS as a collective group based both on public nominations and because it would have been "difficult and challenging." Notably, EPA did not state that it would have been unduly burdensome or against scientific data to have analyzed one or more PFAS chemicals or groups of chemicals. Rather, EPA noted that:

Including the broad group of PFAS on the Draft CCL 5 demonstrates the agency's commitment to prioritizing and building a strong foundation of science on PFAS while working to harmonize multiple authorities to address the impacts of PFAS on public health and the environment.

It was inappropriate for EPA to base inclusion of the entire class of PFAS on public nominations rather than on the scientific method discussed above. Although SWDA section 1412 does not proscribe a specific method for including a chemical on the CCL, EPA should follow its own method in determining whether individual PFAS "are known or anticipated to occur in public water systems, and which may require regulation" such that one or more should be included on the CCL 5. [FN6: 42 U.S.C.A. § 300g-1.]

4. EPA should analyze inclusion of a PFAS on a chemical basis or at least on a smaller subclass basis.

As noted above, the varying chemistries of PFAS makes it inappropriate to cast the entire universe of chemicals a single group. EPA should perform the same three step analysis on relevant PFAS chemicals to determine potential inclusion in the CCL 5. To reduce the regulatory burden, EPA may find it appropriate to group of some substances within the broad PFAS class based on similar physical, chemical, and biological properties. LCA would support this more nuanced approach instead of

Comments Received on PFAS

inappropriately grouping all PFAS as a class. For example, see Buck, R.C., Korzeniowski, S.H., Laganis, E. and Adamsky, F. (2021), Identification and classification of commercially relevant per- and poly-fluoroalkyl substances (PFAS). Integr Environ Assess Manag, 17: 1045-1055 (available at; https://setac.onlinelibrary.wiley.com/doi/10.1002/ieam.4450) (last visited Sept. 15, 2021). LCA does not comment on the specific way in which the study sub-divided PFAS chemicals or whether all PFAS could be subjected to subdivision. In fact, the grouping of substances under a single standard is justified only when the substances are believed to cause adverse health effects by the same mechanism. Rather, the LCA suggests that EPA should have considered this type of approach instead of inappropriately grouping all PFAS as a class.

LCA appreciates the opportunity to submit comments on this rulemaking.

Tokesha Collins Wright

LCA Vice President of Environmental

Affairs and General Counsel

Individual Response: Please see Discussion on PFAS, General Comments, and Other Drinking Water Programs.

Comment Excerpt from Commenter 83
Submitted via Regulations.gov

September 17, 2021

Administrator Michael Regan

U.S. Environmental Protection Agency 1200 Pennsylvania Ave, N.W.

Washington, DC 20460-0001

Re: Docket Nos. EPA-HQ-OPPT-2020-0549, EPA-HQ-OW-2018-0594; Toxic Substances Control Act Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, and Drinking Water

Contaminant Candidate List 5-Draft

Dear Administrator Regan,

The undersigned are scientists with expertise in per- and polyfluoroalkyl substances ("PFAS") chemistry and toxicity. We are dedicated to better understanding the use and impacts of PFAS and deriving solutions to reduce serious adverse human and environmental health outcomes as a result of PFAS exposure.

We submit these comments in response to two recent actions proposed by the United States Environmental Protection Agency ("EPA" or the "Agency"): (1) a proposed rule under section 8(a)(7) of the Toxic Substances Control Act ("TSCA"), [FN1: TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 86 Fed. Reg. 33,926 (proposed June 28, 2021) (to be codified at 40 C.F.R. pt. 705).] which would require reporting and recordkeeping for

Comments Received on PFAS

PFAS chemicals manufactured in (including imported into) the United States since 2011, and (2) a listing of PFAS on the Safe Drinking Water Act ("SDWA") Draft Contaminant Candidate List 5 ("Draft CCL 5"), which is the first step in the screening and evaluation of chemicals that may warrant future regulation under the SDWA. [FN2: Drinking Water Contaminant Candidate List 5 – Draft, 86 Fed. Reg. 37,948 (proposed July 19, 2021) (to be codified at 40 C.F.R. pt. 141).] We support EPA's efforts to acquire detailed information on PFAS and its initial steps toward greater regulation of PFAS in drinking water.

One of the strengths of both proposals is that they apply a class-based approach to addressing PFAS. However, in both proposed agency actions, EPA employs a "working definition" [FN3: TSCA Section 8(a) Reporting, 86 Fed Reg. at 33,929; Drinking Water Contaminant Candidate List 5, 86 Fed. Reg. at 37,962.] of PFAS that is inconsistent with the commonly accepted definition recently adopted by the Organisation for Economic Co-operation and Development ("OECD") [FN4: OECD. (2021). Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance. https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-per-andpolyfluoroalkyl-substances.pdf.] and used in most U.S. legislation. This overly narrow definition would exclude many PFAS of known concern, undercutting the benefits of the Agency's actions. [FN5: Working definition from both TSCA and SDWA proposed agency actions: "[T]he structural definition of PFAS includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R''. Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R'') can be hydrogen." TSCA Section 8(a) Reporting, 86 Fed Reg. at 33,929; Drinking Water Contaminant Candidate List 5, 86 Fed. Reg. at 37,962.] For the reasons set forth below, we urge EPA to instead use the PFAS definition recently adopted by the OECD ("OECD definition"), which is scientifically sound and consistent with definitions that have been included in federal and state laws regulating PFAS.

I. EPA's Definition of PFAS in the Proposed TSCA Section 8(a)(7) Rule and SDWA Draft CCL 5 Does Not Include All PFAS.

PFAS as a class pose dangers to human and environmental health. Due to the presence of the highly stable, fully fluorinated carbon moieties, PFAS are either extremely resistant to environmental degradation—or transform into other highly persistent PFAS. Studies have shown that some PFAS take thousands of years to fully degrade. Their highly persistent nature further enables PFAS to accumulate in the environment, including in water, sediment, soil, and plants. [FN6: Kwiatkowski, C. F., Andrews, D. Q., Birnbaum, L. S., Bruton, T. A., DeWitt, J. C., Knappe, D. R. U., Maffini, M. V., Miller, M. F., Pelch, K. E., Reade, A. Soehl, A., Trier, X., Venier, M., Wagner, C. C., Wang, Z., & Blum, A. (2020). Scientific Basis for Managing PFAS as a Chemical Class. Environmental Science & Technology Letters, 7(8), 523–543. https://doi.org/10.1021/acs.estlett.0c00255.] Multiple lines of scientific evidence suggest that many PFAS can contribute to a wide range of adverse health outcomes, including cancer, endocrine disruption, reproductive harm, and immunosuppression. [FN7: Pelch, K. E., Reade, A., Kwiatkowski, C., Schultz, K., Varshavsky, J., Cavalier, H., MercedNieves, F., & Wolffe, T. (2021, June 7). PFAS Health Database: A Systematic Evidence Map. OSF. Retrieved September 15, 2021, from https://osf.io/f9upx/; Kwiatkowski et al., supra note 6.]

Due to these shared characteristics, many of us co-authored a scientific review of the studied human

Comments Received on PFAS

and environmental health harms posed by PFAS in which we recommend wide adoption of a "class-based approach to managing the human and environmental risks associated with all PFAS, including polymers." [FN8: Kwiatkowski et al., supra note 6, at 537.] When regulatory agencies use a class-based approach to regulate and/or gather data on PFAS, they should use a consistent and comprehensive definition of PFAS to ensure that they gather information on all PFAS and avoid missing key data on unknown or newer PFAS, as well as PFAS breakdown- or by-products. EPA's PFAS definition used in both the TSCA section 8(a)(7) proposed rule and the proposed SDWA Draft CCL 5 listing, copied below, is scientifically unsupported, does not include all PFAS, and denies the Agency critical information about PFAS:

[T]he structural definition of PFAS includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R''. Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R'') can be hydrogen. [FN9: TSCA Section 8(a) Reporting, 86 Fed Reg. at 33,929; Drinking Water Contaminant Candidate List 5, 86 Fed. Reg. at 37,962.]

EPA did not identify any scientific support for this definition in the TSCA section 8(a)(7) proposed rule, and the only support cited in the proposed SDWA Draft CCL 5 listing was a cite back to the TSCA section 8(a)(7) proposed rule.

It is particularly concerning that EPA's definition excludes many high production volume PFAS due to its unduly narrow requirement for the presence of at least two adjacent fluorinated carbons. For example, polyvinylidene fluoride ("PVDF"), a fluoropolymer that EPA has previously identified as a PFAS [FN10: EPA. (2018, June 1). EPA Activities on Per- and Polyfluoroalkyl Substances (PFAS) [PowerPoint slides]. https://yosemite.epa.gov/sab/sabproduct.nsf/708FDD305E55DC7E8525829C005F9EB4/$File/PFAS+Presentation+SAB.pdf; Phelps, L.P. (2020, August 4). Understanding Per- and Polyfluoroalkyl Substances (PFAS) in Air [PowerPoint slides]. EPA. https://cfpub.epa.gov/si/si_public_file_download.cfm?p_download_id=541095&Lab=CEMM] and that is widely used to line plastic shipping containers, [FN11: Currently, PVDF is not reportable under the Toxics Release Inventory under the Emergency Planning and Community Right-to-Know Act)] does not meet EPA's definition due to its alternating fully fluorinated carbon structure.

EPA's definition also excludes other high production volume fluorinated chemicals, such as many hydrofluorocarbon ("HFC") and hydrofluoroolefin ("HFO") refrigerant compounds, even though they have been categorized as PFAS by at least five European countries. [FN12: European Chemicals Agency. (n.d.). Registry of restriction intentions until outcome. Retrieved September 15,2021,fromhttps://echa.europa.eu/de/registry-of-restriction-intentions//dislist/details/0b0236e18663449b.] This concern is compounded by the fact that the exclusion of HFCs and HFOs from the definition makes it harder (if not impossible) to track their environmental breakdown products, particularly those that are PFAS themselves and also fall outside of the definition. For example, trifluoroacetic acid ("TFA") is a common HFC and HFO degradation product that poses risk to human and ecological receptors. [FN13: Several of us have co-authored a rebuttal to industry comments in which we highlighted health concerns posed by TFA, and we refer readers to that rebuttal for the details of these concerns: Kwiatkowski, C. F., Andrews, D. Q.,

Comments Received on PFAS

Birnbaum, L. S., Bruton, T. A., DeWitt, J. C., Knappe, D. R. U., Maffini, M. V., Miller, M. F., Pelch, K. E., Reade, A. Soehl, A., Trier, X., Venier, M., Wagner, C. C., Wang, Z., & Blum, A. (2021). Response to "Comment on Scientific Basis for Managing PFAS as a Chemical Class". Environmental Science & Technology Letters 8(2), 195– 197. https://doi.org/10.1021/acs.estlett.1c00049.] and has been widely recognized as a PFAS by the California Department of Toxic Substances Control and others, [FN14: Safer Consumer Products, Department of Toxic Substances Control, & California Environmental Protection Agency. (2019). Product – Chemical Profile for Treatments Containing Perfluoroalkyl and Polyfluoroalkyl Substances for Use on Converted Textiles or Leathers. https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/11/Product-Chemical-Profile-forTreatments-with-PFASs.pdf.] but it falls outside of EPA's definition because it only possesses one fully fluorinated carbon. Like other PFAS, TFA is highly persistent and mobile in the environment, and has also been linked to adverse health outcomes like skin and eye damage and harm to aquatic life. [FN15: Kwiatkowski et al., supra note 13.] Without accurate and robust reporting and recordkeeping of HFCs and HFOs, accurate environmental tracking of PFAS breakdown products like TFA is not possible.

In addition, EPA's overly narrow definition creates opportunity and incentive for the chemical industry to evade future regulatory requirements by manufacturing chemicals that possess the characteristics associated with PFAS but fall outside of EPA's narrow definition. DuPont, one of the leading manufacturers of PFAS in the United States, has been studying such compounds for nearly a decade. [FN16: Peng, S., & Hung, M. (2012). Fluorinated sulfonate surfactants. Journal of Fluorine Chemistry 133, 77–85. https://doi.org/10.1016/j.jfluchem.2011.10.007; Coope, T., Moloy, K., Yake, A., Petrov, V., Taylor, C., Hung, M., & Peng, S. (2014). Fluorinated sulfamido amphoteric surfactants. Journal of Fluorine Chemistry 161, 41–50. https://doi.org/10.1016/j.jfluchem.2014.01.022.]

The chemical industry has a long history of tweaking PFAS chemistry to evade regulation, including the recent manufacturing shift from long-chain PFAS (like PFOA [FN17: PFOA is an abbreviation for perfluorooctanoic acid.] and PFOS [FN18: PFOS is an abbreviation for perfluorooctanesulfonic acid.]) to shorter-chain "replacement" PFAS that were erroneously assumed to be less problematic and now pose widespread environmental contamination issues, threatening human and ecological health. [FN19: Sun, M., Arevalo, E., Strynar, M., Lindstrom, A., Richardson, M., Kearns, B., Pickett, A., Smith, C., & Knappe, D. R. U. (2016). Legacy and Emerging Perfluoroalkyl Substances Are Important Drinking Water Contaminants in the Cape Fear River Watershed Of North Carolina. Environmental Science & Technology Letters 3(12), 415–419. https://doi.org/10.1021/acs.estlett.6b00398; Zhang, X., Lohmann, R., Dassuncao, C., Hu, X. C., Weber, A. K., Vecitis, C. D., & Sunderland, E. M. (2016). Source Attribution of Poly- and Perfluoroalkyl Substances (PFASs) in Surface Waters from Rhode Island and the New York Metropolitan Area. Environmental Science & Technology Letters 3(9), 316–321. https://doi.org/10.1021/acs.estlett.6b00255.]

II. EPA Should Adopt the OECD Definition of PFAS and Use this Definition in All EPA Rulemakings.

Rather than use the PFAS definition in the proposed TSCA and SDWA actions, we recommend that EPA adopt the PFAS definition recently published by OECD, in which PFAS are defined as:

fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom

Comments Received on PFAS

(without any H/Cl/Br/I atom attached to it). [FN20: OECD, supra note 4, at 23.]

As stated in the report supporting this definition, "the intention of the revision of the PFAS definition is not to expand the PFAS universe, but to comprehensively reflect it. More concretely, the rationale behind the revision is to have a general PFAS definition that is coherent and consistent across compounds from the chemical structure point of view and is easily implementable for distinguishing between PFASs and non-PFASs, also by non-experts." [FN21: Id. at 23.] The OECD definition is scientifically sound and comprehensive; indeed, EPA scientists were members of the OECD group that prepared this definition. [FN22: Id. at 5.]

The OECD definition offers several benefits over the EPA definition, as detailed below.

First, the OECD definition covers all fluorinated chemicals that share common characteristics of PFAS, including persistence in the environment. Applying this definition across all EPA rulemakings in a uniform and consistent manner will help to avoid confusion about which chemicals are considered PFAS, and it will eliminate potential loopholes that incentivize the production of chemicals that fall outside of regulatory definitions but that still possess physicochemical characteristics of PFAS and behave like PFAS in the environment.

Second, using the broader OECD definition in the context of regulations that require submission of information will expand the data EPA receives about use of, and exposures to, PFAS in the United States. EPA's Comptox Database now indicates that there are over 9,000 PFAS, [FN23: EPA. (n.d.). PFAS Master List of PFAS Substances (Version 2). Retrieved September 15, 2021, from https://comptox.epa.gov/dashboard/chemical_lists/pfasmaster.] and only 175 of these are subject to recordkeeping and reporting requirements under the Toxics Release Inventory; [FN24: EPA. (2021). Chemicals Added to the Toxics Release Inventory Pursuant to Section 7321 of the National Defense Authorization Act. https://www.epa.gov/sites/default/files/202101/documents/tri_non-cbi_pfas_list_1_8_2021_final.pdf.] PVDF and HFCs are not among the 175 PFAS subject to these reporting requirements. Adopting OECD's PFAS definition in both the TSCA and SDWA proposed agency actions would enable information gathering for PFAS (like PVDF and HFCs) that currently fall through regulatory cracks and could pose widespread exposure risks to humans.

Third, several federal and state laws have already employed definitions of PFAS that are consistent with the OECD definition. For example, the National Defense Authorization Act for Fiscal Year 2020 defined PFAS as "perfluoroalkyl and polyfluoroalkyl substances that are manmade chemicals with at least one fully fluorinated carbon atom." [FN25: National Defense Authorization Act for Fiscal Year 2020, Pub. L. No. 116-92, § 332(c)(3), 133 Stat. 1198, 1314 (2019).] Since 2019, eight states have passed laws using similar, broad definitions of PFAS that are consistent with OECD's, including

California, [FN26: S. 1044, 2019 Leg., Reg. Sess. (Cal. 2020).] Colorado, [FN27: H.R. 19-1279, 72nd Gen. Assemb., Reg. Sess. (Colo. 2019).] Maine, [FN28: H.R. 1043, 129th Leg., Reg. Sess. (Me. 2019).] Vermont, [FN29: S. 20, 2021 Gen. Assemb., Reg. Sess. (Vt. 2021).] and Washington. [FN30: S. 5135, 66th Leg., Reg. Sess. (Wash. 2019).] It would create needless confusion if EPA's new regulatory actions adopted different definitions of PFAS than those already in place in federal and state laws.

Comments Received on PFAS

III. Conclusion

For the reasons set forth above, EPA should apply the OECD definition in all PFAS-related actions the Agency takes across programs, including in the proposed agency actions under TSCA and SDWA discussed here. The TSCA section 8(a)(7) proposed rule presents an important opportunity for EPA to obtain much-needed information about all PFAS in commerce in the United States over the last decade. And the SDWA Draft CCL 5 listing is a critical first step toward regulating PFAS in drinking water. For these actions to be as consequential as possible, we strongly urge EPA to consistently use a definition of PFAS that is comprehensive and scientifically sound, such as the OECD definition. If EPA finalizes the TSCA section 8(a)(7) rule with the narrower definition it proposed, it will deny the Agency—and the public—much needed information about PFAS, and it will create inconsistencies with federal and state laws that are already in place. Moreover, a narrower definition of PFAS in the SDWA Draft CCL 5 listing will limit EPA's ability to adopt primary drinking water regulations for PFAS in the future, undermining the Agency's promise of ensuring safe drinking water for all. Accordingly, we urge EPA to adopt the scientifically supported OECD definition of PFAS in all of its rulemakings pertaining to PFAS across programs.

If you have any questions about these comments, please contact Rashmi Joglekar, Earthjustice, at rjoglekar@earthjustice.org.

Respectfully submitted,

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Comments Received on PFAS

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Erika Schreder, MS

Science Director, Toxic Free Future

Individual Response: Please see Discussion on PFAS, General Comments, Other Drinking Water Programs, and Other EPA Programs. EPA is proposing its first rule under the American Innovation and Manufacturing (AIM) Act of 2020 to phase down the production and consumption of hydrofluorocarbons (HFCs), highly potent greenhouse gases commonly used in refrigerators, air conditioners, and many other applications. The AIM Act, which was included in the Consolidated Appropriations Act, 2021, provides EPA new authorities to address HFCs in three main areas: phasing down the production and consumption of listed HFCs, maximizing reclamation and minimizing releases (via air, water, or soil) of these HFCs and their substitutes in equipment (e.g., refrigerators and air conditioners), and facilitating the transition to next-generation technologies by restricting the use of HFCs in particular sectors or subsectors.

Comments Received on PFAS

Comment Excerpt from Commenter 84

September 17, 2021
Radhika Fox
Assistant Administrator
Office of Water
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW

Washington, DC 20460

Re: Docket: EPA-HQ-OW-2018-0594-0031

Dear Administrator Fox:

The Maryland Department of the Environment (MDE) appreciates the opportunity to comment on the Fifth Contaminant Candidate List (CCL5). MDE's comments mainly address the inclusion of the group of PFAS compounds under CCL5. MDE understands that EPA is proposing to add "PFAS" as a group under CCL5 and is using the following definition of PFAS:

"The structural definition of PFAS includes per- and polyfluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R". Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R") can be hydrogen."

This definition appears to be the same definition of PFAS that EPA included in its recently proposed TSCA Section 8 rule for PFAS. In that proposed rule, EPA explains that this definition covers "at least 1,364 chemical substances and mixtures".

Typically, the listing of compounds on a CCL (Contaminant Candidate List) occurs before a decision to add such compounds to an Unregulated Contaminant Monitoring Rule (UCMR). In this case, 29 of the PFAS compounds proposed for inclusion on the CCL5 seem to have already been added to the UCMR5 (in March of 2021), so MDE understands that the next decision for EPA with regard to these 29 compounds will be to decide (based on monitoring results) whether to proceed to develop drinking water regulatory standards for these 29 PFAS compounds. MDE urges EPA not to delay that decision for this subset of 29 PFAS compounds during the pendency of an EPA decision on whether to include the other approximately 1,335 PFAS compounds included in the CCL5 in the next UCMR (UCMR6). EPA should make clear in the final CCL5 action how the CCL5 listing that includes these 29 PFAS relates to the UCMR 5 sampling and the timing of decisions on whether to pursue MCLs for any of these 29 compounds. While further study is always helpful, it is important to ensure that including these 29 PFAS in CCL5 does not inadvertently introduce additional delays in EPA decisions on MCLs for these compounds.

Moreover, Maryland, similar to many states across the nation, has already initiated a substantial statewide effort to assess the occurrence of PFAS in state drinking water sources, and MDE urges EPA to consider using State data on the occurrence of PFAS compounds in public water systems to expedite decision making on SDWA standards for certain PFAS compounds. Specifically, MDE urges EPA to expedite decision making on the need for SDWA standards for the 18 PFAS compounds listed under EPA Method 537.1 and not wait for the results of the UCMR5 for these 18 compounds if sufficient state-generated data already exists to assess occurrence.

The effort between MDE and the Maryland Department of Health (MDH) to assess occurrence of 18 PFAS in public water systems in Maryland has involved the analysis by MDH of drinking water samples

Comments Received on PFAS

for the 18 PFAS listed under EPA Method 537.1. Attached is MDE's Final Report on the results of the first phase of this effort. In brief, this report indicates that of the 18 PFAS compounds looked for, that the following PFAS compounds may be the most commonly found in Maryland drinking water resources (list of compounds listed from most commonly found to least commonly found): PFOA, PFBS, PFHxA, PFHxS, PFOS, PFHpA, PFNA, PFDA (detected in only 1 sample), and 9Cl-PF3ONS (detected in only 1 sample). Additional sampling is being conducted across the State, and MDE estimates that its statewide assessment for PFAS in Community Water Systems will be completed in 2022--before the start of UCMR5. The State is also already collecting non-targeted data on water from hundreds of sites across Maryland. This new methodology should provide a large dataset to assess the 1300+ PFAS defined in CCL5, provided that standardized high-quality libraries become available for the analysis of this collected data.

With regard to EPA's proposal to list PFAS as a group of 1300+ PFAS compounds on CCL5, while MDE agrees that the grouping of certain PFAS may be beneficial, the Department encourages that groupings are scientifically based, but cautions that re-evaluating and/or broadening the R-(CF2)-C(F)(R')R'' definition may be warranted to ensure that it does not exclude any relevant species.

With variations in the extent of fluorination, chain length, and other chemical and physical properties, no two PFAS compounds are the same. The structural differences amongst the compounds may result in important differences in toxicity, fate and transport, safe disposal options, and more. Because of this, MDE encourages that if the EPA pursues a group-based regulation for PFAS compounds, the toxicity and science behind these regulations must be able to address the variability among compounds in order to construct scientifically defensible MCLGs and MCLs.

MDE also recommends that EPA facilitate or provide:

- Increased data sharing of PFAS occurrence data in drinking water sources among states, especially within the same region.
- Training on how states can access PFAS occurrence data from others.
- More tailored resources and/ or training for water utilities and state agencies on the treatment of PFAS containing source water. Training should specifically address removal options, cost of treatment, and the maintenance of treatment systems at certain concentrations of PFAS.
- Resources for water utilities impacted by historical releases of PFAS from industries, manufacturers, and other users of the compounds.

Sincerely,
D. Lee Currey
cc: Ben Grumbles, Secretary, Maryland Department of the Environment
Attachment

Individual Response: Please see Discussion on PFAS, Other Drinking Water Programs, and Other EPA Programs.

Comment Excerpt from Commenter 88
September 17, 2021

Environmental Protection Agency

Comments Received on PFAS

1200 Pennsylvania Avenue, NW Washington, DC 20460

Submitted electronically via regulations.gov

Re: The Safe Drinking Water Act ("SDWA") Draft Contaminant Candidate List 5

Silent Spring Institute is an independent research organization that investigates links between the environment and women's health, with a focus on breast cancer. It was founded as a collaboration of scientists, clinicians, and families affected by breast cancer, with a mission to conduct environmental health research that can inform disease prevention. We have studied PFAS in drinking water [FNi: Schaider, L. A., Rudel, R. A., Ackerman, J. M., Dunagan, S. C., & Brody, J. G. (2014). Pharmaceuticals, perfluorosurfactants, and other organic wastewater compounds in public drinking water wells in a shallow sand and gravel aquifer. Science of the Total Environment, 468, 384-393.] [FNii: Hu, X. C., Andrews, D. Q., Lindstrom, A. B., Bruton, T. A., Schaider, L. A., Grandjean, P., ... & Sunderland, E. M. (2016). Detection of poly-and perfluoroalkyl substances (PFASs) in US drinking water linked to industrial sites, military fire training areas, and wastewater treatment plants. Environmental science & technology letters, 3(10), 344-350.] consumer products, [FNiii: Schaider, L. A., Balan, S. A., Blum, A., Andrews, D. Q., Strynar, M. J., Dickinson, M. E., ... & Peaslee, G. F. (2017). Fluorinated compounds in US fast food packaging. Environmental science & technology letters, 4(3), 105-111.] [FNiv: Boronow, K. E., Brody, J. G., Schaider, L. A., Peaslee, G. F., Havas, L., & Cohn, B. A. (2019). Serum concentrations of PFASs and exposure-related behaviors in African American and non-Hispanic white women. Journal of exposure science & environmental epidemiology, 29(2), 206-217.] and blood [FNv: Trowbridge, J., Gerona, R. R., Lin, T., Rudel, R. A., Bessonneau, V., Buren, H., & MorelloFrosch, R. (2020).] Exposure to perfluoroalkyl substances in a cohort of women firefighters and office workers in San Francisco. Environmental science & technology, 54(6), 3363-3374. as this class of chemicals is associated with a wide range of adverse health outcomes including cancers, hormone disruption, thyroid disease, and reproductive, developmental, and immune toxicity. [FNvi: Agency for Toxic Substances & Disease Registry (ATSDR). (2019a). Toxicological Profile for Perfluoroalkyls. https://www.atsdr.cdc.gov/toxprofiles/tp.asp?id=1117&tid=237] Silent Spring currently has 3 federally funded research studies on PFAS, including 1) Massachusetts PFAS and Your Health Study, part of a larger study funded by CDC/ATSDR to study health effects of PFAS exposures from drinking water, 2) PFAS-REACH, which is assessing the relationship between PFAS and pediatric immunotoxicity, and 3) STEEP, led by the University of Rhode Island, which is investigating the environmental transport of PFAS and health effects related to exposure.

We appreciate the opportunity to provide comments on a listing of PFAS on the Safe Drinking Water Act ("SDWA") Draft Contaminant Candidate List 5. While we commend EPA for listing PFAS as a group in these initial steps toward increased regulation of PFAS in drinking water, the current structural definition of PFAS in the proposed rule [FN1: EPA's definition is the following: "[T]he structural definition of PFAS includes per- and poly-fluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R". Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R'') can be hydrogen."] is too narrow. Rather than this definition, EPA could include all the PFAS included in its Master List of PFAS, [FNvii: U.S. Environmental Protection Agency (EPA). (2021). PFAS Master List of PFAS Substances (Version 2).

Comments Received on PFAS

https://comptox.epa.gov/dashboard/chemical_lists/pfasmaster] a list which currently contains 9252 chemicals and continues to expand.

Moreover, EPA needs to increase its analytical capacity to regulate PFAS as a class. Current EPA methods 533, 537, and 537.1 support the analysis of only 29 PFAS chemicals in drinking water, a small subset of PFAS present in the environment, and do not include many precursor compounds. These precursors have the potential to transform into PFOS, PFOA, and other highly stable PFAS endpoints in the environment and in our bodies. Because many PFAS are detected outside of those included in EPA's methods, it makes sense for EPA to develop approved methods that measure total impact from PFAS. One analytical method that could complement existing EPA methods is the total oxidizable precursor assay, or TOP assay, which is a commercially available method for evaluating the presence of precursor compounds. Using the TOP Assay would provide a more complete evaluation of PFAS precursors in water. Another approach for measuring all PFAS emissions would be Total Organic Fluorine (TOF), which is a rapid screening tool to identify total PFAS presence. We also suggest EPA consider additional analytical methods as they become available. For instance, the European Commission announced in December 2019 that it would develop a method to measure total PFAS in water within 3 years and to set a limit for drinking water. [FNviii: European Parliament. Trilogue results of the revision of the Drinking Water Directive. https://sven-giegold.de/wp-content/uploads/2019/12/Media-briefing-Drinking-water-19.12.2019.pdf]

There are multiple ways that EPA could incorporate total organofluorine measurements into drinking water standards, and we urge EPA to allocate the appropriate resources for rapidly developing the capacity to do so in advance of promulgating new drinking water regulations for PFAS.

Thank you for the opportunity to provide comments. We look forward to EPA's response.

Sincerely,

Jennifer Liss Ohayon, PhD

Research Scientist

Robin E. Dodson, Sc.D.

Research Scientist

Laurel Schaider, PhD

Senior Research Scientist

Individual Response: Please see Discussion on PFAS. PFASMASTER serves as a consolidated list of PFAS substances spanning and bounded by the lists of chemicals of current interest to researchers and regulators worldwide. The consolidated list contains a number of PFAS CAS-name substances, with a subset represented with defined chemical structures. For the PFASMASTER list, there is no precisely clear definition of what constitutes a PFAS substance given the inclusion of partially fluorinated substances, polymers, and ill-defined reaction products on these various lists. At this time,

Comments Received on PFAS
EPA is opting to use a more inclusive CCL 5 PFAS definition, with chemically defined substructures, to represent those chemicals that are known or anticipated to occur in public water systems and is not prematurely excluding volatiles or fluoropolymers from further evaluation. 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).
Comment Excerpt from Commenter 89 I. EPA SHOULD ADDRESS PFAS AS A CLASS A. EPA Should include PFAS as a Class, Broadly Defined Several scientists with extensive expertise in per- and polyfluoroalkyl substances (PFAS) chemistry and toxicity, many affiliated with the Global PFAS Science Panel, [FN1: https://www.pfassciencepanel.org/about-us] have submitted extensive comments supporting listing PFAS as a class on CCL5 but noting that EPA's proposed definition is unduly narrow. We hereby join those comments and incorporate them by reference. As the scientists note, a strength of the proposal is that it applies a class-based approach to addressing PFAS. However, as they point out, EPA's "overly narrow definition of PFAS would exclude many PFAS of known concern, undercutting the benefits of the agency's action." [FN2: Proposed definition from both TSCA and SDWA proposed rulemakings: "[T]he structural definition of PFAS includes per- and poly-fluorinated substances that structurally contain the unit R-(CF2)C(F)(R')R''. Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R'') can be hydrogen." https://www.regulations.gov/document/EPA-HQ-OPPT-2020-0549-0001; https://www.regulations.gov/document/EPA-HQ-OW-2018-0594-0031] For the reasons set forth in the scientists' letter and the attached scientific journal article, we urge EPA to use the OECD PFAS definition, [FN3: OECD (2021), Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris. Available at: https://www.oecd.org/chemicalsafety/portal-perfluorinatedchemicals/terminology-per-and-polyfluoroalkyl-substances.pdf] which is scientifically sound and consistent with definitions that have been included in federal and state laws regulating PFAS. As the scientists' letter emphasizes, PFAS as a class pose dangers to human and environmental health. Due to the presence of the highly stable fully fluorinated carbon moieties, PFAS are either extremely resistant to environmental degradation – or transform into other highly persistent PFAS. Studies have shown that some PFAS take thousands of years to fully degrade. Their highly persistent nature further enables PFAS to accumulate in the environment, including in water, sediment, soil, and plants. [FN4: Kwiatkowski, C. F.; Andrews, D. Q.; Birnbaum, L. S.; Bruton, T. A.; DeWitt, J. C.; Knappe, D. R. U.; Maffini, M. V.; Miller, M. F.; Pelch, K. E.; Reade, A.; Soehl, A.; Trier, X.; Venier, M.; Wagner, C. C.; Wang, Z.; Blum, A. Scientific Basis for Managing PFAS as a Chemical Class. Environ. Sci. Technol. Lett. 2020, 7 (8), 532– 543, DOI: 10.1021/acs.estlett.0c002] Multiple lines of scientific evidence suggest that many PFAS can contribute to a wide range of adverse health outcomes, including cancer, endocrine disruption, reproductive harm, and immunosuppression. [FN5: Pelch, K., Reade, A., Kwiatkowski, C., Schultz, K., Varshavsky, J., Cavalier, H., … Wolffe, T. (2021, June 7). PFAS Health Database: A Systematic Evidence Map. https://doi.org/10.17605/OSF.IO/F9UPX; Kwiatowski et al, 2020 note 6 supra.] The attached scientific review of the studied human and environmental health harms posed by PFAS recommends adoption of a "class-based approach to managing the human and environmental risks associated with all PFAS,

Comments Received on PFAS

including polymers." [FN6: Kwiatowski et al, 2020 note 6 supra] The scientists' letter concludes that EPA's proposed PFAS definition in the SDWA CCL5 listing, quoted below, "is scientifically unsupported, does not include all PFAS, and denies the Agency critical information about PFAS." The agency definition is: "[T]he structural definition of PFAS includes per- and poly-fluorinated substances that structurally contain the unit R-(CF2)-C(F)(R')R". Both the CF2 and CF moieties are saturated carbons and none of the R groups (R, R' or R'') can be hydrogen." [FN7: Cite to definition in TSCA and SDWA proposed agency actions.]

As the scientists point out, EPA did not identify any scientific support for this proposed definition, and it "is particularly concerning that EPA's proposed definition excludes many high production volume PFAS due to its unduly narrow requirement for the presence of at least two adjacent fully-fluorinated carbons. For example, trifluoroacetic acid ("TFA") is a common HFC and HFO degradation product that poses risk to human health. [FN8: Several of the commenting scientists noted above co-authored a rebuttal to industry comments in which they highlighted health concerns posed by TFA. See, Response to "Comment on Scientific Basis for Managing PFAS as a Chemical Class." Carol F. Kwiatkowski, David Q. Andrews, Linda S. Birnbaum, Thomas A. Bruton, Jamie C. DeWitt, Detlef R.U. Knappe, Maricel V. Maffini, Mark F. Miller, Katherine E. Pelch, Anna Reade, Anna Soehl, Xenia Trier, Marta Venier, Charlotte C. Wagner, Zhanyun Wang, and Arlene Blum. Environmental Science & Technology Letters 2021 8 (2), 195-197. DOI: 10.1021/acs.estlett.1c00049] and has been widely recognized as a PFAS by the California Department of Toxic Substances Control and others, [FN9: https://dtsc.ca.gov/wp-content/uploads/sites/31/2019/11/Product-Chemical-Profile-for-Treatmentswith-PFASs.pdf] but falls outside of EPA's proposed definition because it only possesses one fully fluorinated carbon. Like other PFAS, "TFA is highly persistent and mobile in the environment, and has also been linked to adverse health outcomes like skin and eye damage and harm to aquatic life." [FN10: Scientists' letter, citing Kwiatkowski et al, note 14 supra.]

EPA's overly narrow proposed definition incentivizes the chemical industry to try to skirt future regulatory requirements by making PFAS that possess the characteristics associated with PFAS but fall outside of EPA's narrow definition. DuPont long studied such compounds. [FN11: https://www.sciencedirect.com/science/article/pii/S0022113911003782; https://www.sciencedirect.com/science/article/pii/S002211391400044X] and the chemical industry has a long history of making minor changes in PFAS chemistry to evade regulation, including the shifting from PFAS like PFOA and PFOS to shorter-chain PFAS that were erroneously claimed to be less toxic and persistent, and now pose have caused widespread environmental contamination threatening human health. [FN12: Buck et al., supra note 3, at 524. See also Mei Sun et al., Legacy and Emerging Perfluoroalkyl Substances Are Important Drinking Water Contaminants in the Cape Fear River Watershed Of North Carolina, 3 Env't Sci. & Tech. Letters 415 (2016), https://pubs.acs.org/doi/full/10.1021/acs.estlett.6b00398; Xianming Zhang et al., Source Attribution of Poly- and Perfluoroalkyl Substances (PFASs) in Surface Waters from Rhode Island and the New York Metropolitan Area, 3 Env't Sci. & Tech. Letters 316 (2016), https://pubs.acs.org/doi/abs/10.1021/acs.estlett.6b00255.]

B. EPA Should Adopt the OECD Definition of PFAS

Comments Received on PFAS

We therefore embrace the scientists' suggestion that rather than use the PFAS definition in the draft CCL5, that EPA adopt the recently-published OECD PFAS definition, in which PFAS are defined as "fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it)." [FN13: OECD (2021), Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management, No. 61, OECD Publishing, Paris. Available at: https://www.oecd.org/chemicalsafety/portal-perfluorinatedchemicals/terminology-per-and-polyfluoroalkyl-substances.pdf.] As OECD stated in explaining this definition, "the intention of the revision of the PFAS definition is not to expand the PFAS universe, but to comprehensively reflect it. As the scientists' letter notes, OECD provides "a general PFAS definition that is coherent and consistent across compounds from the chemical structure point of view and is easily implementable for distinguishing between PFASs and non-PFASs, also by non-experts." [FN14: Id. at 23.] The OECD definition is scientifically sound and comprehensive; indeed, EPA scientists were members of the OECD group that prepared this definition." [FN15: Id. at 5.]

The scientific validity and benefits of the OECD definition are detailed in the scientists' comments and the OECD report noted above, and we refer EPA to those comments. In sum, the scientists note that the OECD definition: (1) covers all fluorinated chemicals that share common characteristics of PFAS, including persistence in the environment; (2) will expand the data EPA receives about use of, and exposures to, PFAS in the United States (as the scientists note, EPA's Comptox Database now indicates that there are over 9,000 PFAS [FN16: PFAS Master List of PFAS Substances (Version2), EPA, https://comptox.epa.gov/dashboard/chemical_lists/pfasmaster] and only 175 of these are subject to recordkeeping and reporting requirements under the Toxics Release Inventory (TRI)); [FN17: https://www.epa.gov/sites/default/files/2021-01/documents/tri_non-cbi_pfas_list_1_8_2021_final.pdf] and (3) is consistent with several federal and state laws that have already employed comparable definitions of PFAS. For example, the National Defense Authorization Act for Fiscal Year 2020 defined PFAS as "perfluoroalkyl and polyfluoroalkyl substances that are man-made chemicals with at least one fully fluorinated carbon atom." [FN18: https://congress.gov/116/plaws/publ92/PLAW-116publ92.pdf, see TITLE II. SEC 322.C.3] Since 2019, eight states have passed laws using similar, broad definitions of PFAS that are consistent with OECD's, including California, [FN19: https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201920200SB1044] Colorado, [FN20: http://leg.colorado.gov/sites/default/files/2019a_1279_signed.pdf] Maine, [FN21: http://www.mainelegislature.org/legis/bills/getPDF.asp?paper=HP1043&item=1&snum=129] Vermont, [FN22: https://legislature.vermont.gov/Documents/2022/Docs/ACTS/ACT036/ACT036%20As%20Enacted.pdf] and Washington. [FN23: http://lawfilesext.leg.wa.gov/biennium/2019-20/Pdf/Bills/Senate%20Passed%20Legislature/5135S.PL.pdf?q=20210811124919] It would create needless confusion if EPA's new regulatory actions adopted different definitions of PFAS than those already in place in federal and state laws.

Individual Response: Please see Discussion on PFAS. EPA is proposing its first rule under the American Innovation and Manufacturing (AIM) Act of 2020 to phase down the production and consumption of hydrofluorocarbons (HFCs), highly potent greenhouse gases commonly used in refrigerators, air

Comments Received on PFAS
conditioners, and many other applications. The AIM Act, which was included in the Consolidated Appropriations Act, 2021, provides EPA new authorities to address HFCs in three main areas: phasing down the production and consumption of listed HFCs, maximizing reclamation and minimizing releases (via air, water, or soil) of these HFCs and their substitutes in equipment (e.g., refrigerators and air conditioners), and facilitating the transition to next-generation technologies by restricting the use of HFCs in particular sectors or subsectors.
Comment Excerpt from Commenter 93 Thank you for including the 3 chemical groups that PFAS is part of in the list. This needs to be tested in our drinking water and treated. **Individual Response:** Please see Discussion on PFAS.
Comment Excerpt from Commenter 98 This proposal to put limits on all of these microbes and chemicals as a part of the new CCL 5 is a no-brainer. The inclusion of PFAS and other long-chain chemical compounds that can bio-accumulate in the human body is a real positive. **Individual Response:** Please see Discussion on PFAS, General Comments, and Other Drinking Water Programs.
Comment Excerpt from Commenter 103 Dear Administrator Regan, Thank you for this opportunity to comment on EPA's draft Fifth Contaminant Candidate List (Draft CCL5) under the Safe Drinking Water Act (SDWA). I support EPA regulating all of the dangerous contaminants on the SDWA candidate list. It is especially important that EPA include and set safe drinking water limits on groups of extremely hazardous chemicals like cyanotoxins, disinfection byproducts, and PFAS. But it is also important that EPA make review and listing of additional unregulated contaminants a priority. I'm talking about all known PFAS. We need EPA to ensure our drinking water is safe from all of the toxic and hazardous chemicals that are being released into the environment. There are known pfas that are not listed on the EPAs radar and that is very concerning to me. Also there there a lack of awareness to what PFAS actually are and not a lot of normal people are aware of this danger and that needs to change NOW. To do that, EPA must increase staffing and speed up the process for reviewing the contaminants and setting legal limits on how much can be in our drinking water. Because the public's health and safety is threatened by so many new contaminants, I am STRONGLY URGING YOU because this problem is BEYOND HORRENDOUS and people are dying because of UNSAFE DRINKING WATER and this problem is ENTIRELY PREVENTABLE that you set strict standards on the most dangerous chemicals/ PFAS and anything like PFAS to cause bodily harm and err on the side of protecting the public when data is limited. The health of our nation, and particularly children and underserved communities, depends on it. Per- and polyfluoroalkyl substances (PFAS) are a group of man-made chemicals that includes PFOA, PFOS, GenX, and many other chemicals. PFAS have been manufactured and used in a variety of industries around the globe, including in the United States since the 1940s. PFOA and PFOS have been the most extensively produced and studied of these chemicals. Both chemicals are very persistent in

Comments Received on PFAS

the environment and in the human body - meaning they don't break down and they can accumulate over time. There is evidence that exposure to PFAS can lead to severe and life threatening adverse human health effects.

PFAS can be found in:

Pretty much everything now..

Food packaged in PFAS-containing materials, processed with equipment that used PFAS, or grown in PFAS-contaminated soil or water.

Commercial household products, including stain- and water-repellent fabrics, nonstick products (e.g., Teflon), polishes, waxes, paints, cleaning products, and fire-fighting foams (a major source of groundwater contamination at airports and military bases where firefighting training occurs).

Workplace, including production facilities or industries (e.g., chrome plating, electronics manufacturing or oil recovery) that use PFAS.

Drinking water, typically localized and associated with a specific facility (e.g., manufacturer, landfill, wastewater treatment plant, firefighter training facility).

Living organisms, including fish, animals and humans, where PFAS have the ability to build up and persist over time.

Studies indicate that PFOA and PFOS can cause reproductive and developmental, liver and kidney, and immunological effects in laboratory animals. Both chemicals have caused tumors in animal studies. The most consistent findings from human epidemiology studies are increased cholesterol levels among exposed populations, with more limited findings related to: infant birth weights, effects on the immune system, cancer (for PFOA), and thyroid hormone disruption (for PFOS).

Oral exposure studies of PFBS in animals have shown effects on thyroid hormone disruption, reproductive organs and tissues, developing fetus, and kidney. Based on dose-response information across different sexes, lifestages, and durations of exposure, the thyroid appears to be particularly sensitive to oral PFBS exposure. The data to evaluate cancer effects associated with PFBS exposure is unknown at this time but will in no way will the data ever show that the health effects are positive.

Do something right now before this is completely irreversible and we all suffer the consequences no matter wealth or age, race nor gender you will doom us all if you don't act now....

Individual Response: Please see Discussion on PFAS.

Pesticides

Agency Discussion on Pesticides

Agency Topic Discussion:
The Agency received a few comments on pesticides regarding health reference levels and concerns about pesticides being more prevalent in agricultural rural areas. Several resources are available that may be used to inform the potential listing of pesticides on the CCL. Under the pesticide registration and registration review processes, EPA conducts human health risk assessments to estimate the nature and probability of adverse health effects in humans who may be exposed to chemicals in contaminated environmental media. From this information, EPA can develop resources such as the Human Health Benchmarks for Pesticides, which may inform whether the detection level of a pesticide in drinking water or source waters for drinking water may indicate a potential health risk and the prioritization of water monitoring efforts. EPA similarly conducts ecological risk assessments for pesticides to determine risks and which pesticides have the potential to contaminate drinking water supplies in both agricultural and urban settings. Many contaminants of drinking water occur at very low concentrations. Whether the contaminants pose a health risk depends on how toxic the pesticides are, how much is in the water, and how much exposure occurs on a daily basis.

Comments Received on Pesticides

Comment Excerpt from Commenter 77
In describing how EPA prepared the Draft CCL 5, the technical support document indicates the Agency utilized existing health effects assessments to the degree possible. In reviewing the health reference levels listed in the Contaminant Information Sheets for pesticides listed on the Draft CCL 5, it appears that EPA made different assumptions in setting the health reference levels used in CCL 5 than in the Human Health Benchmarks for Pesticide update, which were published in parallel. [FN24: EPA. 2021. Human Health Benchmarks for Pesticides (HHBPs). Accessed 9/8/2021 at https://ordspub.epa.gov/ords/pesticides/f?p=HHBP:home.]

In part this difference appears to be the result from choosing different sensitive subpopulations. While it may be sound practice for EPA to utilize different assumptions compared to FIFRA assessments that are several years old, it is not clear why 16 of 24 contemporaneous health reference levels prepared by the Office of Water would differ with 14 citing different sensitive subpopulations.

Individual Response: EPA understands the concerns raised about the differences in the selection of the most sensitive subpopulation that were used in EPA's CCL 5 and EPA's HHBP processes. The commenter accurately states that for 14 pesticides, while the selected toxicity value (e.g., chronic population-adjusted dose (cPAD)) used as the basis of the CCL 5 health reference level (HRL) and HHBP were the same, the selected sensitive subpopulation and subsequent selection of the drinking water ingestion rate input were different. In the CCL 5 process, EPA's Office of Water (OW) used a consistent approach of selecting the most health-protective target population for all contaminants, including pesticides with available assessments published by the Office of Pesticide Programs (OPP). In this approach, the most sensitive subpopulation was selected among five populations (i.e., general population, bottle-fed infants, women of childbearing age (13-49 years), pregnant women, and lactating women) by examining the critical study and critical effect that was used to derive the PAD extracted from an OPP health assessment.

The updated Human Health Benchmarks for Pesticides (HHBPs) were developed by OW in

Comments Received on Pesticides
collaboration with OPP. HHBPs were established for acute and chronic effects by applying PADs established for the most sensitive life stage/population as determined by OPP, based on the available toxicity data from OPP's pesticide registration and reregistration review processes. For further information about derivation of EPA's HHBPs, see https://www.epa.gov/system/files/documents/2021-07/hh-benchmarks-technical-document-2021.pdf.
Comment Excerpt from Commenter 91 I support expanding the list of chemicals to be regulated under the Safe Drinking Water Act. I read through the list of currently unregulated chemicals and recognized a number of pesticides that I have experience with. Several of them I know to be fairly broad spectrum and while they may not be acutely toxic in mammals I don't want them building up in our water supply. The water supply is the foundation of human life in America and if we poison our water the results will be catastrophic. I would like to point out that concentrations of these chemicals will be much higher in the water supply in rural, agricultural regions, and could affect much wider swaths of land than other pollutants, making detection more difficult. **Individual Response:** Please see Discussion on Pesticides.
Comment Excerpt from Commenter 92 I would support the drafting of this list and potential future regulation of the chemicals contained by it. The Clean Drinking Water Act is a fundamentally important environmental law and the list of chemicals that are regulated by it should be updated to reflect the pollutants we are putting in our water supply. In reading this document I recognized a fair number of pesticide active ingredients and many of them were fairly broad-spectrum. Even if they are not acutely toxic in mammals I don't want them to build up in our water supply and potentially in human bodies. The water supply is the foundation of life in this country and every country and if we destroy it then the results will be catastrophic. I would like to note that these chemicals will likely be found in greater concentrations in rural, agrarian regions and therefore be present across wider tracts of land, making detection potentially more challenging, **Individual Response:** Please see Discussion on Pesticides.

Individual Chemical Contaminants

Agency Discussion on Comments on Individual Chemical Contaminants
Agency Topic Discussion: EPA received several comments 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. Some commenters provided resources and analyses that they recommended EPA consider when listing a contaminant of interest. EPA followed protocols and established hierarchies for the data used at each step of the CCL 5 process. These protocols and hierarchies were applied uniformly across all chemical contaminants [See Chapter 4 Classification of PCCL Chemicals to Select the CCL of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a)]. For example, toxicity values (i.e., reference doses) used to derive health reference levels and final hazard quotients were preferentially

Agency Discussion on Comments on Individual Chemical Contaminants

selected from health assessments that are externally peer-reviewed, publicly available, and published by EPA and other health agencies that follow methodologies consistent with EPA's current health effects guidelines and risk assessment policy documents. The recommendations provided by commenters often conflicted with this protocol and other procedures used during the CCL 5 process. However, public comments about the CCL 5 protocol's strengths and weaknesses will be useful when reviewing whether to make protocol modifications in future CCLs.

Some commenters recommended considerations or analyses that are outside the scope of the CCL process. However, placement on the CCL enables EPA to subsequently examine the available toxicity and occurrence databases in the more focused Regulatory Determination process to determine if a contaminant has sufficient data for regulation in drinking water. Regulatory Determination under SDWA will be the next stage in the regulatory process for all contaminants listed on the Final CCL 5.

1,4-Dioxane

Comments Received on 1,4-Dioxane

Comment Excerpt from Commenter 75

1,4-dioxane

ASDWA supports the inclusion of 1,4-dioxane as a contaminant on CCL 5. 1,4-dioxane has been widely used as a solvent and organic solvent stabilizer in the past. It has also been a component of many personal care products. EPA has classified 1,4-dioxane as a likely human carcinogen and established a 1-day health advisory of 4.0 milligrams per liter (mg/L) and a 10-day health advisory of 0.4 mg/L for 1,4dioxane in drinking water for a 10-kilogram child. EPA also established a lifetime health advisory of 0.2 mg/L for 1,4-dioxane in drinking water.

Contamination of both groundwater and surface water sources of drinking water from 1,4- dioxane is extensive. The results of the Third Unregulated Contaminant Monitoring Rule (UCMR3) found that of the 4,916 public water systems (PWS) tested, 1,077 PWSs in 45 states detected 1,4-dioxane above 0.07 ppb, and 6.9% of PWSs detected 1,4-dioxane above 0.35 ppb. Since the UCMR monitoring universe is the approximately 4,000 PWSs that serve over 10,000 people plus approximately 800 smaller systems, these sample results represent only a fraction of the over 50,000 Community Water Systems (CWSs), which are a subset of the over 150,000 PWSs. The additional PWSs that may be impacted by 1,4-dioxane and were not included in the UCMR3 are typically small groundwater systems with limited capacity to assess and address 1,4- dioxane. The vast majority of UCMR3 PWSs were surface water systems.

In the absence of a federal standard, some states across the country are taking additional actions to address public health impacts from 1,4-dioxane drinking water contamination in both surface water and groundwater sources. However, other states are unable to develop their own guidelines or regulations that are more stringent than federal standards, and/or do not have the resources to conduct sampling programs. Four states have developed state-level regulatory actions in the absence of a federal standard: New York established a MCL for 1,4-dioxane at 1 ppb; Massachusetts established a drinking water guideline at 0.3 ppb; California established a health action level of 1 ppb; and New Hampshire established an ambient groundwater quality standard (AGQS) level of 0.32 ppb. Additionally, 14 other states have established groundwater or drinking water standards or guidelines

Comments Received on 1,4-Dioxane

with levels ranging from 0.3 to 77 ppb.

EPA taking a leadership in driving this chemical through its drinking water standards development process would benefit several states, as setting and implementing a drinking water exposure limit for 1,4-dioxane presents challenges to the states. Additionally, ASDWA requests the Office of Water continue to coordinate with EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) to ensure the risk evaluation for 1,4-dioxane under the Toxic Substances Control Act (TSCA) includes drinking water as an exposure pathway.

Individual Response: Please see Discussion on Individual Chemical Contaminants and Other Drinking Water Programs. EPA appreciates the information provided by the commenter that supports the inclusion of 1,4-dioxane on the CCL 5. EPA acknowledges the commenter's concerns about 1,4-dioxane and challenges faced by states with known surface water and/or groundwater contamination. Nationally representative finished drinking water occurrence data for 1,4-dioxane are available from the Third Unregulated Contaminant Monitoring Rule (UCMR 3; docket EPA-HQ-OW-2009-0090). Please see the Discussion on Individual Chemical Contaminants for information about the next steps in the regulatory process for 1,4-dioxane.

The Office of Pollution prevention and Toxics (OPPT) published the Risk Evaluation for 1,4-Dioxane in December 2020 (docket EPA-HQ-OPPT-2019-0238; https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0091). During the risk evaluation process for 1,4-Dioxane, OCSPP collaborated with offices within EPA that administer and implement regulatory programs under the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA). The agency is continuing to evaluate 1,4-dioxane. More information on the Risk Evaluation for 1,4-dioxane is available at Assessing and Managing Chemicals under TSCA: Final Risk Evaluation for 1,4-Dioxane.

Chlorpyrifos

Comments Received on Chlorpyrifos

Comment Excerpt from Commenter 89

Similarly, EPA issued a 2016 Revised Human Health Risk Assessment (HHRA) that demonstrated that chlorpyrifos results in unsafe drinking water exposures and adverse neurodevelopmental effects and that EPA therefore was required to issue a final rule revoking all chlorpyrifos tolerances. [FN31: Summarized in EPA, Chlorpyrifos; Tolerance Revocations, August 18, 2021, https://www.epa.gov/system/files/documents/2021-08/pre-pub-5993-04-ocspp-fr_2021-08-18.pdf] The agency recently issued a final rule revoking all chlorpyrifos tolerances based on aggregate exposures including drinking water. [FN32: Ibid.] However, chlorpyrifos is still in use, is allowed for non-food uses, and its toxic degradates may remain in the environment for years. We urge an affirmative regulatory determination without further delay.

Individual Response: Please see Discussion on Individual Chemical Contaminants, Other Drinking Water Programs, and Other EPA Programs.

Cobalt

Comments Received on Cobalt

Comment Excerpt from Commenter 74

Comments on the draft chemical contaminant list 5 (CCL5) with reference to cobalt
Submitted by Cobalt Institute

EPA Document ID: EPA-HQ-OW-2018-0594-0031

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The Cobalt Institute (CI) is a trade association composed of producers, users, recyclers, and traders of cobalt. We promote the sustainable and responsible production and use of cobalt in all its forms. Both the CI and the Cobalt REACH Consortium (European Union) have invested in high quality, guideline compliant studies to address human health hazard characterization and accompanying risk assessment for different global jurisdictions.

We submit the following comments with regards to the draft chemical contaminant list 5 (CCL5) cobalt assessment.

1. The use of the chronic RfD from USEPA PPRTV 2008 to derive the cobalt HRL

• We raise concerns regarding the use of Roche and Layrisse 1956 reference [FN1: Roche, M. and M. Layrisse. 1956. Effect of cobalt on thyroidal uptake of I131. J. Clin. Endocrinol. Metab. 16:831-833.] as the point-of departure for the sub- and chronic RfD in PPRTV 2008 [FN2: USEPA. 2008. Provisional Peer Reviewed Toxicity Values for Cobalt (CASRN 7440-48-4). PA/690/R-08/008F. U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Superfund Health Risk Technical Support Center, Cincinnati, OH.], and thereby used in the derivation of the cobalt HRL in the draft CCL 5 CIS. The aforementioned reference was a two-page letter to the editor (i.e. unclear if peer-reviewed) and further, the genders of the 12 euthyroid participants were not specified. These points were also published in a peer-reviewed manuscript [FN3: Finley et al. 2012. Derivation of a chronic oral reference dose for cobalt. Reg. Tox. And Pharm. 64: 491 – 503].

• The effect that the HRL is derived for is listed in the draft Co CIS as 'reproductive/developmental' and associated with a target population of 'women of childbearing age'. As listed in point 1 above, the key study did not specify gender and the key effect was decreased radioactive iodine uptake. In addition, there was argumentation in the derivation of the RfD (PPRTV 2008) to derive a safe level based on the thyroid effect instead of hematological effect, as the former was hypothesized to lead to increased toxicity at a longer duration or higher dose in a sensitive population specifically relating to goiter in previously anemic children.

Comments Received on Cobalt

• The chronic RfD derivation contains an uncertainty factor of 10 as 'cobalt may not be rapidly eliminated from the body' (after subcutaneous treatment). This should be reviewed using Danzeisen et al. 2020, as listed under point 2 below; in which GLP, OECD compliant toxicokinetic data have been published for a highly bioavailable cobalt substance. As observed after an oral bolus dose (in water) of cobalt dichloride hexahydrate, 10% of the dose was bioavailable, the plasma half-life elimination was 14 hours and total elimination was observed by 72 hours.

• If protecting against the thyroid effect, we ask EPA to consider the Finley et al. 2012 [FN4: Finley et al. 2012 derivation of a chronic oral reference dose for cobalt. Reg. Tox. And Pharm. 64: 491 – 503.] derivation of a chronic RfD using Jaimet and Thode 1955 [FN5: Jaimet and Thode 1955. Thyroid function studies on children receiving cobalt therapy. JAMA 158: 1353 – 1355. 311325.] as point-of-departure (not referenced in PPRTV 2008) and use of uncertainty factors, specifically contrasted with those used in EPA's perchlorate assessment based on thyroid effects. Based on our own guideline compliant studies we would recommend using the hematological effect as point of departure, as outlined below, since (at least in our studies) it is a more sensitive endpoint than the thyroid effect and followed a dose response with the possibility to set a LOAEL and a NOAEL.

• We ultimately ask EPA to consider deriving a HRL based on the well-documented hematological effect induced by bioavailable cobalt substances, using the argumentation that this is a more sensitive effect in humans, occurring at doses lower than those inducing a thyroid effect and demonstrated as a key outcome in the mode-of-action for highly bioavailable cobalt substances.

2. The derivation of a cobalt HRL based on protection against a hematological effect (most sensitive effect)

• We request that the EPA review and include in the draft CCL5 cobalt assessment, the peer-reviewed reference Danzeisen et al. 2020 [FN6: Danzeisen et al. 2020. Bioelution, bioavailability, and toxicity of cobalt compounds correlate. Tox Sci. 174(2): 311325.]. This article outlines that the hematological effect (reversible) is the most sensitive effect/occurs at lower doses than the thyroid effect; manifesting in large (+20%) increases in hematological parameters and erythroid hyperplasia in a 90-day oral repeated-dose toxicity study in male and female rats (i.e. LOAEL = 10 mg cobalt dichloride hexahydrate/kg bw/d, corresponding to 2.5 mg cobalt/kg bw/d) and a NOAEL of 3 mg cobalt dichloride hexahydrate/kg bw/d, corresponding to 0.75 mg cobalt/kg bw/d). No alterations were observed in the thyroid (histopathology, gross pathology, organ weight) or clinical chemistry parameters associated with the thyroid; no changes to reproductive parameters and no spermatagonial aberrations observed at doses up to 30 mg cobalt dichloride hexahydrate/kg bw/d or 7.5 mg Co/kg bw/d (Danzeisen et al. 2020).

• We ask the EPA to consider derivation of a chronic RfD based on Danzeisen et al. 2020, which would equate to 30 µg Co/kg-d; using:
o Point-of-departure: NOAEL = 0.75 mg Co/kg-d

Assessment Factor	Accounting for	Value applied
Interspecies variability	Correction for differences in metabolic rate (allometric scaling)	1*

Comments Received on Cobalt

	Remaining differences (e.g. TK, TD)	2.5
Intraspecies	General population	5**
Exposure duration	Sub-chronic to chronic	2
Dose response	NOAEL as POD with reliable information on dose response	1
Database	Quality of database high	1***
Overall Uncertainty factor		25

Explanations:
*: metabolism of cobalt as an inorganic substance can be excluded. There are no reasons to assume that this behavior which is based on the physico-chemical properties of the substance will be different between rats and humans. Therefore, it is considered to be justified to apply substance-specific assessment factors accounting for a correction for differences in metabolic rate of 1 instead of using the respective default factors of 4.
**: This assessment factor is used to account for an expected greater variability in response from the most to least sensitive human would be seen, relative to an experimental animal population. ECETOC (2003) has reviewed scientific literature on the distribution of human data for various toxicokinetic and toxicodynamic parameters to assess intra-species variability within the human population, specifically by Renwick and Lazarus (1998) and Hattis et al. (1999). Considering that the data analyzed by these authors includes both sexes, a variety of disease states and ages, the use of the 95th percentile of the distribution of the variability for these datasets is considered sufficiently conservative to account for intraspecies variability for the general population. Based on this, a default assessment factor of 5 is recommended by ECETOC (2003).
***: key study guideline compliant OECD 408 with reproductive toxicity screening and dose response for leading effect (hematology)

3. Consideration of the essentiality of cobalt in vitamin B12, natural background levels of cobalt and the approximate levels in food

• The general population is exposed to anthropogenic and natural sources of cobalt through the air, water and diet. Diet and oral exposure are the main source of cobalt intake for the general public. Vitamin B12 has a reference nutrient intake (RNI) value of 2.4 µg of Vitamin B12/day for adults and 2.5 µg/day during pregnancy. Based on figures quoted in ATSDR 2004 [FN7: ATSDR. 2004. Toxicological Profile for Cobalt. U.S. Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry (ATSDR), Atlanta, GA.], the average daily intake of cobalt through food is between 5 – 40 µg Co/day. Inorganic cobalt is not essential to humans and has a tolerable daily intake value, e.g. set by France at 1.6 – 8 µg/kg bw/d. Cobalt is found in a variety of food sources such as meat, offal, coffee, yeast products, dairy products, fish, green leafy vegetables, fresh cereals and nuts. Depending on place of living and background occurrence of cobalt, daily exposure through the diet can be significantly higher.

• In the form of vitamin B12, cobalt is an essential nutrient for humans. Mammals are not capable of synthesizing vitamin B12 and need to obtain it through the diet, where it is found only in some fermented foods or in animal-based food products [FN8: Combs, G.F. and McClung, J.P (eds) 2017. The Vitamins (5th Edition), Chapter 18 – Vitamin B12. Academic Press, pages 431-452. ISBN: 9780128029657.].

We thank you in advance for the consideration of the points outlined above.

Comments Received on Cobalt

Individual Response: Please see Discussion on Individual Chemical Contaminants. EPA recognizes the comments about the critical study used in the PPRTV and appreciates the commenter providing additional references. It is important to note that the PPRTV value is supported by a second study (Davis and Field, 1958) that identified polycythemia as the critical effect at similar doses as the thyroid critical effect. Therefore, there is evidence of two different health endpoints observed after cobalt exposure in the same dose range. Further, there are multiple human studies that demonstrate the Davis and Field link between cobalt and polycythemia that support this second health effect resulting from cobalt exposure.

The connection of the HRL to the reproductive/developmental category is based on the selection of women of childbearing age as the most sensitive subpopulation for the derivation of the HRL. The critical effect (decreased iodide uptake by the thyroid) can lead to developmental effects because of the recognized neurodevelopmental impacts of low dietary iodide on the fetus. The Dietary Reference Intake (DRI) guidelines recognize the importance of iodide during pregnancy and support use of the drinking water intake and body-weight ratio selected by EPA for derivation of the HRL (IOM, 2006).

The EPA literature search for recent publications related to the health effects associated with cobalt in humans and laboratory animals was conducted on October 22, 2019 and therefore did not identify the Danzeisen et al. (2020) publication. EPA appreciates that the commenters provided a copy of the article. The publication will be considered as part of the future CCL and Regulatory Determination evaluations. The Finley publications mentioned in the comment were among the materials reviewed when cobalt was evaluated for potential regulation during Regulatory Determination 3. Any studies submitted to EPA that were not among the data collected for previous Regulatory Determination cycles will be added to the data set evaluated for a future Regulatory Determination 5 evaluation.

EPA is aware of the presence of cobalt within the Vitamin B-12 complex as well as the Institute of Medicine's Vitamine B-12 guidelines for various life-stage groupings including pregnancy and lactation periods (IOM, 2006). There is an ongoing ATSDR update to the 2004 cobalt Toxicological Profile that includes information on Vitamin B-12. The updated ATSDR Toxicological Profile was a factor in the previous decision to delay the Regulatory Determination for Cobalt. When finalized, the updated assessment will be considered for the next Regulatory Determination process.

Manganese

Comments Received on Manganese

Comment Excerpt from Commenter 75

ASDWA supports the inclusion of manganese on CCL 5. The health advisory for manganese (2004) is outdated and needs to be updated in a timely manner. Research linking the secondary standard to aesthetic issues has also been criticized, as the aesthetic issues are seen at levels much lower than 0.05 mg/L. ASDWA recommends that EPA conduct an updated risk assessment on manganese in a timely manner, so that the manganese health effects data can catch up with the occurrence data from the Fourth Unregulated Contaminant Rule (UCMR4) and regulatory decisions, i.e., a regulatory determination can be made in a timely manner.

Several recent health effects studies have shown adverse neurotoxic effects of high levels of

Comments Received on Manganese

manganese in drinking water and many states have been taking action to address the contaminant. For example, Massachusetts has undertaken an initiative to make its public water suppliers and their customers more aware of the existing US EPA health advisory values for manganese and the health implications of having exposures greater than those guidelines. This initiative included a monitoring requirement to better understand the extent of manganese contamination. The initiative found a significant number of samples had manganese concentrations greater than the US EPA lifetime Health Advisory level of 0.3 mg/L. Sampling data indicated that approximately 35-40% of raw groundwater samples and about 12-26% of finished water samples used by these public water suppliers exceed this limit. Additionally, New Hampshire has recently adopted a state advisory of 0.1 mg/L for manganese for protection of infants and has also adopted a state ambient groundwater quality standard of 0.3 mg/L. With numerous studies pointing to the negative impacts of high levels of manganese in drinking water, ASDWA recommends that EPA evaluate the need to update the manganese health advisory and make a regulatory determination.

Individual Response: Please see Discussion on Individual Chemical Contaminants. EPA agrees that manganese should be listed on the CCL 5 and that the database for studies on both its health benefits as a nutrient and its adverse neurodevelopmental impacts as a toxic agent has increased since the Regulatory Determination decision to not regulate manganese in 2003. The Office of Water decision at that time was based on a conclusion that the existing Secondary Maximum Contaminant Level (SMCL) assessment would provide adequate protection when coupled with the 2003 Health Advisory guideline that limited early life exposures to manganese through formula, and the lifetime drinking water concentration to 0.3 mg/L and the ten-day exposure value to 1 mg/L.

The UCMR 4 monitoring data provide the occurrence data to support including manganese on CCL 5. A number of states, countries, and the World Health Organization (WHO) recently updated their manganese risk assessments and guidelines based on health effects data published after the Regulatory Determination 1 manganese decision. EPA will consider these data when evaluating manganese under the Regulatory Determination 5 process.

Comment Excerpt from Commenter 82

I. Introduction

On behalf of the Manganese Interest Group ("MIG"), we are pleased to submit the following comments concerning the U.S. Environmental Protection Agency's ("EPA" or "Agency") notice concerning Drinking Water Contaminant Candidate List 5 – Draft ("CCL 5"). See 86 Fed. Reg. 37,948 (July 19, 2021) (referring to docket EPA-HQ-OW2018-0594) (hereinafter "the Notice"). MIG is an ad hoc coalition of trade associations and companies interested in the scientifically sound evaluation and regulation of manganese compounds. MIG's members include steel producers, metalworkers, chemical manufacturers, ferroalloy producers, and other like-minded stakeholders, most of which operate in the United States. [FN 1: Group members include: the American Iron and Steel Institute, the Steel Manufacturers Association, the Specialty Steel Industry of North America, the International Manganese Institute, the National Slag Association, Afton Chemical Corporation, American Zinc Recycling, Cleveland-Cliffs, Inc., Eramet Marietta, Inc., New Castle Stainless Plate LLC, North American Stainless, Nucor Steel, S.H. Bell Company, and U.S. Steel]

MIG's principal interest in the Notice is the scientific merit of maintaining manganese on the CCL 5. As the Agency has openly acknowledged in other regulatory settings, manganese is an essential nutrient

Comments Received on Manganese

that is subject to strict homeostatic control in the human body. Large amounts of manganese are naturally present in many foods consumed as a part of a normal diet, so manganese in drinking water at the levels typically measured is unlikely to add materially to the normal daily ingestion of manganese from diet. Against this backdrop, the best available peer-reviewed science does not support maintaining manganese on the CCL 5.

A validated human physiologically-based pharmacokinetic ("PBPK") model that EPA is primarily responsible for developing has very recently been applied specifically to address EPA's main concern about manganese in drinking water - namely, whether manganese in drinking water might lead to developmental impacts in children. The relevant citation is Yoon, M., et al., "Assessing children's exposure to manganese in drinking water using a PBPK model," Toxicology and Applied Pharmacology 380 (2019) 114695 (hereafter "Yoon 2019"). The Yoon 2019 paper states, "[t]hese simulations indicate that drinking-water Mn at levels commonly encountered is expected to have minimal effect on globus pallidus Mn concentrations in very young children through age 18" (referring to Figure 6). The stated conclusion is based on an "expanded Mn PBPK model" that

> describes age-dependent Mn homeostasis at dietary steady state, introduces environmentally relevant inhalation and drinking water exposure conditions, and accounts for differences in oral bioavailability of Mn for infants ingesting breast milk, formula milk, or drinking water. This biologically-based model provides internal dose information for children exposed by both inhalation and drinking-water and allows a better understanding of the question whether there is age-related sensitivity to Mn exposure via drinking water. Based on the results of the model, infants and children are not expected to be at greater exposure than adults to Mn in drinking water.

Accordingly, MIG respectfully requests that manganese be deleted from the CCL 5. MIG appreciates the opportunity to provide these comments.

II. EPA Has Long Recognized the Importance of PBPK Models for Risk Assessment, Particularly for Essential Metals Such as Manganese

EPA has long recognized the potential importance of PBPK models to risk assessment [FN 2: See "Approaches for the Application of Physiologically Based Pharmacokinetic (PBPK) Models and Supporting Data in Risk Assessment," (EPA/600/R-05/043F) (2006) available at http://epa.gov/ncea.]. PBPK models consist of a series of mathematical representations of biological tissues and physiological processes in the body that simulate the absorption, distribution, metabolism, and excretion of chemicals that enter the body. PBPK models are designed to estimate how much of a chemical reaches target tissues (i.e., the internal dose) from a particular level of exposure to that chemical (i.e., an administered dose). The choice of an internal dose metric (sometimes called the biologically effective dose) replaces the administered dose in the derivation of the quantitative dose-response relationship, with the intent of reducing the uncertainty inherent in risk assessments based on an applied dose (i.e., exposure level). This reduction in uncertainty and the improved scientific basis for the dose-response value are the main advantages of PBPK models. PBPK models reduce uncertainty and improve the scientific basis for determining the relationship among: (a) exposure to the substance of interest; (b) dose to target tissues; and (c) biological response, i.e., toxicity. PBPK models are typically used for interspecies extrapolation, estimating intraspecies variability, route-to-route extrapolation, and duration of exposure adjustment in the risk assessment by means of

Comments Received on Manganese

chemical-specific adjustment factors rather than traditional uncertainty factors. [FN 3: Id.]

In the case of manganese, EPA had the foresight to mandate the generation of the data necessary to develop human PBPK models as part of the registration testing program for the manganese-based octane-enhancing fuel additive known as mmt® [FN4: mmt® is a registered trademark owned by Afton Chemical Corporation.]. As explained by several EPA scientists in a paper published in 2018, the test rule for mmt addressed a wide range of issues adding uncertainty for the risk assessment of manganese:

> Among the uncertainties identified were: the chemical forms of Mn emitted in automotive exhaust; the relative toxicity of different Mn species; the potential for exposure among sensitive subpopulations including females, the young and the elderly; differences in sensitivity between test species and humans; differences between inhalation and oral exposures; and the influence of dose rate and exposure duration on tissue manganese accumulation. [FN5: Smith, D., et al., Manganese Testing Under a Clean Air Act Test Rule and the Application of Resultant Data in Risk Assessment, Neurotoxicology. 2018 January; 64: 177-184.]

As these same authors explained in their paper, "It was anticipated that development of specific sets of pharmacokinetic (PK) information and models regarding Mn could help resolve many of the identified uncertainties *and serve as the best foundation for available data integration*." [FN6: Id. (emphasis added).] The validated human PBPK model for manganese affords EPA a clear opportunity to integrate the available scientific data in the best possible way, just as EPA hoped would ultimately occur when it developed and imposed the mmt registration test rule more than two decades ago. As reflected in Attachment 1 to these comments, EPA's registration test rule for mmt has resulted in not less than 45 publications in the peer-reviewed scientific literature, the culmination of which is a validated human PBPK model for manganese.

III. EPA Must Rely on the Best Available Science for All Aspects of the Safe Drinking Water Act Program

EPA is obligated to rely upon the best available science for any of its decisions relating to the CCL 5 [FN7: 42 U.S.C. § 300g-1(b)(3)(A).] EPA's proposal makes plain that it relies on the 2019 Health Canada drinking water assessment for manganese as the basis for the Agency's manganese proposal [FN9: Guidelines for Canadian Drinking Water Quality, Guideline Technical Document, Manganese, Health Canada (May 2019) (hereafter "Canadian Manganese Assessment")][FN8: See Technical Support Document for the Fifth Contaminant Candidate List (CCL 5) – Contaminant Information Sheets, p. A-522, EPA 815-R-21-006 (July 2021). [FN9: Guidelines for Canadian Drinking Water Quality, Guideline Technical Document, Manganese, Health Canada (May 2019) (hereafter "Canadian Manganese Assessment")] Reliance upon the Canadian Manganese Assessment is unwarranted, however, because it does not meet the "best available science" standard.

First, although Health Canada acknowledged the existence of the manganese PBPK models in its assessment, Health Canada opted not to apply them in any respect, apparently based on the misguided understanding that the manganese PBPK models have not been validated [FN10: Id., p. 47 ("Although the model can be used to estimate manganese concentrations in brain tissue, such

Comments Received on Manganese

simulations have not been validated in humans.").]. In fact, the manganese PBPK models have been validated a number of times, including the human manganese PBPK models [FN11: See Ramoju, S.P., et al., "The application of PBPK models in estimating human brain tissue manganese concentrations," Neurotoxicology 58 (2017) 226-237 (Figure 2); Gentry, P.R., et al., "A tissue dose-based comparative exposure assessment of manganese using physiologically based pharmacokinetic modeling - The importance of homeostatic control for an essential metal," Toxicology and Applied Pharmacology 322 (2017) 27-40 (Figures 1-5); Schroeter, J.D., et al., "Analysis of tracer kinetics and target tissue dosimetry in monkeys and humans with multi-route physiologically-based pharmacokinetic models," Toxicological Sciences 120(2) (2011) 481-498. The Yoon 2019 paper also includes validation as follows: "[A]ll the simulated brain concentrations in the globus pallidus region were within the range observed in human cadavers" and "[t]he age-profiles of whole-blood Mn concentrations are consistent with the reported human data."].

Second, the literature review completed by Health Canada does not include a number of key references which were not yet available when Health Canada completed its assessment of the scientific literature. As explained in more detail in the following section, the omitted references directly address EPA's concerns about manganese in drinking water and the likelihood of any adverse developmental impacts. As noted, these studies specifically incorporate drinking water as a component of the validated PBPK models for manganese.

Finally, EPA has stated that it will use the Umbrella Quality Assurance Project Plan ("QAPP") for PBPK Models (i.e., EPA ORD QAPP ID Number: B-0030740-QP-1-0) "as an internal QA Project Plan in support of U.S. EPA's Human Health Risk Assessment ("HHRA") research plan." The documentation needed to fulfill the QAPP for the manganese PBPK model can be provided to EPA upon request.

IV. An Updated Human PBPK Model for Manganese Confirms that Children Are Not Susceptible to Brain Manganese Tissue Increases When Exposed to Concentrations of Manganese Measured in Drinking Water

The Canadian Manganese Assessment does not address two important papers that have updated the validated human PBPK model for manganese to include a drinking water component that now covers children ranging in age from infants to 18 years. The two papers are:

1. Song, G., "Physiologically-based pharmacokinetic modeling suggests similar bioavailability of Mn from diet and drinking water," Toxicology and Applied Pharmacology 359 (2018) 70-81; and
2. Yoon 2019.

As both papers are open-source publications, the papers are included with these comments as Attachments 2 and 3.

Of particular importance to EPA's Notice, the Yoon 2019 paper applies the human PBPK model for manganese to cover the following exposure scenarios:

1. A male infant exclusively breast-fed for 6 months after birth;
2. A male infant exclusively formula-fed for 6 months after birth, assuming the average daily

Comments Received on Manganese

intake from formula powder of 1.145 mg Mn/day;
3. A male infant exclusively formula-fed for 6 months after birth, assuming the average daily intake from formula powder of 0.05 mg Mn/day;
4. A 3-year-old male toddler;
5. A 10-year-old male child;
6. An 18-year-old male teenager;
7. A male adult;
8. A female adult; and
9. A pregnant female and a male fetus.

According to the authors, the simulations run with the updated human PBPK model indicate "that drinking-water Mn at levels commonly encountered is expected to have minimal effect on globus pallidus Mn concentrations in very young children through age 18." Figure 6 from Yoon 2019, which is replicated below, clearly shows very little or no change in brain manganese concentrations for any childhood life stage exposed to manganese concentrations in drinking water at or below 100 µg/liter. According to EPA's own "occurrence data" for manganese, very few samples of drinking water in the United States reach such a high level of manganese given that the 90th percentile measurement is more than three-fold lower [FN12: Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) - Contaminant Information Sheets, pp. A521-524.]. [Figure 6: see docket ID 0082]

For very young children, moreover, the authors observe, "The PBPK modeling analysis strongly indicated that the apparent difference in uptake in neonates is not due to immature homeostatic mechanisms as previously inferred from earlier studies (Ballatori et al., 1987; Keen et al., 1986) *but rather the need to sequester Mn to build up tissue levels*."

The authors of Yoon 2019 ultimately conclude: "Simulations with this expanded multi-dose route, multi-age model structure indicate that the effect of adding drinking-water exposure along with dietary intake and ambient air inhalation on tissue Mn concentrations in children is not expected to be any greater than the effects in adults, even at drinking-water concentrations approximately twice the Lifetime Health Advisory value set by the USEPA."

MIG strongly encourages EPA to consider this important new scientific information before the Agency makes any final decisions concerning the CCL 5.

V. Conclusion

As explained in these comments, the best available science does not support maintaining manganese on the CCL 5. EPA's chemical contaminants screening process inappropriately relies on the 2019 Health Canada drinking water assessment. Manganese would not have been included on the CCL 5 if EPA's chemical contaminants screening process had appropriately relied on the best available science, specifically the use of the validated human PBPK model for manganese updated to include a drinking water component. Accordingly, MIG respectfully requests that EPA delete manganese from the CCL 5.

MIG very much appreciates the opportunity to provide comment on EPA's proposed CCL 5.

Comments Received on Manganese

Individual Response: Please see Discussion on Individual Chemical Contaminants. EPA respectfully disagrees with the Manganese Interest Group's conclusion that the available science does not support maintaining manganese on the CCL 5.

EPA is aware of the substantial number of post-CCL 4 toxicological and epidemiological publications on manganese that identified a number of different adverse health outcomes. EPA identified the Yoon, Young, and Song publications as part of the rapid systematic literature review conducted to support development of CCL 5 [See Chapter 4 Classification of PCCL Chemicals to Select the CCL of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a)]. The Yoon paper is one of several pharmacokinetic models for manganese published after the current 2003 Health Advisory was issued. EPA agrees that physiologically-based pharmacokinetic (PBPK) models can be useful, although not necessary, in conducting a risk assessment and will further evaluate the available literature for manganese during the Regulatory Determination 5 process. Both the Young and Song papers are included in the recent Canadian and World Health Organization updates to their manganese assessments. EPA will evaluate the available manganese health effects literature, including the recent publications, as part of the Regulatory Determination 5 process.

Per the CCL 5 process, manganese was included on the CCL 5 because available data from UCMR 4 indicate that manganese is known to occur in public water systems and that the available health data indicate it may require drinking water regulation. EPA therefore maintains that its decision to include manganese on the CCL 5 is justified.

Tungsten

Comments Received on Tungsten

Comment Excerpt from Commenter 68

Dear Sir/Madam - ITIA appreciates the Agency's dedication to the ongoing evaluation of drinking water standards to protect human health. On 19 July 2021 the US EPA released the Drinking Water Contaminant Candidate List 5-Draft where tungsten (CASN 7440-33-7; DTXSID8052481) is included. We are aware the Final Hazard Quotient (HQ) for tungsten is calculated using the Reference Dose (RfD) listed in the 2015 Provisional Peer-Reviewed Toxicity Values (PPRTV) for Soluble Tungsten Compounds (US EPA, 2015). Since the PPRTV was prepared, new data has become available that we believe warrants a revision of the Tungsten Contaminant Information Sheet to reflect a RfD based on more up to date toxicity data. This new data generated by US NTP on sodium tungstate determined that the target organ in female and male rats and mice is the kidney instead of the glomerular stomach. Please review the attached information for additional details on this matter.

It is the hope of ITIA that further discussions can be held and a consensus reached with regard to the revision of the provisional oral -RfD for soluble tungsten compounds.

Individual Response: Please see Discussion on Individual Chemical Contaminants. While the National Toxicology Program (NTP) provides valuable data on health effects, including potential dose-response data, these technical reports do not include derivation of Reference Doses or Cancer Slope Factors used to develop Health Reference Levels for the CCL 5 Classification process [See Chapter 4 Classification of PCCL Chemicals to Select the CCL of the Final CCL 5 Chemical Technical Support

Comments Received on Tungsten

Document (USEPA, 2022a)]. During the Regulatory Determination process, EPA will have the opportunity to examine tungsten's entire toxicity database, including recently published toxicological information such as the NTP *Technical Report on the Toxicology and Carcinogenesis Studies of Sodium Tungstate Dihydrate (CASRN 10213-10-2) in Sprague Dawley (Hsd:Sprague Dawley® SD®) Rats and B6C3F1/N Mice (Drinking Water Studies)* (NTP, 2021).

Vanadium

Comments Received on Vanadium

Comment Excerpt from Commenter 86
September 17, 2021
Submitted via http://www.regulations.gov

Water Docket
U.S. Environmental Protection Agency
Mail Code 28221T
1200 Pennsylvania Avenue, NW Washington, DC 20460
ATTN: The Honorable Radhika Fox, Assistant Administrator for the Office of Water

Re: Docket No. EPA-HQ-OW-2018-0594, Notice of Availability, Request for Comments, Draft Drinking Water Contaminant List 5; 86 Fed. Reg. 37948 (July 19, 2021)

Dear Assistant Administrator Fox:

The Vanadium Producers and Reclaimers Association (VPRA) would like to thank you for the opportunity to comment on the Environmental Protection Agency's (EPA's) fifth Contaminant Candidate List (CCL 5). VPRA is the not-for-profit corporation that is representing the domestic vanadium industry in the United States and is the primary industry stakeholder expert on vanadium compounds. However, our members operate in a highly competitive international environment, and our resources are modest. Specifically, VPRA and its 3 producing members qualify as small businesses with from 9 to no more than 250 employees. Vanadium is among the 35 minerals and metals the U.S. Geological Survey has deemed critical to the United States. The following industry website contains information on the strategic defense uses of vanadium as well as environmentally beneficial applications: http://vanitec.org/vanadium/using-vanadium

VPRA finds that the scientific basis for inclusion of vanadium on the CCL 5 is flawed and recommends removing it from CCL 5 listing under the Safe Drinking Water Act (SDWA). First, the occurrence data used by EPA to support vanadium's listing in CCL 5 are not relevant due to lack of consideration on the forms of vanadium to which the public may be exposed. Second, the health effects data available on vanadium at this time are inappropriate for fully understanding the potential risks, if any, associated with vanadium species. We think that EPA's information on vanadium occurrence and toxicity does not meet the criteria for inclusion on the Contaminant Candidate List (CCL) and the historical retention of vanadium on this list should be discontinued until such time as these data gaps can be appropriately addressed.

I. Background

Comments Received on Vanadium

Pursuant to section 1412(b)(1)(B)(i) of the 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) that may require regulation under the SDWA. SDWA section 1412(b)(1) requires EPA to make determinations every five years on whether to regulate at least five contaminants from the CCL. SDWA also 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
- The regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

VPRA thinks that CCL listings should exhibit strong potential to meet these criteria and that EPA's case for vanadium's placement on the CCL is weak. On July 19, 2021, EPA published the fifth CCL since the issuance of the SDWA amendments of 1996. Although EPA has included vanadium on every CCL list since 1998 and is proposing to retain vanadium in CCL 5, we do not think EPA has ever established that vanadium has the potential to meet the criteria for regulation above. These comments explain why it is reasonable and appropriate for EPA to remove vanadium from the proposed CCL 5 list.

The July 19th Federal Register Notice states that 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 Federal Register Notice also states that the draft CCL 5 list utilizes the best available data to characterize the occurrence and adverse health risks a chemical may pose from drinking water exposure (86 Fed. Reg. at 37951).

Due to data deficiencies and the utilization of inaccurate and/or low confidence information, vanadium cannot and should not be among the contaminants considered as the greatest public health concern. EPA has not utilized the best available data to determine either vanadium's occurrence or adverse health risks and, therefore, EPA cannot conclude that vanadium is a concern for drinking water or a national concern for which federal regulation may be appropriate or supportable.
II. Vanadium Chemistry Considerations are Not Factored into Occurrence Information
In developing regulations for chemical compounds containing vanadium in drinking water several chemistry-based factors must be considered. Vanadium is a naturally occurring element and is the 20th most abundant element in the earth's crust. Like most metals, it does not occur in the native, metallic form, but instead occurs naturally in about 65 different minerals. Notably, the most widely toxicologically studied vanadium compound, vanadium pentoxide, V2O5, does not occur naturally (with the one very rare exception of a volcano caldera in Siberia), and chemically reacts with water to form a range of vanadium containing anions and cations, depending on the exact conditions of the solution.

The aqueous chemistry of vanadium is complex as compared to other metals such as nickel or copper. In simple solutions, not containing any other ligands, vanadium can occur as separate inorganic species with four possible oxidation states (+2, +3, +4, +5) and nine different charges, including both anions and cations. [FN1: Kelsall et al., Redox chemistry of H2S oxidation by the British Gas Stretford

Comments Received on Vanadium

process part IV: V-S-H2O thermodynamics and aqueous vanadium reduction in alkaline solutions. Journal of Applied Electrochemistry 23, 41-426, 1993. https://doi-org/10.1007/BF00707617.] The presence of other chemicals routinely used to treat public drinking water supplies (for example Cl and F compounds routinely added to water systems in the USA) only increases this complexity

There is evidence that the vanadium speciation can alter toxicity.[FN2: Roberts GK, Stout MD, Sayers B, Fallacara DM, Hejtmancik MR, Waidyanatha S, Hooth MJ. 14-Day Toxicity Studies of Tetravalent and Pentavalent Vanadium Compounds in Harlan Sprague Dawley Rats and B6C3F1/N Mice via Drinking Water Exposure. Toxicol Rep. 2016; 3:531-538. https://doi.org/10.1016/j.toxrep.2016.05.001. Epub 2016 May 12. PMID: 28042531; PMCID: PMC5193388. At the request of the Office of Water, the National Toxicology Program (NTP) is investigating the toxicity of solutions of sodium metavanadate and vanadyl sulfate and found toxicological differences in mice. However, corresponding data on the speciation of vanadium compounds present in US drinking water is, to the best of our knowledge, simply not available at this time. Absent this and other information, EPA has not demonstrated that vanadium presents the potential for a meaningful opportunity for health risk reduction for persons served by public water systems.

For CCL 5, EPA uses data collected from the Unregulated Contaminant Monitoring Phase 3 rule (UCMR3) where drinking water systems only measured total vanadium to score and rank vanadium. As a result of UCMR3, extensive data on the occurrence of vanadium species (measured as total V) were generated for water systems across the USA. VPRA believes that measuring total vanadium in drinking water is inappropriate and this approach was used against our recommendation during UCMR3. [FN3: https://www.regulations.gov/comment/EPA-HQ-OW-2009-0090-0059.] Specifically, the UCMR3 data capture all of the various oxidation states of vanadium under a single “vanadium” heading. EPA is inappropriately relying on the totality of occurrence data to grossly mischaracterize all vanadium species in drinking water as presenting a public health concern. It is not possible based on this data set for EPA to know the forms of vanadium that occur in drinking water or whether any forms of vanadium that may have an adverse effect on public health are “known to occur” in drinking water.

III. Toxicity Data Are Lacking to Support a Continued CCL Listing

While there are many safety studies of oral exposure to vanadium species available in literature, a close assessment of nearly all of them will show that they are inadequate for that purpose. The available studies have significant limitations compared to the traditional designs for studies conducted to support safety evaluations. The vanadium studies often don’t use standard designs or methods, leading to an inability to make comparisons between data sets. In most available studies, very limited endpoints have been evaluated, often only a few, which makes comparison of the effects to those reported in other studies impossible. Other deficiencies include that the test compound is often not sourced or analyzed, therefore the vanadium concentrations already present in food or water are not measured making the actual dose uncertain. As a result, it is not possible to establish the form of vanadium that may have an adverse effect on the health of persons with the current data set. These weaknesses in safety studies have resulted in divergent approaches to the derivation of an oral reference dose for vanadium compounds that can span two orders of magnitude.

Comments Received on Vanadium

For CCL 5, EPA is using the outdated Provisional Peer-Reviewed Toxicity Value (PPRTV) developed by EPA in 2009. [FN4: U.S. EPA, Provisional Peer-Reviewed Toxicity Values for Vanadium and Its Soluble Inorganic Compounds Other Than Vanadium Pentoxide (CASRN 7440-62-2 and Others) Derivation of Subchronic and Chronic Oral RfDs, EPA/690/R-09/070F Final 9-30-2009.] The toxicity value is orders of magnitude different from a more recent assessment of vanadium conducted by the Agency for Toxic Substances and Disease Registry (ATSDR) and is too uncertain to be utilized for the CCL listing. In fact, the PPRTV document acknowledges that the key study used (Boscolo et al., 1994) has low confidence, so much so that EPA has applied a 3000 fold uncertainty factor in total, the greatest amount that can be used in the development of a reference dose. [FN5: Boscolo, P; Carmignani, M; Volpe, AR; Felaco, M; Del Rosso, G; Porcelli, G; Giuliano, G. (1994). Renal toxicity and arterial hypertension in rats chronically exposed to vanadate. Occup Environ Med 51: 500-503. http://dx.doi.org/10.1136/oem.51.7.500.]

In a more recent review of vanadium safety, ATSDR determined the Boscolo 1994 study should not be utilized for development of a benchmark, specifically noting the effect in Boscolo was not consistently observed in other animal studies or in a study of healthy adults (Fawcett et al. 1997). [FN6: Fawcett JP, Farquhar SJ, Walker RJ, Thou T, Lowe G, Goulding A. The effect of oral vanadyl sulfate on body composition and performance in weight-training athletes. Int J Sport Nutr. 1996 Dec; 6(4):382-90. http://doi.org/10.1123/ijsn.6.4.382. PMID: 8953340.] As a result, EPA's reliance on the PPRTV is insufficient to establish a substantial likelihood that forms of vanadium which may have an adverse effect on public health will occur in public water systems with a frequency and at levels of public health concern. We also want to note that food is the primary route of exposure for the general population; with estimates of dietary vanadium intake ranging from 0.09 to 0.34 µg/kg/day in adults. [FN7: U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry. Toxicological Profile for Vanadium, September 2012. Page 31.] These estimated concentrations in daily food ingestion far exceed the toxicity benchmarks EPA is utilizing to develop the CCL 5 list.

EPA is aware of the shortcomings of the safety database on vanadium. At the Office of Water's request, the NTP is currently conducting toxicity studies on vanadyl sulfate (+4) and sodium metavanadate (+5) to fill identified gaps in science. These draft NTP reports have yet to be released. The utility of these studies will be limited without being able to correlate the results to speciated vanadium concentrations in drinking water. At EPA's Office of Water's request, the IRIS program also is conducting a review of vanadium and VPRA has raised similar concerns on the approach in comments. [FN8: https://www.regulations.gov/comment/EPA-HQ-ORD-2020-0183-0014.] [FN9: https://www.regulations.gov/comment/EPA-HQ-ORD-2020-0183-0027.] VPRA does not believe it is appropriate for EPA to continue to include vanadium as part of the SDWA regulatory process when EPA is not aware if any vanadium species are present in drinking water that present a public health concern, and in light of the significant uncertainties and low confidence in the toxicity information currently available.

IV. Conclusions

VPRA believes that vanadium does not meet the criteria for inclusion on the CCL. We recommend removing vanadium from inclusion on CCL 5 until data are available on the form of vanadium to which humans are exposed through drinking water and the toxicity of that form is understood.

Comments Received on Vanadium

It would be beneficial for EPA to carry out a program of research to identify the vanadium species actually present in drinking water and establish that they meet the CCL listing criteria as an important step toward correlating available toxicological data with the predominant vanadium compound the American public is exposed to in drinking water. Our industry is in the formative stage of planning a public workshop on the speciation and environmental fate of vanadium compounds and we would welcome an expression of interest and support from your office.

Individual Response: Please see Discussion on Individual Chemical Contaminants, Other Drinking Water Programs, and Other EPA Programs. 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.
https://ntp.niehs.nih.gov/ntp/results/pubs/posters/roberts_sot20190300.pdf
The critical study for the 2009 PPRTV assessment is described as a low confidence study by EPA's Office of Research and Development in the PPRTV document, though the confidence in the database is medium. The observed kidney toxicity endpoint selected as the critical effect is supported by a subchronic study (Domingo et al., 1985) that serves as the basis for the Institute of Medicine (IOM) Tolerable Upper Limit value (IOM, 2001). The PPRTV document includes a statement acknowledging the corroborating evidence provided by the Domingo et al. (1985) study. EPA acknowledges that the oxidation state of vanadium may influence the observed health effects. The exposure estimates in all of the toxicity studies in the PPRTV were converted to equivalent vanadium doses for the purpose of dose-response assessment since oral exposures to either vanadyl (+4) or vanadate (+5) result in internal exposures to a mixture of vanadyl and vanadate complexes as a result of reduction/oxidation (redox) reactions that occur in the gastrointestinal tract as well as in the blood and tissues. As a result of these physiological interconversions, the PPRTV document states that there is no firm toxicological basis for distinguishing dose-response relationships for these two forms given the currently available data. As such, the PPRTV applies to soluble inorganic vanadyl (+4) and vanadate (+5) compounds (other than vanadium pentoxide which is the subject of an IRIS review and separate PPRTV document). UCMR monitoring provides high quality nationally representative drinking water data for the water sector and EPA believes it was appropriately used in CCL 5 to evaluate the occurrence of total vanadium.

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.
https://ntp.niehs.nih.gov/ntp/results/pubs/posters/roberts_sot20190300.pdfThis study will contribute to the vanadium health effects database to be considered for the Regulatory Determination Process and/or future CCL cycles. The Roberts et al. (2014) study cited by the commenter was conducted in response to an EPA post Regulatory Determination 2 request to NTP to examine whether there are differences in the dose-response and target tissues between the vanadyl and vanadate ions. The authors concluded that there are potential differences in toxicity between vanadyl sulfate and sodium metavanadate but recognized that further studies are needed to fully understand the mechanisms of toxicity underlying these differences. With this information lacking, EPA must rely on the currently available health assessments and monitoring data for vanadium.

Comments Received on Vanadium

Additional health effects data for vanadium have become available since it was last considered through the CCL process. Inclusion of Vanadium on the CCL 5 indicates that vanadium will be considered for Regulatory Determination if both the occurrence and health effects data are adequate to support guideline development.

Molybdenum

Comments Received on Molybdenum

Comment Excerpt from Commenter 104

The International Molybdenum Association is aware from the Federal Register Vol. 86 No. 135 of 19 July 2021, that molybdenum (CAS No. 7439-98-7) is included in the US-EPA Drinking Water Draft Contaminant Candidate List 5. Molybdenum was also listed on CCL4 and CCL3, and was a substance for which occurrence monitoring took place under the UCMR 3 between 2013-2015.

When commenting on the Draft CCL4 in 2015, IMOA listed a series of technical submissions which we had already provided to US EPA Office of Water, to the attention of Dr. Joyce Donohue. (The list is repeated overleaf). Since then, further studies and documentation have become available, as summarized below:

- A two-generation reproductive toxicity study of sodium molybdate, dihydrate administered in drinking water or diet to Sprague-Dawley rats. Murray et al, 2019. Reproductive Toxicology 84 (2019) 75-92. https://doi.org/10.1016/j.reprotox.2018.11.004 . This Open Access peer-reviewed publication was submitted by IMOA in 2019 to EPA OoW (Dr. Donohue).

A copy of the following very recent documentation can be made available upon request to IMOA:

- In Vivo Micronucleus Assay of Sodium Molybdate Dihydrate by Oral Gavage in Sprague Dawley Rats. CRL Study No. 01439003. OECD 474 guideline compliant GLP study, May 2021.

- Oral (Diet) Developmental Toxicity Study of Sodium Molybdate Dihydrate in Rats, extending the dose ranges of the earlier Tyl 2013 study by 2 and 3-fold. CRL Study No. 20222165. OECD 414 guideline compliant GLP study, June 2021

- September 2021 Molybdenum Hazard identification and Risk Assessment Chemical Safety Report (300+ pages) prepared for compliance with the EU REACH Regulation.

US ATSDR published its Toxicological Profile for Molybdenum in May 2020, downloadable from: https://www.atsdr.cdc.gov/toxprofiles/tp212.pdf. Whilst largely an excellent document, worthy of particular note is that IMOA disagrees with the application of the Modifying Factor of 3 used to derive the intermediate oral Minimum Risk Level, and placed its concerns in writing to US ATSDR in correspondence dated 24 March 2021, also copied to EPA (Drs. Betsy Behl & Joyce Donohue).

The available toxicity datasets (including the most recent above-indicated data), assessments, and monitoring data, in IMOA's assessment do not warrant molybdenum remaining on the CCL list.

Comments Received on Molybdenum

Also noteworthy is that since 2011 the World Health Organisation Guidelines for Drinking Water Quality, Fourth Edition no longer establishes a formal guideline value for molybdenum in drinking water. Only for guidance purposes is a health-based value of 0.07 mg Mo/L indicated. The rationale for not deriving a formal guidance value is indicated as: '(Molybdenum) occurs in drinking water at concentrations well below those of health concern'. (Reference: pages 177 & 394 of The World Health Organization Guidelines for Drinking-Water Quality, Fourth Edition, 2011. ISBN 978 92 4 154815 1).

Key documentation already provided to EPA OoW between 2011-2015:

- Molybdenum Hazard Identification and Risk Assessment Report – 330 pages, (as prepared for the EU REACH Regulation No. 1907) - (E-mailed on 30 April 2011 & 8 August 2011)
- Final Report of GLP OECD protocol 408-compliant, sub-chronic 90-day oral repeated dose toxicity study, using sodium molybdate - (E-mailed 15 November 2011)
- Final Report of GLP OECD protocol 414-compliant Prenatal Developmental Toxicity study, using sodium molybdate - (E-mailed 13 August 2013)
- Links to Open Access peer-reviewed journal publications for both studies - (E-mailed on 11 May 2014 and 12 March 2015 respectively)

Copies of all the above are available upon request to IMOA.

Individual Response: Please see Discussion on Individual Chemical Contaminants. EPA appreciates the materials submitted to the Office of Water and communications about ongoing research activities of the International Molybdenum Association. The submitted publications that were published prior to Regulatory Determination 4 were considered during the Regulatory Determination 4 process. The available literature on molybdenum, including the publications provided and the final ATSDR Toxicological Profile for Molybdenum described in the comment, will be reviewed and considered during the Regulatory Determination 5 process.

Chemical Technical Support Documents

Agency Discussion on Chemical Technical Support Documents

Agency Topic Discussion:
EPA received multiple comments in support of continued improvement to CCL documentation, with several commenters recommending specific steps to facilitate transparency and clear communication of the CCL process. EPA appreciates this feedback and welcomes ways it can improve the public's understanding of how drinking water contaminants are listed to the CCL.

In drafting the CCL 5 documents, EPA attempted to strike a balance between providing enough detail to adequately describe the three-step selection process, while also being concise enough with descriptions for the public to be able to review all published materials within the allotted review time. As one commenter noted, however, there were still more than 1,300 pages of technical support documentation for the public to review and evaluate within a 60-day comment period for the Draft CCL 5 Federal Register Notice. EPA recognizes this user-side challenge and will consider reducing the overall length of supporting materials and/or providing a longer 90-day comment period for future

Agency Discussion on Chemical Technical Support Documents

draft CCLs.

One notable change to CCL 5 compared to previous CCLs is to the overall support document organization; unlike with the CCL 3 and CCL 4 technical support documents that contained descriptions for the three process steps (i.e., Building the Universe, Screening, and Classification/Selection) across multiple documents, CCL 5 consolidated the descriptions for these steps under single documents for both the chemical and microbial processes. EPA believes this streamlined approach improves users' accessibility to the published materials and better communicates how Steps 1-3 of the CCL process function in their sequential order.

Two commenters requested that EPA expand on the process used to "off-ramp" contaminants that appeared previously for CCL 4 but were not listed on CCL 5. Out of the 97 chemicals or chemical groups listed on CCL 4, there were 67 not listed onto CCL 5; below is a summary for those 67 chemicals (a more detailed table is provided in Appendix O of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a):

- 45 chemicals from CCL 4 failed to qualify for the PCCL 5 based on screening points calculated below the inclusion threshold during Step 2 of the process (see Chapter 3 of the Final CCL 5 Chemical Technical Support Document).
- 11 chemicals from CCL 4 that qualified for the PCCL 5 were determined as "not list" decisions by EPA's chemical evaluators during Step 3 of the process (see Section 4.5 of the Final CCL 5 Chemical Technical Support Document).
- 8 chemicals from CCL 4 that qualified for the PCCL 5 were removed from consideration due to their pending review status under Regulatory Determination 4 (see Section 3.7.1 of the Final CCL 5 Chemical Technical Support Document).
- 2 chemicals from CCL 4 that qualified for the PCCL 5 were removed from consideration based on their status as cancelled, not-persistent pesticides (see Section 3.7.2 of the Final CCL 5 Chemical Technical Support Document).

EPA also received one comment in support of the improvements made for the Contaminant Information Sheets (CIS) for the CCL 5 and another comment stating concerns about "under-representation of data for contaminants with isomers" on the CIS.

EPA developed a chemical CIS, a concise 4-page profile, for each chemical on the PCCL 5 that was evaluated by the chemical evaluators to assist them in making listing recommendations for the CCL 5. Each CCL 5 chemical CIS presents a chemical's health and occurrence data gathered from primary and supplemental data sources, health and occurrence statistical measures and attribute scores, usage information, identity information (i.e., chemical name, CASRN, and DTXSID), past CCL status, CCL 5 public nomination status, and past negative regulatory determination information.

For CCL 5, EPA improved upon the CCL 3 and CCL 4 CISs by modifying the CIS format to make the Chemical data easier to use and interpret. EPA utilized principles of effective data visualization for the new CIS design, such as: incorporating visual elements such as color and shading, simplifying data tables, and emphasizing key areas most important to the chemical evaluators and stakeholders. Additional improvements included a simplified CIS Key, an annotated graphic illustration, to assist with interpretation of the updated CIS design and a reference page for each CIS that contains full

Agency Discussion on Chemical Technical Support Documents

references for bracketed citations located on the CIS.

EPA will continue to improve the CIS design and chemical data presentation for future CCL cycles.

Comments Received on Chemical Technical Support Documents

Comment Excerpt from Commenter 55

However, to me, the more concerning point is that there seems to be under-representation of data for contaminants with isomers. I'll use cypermethrin as an example and point specifically to (what I consider) the misuse of the estimated annual USGS pesticide application use data. According to the data presented in the Contaminant Information Sheets, in 2016, there were 14 states with estimated cypermethrin application. However, when one goes to the 2016 USGS Pesticide Use Data (https://water.usgs.gov/nawqa/pnsp/usage/maps/county-level/), there's more to the story. While what is labelled as cypermethrin was used in 14 states, alpha-cypermethrin is used in 20 states, and zeta-cypermethrin is used in 45 states. However, both alpha-cypermethrin and zeta-cypermethrin are conspicuously absent from the PCCL, presumably because they aren't considered distinct enough for their own consideration -- after all, cypermethrin often contains one or both of these isomers. But if that's the case, data on those isomers should certainly be included with cypermethrin. The estimated amount applied per year is also way underestimated if all isomers are considered. The value given in the CIS form for cypermethrin matches the low estimate from USGS for only "cypermethrin": 23,804 lb/year. In reality, when one looks at all three isomers ("cypermethrin", "alpha cypermethrin", "zeta cypermethrin") in the USGS report, even by the low estimate, there are an estimated 180,600 lb applied per year. That's a whole order of magnitude. I didn't even get a chance to look at the NAWQA occurrence data for cypermethrin, but in the final CCL, I'd like to see some confirmation that the NAWQA data includes applicable isomers. As it stands, prevalence and magnitude are under-reported for cypermethrin and likely several other contaminants that consist of multiple isomers.

It seems the methodological problem is resulting from each isomer having its own DTXSID. But though they have different DTXSIDs, it's clear that these isomers should be taken into consideration. So in conclusion, there should be (1) some reconsideration of how to combine data on isomers, since those contaminants' occurrence data are otherwise under-reported; and beyond that, (2) some consideration on how to consider functional analogs that themselves lack important data.

And again, while I only touched briefly on one contaminant (cypermethrin) in one functional group (pyrethroids), there are other contaminant groups, especially some other pesticides such as triazines, that EPA should consider in terms of the issues of isomerism and functional groupings.

Individual Response: Please see Discussion on Chemical Technical Support Documents.
EPA has also updated the Contaminant Information Sheets (CISs) for cypermethrin and four other contaminants to clarify which data entries are associated with other forms of the contaminant; the other contaminant include, lithium, manganese, propiconazole, and vanadium (please see Technical Support Document for the Final Fifth Contaminant List (CCL 5) – Contaminant Information Sheets, hereafter referred to as the Final CCL 5 CIS Technical Support Document (USEPA, 2022b).

Comment Excerpt from Commenter 60

As a regular user of water, like many other Americans, it is imperative that the EPA continue to

Comments Received on Chemical Technical Support Documents
generate the Containment Candidate List (CCL) which the Safe Drinking Water Act (SDWA) mandates is published every five years. After reviewing the lists of different contaminants in our water, the EPA has done a thorough job of listing and also providing explanations to the public of what these contaminants are so it is easier for the public to understand. The list can be intimidating to some and also has the ability to put fear of drinking water into others. Though I understand that simplifying most of the list for the general public is difficult, there should be a way to provide a more general breakdown of the list to everyone. Unfortunately in the U.S. there are areas where water contamination is terrible, thankfully this is not the norm. I appreciate the publishing of this list since 1996 and hope the EPA continues to do so, in hopes that efforts are made to continue to make our water safer for everyone. I propose the EPA make a more easily digestible document for the public, maybe one with pictures and explanations so all can learn from it and have any fears set aside. Thank you. **Individual Response:** Please see Discussion on Chemical Technical Support Documents. For general information on CCL and the process, please visit the EPA CCL website.
Comment Excerpt from Commenter 71 In this same vein, AMWA requests that EPA clarify the process for removing a contaminant from the CCL. In a 2016 report from the Science Advisory Board (SAB) reviewing the agency's draft CCL 4, the SAB requested that EPA clearly describe the "off-ramp" process for removing contaminants from one CCL to another. This process was unclear to the SAB and continues to be unclear to AMWA. If no process currently exists, AMWA urges EPA, with the help of the SAB, to develop a clear and concise protocol to help the agency further prioritize contaminants on future CCLs. A process of this type is critical to maintaining a more concise CCL, which the agency could use more effectively for prioritizing research. If this process already exists and was used for CCL 5, AMWA requests that EPA make this more apparent by including the relevant documents within the docket. Correspondingly, AMWA requests that EPA provide a simple one or two-page document highlighting any changes from the previous CCL. Most importantly, this document should contain information on which chemicals were carried over, removed, and added. Currently, to determine this, a member of the public must dig through supplemental documents within the docket. AMWA also suggests that EPA include a simple explanation as to why a substance was removed or retained. Including a single document explaining which chemicals were added or removed would improve transparency and clarity for the public. **Individual Response:** Please see Discussion on Chemical Technical Support Documents and Other Drinking Water Programs. The commenter mentions an "off-ramp" process for removing contaminants from one CCL to another. The CCL 5 was developed using the best available occurrence and health effects data at the time and utilizing an improved process. Based on that data and the process used for CCL 5, some contaminants from previous CCL were also listed on CCL 5 while other were not. In regard to the commenter's statement related to the prioritization of the CCL, EPA has provided a table that includes the data availability of occurrence data and health effects data 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), is presented in Exhibit 4.
Comment Excerpt from Commenter 71 AMWA thanks EPA for including a table within the Federal Register notice that summarizes the available occurrence data, health assessments, and analytical methods for each CCL 5 contaminant.

Comments Received on Chemical Technical Support Documents
AMWA encourages EPA to show similar documentation for the ongoing state of prioritization for the contaminants included in the CCL. This documentation might be as simple as stating a contaminant is currently a "high," "low," or "medium" priority and including the agency's rationale behind the characterization. The association also suggests that EPA develop similar documentation on the state of the research for each contaminant. AMWA encourages the agency to provide this information online and to update this information regularly outside of the standard CCL publication within the Federal Register **Individual Response:** Please see Discussion on Chemical Technical Support Documents and Other Drinking Water Programs. In developing CCL 5, EPA purposely avoided establishing a prioritization schema for the listed contaminants; rather, the determination regulatory priorities for drinking water contaminants fall within the scope of EPA's Regulatory Determination programs, which follows the CCL listing process.
Comment Excerpt from Commenter 75 ASDWA supports the process EPA used to develop CCL 5. The work the Agency completed to profile and review thousands of contaminants is appreciated. ASDWA supports the approach of not automatically carrying over contaminants from CCL 4 to CCL 5. However, ASDWA recommends that EPA provide further details on why contaminants from CCL 4 were not also listed on CCL 5 when no regulatory determination was made. For example, did new research come to light on the contaminant's occurrence or health effects? Did another EPA program address this contaminant making it less of a threat for drinking water sources? ASDWA recommends that EPA develop a summary for the final CCL 5 for the 68 contaminants listed on CCL 4 but not listed on draft CCL 5. A chart or table with some basic explanatory text would suffice. EPA's transparency in this determination process is appreciated and especially helpful for state programs that may be monitoring and tracking emerging drinking water contaminants. **Individual Response:** Please see Discussion on Chemical Technical Support Documents.

Comments Received on Chemical Technical Support Documents

Comment Excerpt from Commenter 77

[AWWA offers the following recommendations for EPA to consider as the CCL 5 is finalized and in the development of future CCLs.]

Contaminant Information Sheets

The EPA Technical support document, "Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) - Contaminant Information Sheets," represents a substantial body of background research. This document is, in many ways, central to EPA's efforts to assure that the CCL process is transparent to the public and interested stakeholders. AWWA commends the Agency for continuing to include these information sheets in the CCL docket and on its efforts to improve on previous CCL contaminant information sheets. [FN13: EPA. 2008. Contaminant Information Sheets for the PCCL Chemicals Considered for CCL 3. EPA-HQ-OW-2007-1189-0043.] [FN14: EPA. 2015. Contaminant Information Sheets (CISs) for the Draft Fourth Preliminary Contaminant Candidate List (PCCL 4) Nominated Contaminants. EPA 815-R-15-003.] [FN15: EPA. 2016. Contaminant Information Sheets (CISs) for the Final Fourth Contaminant Candidate List (CCL 4). EPA 815-R-16-003.] The improvements to the formatting of the sheets for CCL 5 facilitate stakeholder review of EPA's use of available data.

The information sheets also set the stage for EPA to elevate the influential aspects of the SDWA decision-making processes in the CCL preamble more clearly:

1. The role of changing assumptions in setting health reference levels
2. Influential data gaps in the CCL process

Individual Response: Please see Discussion on Chemical Technical Support Documents.

Comments Received on Chemical Technical Support Documents

Comment Excerpt from Commenter 77

Transparency

EPA has a duty to transparently present the evidentiary basis for its decision-making not only as a matter of sound government but also in order to comply with Executive Orders and statutory requirements. [FN16: Presidential Memorandum. 2021. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking.] [FN17: OMB. 2002. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication.] This duty applies to influential documents, like the CCL, as well as formal rulemakings.

The Draft CCL 5 Federal Register notice docket is much more concise and focused than many EPA dockets (in large part due to the organization provided by the chemical information sheets). That the CCL 5 universe is more than three times larger than the CCL 3 universe dataset illustrates the growing need for of a concise summary. [FN18: EPA. 2008. Contaminant Candidate List 3 Chemicals: Identifying the Universe. EPA 815-R-08-002. EPA-HQ-OW-2007-1189-0037.] Even so, there are more than 1,300 pages of technical support documentation for the public to review and evaluate within a 60-day comment period. It is not clear from the contaminants listed and the information provided in the Draft CCL 5 Federal Register notice and technical support documents that EPA fully explained how it created the Draft CCL 5. This is not a new challenge. In reviewing the draft CCL 3, the Science Advisory Board observed that the Agency made judgements within the CCL 3 process that were not readily apparent in CCL process documentation. [FN19: SAB. 2009. SAB Advisory on EPA's Draft Third Drinking Water Contaminant Candidate List (CCL3).]

Individual Response: Please see Discussion on Chemical Technical Support Documents.

Microbial Screening Process/Criteria

Agency Discussion on Microbial Screening Process/Criteria

Agency Topic Discussion:

The CCL microbial process consists of 12 exclusionary screening criteria developed during CCL 3 and is used for initial screening of pathogens in the microbial universe for placement on the PCCL. As the pathogens are screened through the 12 criteria, if a pathogen meets one criterion, the pathogen will be excluded from moving on to the PCCL. All pathogens that pass through all screening criteria are moved to the PCCL.

For the CCL 5, EPA re-evaluated the 12 criteria for applicability to microbes and reviewed certain criteria in depth per recommendations received from previous CCL Science Advisory Boards.
For past CCLs, microorganisms that had outbreaks with no connection to contaminated distribution system water as their cause were screened out. Thus, outbreaks occurring due to nosocomial exposure or attributable to recreational water resulting from post-delivery contamination of drinking water were not sufficient to place a microorganism on the PCCL unless the drinking water was shown to be contaminated. A literature search was conducted for citations from 2009-2019 to look for

Agency Discussion on Microbial Screening Process/Criteria

evidence of waterborne diseases for certain microbes that were excluded using Criterion 9 (Natural habitat is in the environment without epidemiological evidence of drinking water-related disease). There is now evidence of either aerosol transmission from water or water-linked transmission for several microorganisms that were excluded from the PCCL 3. Therefore, for CCL 5, criterion 9 was revised to also allow microorganisms that cause nosocomial infections where drinking water was is implicated to be screened through for evaluation of listing on the CCL.

Comments Received on Microbial Screening Process/Criteria

Comment Excerpt from Commenter 77

In reviewing the CCL 5 process as described by the Agency, AWWA found:

1. The Science Advisory Board review of CCL 4 led EPA to modify Criterion 9 in its screening of microbial contaminants to no longer exclude pathogens for which the only drinking water-related infections were nosocomial epidemiology. [FN20: SAB. 2016. Review of the EPA's Draft Fourth Contaminant Candidate List (CCL4).] This is a substantial and important change to the CCL process as nosocomial infections occur under a unique combination of exposure scenarios and involve individuals that are very susceptible to infection. Nosocomial infections often involve individuals or exposure scenarios that require a completely sterile environment. This change was important to the inclusion of *Mycobacterium abscessus* and *Pseudomonas aeruginosa* in CCL 5, but neither the Draft CCL 5 Federal Register Notice nor the "Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) - Microbial Contaminants" describe the weight-of-evidence approach used when applying the revised Criterion 9. If EPA finalizes CCL 5 retaining the incorporation of this modified criterion, it must more clearly describe its approach to implementing the revised criterion.

Individual Response: Please see Discussion on Microbial Screening Process/Criteria.
EPA addresses this comment in the document Technical Support Document for the Final Fifth Contaminant Candidate List (CCL 5) - Microbial Contaminants.

Draft CCL 5-Microbes

Agency Discussion on Draft CCL 5-Microbes

Agency Topic Discussion:
As specified in Section 1412(b)(1) of the 1996 Safe Drinking Water Act (SDWA) Amendments, the CCL must include contaminants that are not subject to any proposed or promulgated National Primary Drinking Water Regulations.

The Microbial Disinfection By-product (MDBP) rulemaking and the Regulatory Determination process are separate processes from the listing of a contaminant on the CCL and are both outside the scope of the CCL process.

Comments Received on Draft CCL 5-Microbes
Comment Excerpt from Commenter 89 We also urge inclusion in the MDBP rulemaking and a positive regulatory determination for key priority microbes, including some of the agency's most highly ranked pathogens including *Naegleria fowleri, Legionella pneumophila, E. coli (O157), Pseudomonas aeruginosa, Helicobacter pylori, Campylobacter jejuni, Mycobacterium abcessus, Shigella sonnei*, Caliciviruses, and *Mycobacterium avium*. These and other pathogens, including those on EPA's proposed CCL 5, can and should be efficiently considered as part of the upcoming MDBP rulemaking. As additional information becomes available, we may add to the list of chemicals and pathogens for which we recommend a positive regulatory determination. Overall, EPA should include in the CCL 5 all 66 individual chemicals and 12 microbes proposed if regulatory action has not been initiated for them with an urgent threat to health finding or a positive regulatory determination. **Individual Response:** Please see Discussion on Draft CCL 5-Microbes and Other Drinking Water Programs (RegDet; UCMR).
Comment Excerpt from Commenter 89 Finally, we believe that several of the pathogens that ranked high on EPA's assessment should also be considered immediately for positive regulatory determinations and inclusion as appropriate in the upcoming MDBP rulemaking, including for example Naeg*leria fowleri, Legionella pneumophila, E. coli (O157), Pseudomonas aeruginosa, Helicobacter pylori, Campylobacter jejuni, Mycobacterium abcessus*, *Shigella sonnei*, Caliciviruses, and *Mycobacterium avium*. **Individual Response:** Please see Discussion on Draft CCL 5-Microbes and Other Drinking Water Programs (RegDet; UCMR).

Legionella pneumophila

Agency Discussion on *Legionella pneumophila*

Agency Topic Discussion: *Legionella pneumophila* is a pathogenic bacterium that is commonly found in moist environments including drinking water sources. *Legionella* bacteria can multiply in water distribution systems and building plumbing under certain conditions, such as inadequate disinfectant level, high water age, and warm water temperatures. These conditions usually occur in buildings with large or complex water piping systems. However, these conditions can also occur under certain circumstances in drinking water distribution systems.

Legionellosis is the name for two diseases, Pontiac Fever and Legionnaires' disease, *Legionella* bacteria can cause. Pontiac Fever is a mild, flu-like illness and usually resolves on its own and Legionnaires' Disease is a type of pneumonia (lung infection) that can have serious health implications generally requires treatment.

Legionella pneumophila is proposed for CCL 5 because it has been identified in numerous Waterborne disease outbreaks and is the most common cause of reported drinking water-associated outbreaks in the U.S.

The Surface Water Treatment Rules (SWTR) (54 FR 27486, USEPA, 1989a) established a maximum contaminant level goal (MCLG) of zero for *Legionella*. Since measuring disease-causing microbes in drinking water was not considered to be feasible at the time of the development of the SWTR, EPA established treatment technique for *Legionella*. However, *Legionella* is subject to limitations through the treatment techniques under the SWTRs.

Because *Legionella pneumophila* is a known public health risk associated with distribution and building water systems, *Legionella pneumophila* is listed on the CCL.

Furthermore, *Legionella pneumophila* was the most nominated contaminant for CCL 5, receiving 18 nominations.

Comments Received on *Legionella pneumophila*

Comment Excerpt from Commenter 62

To argue in reference to the already existing nominations, this commentary seeks to add further support of 2 contaminants: a) *Legionella pneumophila*; and b) HAA6Br, known as brominated halo acetic acids.
We maintain that these 2 contaminants have been overlooked over the years due to poor plumbing or outdated rules, and their dangers have been caused to prove illness either in humans or laboratory animals.

Individual Response: Please see Discussion on *Legionella pneumophila* and DBPs. EPA agrees with listing *Legionella pneumophila* on the CCL 5.

Comment Excerpt from Commenter 62

A) *Legionella pneumophila*: a naturally occurring bacterium found in water, particularly in fresh bodies of water. When inhaled by small droplets, it can cause serious lung disease (Legionnaires Disease), particularly with the vulnerable. The bacterium can be present in old water pipes, outdated air conditioners, and sewage systems and is very difficult to treat as the bacteria attaches itself to pre-existing biofilms and is resilient to biocides (1)

Comments Received on *Legionella pneumophila*

(1)Kim, B. R., Anderson, J. E., Mueller, S. A., Gaines, W. A., and Kendall, A. M. (2002). "Literature review-efficacy of various disinfectants against Legionella in water systems." Water Res. 36, 4433-4444. doi: 10.1016/S0043-1354(02)00188-4.

Individual Response: Please see Discussion on *Legionella pneumophila* and DBPs.

Comment Excerpt from Commenter 75

The following comments provide additional detail on contaminants listed on the Draft CCL 5 that are a particular concern for state drinking water programs.]

Legionella

Legionella continues to present a microbial concern for states and is the most significant cause of waterborne disease outbreaks. Although the key to preventing Legionnaires' disease is ensuring building owners and managers maintain building water systems to reduce the risk of *Legionella* growth and spread, water systems play a crucial role in delivering safe and high-quality water to these buildings.

Part 141.3 of the National Primary Drinking Water Regulations, which is based on Section 300g-1 (a) of the Safe Drinking Water Act, specifies that buildings served by a public water system that meet criteria that might otherwise make them a consecutive water system, are not regulated if they meet four criteria, the first of which is that they do not treat the water. Treatment is not defined in this exception which leaves it open to state interpretation, although EPA has issued guidance on the definition of treatment (EPA WSG 8, 8A & H26). As awareness of *Legionella* continues to grow, some buildings are installing devices or treatment to address microbial contaminants, including *Legionella*, in their plumbing. States have taken various approaches to address building water systems, ranging from regulating them as public water systems, contacting critical categories of water users (like health care facilities) to request documentation about any treatment that might be installed to relying on state or local building codes to govern these facilities rather than actively regulating them. The biggest concern for states as they consider how to address building water systems is the state resources needed to regulate these facilities. Also, assuring treatment effectiveness and optimization coupled with a health care facility's CMS-required Water Management Plan are additional challenges for all involved professionals. While many thousands of new public water systems could result from aggressively identifying and regulating buildings water systems, potential adverse public health consequences can occur by not regulating building water systems, including chemical overfeeds.

While it is primarily considered a premise plumbing problem, studies have also linked *Legionella pneumophila* to detections and amplification in storage tanks, and the water sector should be looking holistically at addressing this contaminant. ASDWA recommends that EPA develop a holistic research strategy in coordination with the Centers for Disease Control and Prevention (CDC) for this contaminant, including new or validated analytical methods, occurrence research and regulatory strategies for reducing occurrence. This should include research on the removal of protozoa that harbor *Legionella* and compare this to the CT (concentration of a disinfectant multiplied by the contact time) and log filtration credit for Cryptosporidium and Giardia. Additional research is needed on amoebae serving as a seeding vehicle for Legionella in the distribution system and premise plumbing to ensure confidence that the existing treatment technique adequately addresses Amoebae-Legionella interactions. Such a research plan should also include developing directions

Comments Received on *Legionella pneumophila*

detailing when and where to test for Legionella pneumophila and remediation actions to take once it is found. Jointly developed guidance from EPA and CDC in this area is needed and welcome.

Individual Response: Please see Discussion on *Legionella pneumophila* and DBPs. EPA agrees that *Legionella pneumophila* is a microbial concern and mitigating *Legionella* in drinking water systems and building water systems is a complex issue. EPA agrees additional research is needed for *Legionella* and will consider the commenter's research recommendations.

Comment Excerpt from Commenter 77

[AWWA offers the following recommendations for EPA to consider as the CCL 5 is finalized and in the development of future CCLs.]

CCL Development Process

There are aspects to the Draft CCL 5 that EPA should address in preparing the Final CCL 5 and in preparation of future CCLs.

Coordination with Other SDWA Processes

The Draft CCL 5 includes many microbial pathogens and disinfection byproducts (M/DBPs). Some of these contaminants, like Legionella pneumophila and brominated haloacetic acids, are currently the focus of EPA's effort to consider potential revisions of M/DBP rules. [FN10: EPA, 2021. Potential Revisions of Microbial and Disinfection Byproducts Rules. Accessed August 24, 2021.] EPA presentations as part of the ongoing stakeholder process have raised the possibility of including a wider range of pathogens and DBPs. [FN11: Ibid] The ongoing regulatory development process for M/DBPs is occurring on a short, fixed schedule to comply with a legal settlement (i.e., the same lawsuit that set a schedule for finalizing the CCL 5). [FN12: 2020. Waterkeeper Alliance, Inc. et al. v. US. EPA and Andrew Wheeler. (19 Civ.899 (LJL), U.S. District Court Southern District of New York).]

Despite the parallel timing of the Draft CCL 5 Federal notice with the M/DBP process, EPA has not provided any information regarding how the inclusion of pathogens and DBPs on the CCL 5 will impact the potential revisions, or vice versa. The Final CCL 5 Federal Register notice should address how these two processes will interplay with respect to M/DBPs.

Individual Response: Please see Discussion on *Legionella pneumophila*, DBPs and Other Drinking Water Programs.

Mycobacterium

Agency Discussion on *Mycobacterium*

Agency Topic Discussion:

Mycobacterium abscessus and *Mycobacterium avium* are listed on the CCL 5. *Mycobacterium abscessus* and *Mycobacterium avium* are species of *Mycobacterium* that have adverse health risks and that have been identified in recent waterborne disease outbreaks**.** Mycobacterium abscessus is a bacterium that has never been on the CCL before. *Mycobacterium avium* has been listed on CCL 3 and 4.

Comments Received on *Mycobacterium*

Comment Excerpt from Commenter 77

Inclusion of Mycobacterium avium and M. abscessus

AWWA supports the inclusion of Mycobacterium avium and M. abscessus on CCL 5. AWWA has previously recommended the inclusion of M. avium for inclusion in the CCL. [FN32: AWWA, 2009, Comment submitted on Drinking Water Contaminant Candidate List 3 – Draft, EPA-HQ-OW-2007-1189-0100.] [FN33: AWWA.2015. Comment submitted on Drinking Water Contaminant Candidate List 4 – Draft, EPA-HQ-OW-2012-0217-0059.] M. avium and M. intracellulare, which are very similar genetically, are responsible for the greatest majority of recognized pulmonary nontuberculous mycobacterial disease in the United States, but the number of cases of M. abscessus is growing rapidly. [FN34: Kasperbauer, Shannon H. 2017. Nontuberculous Mycobacteria (NTM) Overview. National Jewish Hospital. Accessed 9/2/2021 at https://www.nationaljewish.org/conditions/ntm-nontuberculous-mycobacteria/ntm-nontuberculous-mycobacteria-overview] [FN35: Johansen, M.D., Herrmann, JL. & Kremer, L. Non-tuberculous mycobacteria and the rise of Mycobacterium abscessus. Nat Rev Microbiol 18, 392–407 (2020). https://doi.org/10.1038/s41579-020-0331-1] CDC does not identify drinking water as a key exposure for M. abscessus but case studies of nosocomial infections have involved on-site uses of potable water. [FN36: CDC. Mycobacterium abscessus in Healthcare Settings. Accessed 9/3/2021 at https://www.cdc.gov/hai/organisms/mycobacterium.html]

For simplicity, researchers and clinicians will refer to “non-tuberculosis Mycobacterium” (e.g., a group of 190 non-tuberculosis Mycobacterium) (NTM). [FN37: Clinical Infectious Diseases, Volume 71, Issue 4, 15 August 2020, Pages e1–e36, https://doi.org/10.1093/cid/ciaa24138] The NTM nomenclature was initially a product of available analytical tools (i.e., phenotypic criteria based on colony morphology and biochemical metabolism) and an international focus on addressing tuberculosis. [FN38: Runyon EH: Typical mycobacteria: their classification. Am Rev Respir Dis. 1965;91:288–9.] Only nine NTM are generally associated with disease. [FN39: Kasperbauer, Shannon H. 2017. Nontuberculous Mycobacteria (NTM) Overview. National Jewish Hospital. Accessed 9/2/2021 at https://www.nationaljewish.org/conditions/ntm-nontuberculous-mycobacteria/ntm-nontuberculous-mycobacteria-overview40] [FN40: Note mycobacteria avium complex is defined as a group of 10 mycobacteria species.] At present, with our understanding of the Mycobacterium species that represent a significant health threat, NTM is not an appropriate grouping to include in the CCL.

Individual Response: Please see Discussion on *Mycobacterium*. EPA agrees with listing speciated Mycobacterium, *Mycobacterium abscessus* and *Mycobacterium avium* on the CCL 5.

Contaminants Not on the Draft CCL 5 (Hepatitis A and *Salmonella enterica*)

Agency Discussion on Contaminants Not on the Draft CCL 5

Agency Topic Discussion:
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 National Outbreak Reporting System indicate that the route of exposure is not waterborne for the majority of infections.

Data reported to CDC's National Outbreak Reporting System suggest that there has been a decline in the occurrence of Hepatitis A outbreaks in public drinking water systems. These findings support the proposal to exclude hepatitis A from CCL 5. In addition, no waterborne outbreaks for Hepatitis A were reported during 2009–2017. However, EPA acknowledges that Hepatitis A reported cases have increased and is a public health issue, however the etiology is unknown.

Although *Salmonella enterica* was listed for CCL 3 and CCL 4, nominated for CCL 5, and continues to have serious health risks, data reported to CDC's National Outbreak Reporting System suggest the route of exposure for outbreaks documented between 2009-2017 were not waterborne. Instead, the numerous *Salmonella* outbreaks within the timeframe examined for CCL are reported as foodborne exposure.

Therefore, Hepatitis A and *Salmonella enterica* are not listed on CCL 5.

Comments Received on Contaminants Not on the Draft CCL 5

Comment Excerpt from Commenter 98
The presence of microbes like the Hep A virus and a strand of salmonella on the list is crucial to the future protection of our water and health in accordance with the SDWA. I acknowledge the possible costs that could come from regulating some of these newer chemicals, but the costs are outweighed by the benefits. The continued battle to keep our drinking water safe in today's age of newfound chemical usage should always be a priority, and the CCL 5 is certainly a step in the right direction.

Individual Response: Please see Discussion on Contaminants Not on the Draft CCL 5. Hepatitis A and *Salmonella enterica* did not have high enough composite scores for occurrence (waterborne disease outbreaks and occurrence supported by literature) and health effects to place them in the 12 highest scoring microbes, placing them on the CCL 5.

Perchlorate

Agency Discussion on Perchlorate

Agency Topic Discussion:
EPA received multiple comments regarding the July 21, 2020, decision to not regulate perchlorate in drinking water; this decision withdrew a previous positive regulatory determination for perchlorate made on February 11, 2011, under the second cycle of the Regulatory Determination process. While CCL and Regulatory Determination are interrelated, they are separate steps to the drinking water regulatory process authorized under SDWA.

Agency Discussion on Perchlorate

In its 2020 decision, EPA determined that perchlorate does not presently occur with a frequency and at levels of public health concern within the meaning of the SDWA. In addition, in the judgment of the EPA Administrator at that time, regulation of perchlorate did not present a "meaningful opportunity for health risk reduction for persons served by public water systems." For a full explanation on why the agency chose to reverse the positive regulatory determination for perchlorate, refer to the federal register notice "Drinking Water: Final Action on Perchlorate" (85 FR 43990, USEPA, 2020).

On March 31, 2022, EPA announced that it completed review of a July 2020 determination and concluded that the 2020 decision is supported by the best available peer reviewed science. Additionally, EPA announced multiple integrated actions to ensure that the public health is protected from perchlorate in drinking water. For additional information see EPA's Plan to Address Perchlorate Contamination.

While EPA is not pursuing a drinking water regulation for perchlorate at this time, the agency will continue to consider new information on the health effects and occurrence for the inclusion of perchlorate on future CCLs and potential future regulation under the Safe Drinking Water Act.

Comments Received on Perchlorate

Comment Excerpt from Commenter 87

Finally, we strongly urge you to reconsider, and to ultimately reverse, the arbitrary, capricious, and unlawful decision by the previous administration not to regulate Perchlorate under the SDWA. As you are undoubtedly aware, EPA correctly determined a decade ago that Perchlorate meets the statutory criteria set forth in SDWA section 1412(b)(1)(A), and the agency thus published a proposed drinking water standard to regulate this extremely dangerous contaminant. As EPA acknowledged when it decided last year to reverse course and not finalize a drinking water standard for Perchlorate, EPA had never before reversed a SDWA regulatory determination. The agency had no legitimate factual or legal basis to do so here. Not only did the decision defy a court order and the law, it ignored the science that—according to the American Academy of Pediatrics and many others—dictates a strong perchlorate standard to protect vulnerable kids. We urge you to reverse the decision of the previous Administration and to re-propose the Perchlorate rule, with a strict standard along the lines of those already adopted in California and Massachusetts.
Respectfully submitted,
Daniel E. Estrin
General Counsel and Advocacy Director

Individual Response: Please see Discussion on Perchlorate.

Comment Excerpt from Commenter 97

EPA must also reverse its 2020 decision not to regulate perchlorate contaminants levels in drinking water under the SDWA.

Individual Response: Please see Discussion on Perchlorate.

Comment Excerpt from Commenter 101

EPA must also reverse its 2020 decision not to regulate perchlorate contaminants levels in drinking water under the SDWA. Perchlorate is an extremely dangerous industrial chemical used for things like rocket fuel and should not be in our tap water. EPA already determined, nearly 10 years ago, that perchlorate meets the SDWA requirements for regulation and already published a proposed standard.

Comments Received on Perchlorate

It is important for the health of our children that EPA adopts safe limits for perchlorate in drinking water and there is no good reason for EPA not to take this action.

Individual Response: Please see Discussion on Perchlorate.

Comment Excerpt from Commenter 103

EPA must also reverse its 2020 decision not to regulate perchlorate contaminants levels in drinking water under the SDWA. Perchlorate is an extremely dangerous industrial chemical used for things like rocket fuel and should not be in our tap water. EPA already determined, nearly 10 years ago, that perchlorate meets the SDWA requirements for regulation and already published a proposed standard. It is important for the health of our children that EPA adopts safe limits for perchlorate in drinking water and there is no good reason for EPA not to take this action.

Individual Response: Please see Discussion on Perchlorate.

Endocrine Disruptor Chemicals (EDCs) and Pharmaceuticals and Personal Care Products (PPCPs)

Agency Discussion on EDCs and PPCPs

Agency Topic Discussion:

Early in the CCL development process, EPA evaluated 134 potential primary data sources that were used for building the CCL 5 Universe. As directed by SDWA, EPA considered health effects and occurrence data sources to identify unregulated contaminants that present the greatest public health concern related to exposures from drinking water. Table 1, Table 2, Appendix A, and Appendix N of the Final CCL 5 Chemical Technical Support Document provide additional details on the data sources used for CCL 5 (USEPA, 2022a). Many of the data sources included health effects data on endocrine disruption, such as the Endocrine Disruption Screening Program (EDSP) data incorporated from the CompTox Dashboard. CCL 5 data sources also included many contaminants which are considered to be pharmaceuticals and personal care products (PPCPs). Therefore, endocrine disruption, as a health effect, and PPCPs were included in the CCL 5 process with the other chemicals in the CCL 5 Universe.

Comments Received on EDCs and PPCPs

Comment Excerpt from Commenter 53

To Whom It May Concern:

I support the regulation of the "66 individual chemicals, 12 microbes, and three chemical groups - per- and polyfluoroalkyl substances (PFAS), cyanotoxins, and disinfection byproducts (DBPs)" (EPA, 2021, para. 3) - that have been included in the Contaminant Candidate List (CCL) 5 Proposed Rule. However, I urge the EPA to add Endocrine Disruptors (EDCs) found in pharmaceuticals and personal care products (PPCPs) to the list of regulated chemicals to prevent the prevalence of drinking water-induced reproductive health impairments.

EDCs include "disinfection byproducts, fluorinated substances, bisphenols, phthalates, pesticides, and natural and synthetic estrogens" (Gonsioroski et al., 2020, p. 1). The National Institute for Environmental Health Sciences (NIEHS) states that these harmful chemicals can be found in plastic bottles, food containers, detergents, toys, cosmetics, and pesticides (NIEHS, 2019). Research shows

Comments Received on EDCs and PPCPs

that EDCs have been proven to undermine the safety of drinking water by affecting development, fertility, and reproductive function. For example, "exposure to water disinfection byproducts in drinking water can cause cardiac anomalies in developing rat and porcine embryos" (Gonsioroski et al., 2020, p. 2). Additionally, pesticide exposure "is associated with low sperm count and adverse pregnancy outcomes in non-human animals and humans" (Gonsioroski et al., 2020, p. 2). The severity of the reproductive and fertility effects of EDCs can clearly be demonstrated by existing research. Thus, it is essential that public health be prioritized through the addition of EDCs on the CCL 5 draft.

It is important to note that PFAS, which can be found in nonstick pans, household products, cleaning products, fabrics, polishes, and waxes (Gonsioroski et al., 2020), was added to the EPA's CCL 5 draft due to its determination as a harmful chemical category that has significant effects on the human body. EDCs should be considered for the CCL 5 draft, as they introduce the same level of severity and harm to the human body. Similarly, EDCs are a group of toxic chemicals that affect fertility, reproductive function, and human development and must be added to the EPA's CCL 5 draft to uphold public safety and prioritize wellness in the United States.

References:

EPA. (2021). EPA identifies drinking water contaminants for potential regulation. https://www.epa.gov/newsreleases/epa-identifies-drinking-water-contaminants-potential-regulation

Gonsioroski, A., Mourikes, V. E., & Flaws, J. A. (2020). Endocrine Disruptors in Water and Their Effects on the Reproductive System. International journal of molecular sciences, 21(6), 1929. https://doi.org/10.3390/ijms21061929

NIEHS. (2019, December 10). Endocrine Disruptors. https://www.niehs.nih.gov/research/supported/exposure/endocrine/index.cfm

Individual Response: Please see Discussion on EDCs and PPCPs.

Suggestions to Improve the Process for Future CCLs

Agency Discussion on Suggestions to Improve the Process for Future CCLs

Agency Topic Discussion:

In each cycle of the CCL, EPA attempts to improve the efficiency and transparency of the CCL development process in response to comments from the Science Advisory Board and the public. In developing the CCL 5, EPA has made many improvements to the CCL process to better identify, screen, and classify potential drinking water contaminants. This included using new approaches to rapidly screen a significantly larger universe of contaminants for the CCL 5, prioritizing data most relevant to drinking water exposure, and identifying contaminants with the potential for the greatest public health concern, with a better consideration for sensitive populations, including children. These improvements resulted in a CCL 5 that can better support prioritization of chemicals for regulatory and research efforts. For more information on improvements made to the CCL 5 process, please see the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a) and Final CCL 5 Microbial Technical Support Document (USEPA, 2022c).

Agency Discussion on Suggestions to Improve the Process for Future CCLs

In EPA's Drinking Water Contaminant Candidate List 5-Draft notice, published in the *Federal Register* on July 19, 2021, the agency requested comment on improvements implemented in the CCL 5 process for consideration in developing future CCLs. EPA received many public comments commending improvements made in the CCL 5 as well as many public comments providing recommendations for EPA to improve specific aspects of the CCL process and how it is presented. EPA has categorized and addressed these comments in other sections of this document where appropriate, such as the discussions on General Comments, Chemical Data/Data Sources, Chemical Technical Support Document, and Microbial Technical Support Document. EPA also received a comment which provided more general recommendations for EPA to improve the process for future CCLs and provide greater clarity around the CCL 5. This comment is included and addressed here in this section of the document. EPA will take all these comments into consideration when developing future CCLs.

Comments Received on Suggestions to Improve the Process for Future CCLs

Comment Excerpt from Commenter 77

[AWWA offers the following recommendations for EPA to consider as the CCL 5 is finalized and in the development of future CCLs.]

Communicate Priorities Within CCL.
The development process for the CCL is complex and the CCL itself is the product of an extensive review of available data. EPA should consider presenting the Final 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. Such an approach would accomplish the following benefits:
1. Help EPA prioritize research needs internally
2. Inform stakeholders on research goals (both short-term and long-term).
3. Clearly indicate to consumers what priorities the Agency has identified and the potential level of concern that they present

Individual Response: Please see Discussion on Suggestions to Improve the Process for Future CCLs, Other Drinking Water Programs, and Other EPA Programs. The commenter noted the complexity of the CCL development process and recommended that the Final CCL 5 and future CCLs be presented as "an organized list that illustrates relative levels of potential risk and the gaps in information needed to craft risk management decisions." The CCL is a list of contaminants, not currently subject to any proposed or promulgated NPDWR that are known or anticipated to occur in public water systems and may require regulation under SDWA. For relative levels of potential risk and information needs for different CCL 5 contaminants, EPA recommends the commenter view the Contaminant Information Sheets (CISs) which display health effects, occurrence, and other data on CCL 5 contaminants (see Final CCL 5 CIS Technical Support Document for chemicals (USEPA, 2022b) and Appendix F of Final CCL 5 Microbial Technical Support Document for microbes (USEPA, 2022c)). In addition, EPA has provided a table summarizing the data availability for CCL 5 chemicals (please see Chapter 5 of the Final CCL 5 Chemical Technical Support Document (USEPA, 2022a)).

Comment Excerpt from Commenter 77

[AWWA offers the following recommendations for EPA to consider as the CCL 5 is finalized and in the development of future CCLs.]

External Peer-Review

Comments Received on Suggestions to Improve the Process for Future CCLs

EPA engaged in an extensive process to develop CCL 5, particularly in comparison to CCLs 1, 2, and 4. However, 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). AWWA appreciates that the draft CCL 5 will be reviewed by the Science Advisory Board but recommends that future CCLs be reviewed by an external expert panel in advance of the proposal. As is demonstrated by the two technical support documents that underpin the Draft CCL 5, it is challenging to develop the CCL process algorithm without resolving a lengthy series of individual questions of process and data quality. Without an external review, it is difficult to evaluate one's own work as to whether the completely assembled product works as it should. The technical support documents do not describe any internal process control measures, making the role of an independent third-party review even more important. The use of multiple chemical evaluator teams only serves as an internal check on one step in preparation of the CCL.

Individual Response: Please see Discussion on Suggestions to Improve the Process for Future CCLs and General Comments. In developing the updated process used to select drinking water contaminants for the CCL 5, EPA considered previous recommendations put forth by external groups, including those contained in the National Drinking Water Advisory Council Report on the CCL Classification Process (NDWAC, 2004), previous SAB reviews, and external expert reviews conducted for CCL 3. As the commenter indicates, the NDWAC report recommended critical review during key milestones of the CCL process: "Expert judgment, possibly including external expert consultation, will be important throughout the process, but particularly at key points, such as: reviewing the screening criteria and process from the Universe to the PCCL; assessing the training data set; and classification algorithm performance during development of the PCCL to CCL classification step." CCL 3 conducted extensive external reviews at each step of the process, including the review of the classification algorithms, yet internal expert judgement was critical for reviewing the output from the classification algorithms and making final listing decisions. While the development of the CCL 5 relied heavily on the internal expert judgement, EPA will consider the need for conducting external expert reviews for future CCLs.

EPA disagrees with the commenter's assertion that the technical support documentation does not describe any internal process control measures; both Chapter 6 "Data Management and Quality Assurance" and Appendix N "Data Management for CCL 5" of the Final CCL 5 Chemical Technical Support Document demonstrate adherence to an internal quality control system (USEPA, 2022a). In addition, EPA worked diligently throughout the development of CCL 5 to ensure that the project adhered to sound methodology for the collection and management of the health effects and occurrence data for each contaminant.

Comment Excerpt from Commenter 77

It is important to note that EPA did identify some issues that warranted more detailed explanation of its methodology and its impact. An example is the treatment of cancelled pesticides, where there is an obvious concern that, while older data may indicate occurrence and there would be available health information, drinking water is much less likely to represent an ongoing source of exposure for a cancelled pesticide. EPA's summary illustrates how available data is and can be used to identify those cancelled pesticides that might pose a continuing risk. A more routine practice of reflecting on the impact of methodological decisions would help the public and facilitate improvement of the CCL process over time.

Comments Received on Suggestions to Improve the Process for Future CCLs

It is also not clear what effect significant methodological changes over past practice have had on the composition of CCL 5. The public would benefit from a fuller explanation of the CCL 5 process and insight into the influential decisions made in the construction of the CCL 5.

Individual Response: Please see Discussion on Suggestions to Improve the Process for Future CCLs, Pesticides, and Chemical Technical Support Documents. EPA describes the impact of methodological changes made in the CCL 5 process throughout the Final CCL 5 Technical Support Document (USEPA, 2022a). The commenter provided one such example related to the treatment of cancelled pesticides. However, the commenter states that "A more routine practice of reflecting on the impact of methodological decisions would help the public and facilitate improvement of the CCL process over time." EPA will consider conducting analyses to assess the potential impact of changes made to the CCL 5 process, identifying areas for improvement, and incorporating them into future CCLs. EPA has worked on making the CCL process more transparent through the Final CCL 5 support documents and will also work to make the process more transparent in documentation for future CCLs.

Comments Outside the Scope of CCL

Agency Discussion on Comment Outside the Scope of CCL

Agency Topic Discussion:
The following comments address topics that are outside the scope of the CCL.

Comments Received on Outside the Scope

Comment Excerpt from Commenter 51
There should be a US Department of Water with cabinet positions.

And water consumption should be as follows: if it doesn't belong in the body, it doesn't belong in our water. Use a white list of chemicals allowed in our drinking water. A black list of what chemicals aren't allowed only let's the water be healthy enough to current standards, which will prove unhealthy in a few years as it always does

Individual response: Please see Discussion on General Comments. The establishment of a U.S. Department of Water with cabinet positions is outside the scope of the CCL.

Comment Excerpt from Commenter 57
1) Is the rule outcome to require neutralization of the final list of contaminants at factories that generate them, and at water treatment plants prior to household use?

2) Where were testing samples drawn?

3) Would there be label warnings on bottled waters on possible traces of the finalized contaminants?

Individual Response: Please see Discussion on General Comments, Other Drinking Water Programs, and Other EPA Programs. The U.S. Food and Drug Administration sets standards for bottled water. For more information on bottled water, please see EPA's Water Health Series document on Bottled Water Basics.

Comments Received on Outside the Scope

Comment Excerpt from Commenter 90

Dear Administrator Regan,

Please ensure that the execrable situation that afflicted Flint, Michigan, never again affects anyone in this country.

Individual Response: EPA continues to take steps to address lead in the nation's drinking water. For more information on EPA's efforts to better protect the public from exposures to lead in drinking water, please see https://www.epa.gov/ground-water-and-drinking-water/basic-information-about-lead-drinking-water

References

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