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Part II

Environmental Protection Agency

Drinking Water Contaminant Candidate List 3—Draft; Notice

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OW–2007–1189 FRL–8529–7]

RIN 2040–AD99

Drinking Water Contaminant Candidate List 3—Draft

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is publishing for public review and comment a draft list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations, that are known or anticipated to occur in public water systems, and which may require regulations under the Safe Drinking Water Act (SDWA). This is the third Contaminant Candidate List (CCL 3) published by the Agency since the SDWA amendments of 1996.

This draft CCL 3 includes 93 chemicals or chemical groups and 11 microbiological contaminants. The EPA seeks comment on the draft CCL 3, the approach used to develop the list, and other specific contaminants.

DATES: Comments must be received on or before May 21, 2008.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OW–2007–1189, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Mail:* Water Docket, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave., NW., Washington, DC 20460.
- *Hand Delivery:* Water Docket, EPA Docket Center (EPA/DC) EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–HQ–OW–2007–1189. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to Unit I.B of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Water Docket, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–2426.

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

Abbreviations and Acronyms

<—less than
≤—less than or equal to
>—greater than
≥—greater than or equal to
µ—microgram, one-millionth of a gram
µg/L—micrograms per liter
ATSDR—Agency for Toxic Substances and Disease Registry
AWWA—American Water Works Association
CASRN—Chemical Abstract Services Registry Number
CDC—Centers for Disease Control and Prevention
CCL—Contaminant Candidate List
CCL 1—EPA's First Contaminant Candidate List
CCL 2—EPA's Second Contaminant Candidate List
CCL 3—EPA's Third Contaminant Candidate List
CFR—Code of Federal Regulations
CUS/IUR—Chemical Update System/Inventory Update Rule
DBP—disinfection byproduct
DWEL—drinking water equivalent level
EPA—United States Environmental Protection Agency
ESA—ethanesulfonic acid
FDA—United States Food and Drug Administration
FR—**Federal Register**
g—gram
HAAs—haloacetic acids
IOCs—inorganic contaminants
IRIS—Integrated Risk Information System
kg—kilogram
L—liter
LD_{50}—lethal dose 50; an estimate of a single dose that is expected to cause the death of 50 percent of the exposed animals; it is derived from experimental data.
lbs—pounds
LOAEL—lowest-observed-adverse-effect level
MCL—maximum contaminant level
MCLG—maximum contaminant level goal
MRDD—maximum recommended daily dose
mg/kg—milligrams per kilogram body weight
mg/kg/day—milligrams per kilogram body weight per day
mg/L—milligrams per liter
MMWR—*Morbidity and Mortality Weekly Report*
NAS—National Academy of Sciences
NCI—National Cancer Institute
NCOD—National Contaminant Occurrence Database
NDWAC—National Drinking Water Advisory Council
NOAEL—no-observed-adverse-effect level

NRC—National Academy of Sciences' National Research Council
NPDWR—national primary drinking water regulation
NTP—National Toxicology Program
OPP—Office of Pesticide Programs
PFOA—perfluorooctanoic acid
PFOS—perfluorooctane sulfonic acid
PWS—public water system
RfD—reference dose
SAB—Science Advisory Board
SDWA—Safe Drinking Water Act
TCR—Total Coliform Rule
TD_{50}—tumorigenic dose 50; The dose-rate which if administered chronically for the standard life-span of the species will have a 50% probability of causing tumors at some point during that period.
TRI—Toxics Release Inventory
TDS—training data set
UCM—Unregulated Contaminant Monitoring
UCMR 1—First Unregulated Contaminant Monitoring Regulation
UCMR 2—Second Unregulated Contaminant Monitoring Regulation
US—United States of America
USDA—United States Department of Agriculture
USGS—United States Geological Survey
WBDO—waterborne disease outbreak
WHO—World Health Organization
yr—year

SUPPLEMENTARY INFORMATION:

I. General Information

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

The draft Contaminant Candidate List 3 (CCL 3) or the final CCL 3, when published, will not impose any requirements on anyone. Instead, this action notifies interested parties of the availability of EPA's draft CCL 3 and seeks comment on the contaminants listed.

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

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

- Explain your views as clearly as possible.
- Describe any assumptions that you used.
- Provide any technical information and/or data you used that support your views.
- Provide specific examples to illustrate your concerns.
- Offer alternatives.

Make sure to submit your comments by the comment period deadline. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Purpose, Background, and Summary of This Action

This section briefly summarizes the purpose of this action, the statutory requirements, previous activities related to the Contaminant Candidate List (CCL), and the approach used to develop the CCL 3.

A. What Is the Purpose of This Action?

The Safe Drinking Water Act (SDWA), as amended in 1996, requires EPA to publish a list of currently unregulated contaminants that may pose risks for drinking water (referred to as the Contaminant Candidate List, or CCL) and to make determinations on whether to regulate at least five contaminants from the CCL with a national primary drinking water regulation (NPDWR) (section 1412(b)(1)). The 1996 SDWA requires the Agency to publish both the CCL and the regulatory determinations every five years. The purpose of this action is to present EPA's draft list of contaminants on the CCL 3, a description of the selection process, and the rationale used to make the list.

This action also includes a request for comment on the Agency's draft CCL 3, the approach used to develop the list, and other specific contaminants.

B. Background on the CCL, Regulatory Determinations, and Unregulated Contaminant Monitoring

1. Statutory Requirements for CCL and Regulatory Determinations

Section 1412(b) (1) of SDWA, as amended in 1996, requires EPA to publish the Contaminant Candidate List every five years. SDWA specifies that the list must include contaminants that are not subject to any proposed or promulgated NPDWRs, are known or anticipated to occur in public water systems (PWSs), and may require regulation under SDWA.

The 1996 SDWA Amendments also specify three criteria to determine whether a contaminant may require regulation:

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

In developing the draft CCL 3, the Agency considered the best available data and information for unregulated contaminants. As required under the Safe Drinking Water Act, EPA evaluated substances identified in section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 and substances registered as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act. In addition to these required data sources, the Agency also developed the National Contaminant Occurrence Database (NCOD) established under section 1445(g) of SDWA. Substances from NCOD were included in the initial set

of contaminants considered for the draft CCL 3.

SDWA also 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. In selecting contaminants for the draft CCL 3, adverse health effects that may pose a greater risk to subgroups which represent a meaningful portion of the population were considered. Adverse health effects associated with infants, children, pregnant women, the elderly, and individuals with a history of serious illness were evaluated for both chemicals and microbes. The specific analyses and evaluations used by the Agency are discussed and cited in the relevant sections of this notice.

2. The First Contaminant Candidate List

Following the 1996 SDWA Amendments, EPA sought input from the National Drinking Water Advisory Council (NDWAC) on the process that should be used to identify contaminants for inclusion on the first CCL (CCL 1). For chemical contaminants, the Agency developed screening and evaluation criteria based on the recommendations provided by NDWAC. For microbiological contaminants, NDWAC recommended that the Agency seek external expertise to identify and select potential waterborne pathogens. As a result, an external group of microbiologists and public health experts developed the criteria for screening, conducted an evaluation of microbial agents, and selected the initial list of microbiological contaminants for the CCL 1.

The draft CCL 1 was published on October 6, 1997 (62 *FR* 52193 (USEPA, 1997)). After consideration of all comments, EPA published the final CCL 1, which included 50 chemical and 10 microbiological contaminants, on March 2, 1998 (63 *FR* 10273 (USEPA, 1998 b)). A more detailed discussion of how EPA developed CCL 1 can be found in the 1997 and the 1998 **Federal Register** notices (62 *FR* 52193 (USEPA, 1997) and 63 *FR* 10273 (USEPA, 1998 b)).

3. The Regulatory Determinations for CCL 1

EPA published its preliminary regulatory determinations for a subset of contaminants listed on CCL 1 on June 3, 2002 (67 *FR* 38222 (USEPA, 2002 b)). The Agency published its final regulatory determinations on July 18, 2003 (68 *FR* 42898 (USEPA, 2003 a)). EPA identified 9 contaminants from the 60 contaminants listed on CCL 1 that had sufficient data and information available to make regulatory determinations. The 9 contaminants were *Acanthamoeba*, aldrin, dieldrin, hexachlorobutadiene, manganese, metribuzin, naphthalene, sodium, and sulfate. The Agency determined that a national primary drinking water regulation was not necessary for any of these 9 contaminants. The Agency issued guidance on *Acanthamoeba* and health advisories for magnesium, sodium, and sulfate.

4. The Second Contaminant Candidate List

The Agency published its draft second CCL (CCL 2) **Federal Register** notice on April 2, 2004 (69 *FR* 17406 (USEPA, 2004)) and the final CCL 2 **Federal Register** notice on February 24, 2005 (70 *FR* 9071 (USEPA, 2005 b)). The CCL 2 carried forward the 51 remaining chemical and microbial contaminants that were listed on CCL 1.

5. The Regulatory Determinations for CCL 2

EPA published its preliminary regulatory determinations for a subset of contaminants listed on CCL 2 on May 1, 2007 (72 *FR* 24015 (USEPA, 2007 d)). EPA identified 11 contaminants from the 51 contaminants listed on CCL 2 that had sufficient data and information available to make preliminary regulatory determinations. The 11 contaminants are boron, the dacthal mono- and di-acid degradates, 1,1-dichloro-2,2-bis (p-chlorophenyl) ethylene (DDE), 1,3-dichloropropene, 2,4-dinitrotoluene, 2,6-dinitrotoluene, s-ethyl propylthiocarbamate (EPTC), fonofos, terbacil, and 1,1,2,2-tetrachloroethane. The Agency has made a preliminary determination that a national primary drinking water regulation is not necessary for any of these 11 contaminants. The Agency is scheduled to publish its final regulatory determinations in 2008. In the May 1, 2007 *FR* notice, the Agency indicated that additional information was needed to make the regulatory determinations for perchlorate and methyl tertiary butyl ether (MTBE) and provided a summary of the current health effects, occurrence, and exposure information.

6. The Unregulated Contaminant Monitoring Rule

SDWA provides EPA with the authority to require all large and a subset of small systems to monitor for unregulated contaminants. EPA may require monitoring for up to 30 contaminants under the Unregulated Contaminant Monitoring Rule (UCMR). Since the 1996 SDWA amendments, the Agency has issued two UCMRs (UCMR 1 and UCMR 2). UCMR 1 was promulgated on September 17, 1999 (64 *FR* 50556 (USEPA, 1999)) and UCMR 2 on January 4, 2007 (72 *FR* 367 (USEPA, 2007 a)), followed by two revisions published later in January 2007 (72 *FR* 3916 (USEPA, 2007 b) and 72 *FR* 4328 (USEPA, 2007 c)). Monitoring under UCMR 2 will take place during the 2008–2010 time period.

UCMR 2 requires monitoring for several pesticides and pesticide degradates, five polybrominated diphenyl ether (PBDE) flame retardants, a group of nitrosamines and two munitions (TNT and RDX). All of the chemicals on UCMR 2 were included among the contaminants evaluated for CCL 3. Data collected under the UCMR are an important source of occurrence information for the CCL process.

7. The Third Contaminant Candidate List

In 1998, the Agency sought advice from the National Academy of Sciences' National Research Council (NRC) on how to improve the CCL process. The NRC published its recommendations on the CCL process in 2001 (NRC, 2001). The NRC proposed a broader, more reproducible process to identify the CCL than the process used by EPA in the first CCL. The NRC recommended that EPA develop and use a multi-step process for creating CCL 3 and future CCLs, whereby a broadly defined ''universe'' of potential drinking water contaminants is identified, assessed, and reduced to a preliminary CCL (PCCL) using simple screening criteria. All of the contaminants on the PCCL would then be assessed in more detail using a classification tool to evaluate the likelihood that specific contaminants could occur in drinking water at levels and at frequencies that pose a public health concern.

In 2002, the Agency sought input from the National Drinking Water Advisory Council (NDWAC) on how to implement the NRC's recommendations to improve the CCL process. NDWAC agreed that EPA should proceed with the NRC's recommendations and provided some additional considerations, including the overarching principles the Agency should follow. The NDWAC workgroup met 10 times between September 2002 and May 2004. The NDWAC issued its recommendations in ''The National Drinking Water Advisory Council Report on the CCL Classification Process to the U.S. Environmental Protection Agency'' (NDWAC, 2004).

NDWAC recommended two guiding principles for construction of the CCL universe, which are:

- The universe should include those contaminants that have demonstrated or have potential occurrence in drinking water, and
- The universe should include those contaminants that have demonstrated or have potential adverse health effects.

These inclusionary principles apply to the selection of contaminants for initial CCL consideration.

The NDWAC also recommended that the universe of contaminants should be screened based on widely available data elements that indicate important health effects and occurrence information. This screening step should be as simple as possible and capable of identifying contaminants of the greatest significance for further consideration. Consideration of a classification approach was also recommended to increase the transparency and reproducibility of the CCL decision process. NDWAC recommended that EPA pursue classification models that build on the screening criteria to further characterize the adverse health effects and occurrence of chemical contaminants. NDWAC noted that the classification models are tools to help prioritize contaminants for the CCL. The model results, available information used by the model, and expert reviews should be used to determine which contaminants are listed for the next CCL. The process to develop the models should be viewed as iterative, and EPA should involve experts and allow opportunities for meaningful public comment on the evaluation of contaminants.

NDWAC recommended several overarching principles that EPA should use to develop the CCL. In addition to the need for transparency and public participation, these overarching recommendations include:

- Integrate expert judgment throughout the CCL process. Expert judgment is inherent throughout the development of the CCL process and in implementing that process once it is developed. Critical reviews, involving various types of expert consultation and collaboration, will be useful at key points in the new, evolving CCL process.
- Conduct an active surveillance and nomination/evaluation processes to ensure timely identification of information relevant to new and emerging agents.
- Apply an adaptive management approach (i.e., an approach that can be refined in future iterations as more knowledge is acquired) to implement the CCL process. The development of any model should be an adaptive process, and should be reviewed by experts with consideration given to updating the process with each successive CCL cycle.

NDWAC also recognized that there were significant differences in the methods and information used to characterize chemical and microbiological contaminants. Chemical contaminants tend to be characterized by toxicological and occurrence data that can be modeled or estimated if measurement is not possible. These discrete characteristics are often captured in data sources. For microbes, the adverse health effects from exposure are characterized by clinical or epidemiological data and there are few methods to estimate or model their occurrence. Limited sources of tabular data for microbes may require evaluation of primary literature, technical reports, monographs, and reference books to identify a universe of microbes for consideration. NDWAC recommended the Agency use human pathogens as the starting point for identifying microorganisms considered for inclusion in the CCL and apply a two-step evaluation of those pathogens.

C. Summary of the Approach Used To Identify and Evaluate Candidates for CCL 3

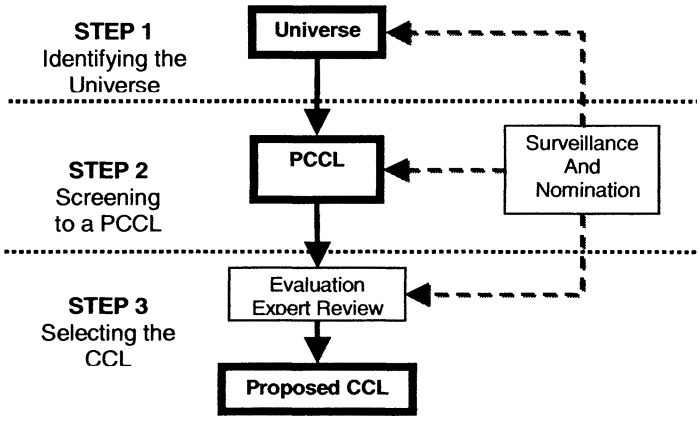
The Agency revised the CCL process used in previous efforts based on the knowledge and experience it has gained from evaluating unregulated contaminants and the recommendations and advice from NRC and NDWAC. Based on these recommendations the Agency developed and implemented a classification approach that identifies priority drinking water contaminants in a transparent and reproducible manner that is amenable to an adaptive management approach.

The Agency's approach to classifying contaminants is based on available data to characterize the occurrence and adverse health risks a contaminant may pose to consumers of public water systems. EPA developed and implemented the following multi-step CCL process to identify contaminants for inclusion on the Draft CCL 3.

- Identify a broad universe of potential drinking water contaminants (called the CCL 3 Universe). EPA evaluated 284 data sources that may identify potential chemical and microbial contaminants and selected a set of approximately 7,500 chemical and microbial contaminants from these data sources for initial consideration.
- Apply screening criteria to the CCL 3 Universe to identify those contaminants that should be further evaluated. Contaminants not passing the screening criteria remained in the universe. The screening criteria EPA developed are based on a contaminant's potential to occur in public water systems and the potential for public health concern. Applying these criteria narrows the universe of contaminants to a Preliminary-CCL (or PCCL).
- Identify contaminants from the PCCL to include on the CCL based on a more detailed evaluation of occurrence and health effects. For chemicals, EPA used structured classification models as tools to evaluate and identify drinking water priority contaminants. Decisions to include chemicals were made using the model results and the best available data to identify contaminants that may occur in PWSs and may cause adverse health effects. EPA used a decision tree approach for microbial contaminants to identify those contaminants that have the potential to occur in PWSs and transmit waterborne disease. These two approaches resulted in a draft list of chemicals and microbes for inclusion on the Draft CCL 3.
- Incorporate public input and expert review in the CCL process. EPA sought public input by asking for nominations of contaminants to consider for the CCL (71 *FR* 60704 (USEPA, 2006 b)) and incorporated these nominations in the three key steps already discussed. EPA also convened several expert panels for both chemicals and microbes to review, and provide input and comment, on the CCL 3 process and on a review of a preliminary draft CCL 3.

Exhibit 1 illustrates the CCL multi-step approach that resulted from the Agency's efforts, input, and collaboration with NRC and NDWAC. This generalized process is applied to both chemical and microbial contaminants, though the specific execution of particular steps differs in detail.

Exhibit 1. Schematic of CCL classification process



EPA provides a more detailed discussion of the analyses and decisions it made to develop the Draft CCL 3 in the EPA Water Docket. EPA prepared several support documents that are available for review at *http://www.regulations.gov.* These documents include:

- Three comprehensive support documents for the chemicals entitled, ''Contaminant Candidate List 3 Chemicals: Identifying the Universe'' (USEPA, 2008 a), ''Contaminant Candidate List 3 Chemicals: Screening to a PCCL'' (USEPA, 2008 b), and ''Contaminant Candidate List 3 Chemicals: Classification of the PCCL to the CCL'' (USEPA, 2008 c). These documents describe in detail how the classification process was developed and used to select the chemicals for the Draft CCL.
- Three comprehensive support documents for the microbes entitled, ''Contaminant Candidate List 3 Microbes: Identifying the Universe'' (USEPA, 2008 d), ''Contaminant Candidate List 3 Microbes: Screening to the PCCL'' (USEPA, 2008 e), and ''Contaminant Candidate List 3 Microbes: PCCL to CCL Process'' (USEPA, 2008 f). These documents describe the microbial listing process in detail.
- The Agency also prepared summaries of stakeholder involvement and reviews conducted on the CCL process and draft list. These documents are also available in the EPA Water Docket and at *http://www.regulations.gov.*
- National Drinking Water Advisory Council Report on the CCL Classification Process to the U.S. Environmental Protection Agency, May 19, 2004.
- A nominations and surveillance report, entitled ''Summary of the Nominations for the Third Contaminant Candidate List'' (USEPA, 2008 g), which describes the nominations process and the contaminants that were nominated as part of EPA's process.
- Two documents summarizing the expert review of the chemical and microbial processes, entitled ''Chemical Expert Input and Review for the Third Contaminant Candidate List'' (USEPA, 2008 h) and ''Microbial Expert Input and Review for the Third Contaminant Candidate List'' (USEPA, 2008 i).

D. What Is on EPA's Draft CCL 3?

EXHIBIT 2.—DRAFT CONTAMINANT CANDIDATE LIST 3: MICROBIAL CONTAMINANTS

Pathogens
Caliciviruses
Campylobacter jejuni
Entamoeba histolytica
Escherichia coli (0157)
Helicobacter pylori
Hepatitis A virus
Legionella pneumophila
Naegleria fowleri
Salmonella enterica
Shigella sonnei
Vibrio cholerae

CHEMICAL CONTAMINANTS

Common name—registry name	CASRN
alpha-Hexachlorocyclohexane	319–84–6
1,1,1,2-Tetrachloroethane	630–20–6
1,1-Dichloroethane	75–34–3
1,2,3-Trichloropropane	96–18–4
1,3-Butadiene	106–99–0
1,3-Dinitrobenzene	99–65–0
1,4-Dioxane	123–91–1
1-Butanol	71–36–3
2-Methoxyethanol	109–86–4
2-Propen-1-ol	107–18–6
3-Hydroxycarbofuran	16655–82–6
4,4'-Methylenedianiline	101–77–9
Acephate	30560–19–1
Acetaldehyde	75–07–0
Acetamide	60–35–5
Acetochlor	34256–82–1
Acetochlor ethanesulfonic acid (ESA)	187022–11–3
Acetochlor oxanilic acid (OA)	184992–44–4
Acrolein	107–02–8
Alachlor ethanesulfonic acid (ESA)	142363–53–9
Alachlor oxanilic acid (OA)	171262–17–2
Aniline	62–53–3
Bensulide	741–58–2
Benzyl chloride	100–44–7
Butylated hydroxyanisole	25013–16–5
Captan	133–06–2
Chloromethane (Methyl chloride)	74–87–3
Clethodim	110429–62–4
Cobalt	7440–48–4
Cumene hydroperoxide	80–15–9
Cyanotoxins (3).	
Dicrotophos	141–66–2
Dimethipin	55290–64–7
Dimethoate	60–51–5
Disulfoton	298–04–4
Diuron	330–54–1
Ethion	563–12–2
Ethoprop	13194–48–4
Ethylene glycol	107–21–1
Ethylene oxide	75–21–8
Ethylene thiourea	96–45–7
Fenamiphos	22224–92–6
Formaldehyde	50–00–0
Germanium	7440–56–4
HCFC–22	75–45–6
Hexane	110–54–3
Hydrazine	302–01–2
Methamidophos	10265–92–6
Methanol	67–56–1
Methyl bromide (Bromomethane)	74–83–9
Methyl tert-butyl ether	1634–04–4

CHEMICAL CONTAMINANTS—Continued

Common name—registry name	CASRN
Metolachlor	51218–45–2
Metolachlor ethanesulfonic acid (ESA)	171118–09–5
Metolachlor oxanilic acid (OA)	152019–73–3
Molinate	2212–67–1
Molybdenum	7439–98–7
Nitrobenzene	98–95–3
Nitrofen	1836–75–5
Nitroglycerin	55–63–0
N-Methyl-2-pyrrolidone	872–50–4
N-nitrosodiethylamine (NDEA)	55–18–5
N-nitrosodimethylamine (NDMA)	62–75–9
N-nitroso-di-n-propylamine (NDPA)	621–64–7
N-Nitrosodiphenylamine	86–30–6
N-nitrosopyrrolidine (NPYR)	930–55–2
n-Propylbenzene	103–65–1
o-Toluidine	95–53–4
Oxirane, methyl-	75–56–9
Oxydemeton-methyl	301–12–2
Oxyfluorfen	42874–03–3
Perchlorate	14797–73–0
Permethrin	52645–53–1
PFOA (perfluorooctanoic acid)	335–67–1
Profenofos	41198–08–7
Quinoline	91–22–5
RDX (Hexahydro–1,3,5–trinitro–1,3,5–triazine)	121–82–4
sec-Butylbenzene	135–98–8
Strontium	7440–24–6
Tebuconazole	107534–96–3
Tebufenozide	112410–23–8
Tellurium	13494–80–9
Terbufos	13071–79–9
Terbufos sulfone	56070–16–7
Thiodicarb	59669–26–0
Thiophanate-methyl	23564–05–8
Toluene diisocyanate	26471–62–5
Tribufos	78–48–8

CHEMICAL CONTAMINANTS—Continued

Common name—registry name	CASRN
Triethylamine	121–44–8
Triphenyltin hydroxide (TPTH)	76–87–9
Urethane	51–79–6
Vanadium	7440–62–2
Vinclozolin	50471–44–8
Ziram	137–30–4

III. What Analyses Did EPA Use To Develop the Draft CCL 3?

A. Classification Approach for Chemicals

1. Identifying the Universe

In the first step in the approach, EPA compiled potential data sources, including sources identified at a stakeholder workshop sponsored by the American Water Works Association (AWWA), to develop a broad universe of potential drinking water contaminants, as shown in Exhibit 1. This compilation identified the 284 data sources that were assessed for the CCL Universe.

EPA developed a decision tree for data source selection that was based on four assessment factors, which were applied to all of the potential data sources:

- Relevance. Ensures that the data source provided information on demonstrated or potential health effects, occurrence, or potential occurrence using surrogate information (e.g., environmental release, environmental fate, and transport properties);
- Completeness. Ensures that the data source had minimum record requirements—contact name, description of the data elements, and how the data were obtained;
- Redundancy. Ensures that the data source does not contain information identical to other more comprehensive data sources; and
- Retrievability. Ensures that the data in the source are formatted for automated retrieval. Each source was accessed on-line (or as provided by the source) and reviewed.

Basic information about the source, its purpose, and the data elements it contained, was compiled and documented. Every source was evaluated using all assessment factors sequentially. Those sources that met all four factors became the prime sources that formed the ''Universe of Data Sources.'' Sources that passed the first three factors, but were not retrievable, were designated as supplemental data sources, to be consulted as necessary (e.g., to fill in data gaps) in the development of the CCL. Some of the sources that were not easily retrievable were identified as ''unique'' or ''exceptional'' because of the importance of their data (i.e., the Hazardous Substance Database). EPA included chemicals from these sources in the Universe.

After application of the four assessment factors, 39 sources (Exhibit 3) met all four factors or were considered as exceptional. These sources were the primary sources used to develop the CCL Chemical Universe. The details of the how EPA compiled the list of data sources is discussed in the document entitled, ''CCL 3 Chemicals: Identifying the Universe'' (USEPA, 2008 a).

EXHIBIT 3.—SOURCES THAT COMPRISE THE CHEMICAL UNIVERSE OF DATA SOURCES FOR THE CCL PROCESS

Name of data source
1. ATSDR CERCLA Priority List.
2. ATSDR Minimal Risk Levels (MRLs).
3. Chemical Toxicity Database—Ministry of Health and Welfare, Japan.
4. Chemical Update System/Inventory Update Rule (CUS/IUR)—EPA.
5. Cumulative Estimated Daily Intake/Acceptable Daily Intake (CEDI/ADI) Database—FDA.
6. Database of Sources of Environmental Releases of Dioxin-Like Compounds in the United States—EPA.
7. Distributed Structure Searchable Toxicity Public Database Network (DSSTox)—EPA.
8. Everything Added to Food in the United States (EAFUS) Database—FDA.
9. Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) List—EPA.
10. Generally Regarded As Safe (GRAS) Substance List—FDA.
11. Guidelines for Canadian Drinking Water Quality (CADW): Summary of Guidelines—Health Canada.
12. Hazardous Substances Data Bank (HSDB)—NLM.
13. Health Advisories (HA) Summary Tables—EPA.
14. High Production Volume (HPV) Chemical List—EPA.
15. Indirect Additives Database—FDA.
16. Integrated Risk Information System (IRIS)—EPA.
17. International Agency for Research on Cancer (IARC) Monographs.
18. International Toxicity Estimates for Risk (ITER) Database—TERA.
19. Joint Meeting On Pesticide Residues (JMPR)—2001 Inventory of Pesticide Evaluations—WHO, FAO.
20. National Drinking Water Contaminant Occurrence Database (NCOD)—Round 1&2—EPA.
21. National Drinking Water Contaminant Occurrence Database (NCOD)—Unregulated Contaminant Monitoring Rule (UCMR)—EPA.
22. National Inorganics and Radionuclides Survey (NIRS)—EPA.
23. National Pesticide Use Database—NCFAP.

EXHIBIT 3.—SOURCES THAT COMPRISE THE CHEMICAL UNIVERSE OF DATA SOURCES FOR THE CCL PROCESS—Continued

Name of data source
24. National Reconnaissance of Emerging Contaminants (NREC)—USGS Toxic Substances Hydrology Program.
25. National Toxicology Program (NTP) Studies.
26. National Water Quality Assessment (NAWQA)—USGS.
27. OSHA 1988 Permissible Exposure Limits (PELs)—NIOSH.
28. Pesticide Data Program—USDA.
29. Pesticides Pilot Monitoring Program—USGS/EPA.
30. Risk Assessment Information System (RAIS)—Department of Energy—Chemical Factors.
31. Risk Assessment Information System (RAIS)—Department of Energy—Health Effects Data.
32. State of California Chemicals Known to the State to Cause Cancer or Reproductive Toxicity.
33. Substances Registry System (SRS)—EPA.
34. Syracuse Research Corporation (SRC)—BIODEG.
35. The Toxics Release Inventory (TRI)—EPA.
36. Toxic Substances Control Act (TSCA) List—EPA.
37. Toxicity Criteria Database—California Office of Environmental Health Hazard Assessment (OEHHA).
38. University of Maryland—Partial List of Acute Toxins/Partial List of Teratogens.
39. WHO Guidelines for Drinking Water Quality: Summary Tables.

There were approximately 26,000 unique substances identified from the 39 data sources. Because of the large number of unique substances identified, EPA developed an initial universe selection process. In the first phase of the data evaluation process, EPA identified the chemicals that were present in both health effects and occurrence data sources. The Agency queried the data sources and found that approximately 7,300 chemicals, or about one-third of the chemicals, were present in both health effects and occurrence data sources. Occurrence was defined broadly to include production data and environmental occurrence data. EPA placed these chemicals in the chemical universe to be further evaluated for screening to the PCCL. EPA then examined the rest of the approximately 18,600 chemicals left in the initial universe more closely to determine whether they were found only in health effects data sources or only in occurrence data sources. EPA found that approximately 5,100 chemicals were in health effects data sources only. Many of these chemicals were biochemical compounds (e.g., amino acids, sugars, steroids); mixtures and natural products (e.g., coal tar, petroleum related substances, rocks, stone, wool); and other entries that were identified as unique ''substances'' in the data sources but were not chemicals (e.g., turbidity, boot and shoe manufacture, surgical implants). EPA evaluated these to identify which ones are chemicals of greatest toxicological concern. Many of the chemicals fell into the category of greatest toxicological concern due to their classification as carcinogens. This is described in the report entitled, ''CCL 3 Chemicals: Screening to a PCCL'' (USEPA, 2008 b). Through this process, a total of 122 chemicals with only toxicity data were added to the 7,300 chemicals already in the CCL Chemical Universe.

The chemicals found only in occurrence sources were also categorized. The approximately 13,500 chemicals with only occurrence data were a diverse group, comprised of many different types of chemicals. Data sources that provide the amount of an individual chemical that is manufactured and produced account for 70 percent (or 9,344) of the total. The remaining 30 percent of chemicals are from various other data sources (i.e., finished water, ambient water, environmental release, environmental fate and transport properties, and food additives). EPA grouped these chemicals by the type of occurrence data for further evaluation. These included the following groupings:

- Chemicals with Finished or Ambient Water Data
- Chemicals with Release Data
- Chemicals with High Production Volumes

EPA added 42 chemicals with finished or ambient water data to the Universe despite the lack of health effects information in the data sources because of their demonstrated occurrence in ambient or potable water. In addition, disinfection byproducts and water treatment additives were added to the Chemical Universe. While there may not have been measured occurrence data for these chemicals in the universe of data sources, they are considered to have ''default'' occurrence data because they are formed in, or intentionally added to, drinking water supplies.

EPA also added 36 chemicals with an environmental release data source (e.g., those on the Toxics Release Inventory or with pesticide application data) to the Chemical Universe even though they lacked health effects data.

The largest group of chemicals found only in occurrence data sources had only production information. These contaminants include: organometallics, elements, salts of the inorganic elements, salts of organic acids, natural product organics (including oils, fatty acids, sugars, intermediary metabolites), and mixtures (e.g., petroleum related compounds, hydrocarbons, and others). Over half of the production chemicals are compounds and/or complexes of elemental constituents; for example, there were about 750 sodium or potassium salt compounds alone. In these cases, health effects data are not available for the exact compound, but are generally available for other related compounds or the key ion or elemental constituent (e.g., sodium). Nearly all elements found in inorganic or organic salts are represented in the Universe by other compounds with both health effects and occurrence data. EPA found only 10 elements (excluding carbon, hydrogen, and oxygen, and the inert gasses krypton, neon, and xenon) that did not otherwise have representative compounds with health effects data in the Universe. EPA added these compounds (i.e., europium, gadolinium, gold, lanthanum, praseodymium, platinum, polonium, samarium, terbium, and yttrium) to the Universe. After evaluation of the characteristics of the chemicals with production data and the amounts produced on a yearly basis, and because the primary constituents (i.e., elements) of the chemicals were already in the Chemical Universe, EPA decided to move only those produced at greater than 1 billion pounds per year to the CCL Chemical Universe when they lacked health effects information.

EPA added a total of 269 chemicals with only occurrence data to the CCL 3 Chemical Universe. The rest of the substances included in the original data sources were not included in the Universe.

The initial selection process brought into the CCL Chemical Universe all substances from the data sources that met the defined selection criteria, described above. Upon further review, EPA found the Chemical Universe also contained regulated as well as unregulated compounds, mixtures, and some substances that were not really chemicals. To further refine the initial list, EPA removed chemicals with a national primary drinking water regulation. These contaminants are already regulated; thus, their inclusion in the CCL process is unnecessary and does not meet the statutory requirement for selection of the CCL. EPA removed 1,006 chemicals, which is more than the number of primary drinking water standards. This is because regulated contaminants can be found in many forms and because many contaminants are regulated as part of a class or group(s). For example, EPA removed approximately 780 radionuclides from the initial list, because they are regulated as alpha and beta emitters. Also removed were various salts of regulated elements, and entries for individual trihalomethanes, haloacetic acids, polychlorinated biphenyls and polyaromatic hydrocarbons that are regulated as a group. The Agency has determined that it is inappropriate to include aldicarbs (aldicarb, aldicarb sulfoxide, and aldicarb sulfone) and nickel on the CCL. These contaminants are subject to regulation under SDWA section 1412(b)(2) and thus are not part of the contaminant selection process specified under SDWA section 1412(b)(1). In response to an administrative petition from the manufacturer Rhone-Poulenc, the Agency issued an administrative stay of the effective date of the maximum contaminant levels (MCLs) for aldicarbs, and they never became effective. NPDWRs for nickel were promulgated on July 17, 1992 (57 *FR* 31776 (USEPA, 1992)), but the MCL was later vacated and remanded by the D.C. Court of Appeals in response to a joint motion by EPA and industry parties challenging the nickel MCL and MCLG. Because these contaminants are subject to separate regulatory consideration, EPA has not included them in the CCL process.

EPA also removed substances that are considered a mixture of chemicals. EPA defines a mixture in this case as a combination of two or more chemicals/items that are not defined as a unique substance. Examples of substances in this category include ''chlorinated compounds, aliphatic alcohols with more than 14 carbon atoms (c>14), coal-tar-containing shampoo, petroleum-related substances, resin acids, and rosin acids.'' Undefined mixtures, such as ''diesel engine exhaust'' were also included in this group.

EPA also removed ''non-chemically defined'' entries from further consideration for the initial list. Examples include: ''solar radiation, wood dust, surgical implants, and welding fumes.'' Some of these substances are present in the data sources because they have been evaluated for their potential to cause cancer.

The final step removed biological agents from the initial list. Contaminants in this category are biological organisms that are being evaluated as part of the CCL 3 Microbiological Universe. Entries for biological entities were uploaded from the universe of data sources from various health effects data sources and pesticide data sources. Many biological entities were also removed as non-chemically defined.

During this phase of the data evaluation, 1,717 chemicals or substances were removed from the initial Chemical Universe, leaving approximately 6,000 chemicals that were designated as the CCL 3 Universe. A list of the CCL Chemical Universe is provided in the docket. EPA further evaluated these 6,000 chemicals in the next key step of the process.

2. Screening from the Universe to a PCCL

The next step in the CCL selection approach involved narrowing the Universe of chemicals to a PCCL, as shown in Exhibit 1. EPA considered and built upon NDWAC recommendations that the screening process be based on a contaminant's potential to occur in public water systems and the potential for public health concern, to select those contaminants that should move to the PCCL for further evaluation. The screening approach:

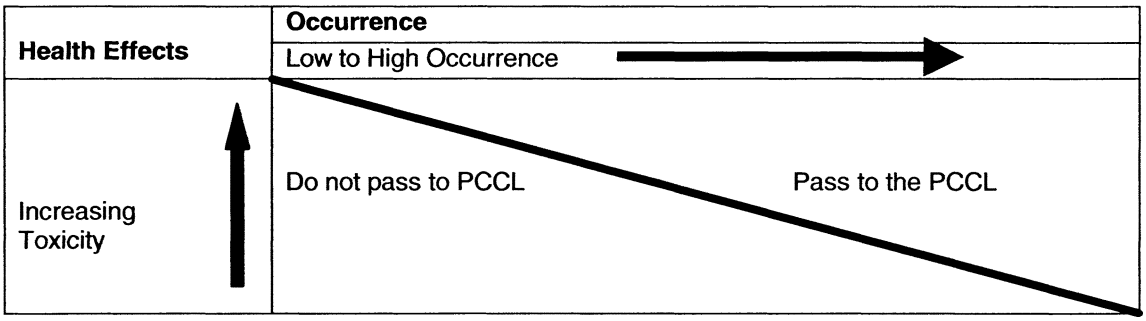
- Identifies chemicals that have relatively high toxicity with high potential to occur in PWSs;
- Identifies chemicals that have relatively high toxicity with minimal actual or potential occurrence in drinking water;
- Identifies chemicals that have high potential to occur in PWSs with relatively moderate toxicity; and
- Considers and uses as many of the available types of health effects and occurrence data identified in the data source evaluations as practical.

EPA compared the chemicals' health effects relative to their occurrence and developed analyses that specifically incorporate many types of available data into the screening criteria. The health effects information included quantitative, descriptive, or categorical information. Within each of these broad types of health effects information, there are multiple types of reported health related values from multiple sources. The health effects analyses conducted by EPA identified approaches to compare each of these data types and identified similarities among chemicals that could be used to define toxicity categories. The occurrence information also included many types of available data representative of a chemical's potential to occur in water. Occurrence data ranged from quantified detection in PWSs, to environmental release, to production data.

The basic framework EPA used in screening is shown in Exhibit 4. EPA categorized the CCL Chemical Universe contaminants by their toxicity along the vertical axis and by their occurrence on the horizontal axis. This allows for separation of chemicals into those that move to the PCCL based on their toxicity and occurrence properties (e.g., upper right in Exhibit 4) and those that are not further evaluated and remain in the CCL Chemical Universe (e.g., lower left in Exhibit 4).

EPA used a set of test chemicals to develop the screening criteria. This set of chemicals included regulated and unregulated chemicals that provided comprehensive information on health effects and occurrence in finished and/or ambient water as well as environmental release and production volume. EPA then used these criteria to select chemicals for the PCCL for further consideration. The following sections summarize how EPA developed the screening criteria by evaluating the available data for chemicals in the Universe, using the framework (Exhibit 4) and the test chemicals. A more detailed discussion is provided in the support document entitled, ''CCL 3 Chemicals: Screening to a PCCL'' (USEPA, 2008 b).

Exhibit 4: Partition for Screening the Universe



a. Health Effects Data Elements

EPA evaluated the toxicity information and health effects data compiled from the data sources in the Universe and these data varied greatly. Some of these data are quantitative (e.g., RfD, LOAEL, NOAEL, LD_{50}) and some are descriptive (e.g., cancer classifications or predictions). EPA designed the screening process to accommodate both types of health effects data.

The quantitative toxicity elements and values available in the Universe included the following:

- RfDs and equivalent (RfD-eq): RfDs, Minimum Risk Levels (MRLs) from ATSDR, Tolerable Daily Intakes (TDIs) from the World Health Organization (WHO), and Public Health Goals (PHGs) from California EPA. A reference dose is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. There are slight differences among Agencies in the methodologies used for some of the RfD equivalents.
- NOAELs—No Observed Adverse Effect Levels. The NOAEL is the highest dose evaluated in a study or group of studies that does not have a biologically significant adverse effect on the species evaluated as compared to controls.
- LOAELS—Lowest Observed Adverse Effect Levels. The LOAEL is the lowest dose evaluated in a study or group of studies that has a biologically significant adverse effect on the species evaluated as compared to the controls.
- TD_{50}s—Tumorigenic dose 50. The dose-rate which if administered chronically for the standard life-span of the species will have a 50 percent probability of causing tumors at some point during that period.
- MRDD—Maximum Recommended Daily Dose. Recommendations for the maximum adult daily therapeutic doses for pharmaceuticals.
- LD_{50}s—Lethal dose 50; an estimate of a single dose that is expected to cause the death of 50 percent of the exposed animals; it is derived from experimental data.

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

- U.S. EPA Cancer Groupings.
- IARC Cancer Groupings.
- NTP weight-of-evidence findings from cancer bioassays.
- National Cancer Institute (NCI) weight-of-evidence findings from cancer bioassays.
- EPA Water Disinfection By-Products with Carcinogenicity Estimates (DBP-CAN) groupings based on carcinogenic potential derived from Quantitative Structure Activity Relationship (QSAR) projections.

EPA divided the chemicals in the Universe into five toxicity categories for screening based upon the distribution of the toxicity value for each type of quantitative data element and/or the qualitative information on cancer weight-of evidence. The five toxicity categories are designated 1 through 5, with Toxicity Category 1 containing chemicals in the most toxic grouping and Toxicity Category 5 the least toxic grouping.

Based upon the distribution of the chemicals for each quantitative data element, EPA selected ranges of toxicity values for each toxicity category that differed based upon the type of data element. For example, the range of toxicity values that place a LOAEL in Toxicity Category 1 differs from the values used for a LD_{50}. Exhibit 5 displays the ranges for each data element and their respective Toxicity Categories.

Additional information which describes how EPA performed the analyses to select the toxicity categories is described in the document entitled, ''CCL 3 Chemicals: Screening to a PCCL'' (USEPA, 2008 b).

EXHIBIT 5.—POTENCY MEASURES FOR UNIVERSE DATA ELEMENTS PARTITIONED BASED ON TOXICITY

[mg/kg/day or mg/kg]

	RfD	NOAEL	LOAEL	MRDD	LD_{50}
Toxicity Category 1	<0.0001	<0.01	<0.01	<0.01	<1
Toxicity Category 2	0.0001–<0.001	0.01–<1	0.01–<1	0.01–<1	1–<50
Toxicity Category 3	0.001–<0.05	1–<10	1–<10	1–<10	50–<500
Toxicity Category 4	0.05–<0.1	10–<1000	10–<1000	10–<1000	500–5000
Toxicity Category 5	>0.1	>1000	>1000	>1000	>5000

EPA partitioned the cancer-related data elements in the Universe into the Toxicity Categories as shown in Exhibit 6. The cancer data placed chemicals in only the three highest Toxicity Categories. EPA did not use quantitative measures of dose-response for carcinogenicity in the screening criteria because more chemicals have categorical data and can be analyzed using this descriptive data than by cancer slope factors. In addition, EPA

did not use descriptors indicating lack of carcinogenic potential or insufficient data to determine carcinogenic potential in categorizing chemicals because those descriptors apply only to the cancer endpoint and do not consider noncancer effects associated with exposure to the chemical.

EXHIBIT 6.—PARTITIONING OF CANCER DATA BASED ON TD_{50} VALUES AND WEIGHT-OF-EVIDENCE DESCRIPTORS

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

** Cancer data placed chemicals in only the three highest Toxicity Categories.
CE = clear evidence, SE = some evidence, EE = equivocal evidence, NE = no evidence.
P = positive, N = Negative, E = equivocal.
H = high probability, HM = high to medium probability, M = medium probability, LM = medium to low probability.

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

b. Occurrence Data Elements

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

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

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

EPA used the following hierarchal approach to select the occurrence data element used to screen a chemical: Finished Water or Ambient Water > Environmental Release Data > Production Data.

The highest data elements in the hierarchy are the finished and ambient water data; the lowest, the production data. Environmental release data from the Toxics Release Inventory (TRI) and pesticide application amounts occupy the middle position in the hierarchy.

EPA also decided that when multiple data values exist for the chemicals within a given component of the hierarchy, the most conservative data value is used. For example, in the case of a chemical that has finished water data and ambient water data, EPA selected the highest reported concentration as the occurrence value used in screening.

EPA obtained the finished water data elements from the National Contaminant Occurrence Database (NCOD), the Unregulated Contaminant Monitoring (UCM) Rounds 1 and 2, the National Inorganic Radionuclides Survey (NIRS), the Unregulated Contaminant Monitoring Regulation (UCMR) monitoring, the Information Collection Rule database for disinfection byproducts, the U.S. Department of Agriculture (USDA) Pesticide Data Program (PDP), and the U.S. Geological Survey (USGS) Pesticides Pilot Monitoring Program (PPMP). These sources included data elements such as percent samples with detections, percent drinking water systems with detections, mean and/or median detected concentrations, and highest observed concentrations.

EPA obtained ambient water values from the USGS National Water Quality Assessment Program (NAWQA), the USGS Toxics Substances Hydrology program's National Reconnaissance of Emerging Contaminants (NREC) and related studies, and the PPMP. These sources included data elements such as percent samples with detections, percent sites with detections, mean and/or median detected concentrations, and highest observed concentrations.

The environmental release data are those reported for 2004 from the TRI and the National Pesticide Use Database, developed by the National Center for Food and Agricultural Policy (NCFAP). The available environmental release data elements include: total releases to the environment (lbs/yr), number of States with releases, pesticide total mass active ingredient applied nationally (lbs/yr), and number of States with pesticide application. EPA chose to use the pounds released per year into the environment for screening because the mass applied to the environment was more directly related to a potential concentration in water than the number of States where a chemical is released or applied.

EPA used the Toxic Substances Control Act (TSCA) chemical production volume ranges reported under the Chemical Update System/Inventory Update Rule (CUS/IUR) to assess production volume. EPA selected the most recent year of data available for each particular chemical. CUS/IUR reports chemical production volume ranges rather than as exact values of

release, and provides production data for all chemicals produced in volumes exceeding 10,000 lbs/yr. The production data are reported in 5 categories that range from less than 10,000 lbs/yr to greater than 1 billion lbs/yr. Therefore, EPA chose to use those ranges as the occurrence subdivisions for the production data.

The occurrence data were grouped by powers of 10 and arrayed from low to high across the horizontal axis of the screening table (Exhibit 4). The document entitled ''CCL 3 Chemicals: Screening to a PCCL'' (USEPA, 2008b) describes the analyses in greater detail.

In some cases, disinfection byproducts and water treatment chemicals lacked quantitative data elements in the Universe. However, both groups have a strong potential to be present in drinking water. EPA moved chemicals in these two categories forward to the PCCL for further evaluation even when limited health effects and/or occurrence information were available.

c. Selection of the PCCL

The last step in the screening process used the intersections between health effects and occurrence data elements in the screening table (Exhibit 4) to establish the PCCL selection line. As noted above, the health data elements were grouped by the 5 toxicity categories with the element showing the highest potency determining placement in the screening table. EPA selected the highest available data element in the occurrence hierarchy to determine placement of a chemical on the horizontal axis in the screening table. Because the chemicals were evaluated using a hierarchical approach for their occurrence elements, EPA developed separate criteria for each of the occurrence elements, and used the placement of a group of test chemicals that had all or nearly all of the occurrence data elements, to establish the position of the PCCL selection line. The test chemicals were selected from regulated and past CCL chemicals. Each had data to illustrate whether it was or was not of concern as a drinking water contaminant.

As a secondary analysis, EPA evaluated existing Drinking Water Equivalent Levels (DWELs) to confirm whether they would make the PCCL. The DWELS were derived from the lower RfD potency for each of the RfD Toxicity Categories. The DWEL (mg/L) is calculated from the RfD in mg/kg/day by multiplying the RfD by an adult body weight of 70 kg and dividing by a drinking water intake of 2 L/day (rounded to one significant figure).When comparing the position of the set of DWELs to the PCCL selection line, all four toxicity categories would be put on the PCCL. This analysis supports the position of the PCCL selection line for chemicals with finished or ambient water concentration data.

EPA also used the test chemicals to determine the PCCL selection line for the other occurrence data elements—total releases to the environment (i.e., TRI, pesticide application data) and production data. For example, the test chemicals were placed in Exhibit 4 based on their release data to guide the placement of the line that separated the ''pass to the PCCL'' chemicals from the ''do not pass to the PCCL'' chemicals. In general, the PCCL selection line was positioned so that regulated and most prior CCL chemicals would be selected for the PCCL.

EPA also analyzed the test chemicals with respect to occurrence, releases, and production data. The test data fit well for the former two categories. For the latter, the fit was not as good so EPA chose to set the PCCL selection line at the point where all chemicals produced at greater than 100 million pounds per year pass to the PCCL even if they fall in the lowest toxicity category.

The criteria for moving a chemical with finished or ambient water, environmental release, and production data to the PCCL are displayed in Exhibit 7.

EXHIBIT 7.—CRITERIA FOR A CHEMICAL TO PASS SCREENING TO THE PCCL

Health effects	Occurrence (by data type)		
	Finished/ambient water concentrations	Release amount (per year)	Production volume (per year)
Toxicity Category 1	All Concentrations	All Amounts	All Amounts.
Toxicity Category 2	≥1 µg/l	≥10,000 lbs/yr	≥500,000 lbs/yr.
Toxicity Category 3	≥10 µg/l	≥100,000 lbs/yr	≥10 M lbs/yr.
Toxicity Category 4	≥100 µg/l	≥1 M lbs/yr	≥50 M lbs/yr.
Toxicity Category 5	≥1000 µg/l	≥10 M lbs/yr	≥100 M lbs/yr.

EPA added DBPs and drinking water additives that lacked quantitative occurrence data but fell in the Toxicity Category 1 or Toxicity Category 2 groupings to the PCCL because of their high probability for being present in disinfected and treated drinking water.

The screening process provides a data-driven, objective, and transparent process for selecting the PCCL from the Universe. All Toxicity Category 1 chemicals (i.e., most toxic) were captured regardless of their occurrence category. The occurrence threshold required for the PCCL selection became less inclusive as the contaminant toxicity decreased. The screening of the CCL 3 Universe resulted in the selection of 532 chemical contaminants for the PCCL from the approximately 6,000 chemicals that were screened. The categorical summary of chemicals that passed the screening is illustrated in Exhibit 8. A complete chemical PCCL list can be found in Appendix B of the document entitled, ''CCL 3 Chemicals: Screening to a PCCL'' (USEPA, 2008b). The 532 PCCL chemicals were further scrutinized as part of the next key step in the process. Some of the contaminants on the PCCL had limited data available for the scoring protocols and could not be run through the models. The 32 contaminants that had limited data identified in the appendixes to the ''Classification of the PCCL to the CCL'' support document (EPA 2008c) and will remain on the PCCL until new data are identified for further evaluation.

EXHIBIT 8.—SUMMARY OF TOTAL CHEMICALS THAT PASSED SCREENING FOR PCCL BY SCREENING CATEGORIES

Toxicity categories	Finished or ambient water concentration	Pesticide app	Total releases	Production volume	Totals
Toxicity Category 1	29	4	56	38	127
Toxicity Category 2	33	26	32	61	152
Toxicity Category 3	36	31	21	66	154
Toxicity Category 4	5	4	10	63	82
Toxicity Category 5	0	0	0	17	17

3. Using Classification Models To Develop the CCL 3

The 532 PCCL chemicals were further scrutinized as part of this key step in the process by using classification models as tools to aid in the selection of the draft CCL 3. As experience is gained, the EPA expects to modify and improve the development of the classification process for future CCLs.

From the inception of the development of the CCL classification process, EPA intended to use classification models as a decision support tool. EPA envisioned that, after testing and evaluation, models would be used to process complex data in a consistent, objective, and reproducible manner and provide a prioritized listing of candidate contaminants for the last stage of the CCL process—an expert review and evaluation. Model application also would help EPA focus resources for the expert review and evaluation of the highest priority potential contaminants.

An overview of the classification model approach used to further evaluate chemicals on the PCCL is described in the following sections. A detailed discussion of the process is provided in a document entitled, ''Contaminant Candidate List 3 Chemicals: Classification of the PCCL to the CCL'' (USEPA, 2008c). The development of this classification process involves the following steps:

- Development of the Attribute Scoring Protocols.
- Development of the Training Data Set.
- Application of the Classification Models.
- Evaluation of Classification Model Output and Selection of the CCL.

To use models to evaluate and classify the PCCL contaminants for listing on the CCL, EPA needed to develop methods to interrelate the important measures (i.e., attributes) that represent a contaminant's health effects and potential for occurrence in drinking water. Four attributes were selected: Potency, severity, prevalence, and magnitude. Protocols were developed for scoring each attribute.

EPA also tested and evaluated the results of several classification models to determine which ones might provide the best decision support tools. To make this evaluation, EPA developed a chemical data set and used the data set to ''train'' the classification models. The selected models were utilized to process the data for the PCCL chemicals and provide a prioritized listing of candidate contaminants for the expert review and evaluation.

a. Development of the Attribute Scoring Protocols

EPA used attributes to characterize different chemicals on the basis of similar qualities or traits. These qualities or traits represent the likelihood of occurrence or potential for adverse health effects of each contaminant. Throughout the process of evaluating the attributes EPA recognized that a wide range of data elements would have to be used for each attribute to characterize chemicals on the PCCL. To evaluate PCCL chemicals with differing types of occurrence and health effects data as potential CCL contaminants, one must be able to establish consistent relationships among the different types of data that represent measures of the attributes. If the same data were available for all contaminants, the comparison and prioritization of candidates would be less complex. To consistently apply the best available data for PCCL chemicals, EPA normalized the different types of data into scales and scoring protocols that accept a variety of input data, apply a consistent framework, and compare different types of data. The following sections describe how EPA developed the scales and scoring protocols for the health effects and occurrence attributes.

i. Health Effects Attributes

Potency and severity are the attributes used to describe health effects. EPA defines potency as the lowest dose of a chemical that causes an adverse health effect and severity is based on the adverse health effect associated with the dose used to define the measure of potency. In other words, potency was scored on the dose that produced the adverse effect and severity was scored based on the health-related significance of the adverse effect (*e.g.*, from dermatitis to organ effects to cancer). These two attributes are interrelated, in that the severity is linked to the measure of potency.

The following toxicological parameters were used to evaluate potency:

- Reference Dose (RfD) or equivalent.
- Cancer potency (concentration in water for 10^{-4} cancer risk).
- No-Observed-Adverse-Effect Level (NOAEL).
- Lowest-Observed-Adverse-Effect Level (LOAEL).
- Rat oral median Lethal Dose (LD_{50}).

EPA developed a ''learning set'' of about two hundred chemicals to calibrate the potency scoring protocols. Once the data for the learning set of chemicals was collected, EPA arrayed and graphically displayed the data to analyze their range and distribution. EPA selected a distribution based on logarithms (base 10) of the toxicity parameters rounded to the nearest integer because it provided a spread of the chemical toxicity parameters across the range and the curve was roughly log-normal.

EPA used a log-based distribution to establish a potency scoring equation for each toxicity parameter. This was accomplished by assigning the most frequent (modal) value in each distribution a score of 5 on a 10 point scale. When the toxicity parameter was one log more toxic than the modal value, a score of 6 was assigned. Similarly, when the parameter was one log less toxic than the modal value a score of 4 was given, and so on. EPA developed an equation for each toxicity parameter that equated the modal value to a score of 5 and calculated the potency score. Because the modal rounded log differed for the different measures of toxicity, it was necessary to use a different equation for each to normalize the mode to a score of 5. The

resultant equations are summarized in Exhibit 9.

EXHIBIT 9.—SCORING EQUATIONS FOR POTENCY

RfD Score = 10 − (Log_{10} of RfD + 7).
NOAEL Score = 10 − (Log_{10} of NOAEL + 4).
LOAEL Score = 10 − (Log_{10} of LOAEL + 4).
LD_{50} Score = 10 − (Log_{10} of LD_{50} + 2).
10^{-4} cancer risk Score = 10 − (Log_{10} of the 10^{-4} cancer risk + 6).

For distributions that spanned more than 5 orders of magnitude above or below the mode, scores for the tails of the distribution were truncated at 1 and 10. Conversely, for distributions that did not span 5 full orders of magnitude above and below the mode, not all scores between 1 and 10 were used. For example, the distribution of the 10^{-4} values for cancer risk was skewed, with values up to 5 orders of magnitude above the modal value (more potent carcinogens) but only 2 orders of magnitude below the mode (less potent carcinogens). This meant that the lowest potency score for this toxicity parameter was a ''3.''

EPA tested the scoring process by using a subset of contaminants with values from multiple data elements considered in the process. In the testing of the potency scoring process, EPA scored all of the chemicals in the learning set for each toxicity parameter to examine the consistency across scores for the non-cancer measures of potency. EPA evaluated the agreement of non-cancer scores across the RfD, NOAEL, LOAEL and LD_{50} inputs and found the scores for any given compound to be generally consistent across parameters. Because of the general consistency among scores, EPA determined that a hierarchy of RfD> NOAEL> LOAEL> LD_{50} would be used in the scoring of potency. This hierarchy gives preference to the potency value with the richest supporting data set (the RfD—or equivalent values) and gives the lowest ranking to the LD_{50} because it is a measure of acute rather than chronic toxicity. If data are available for both the cancer and noncancer endpoints, the higher of the cancer or noncancer potency is selected and the critical effect of the higher measure of potency is used to score the severity.

Severity refers to the relative impact of an adverse health affect. Just as toxicity increases with dose, the severity of the observed effect also increases. A low dose effect could be a simple increase in liver weight while the same chemical at a higher dose could cause cirrhosis of the liver. For consistency, the measure of severity that was used for scoring the PCCL chemicals was the effect or effects seen at the LOAEL. Restricting severity scores to the effects at the LOAEL ties them to the data used to derive the potency score.

The severity measures used to score the PCCL chemicals differ from those used for potency, prevalence, and magnitude because they are descriptive rather than quantitative. Accordingly, they are less amenable to automation and often require more scientific judgment in their application. To guide scoring for severity, EPA developed the nine-point scale displayed in Exhibit 10, and a compendium of nearly 250 descriptions of critical effects grouped by their severity scores (*e.g.*, ''Chronic irritation without histopathology changes'' equals a score of 3).

EXHIBIT 10.—FINAL NINE-POINT SCORING PROTOCOL FOR SEVERITY

Score	Critical effect	Interpretation
1	No adverse effect.	
2	Cosmetic effects	Considers those effects that alter the appearance of the body without affecting structure or functions.
3	Reversible effects; differences in organ weights, body weights or changes in biochemical parameters with minimal clinical significance.	Transient, adaptive effects.
4	Cellular/physiological changes that could lead to disorders (risk factors or precursor effects).	Considers cellular/physiological changes in the body that are used as indicators of disease susceptibility.
5	Significant functional changes that are reversible or permanent changes of minimal toxicological significance.	Considers those disorders in which the removal of chemical exposure will restore health back to prior condition.
6	Significant, irreversible, non-lethal conditions or disorders	Considers those disorders that persist for over a long period of time but do not lead to death.
7	Developmental or reproductive effects	Considers those chemicals that cause developmental effects or that impact the ability of a population to reproduce.
8	Tumors or disorders likely leading to death	Considers chemical exposures that result in a fatal disorder and all types of tumors.
9	Death.	

Severity scores 1 through 6 represent a progression in the severity of the observed effect. Severity score 7 is used for all studies where the effect observed is a reproductive and/or developmental effect allowing the Agency to track the chemicals that pose developmental or reproductive concerns consistent with the 1996 SDWA. A severity score of 8 was used to track all cases where cancer is the basis for the potency score.

ii. Occurrence Attributes

EPA used prevalence and magnitude to describe the potential to occur in drinking water. Prevalence measures how widespread the occurrence of the contaminant is in the environment or how widely the contaminant may be distributed. The prevalence measure indicates the percent of public water systems or monitoring sites across the nation with detections, number of States with releases, or the total pounds produced nationally. Magnitude relates to the quantity of a contaminant that may be found in the environment. The magnitude measures include the median concentration of detections in water or the total pounds of the chemical released into the environment. In most cases the same data element (*e.g.*, detections in drinking water or amount released into the environment) could be used to determine the prevalence, based on the spatial distribution and magnitude based on the amounts. However, where production data were used to determine prevalence, there was no corresponding direct measure of magnitude, so persistence and mobility data were used as surrogate indicators of potential magnitude.

Production/persistence and mobility data are assigned the lowest level in the hierarchy of data available for prevalence and magnitude. Persistence-mobility is determined by chemical

properties that measure or estimate environmental fate characteristics of a contaminant and affect their likelihood to occur and persist in the water environment. Data sources that could provide occurrence data ranged from direct measure of concentrations in water to annual measures of environmental release or production. EPA compiled a second subset or learning set of 207 chemicals, with available data for all of the occurrence attribute data elements that measured prevalence and each of the data elements that measured magnitude, to calibrate protocols for prevalence and magnitude.

The data available for the prevalence attribute consisted of measurements of a contaminant's occurrence across the United States. The prevalence measures have finite ranges such as zero to 100 percent of samples/sites or 1 to 50 States depending on the reporting requirements of the available data source. Accordingly, the scaling of scores for prevalence focused on establishing appropriate groupings of the number of sites or States impacted across the 1 to 10 scoring scale.

The relationship between production or even environmental release data and the actual occurrence in drinking water is complex. Where actual water measurements are available, they are the preferred data element to score prevalence because they are the most direct measures of occurrence in drinking water. EPA selected the following hierarchy for scoring prevalence:

- Percent of PWSs with detections (national scale data).
- Percent of ambient water sites or samples with detections (national scale data).
- Number of States reporting application of the contaminant as a pesticide.
- Number of States reporting releases (total) of the chemical.
- Production volume in lbs/yr.

The production data provide the pounds produced annually of a chemical product in the United States. To some extent, this production rate represents the commercial importance of the chemical, so EPA interpreted the high production tonnage as a likely indication of wide use of a commodity chemical and used this information to score prevalence. For example, a chemical produced at a billion lbs/yr is more likely to be used and released more widely than a compound produced at only 10,000 lbs/yr.

Magnitude represents the quantity of a contaminant that may be in the environment. The data sources that provided the first four levels of the prevalence hierarchy provided direct measurements of water and environmental release that could be used to score magnitude. However, the production categories did not supply an appropriate measure for magnitude. EPA used the persistence and mobility for chemicals with only production data as the basis of the magnitude attribute.

To keep the process straightforward, EPA used one scale for all water concentration data. EPA distributed scores across the range of values so that organic contaminants could receive high scores as well as the inorganic contaminants (IOCs). Comparisons and adjustments were made until there was a reasonable distribution of the scores for organic and inorganic contaminants by using a semi-logarithmic scale. EPA selected the single scale approach and this is discussed in more detail in the report entitled ''CCL 3 Chemicals: Classification of the PCCL to the CCL'' (USEPA, 2008 c).

When developing the calibration scales for the release data, the ranges of data were similarly arrayed using a scale based on half-log units with a distribution of scores that reflected the distribution of the data in the learning set.

EPA based the persistence and mobility scores on chemical and physical properties combined with environmental fate parameters. Persistence and mobility act as measures of potential magnitude because both fate (i.e., persistence) and transport (i.e., mobility) affect the amount of a contaminant to be found in water. The length of time a chemical remains in the environment before it is degraded (persistence) affects its concentration in water. Similarly, the mobility of a chemical, or its ability to be transported to and in water, affects its potential to reach and dissolve in the source waters, and thus, the ultimate concentration of the chemical in the water.

EPA considered a number of data elements to measure the mobility of a chemical in the environment. The physical/chemical parameters that were chosen for the CCL process are:

- Organic Carbon Partition Coefficient (K_{oc})
- Octanol/Water Partition Coefficient (K_{ow})
- Soil/Water Distribution Coefficient (K_d)
- Henry's Law Coefficient (K_H)
- Solubility

The first 4 measures of mobility represent the equilibrium ratio for the partitioning of the contaminant from one medium to another: K_{oc} (soil/sediment organic carbon: water), K_{ow} (octanol: water), K_d (soil/sediment: water) and Henry's Law Coefficient (air: water). K_{oc}, K_{ow} and K_d are sometimes expressed as logs of the original measurements. The measures of persistence reflect the time the chemical will remain unchanged in the environment. Persistence is reflected in the following measures of environmental fate:

- Half-Life
- Measured Degradation Rate
- Modeled Degradation Rate

Each of the mobility and persistence data elements listed above are presented in hierarchical order, with the most desirable at the top (i.e., the first data to be used if available).

As was the case with prevalence, EPA used a hierarchy in scoring magnitude. The hierarchy uses finished water occurrence data if available, and if not, the highest available element in the hierarchy of finished water data > ambient water data > environmental release data > persistence and mobility data. The data elements used in scoring magnitude follow:

- Median value of detections from finished water systems (PWSs) (national scale data)
- Median value of detections from ambient water sites or samples (national scale data)
- Amount of pesticide applied (annual, in pounds)
- Amount of total releases (annual, in pounds)
- Persistence and mobility data

EPA developed attribute scoring protocols through a step-wise process of data selection, data analysis, calibration of scales, and evaluation of the functionality of the scores in PCCL to CCL decision-making. This is discussed in more detail in the report entitled ''Contaminant Candidate List 3 Chemicals: Classification of the PCCL to the CCL'' (USEPA, 2008 c). EPA used the attribute protocols to normalize the data for the PCCL chemicals and develop a set of scores for the four attributes that are the input into the models. By normalizing the data elements, EPA developed a process that can use different kinds of data and information (e.g., quantitative and descriptive) to develop input to the models and provide a relative score for potential contaminants using the attribute scores.

b. Training Data Set for the Classification Models

The training data set (TDS) for chemicals is the set of data used to train

(or teach) the classification models to mimic EPA expert list-not list decisions for PCCL chemicals. EPA compiled this data set in addition to the two learning sets to represent the types of chemicals likely to move forward to the PCCL. This data set also represents the range of possible attribute scores and listing decisions needed to train and calibrate the classification models. The TDS used to train the models for CCL 3 was comprised of 202 discrete sets of attribute scores for chemicals and consensus list-not list decisions made by a team of EPA subject matter experts.

Classification models use statistical approaches for pattern recognition and derive mathematical relationships among input variables (e.g., measurements or descriptive data) and output from a TDS. EPA used classification models to develop a relationship between the contaminant attribute scores (input variables) and the classification of these contaminants into list-not list categories (output). EPA subject matter experts familiar with the technical aspects of the attribute data and the selection of drinking water contaminants for listing and regulation made the list-not list decisions for the TDS. EPA then applied the models to the PCCL to predict likely list-not list decisions.

EPA considered the following key factors in developing the training data set:

- Selection of contaminants representing a range of outcomes and decisions likely to be encountered in developing a CCL;
- A variety of input data ensuring adequate coverage of attribute scores and combinations of scores;
- Chemicals that, when present in drinking water, would present a meaningful opportunity for public health improvement if regulated; and
- Contaminants that would likely be selected for the PCCL.

The TDS used for training the classification models consisted of 202 combinations of attribute scores and the decisions made by EPA experts. The TDS included some of the contaminants from the learning sets used in developing the scoring protocols for toxicity and occurrence. It also included additional contaminants to meet the key factor requirements described above. The set of known chemicals chosen for the TDS was supplemented with a set of attribute scores and decisions that were selected to balance the range of scored attributes the classification model would need to evaluate as described further below.

Initially, EPA selected ''data rich'' contaminants from among regulated contaminants and previous CCLs because they had a range of readily available occurrence and health effects information. EPA drinking water subject matter experts and stakeholders reviewed the initial list of contaminants and identified additional candidates for the TDS. This initial selection process identified 51 chemical contaminants. Subsequently, EPA randomly chose 50 contaminants from chemicals in the CCL 3 Universe with high health effects potency values and accompanying occurrence data because they represented contaminants likely to make it to the PCCL. The addition of these 50 contaminants resulted in 101 contaminants with data to score attributes.

The performance of the classification models using the initial TDS gave an indication of gaps in the possible attribute space that the set of 101 TDS contaminants did not adequately cover. This led EPA to add the sets of possible attribute scores to the TDS based on Latin hypercube sampling (NIST, 2006; *http://www.itl.nist.gov/div898/handbook/glossary.htm#LHC).* Using this approach, EPA added 101 specific combinations of attribute scores to fill in gaps in the space defined by total possible attribute scores and improve the performance of the models. This set of 202 scores and decisions ensured good coverage of both ''list'' and ''not list'' outcomes and became the TDS. Models trained with the TDS with 202 decisions had greater agreement with EPA subject matter experts than those trained with the TDS of 101 contaminants.

List-not list decisions were a key component of the TDS. EPA subject matter experts made list-not list decisions as individuals and as a group, based on attribute scores and based on data that had not been converted to attribute scores (actual or raw data). The development of the list-not list decisions was an iterative process that incorporated revisions to the attribute scoring protocols as experience was gained by the EPA experts. EPA resolved differences between the decisions based on the scored attributes and the raw data by revising the scoring protocols based on the EPA experts' experience to improve the correlation of decisions based on scores to those based on raw data.

EPA subject matter experts reviewed and evaluated the health effects and occurrence data for each contaminant. Each individual reviewer made decisions about how to classify the contaminant and then met as a group to discuss their decisions. Early in the process the reviewers recognized that clear list or not-list decisions could easily be made for some contaminants, but not for other contaminants. For the chemicals where the decision whether to list contaminants was not clear, two categories were added to the analyses. The categories of List? (L?) or Not List? (NL?) allowed the group to identify chemicals that were close to the boundary for a List-Not List decision. That is L? signifies that the decision is leaning towards listing but with some uncertainty, and NL? signifies that the decision is leaning towards not listing but with some uncertainty. These additional two categories were incorporated into the evaluation and model training process.

The EPA subject matter experts also reached a consensus decision for each contaminant. This consensus decision was used to train the models. This is discussed in more detail in the report entitled ''Contaminant Candidate List 3 Chemicals: Classification of the PCCL to the CCL'' (USEPA, 2008c).

c. Evaluation of Classification Models

EPA identified several different models for possible use in selecting contaminants from the PCCL for the CCL: Artificial neural networks, classification decision trees, linear models, and multivariant adaptive regression splines. EPA evaluated the classification models in a two-step process. The first step was the evaluation and selection of models from within each of the model classes that best predicted the consensus decisions of the subject matter experts. The second step was the evaluation of the performance of the best models selected from each class (USEPA, 2008c).

EPA evaluated models based on the 4 attributes that the model was able to consider, the types of relationships or mathematical functions that the model utilized, and the model's ability to predict classifications of the TDS. The iterative training process minimized the model's predictive error, thereby reducing incorrect model predictions. EPA also evaluated the impact of the attributes used by the models and the effects of missing data on the performance of the models during the various stages of development.

EPA evaluated the performance of five models. Three models, Artificial Neural Network (ANN), Quick, Unbiased and Efficient Statistical Tree (QUEST), and Linear Regression demonstrated consistent performance when trained and evaluated with the TDS. The classification models were assessed and compared with respect to:

• The number of correct and incorrect classifications for the 202 TDS contaminants.
• The number of ''large'' misclassifications (off by more than one category).
• The weighted sum of TDS classification errors.
• Ability to identify intermediate classifications.
• Consistent behavior (e.g., no decreasing classification as attribute scores increase).

This is discussed in more detail in the report entitled ''Contaminant Candidate List 3 Chemicals: Classification of the PCCL to the CCL'' (USEPA, 2008c).

d. Application and Use of Model Results

From the inception of the development of the CCL classification process, EPA intended to use classification models as decision support tools. It was envisioned that the models would be used to process complex data in a consistent, objective, and reproducible manner and provide a prioritized listing of contaminants, allowing EPA to focus resources on the expert review and evaluation of the highest priority potential contaminants. The ANN, Linear, and QUEST models are three different classes of models, with three different mathematical approaches, yet they all provided similar results and logical determinations. EPA explored simple ways to combine the results of all three models, to capture both agreement among models and unique results. Both a straightforward, additive approach, and a collective, rank-order approach were utilized to provide a prioritized listing of contaminants to be considered further and evaluated for possible inclusion on the draft CCL 3.

e. Model Outcome and Expert Evaluation

In the last step of the process, the chemicals on the PCCL were scored for their attributes and evaluated by the three models. Some of the contaminants on the PCCL had limited data available for the scoring protocols and could not be run through the models. The 32 contaminants that had limited data are identified in the appendixes to the ''Classification of the PCCL to the CCL'' support document (EPA 2008c) and will remain on the PCCL until new data are identified for further evaluation. As part of the evaluation of model output, EPA formulated several post-model refinements that were added to the CCL selection process. Exhibit 11 illustrates the results of the model output for the PCCL contaminants. The PCCL consisted of chemicals with variable health effects data, ranging from reference doses (RfD) to Lethal Dose 50s (LD_{50}), and occurrence data ranging from measured water concentration data from Public Water Systems (PWS) to production volume data.

EXHIBIT 11.—MODEL RESULTS FOR THE PCCL CHEMICALS

3-Models decision	% of PCCL	Total # PCCL	Finished or ambient water	Release	Production
L	9	44	3	24	17
L–L?	12	58	9	29	20
L?	33	163	26	64	73
NL?–L?	6	30	6	11	13
NL?	28	139	29	28	82
NL?–NL	4	20	7	9	4
NL	9	46	21	7	18
N (all)	100	500	101	172	227

Four of the seven decision categories, L, L?, NL?, NL, in the first column of Exhibit 11 signify that all of the models were in unanimous agreement with the listing decision. The other categories (e.g., NL?–L?) represent varied agreement where one or two of the models chose one category and the other model(s) resulted in a different category. Note that none of the models placed a contaminant in a category more than one category higher or lower than the other models. That is, no contaminants were categorized as ''L'' by one model and as ''NL?'' by one of the other models, or visa versa. The models categorized approximately one-half of the chemicals on the PCCL as L? or above. When analyzed by data type, the majority of chemicals in the List category used LD_{50} data for health effects. This was a concern and became an important issue for consideration. The role LD_{50} played in the health effects scoring was discussed extensively during the post-model evaluation process.

As part of the last stage in the CCL classification process, the model output was reviewed by a group of internal EPA experts representing several offices. This step involved a detailed review of the data used for the models and the available supplemental data for the chemicals. The EPA experts also deliberated on the method of using the model data to produce a draft proposal for CCL 3. The function of this review was to critically compare the results from the model to the data for the chemicals for a cross section of the modeled contaminants.

Based upon issues identified by the evaluators, several post model refinements were added to the CCL process. Three major issues and refinements are described below.

The relationship between potency and concentration was important when deciding whether to list a chemical. However this ratio could only be developed when water concentration data were available. Accordingly, calculation of the ratio between the health-based value and the 90th percentile concentration in finished or ambient water was added as a post-model process. The potency/concentration ratio serves as a benchmark that suggests a greater concern for a contaminant if the ratio is low and a lesser concern when it is high.

The addition of modeled occurrence data for pesticides and estimated concentration in surface and ground water was obtained from the EPA Office of Pesticide Programs (OPP). The modeled estimates of concentration in water for pesticides are part of the EPA's pesticide registration and re-registration evaluations. Once the availability of the OPP data for some of the pesticides was confirmed, the data were extracted from OPP documents and used to generate a potency/concentration ratio similar to that used with the water concentration data.

Data certainty was factored into the decision process by characterizing health effect and occurrence data

elements and their relative certainty based upon the type of data that was used to score the attribute for the model classification. This characterization tagged data elements with high certainty and low certainty. The combined certainty measure for a single contaminant (i.e., health effects and occurrence tags) was used to place contaminants in bins of high, medium and low certainty.

The high certainty bin consisted of chemicals with direct occurrence measured in water and well-studied data for health effects. Such contaminants are expected to be good candidates for regulatory determination because they provide information that can be considered in that process and have minimal research needs. Examples of the data used to characterize chemicals in the high certainty bin include chemicals with RfDs, LOAELs, and NOAELs, and water concentration data. The medium bin consists of chemicals that will need further occurrence and/or health effects research. For example, chemicals with well studied health effects that only have environmental release data are included in the medium bin. Chemicals that are released to the environment and need further health effects research are also included in the medium bin. The low certainty bin consists of chemicals that have limited data, yet these data suggest that further evaluation should be pursued. These chemicals may need extensive health effects and occurrence research that may require significant resources before regulatory determinations can be made. Examples include chemicals with only LD_{50} and/or production volume data. The CCL should consist both of chemicals that provide sufficient data to support regulatory determinations as well as chemicals that are of concern and need to be targeted for additional drinking water research. Contaminants from each bin were scrutinized separately in selecting which ones should be listed on the CCL 3.

4. Selection of the Draft CCL 3—Chemicals

The chemicals for the draft CCL 3 were selected from within the three certainty bins with the emphasis placed on the source of the occurrence data (e.g., measured concentrations, release, and production). Four groups of chemicals were placed on the CCL based on their modeled scores, the potency-concentration ratios, where available, and the estimate of data certainty. They included:

- 36 chemicals in the high certainty bin with finished or ambient water data and a potency/90th percentile concentration ratio ≤10.
- 24 pesticide chemicals in the medium certainty bin with modeled surface and/or ground water data that yielded a potency/concentration ratio ≤10.
- 27 chemicals in the medium certainty bin with release data that gave modeled L or L-L? rankings.
- 8 chemicals in the low certainty bin that were added to the CCL as recommended by the public in response to EPA's **Federal Register** notice (71 FR 60704, USEPA, 2006b). The notice requested that the public submit chemical and microbial contaminant nominations that should be considered for CCL 3. This process is discussed in section III.C.1.

The potency and concentration were compared to develop a ratio that was used to select contaminants for the draft CCL 3 from the high certainty bin. A ratio between the health-based value and the 90th percentile was taken for chemicals with measurements in finished and ambient water. Contaminants for this bin were selected for the draft CCL 3 when the ratio was ≤10, representing occurrence in water at a level of concern related to its health effects data.

The pesticides in the medium bin, where modeled data was obtained from OPP, were selected for the draft CCL 3 based on their potency/concentration ratios. Similar to the chemicals in the high certainty bin, pesticides were selected for the draft CCL 3 when the potency/concentration ratio was <10, representing potential occurrence in water at a level of concern related to its health effects data. The other chemicals in the medium bin were selected for the draft CCL 3 based on a review of their data and their prioritization from the classification models.

Chemicals in the low certainty bin were selected for the draft CCL 3 based on a review of their supplemental data and the data submitted through the nominations process. Some of the chemicals identified through the nominations process were already on the draft CCL 3 based on the data EPA collected for the universe. The supplemental data provided with the nominations were used to screen the nominated chemicals and score the attributes for those that passed the screen. The scored attributes were then processed through the models and the post-model evaluations. Those that were listed demonstrated adverse health effects and a potential to occur in PWSs. Chemicals not selected for the draft CCL 3 will remain on the PCCL until additional occurrence or health effects data become available to support their reevaluation.

B. Classification Approach for Microbial Contaminants

As discussed in CCL 2 (USEPA, 2005b), the Agency evaluated the NDWAC, NRC and other recommendations, and used the information to develop a pragmatic approach for classifying the microorganisms on the draft CCL 3. The CCL 3 approach for microbes, like the approach used for chemicals, uses the attributes of occurrence and health effects to select the microbial contaminants. EPA's objective is to target microorganisms with the highest potential for human exposure and the most serious adverse health effects. Parallel to the chemical selection process, the Agency considers a broad universe of microbial contaminants and systematically narrows that universe down to develop the draft CCL 3 in a transparent and scientifically sound CCL process. The first step of the CCL 3 approach for microbes identifies a universe of potential drinking water contaminants. The second step screens that universe of microbiological contaminants to a Preliminary Contaminant Candidate List (PCCL). Lastly, EPA selects the draft CCL 3 microbial list by ranking the PCCL contaminants based on occurrence in drinking water (including waterborne disease outbreaks) and human health effects.

1. Developing the Universe

EPA defined the microbial Universe for the draft CCL 3 as all known human pathogens. The Universe process began with the list of 1,415 recognized human pathogens compiled by Taylor *et al.* (2001). The Agency added organisms to the Universe and updated nomenclature in Taylor *et al.* (2001) to account for emerging pathogens and new taxonomy research.

As EPA reviewed Taylor *et al.* (2001), additional pathogens were also identified. EPA surveyed fungi in drinking water and identified six fungi reported to occur in drinking water distribution systems that did not appear on the Taylor list. The added fungi are shown in Exhibit 12. EPA also added reovirus to the Universe based on additional health effects information (Tyler, *et al.*, 2004).

In October 2006, EPA published a notice (71 FR 60704 (USEPA, 2006b)) requesting chemical and microbial contaminant nominations as part of the process to identify emerging contaminants that should be considered for the CCL. As a result of the

nominations process, 24 microbial contaminants were nominated by the public. Twenty-two of the microbes were previously identified by Taylor *et al.* (2001) and are already in the Universe. The two additional pathogens nominated were *Methylobacterium* (with two species) and Mimivirus. These two bacterial species, two viral groups and six fungal species were added to the Microbial Universe which brings the Microbial Universe list to 1,425 pathogens. The full Universe list is available in the document, ''Contaminant Candidate List 3 Microbes: Identifying the Universe'' (USEPA, 2008d).

EXHIBIT 12.—FUNGI ADDED TO THE MICROBIAL UNIVERSE

Pathogen
Arthrographis kelrae
Chryosporium zontatum
Geotrichum candidum
Sporotrichum pruinosum
Stachybotrys chartarum
Stemphylium macrosporoideum

2. The Universe to PCCL

EPA developed screening criteria to reduce the Universe of all human pathogens to just those pathogens that could be transmitted through drinking water. For example, pathogens transmitted solely by animals, such as the virus that causes rabies, were screened out of the Universe and are not included on the PCCL. Screening is based on a pathogen's epidemiology, geographical distribution, and biological properties in their host and in the environment. EPA moved pathogens forward to the PCCL if there was any evidence linking a pathogen to a drinking water-related disease. The screening criteria restrict the microbial PCCL to human pathogens that may cause drinking water-related diseases resulting from ingestion of, inhalation of, or dermal contact with drinking water. EPA used 12 screening criteria (Exhibit 13) to reduce the pathogens in the microbial CCL universe to the PCCL.

EXHIBIT 13.—CCL SCREENING CRITERIA FOR PATHOGENS

1. All anaerobes.
2. Obligate intracellular fastidious pathogens.
3. Transmitted by contact with blood or body fluids.
4. Transmitted by vectors.
5. Indigenous to the gastrointestinal tract, skin and mucous membranes.
6. Transmitted solely by respiratory secretions.
7. Life cycle incompatible with drinking water transmission.
8. Drinking water-related transmission is not implicated.
9. Natural habitat is in the environment without epidemiological evidence of drinking water-related disease.
10. Not endemic to North America.
11. Represented by a pathogen for the entire genus or species (that are closely related).
12. Current taxonomy changed from taxonomy used in Universe.

Pathogens meeting any single criterion of the 12 criteria were removed from further consideration and not moved forward to the PCCL. Based upon this screening exercise, 1,396 of the 1,425 pathogens were excluded and 29 pathogens moved on to the PCCL. The results of the screening process are summarized in Exhibit 14. The screening criteria and results of the screening process are discussed in greater detail in the supporting document titled ''Contaminant Candidate List 3 Microbes: Screening to the PCCL'' (USEPA, 2008 e).

EXHIBIT 14.—APPLICATION OF TWELVE SCREENING CRITERIA TO PATHOGENS IN THE MICROBIAL CCL UNIVERSE

Pathogen class	Total	Screening Criteria												Pathogens screened out	On PCCL
		1	2	3	4	5	6	7	8	9	10	11	12		
Bacteria	540	125	14	10	37	117	7	0	29	154	2	28	5	528	12
Viruses	219	0	0	26	104	0	19	1	18	0	36	8	0	212	7
Protozoa	66	0	0	1	29	3	0	4	7	7	0	6	0	57	7*
Helminths	287	0	0	0	25	0	0	106	0	0	156	0	0	287	0
Fungi	313	0	0	0	0	12	1	0	0	297	0	0	0	310	3
Total	1,425	125	14	37	195	132	27	111	54	458	194	42	5	1,394	29*

*Two additional protozoa, *Cryptosporidium* and *Giardia* were not considered for CCL 3 and they are discussed in more detail later.

3. The PCCL to Draft CCL Process

Pathogens on the PCCL were scored for placement on the draft CCL. EPA devised a scoring system to assign a numerical value to each pathogen on the PCCL.

Each of the pathogens on the PCCL was scored using three scoring protocols, one protocol each for waterborne disease outbreaks (WBDO), occurrence in drinking water, and health effects. The higher of the WBDO score or the occurrence score is added to the normalized health effects score to produce a composite pathogen score. Pathogens receiving high scores were considered for placement on the CCL.

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

the three protocols used to score the pathogens on the PCCL and the process by which the scores are combined.

a. Waterborne Disease Outbreak Protocol

The Centers for Disease Control and Prevention (CDC), EPA and the Council of State and Territorial Epidemiologists (CSTE) have maintained a collaborative surveillance system for collecting and periodically reporting data related to occurrences and causes of WBDOs since 1971. EPA used the CDC surveillance system as the primary source of data for the waterborne disease outbreaks protocol. Reports from the CDC system are published periodically in *Morbidity and Mortality Weekly Report* (MMWR).

For this protocol (Exhibit 15), a pathogen is scored as having a WBDO(s) in the U.S. if that pathogen is listed in a CDC waterborne disease drinking water surveillance summary (i.e., in the MMWR). A pathogen with multiple WBDOs listed by CDC is given the highest score under this protocol. EPA also scored non-CDC reported WBDOs and WBDOs outside the U.S. as well; however these were given lower scores. WBDOs outside the U.S. were scored when information was available from World Health Organization publications or other peer-reviewed publications.

In addition, CDC and EPA acknowledge that the WBDOs reported in the surveillance system represent only a portion of the burden of illness associated with drinking water exposure (CDC, 2004). The surveillance information does not include endemic waterborne disease risks, nor are reliable estimates available of the number of unrecognized WBDOs and associated cases of illness. Therefore, EPA also considered data as indicating a WBDO (even though CDC does not list a WBDO in their MMWR) if the non-CDC data showed a link between human illness defined by a common water source, a common time period of exposure and/or similar symptoms. EPA also considered the use of molecular typing methods to link patients and environmental isolates.

Only two pathogens were given a WBDO score on this basis, *Mycobacterium avium* and *Arcobacter butzlerei*. They are discussed in greater detail in the ''Contaminant Candidate List 3 Microbes: PCCL to CCL Process'' (USEPA, 2008 f).

EXHIBIT 15.—WATERBORNE DISEASE OUTBREAK SCORING PROTOCOL

Category	Score
Has caused multiple (2 or more) documented WBDOs in the U.S. since CDC surveillance initiated in 1973	5
Has caused at least one documented WBDO in the U.S. since CDC surveillance initiated in 1973	4
Has caused documented WBDOs at any time in the U.S.	3
Has caused documented WBDOs in countries other than the U.S.	2
Has never caused WBDOs in any country, but has been epidemiologically associated with water-related disease	1

b. Occurrence Protocol

The second attribute of the scoring process evaluates the occurrence of a pathogen in drinking water. Because water-related illness may also occur in the absence of recognized outbreaks, EPA scored the occurrence (direct detection) of microbes using cultural, immunochemical, or molecular detection of pathogens in drinking water under the Occurrence Protocol (Exhibit 16). Occurrence characterizes pathogen introduction, survival, and distribution in the environment. Occurrence implies that pathogens are present in water and that they may be capable of surviving and moving through water to produce illness in persons exposed to drinking water by ingestion, inhalation, or dermal contact.

Pathogen occurrence is considered broadly to include treated drinking water, and all waters using a drinking water source for recreational purposes. This attribute does not characterize the extent to which a pathogen's occurrence poses a public health threat from drinking water exposure. Because viability and infectivity cannot be determined by non-cultural methods, the public health significance of non-cultural detections is unknown.

EXHIBIT 16.—OCCURRENCE SCORING PROTOCOL FOR PATHOGENS

Category	Score
Detected in drinking water in the U.S.	3
Detected in source water in the U.S.	2
Not detected in the U.S.	1

c. Health Effects Protocol

EPA's health effects protocol evaluates the extent or severity of human illness produced by a pathogen across a range of potential endpoints. The seven-level hierarchy developed for this protocol (Exhibit 17) begins with mild, self-limiting illness and progresses to death.

The final outcome of a host-pathogen relationship resulting from drinking water exposure is a function of viability, infectivity, and pathogenicity of the microbe to which the host is exposed and the host's susceptibility and immune response. SDWA directs EPA to consider subgroups of the population at greater risk of adverse health effects (i.e., sensitive populations) in the selection of unregulated contaminants for the CCL. Sensitive populations may have increased susceptibility and may experience increased severity of symptoms, compared to the general population. SDWA refers to several categories of sensitive populations including the following: children and infants, elderly, pregnant women, and persons with a history of serious illness.

Health effects for individuals with marked immunosuppression (e.g., primary or acquired severe immunodeficiency, transplant recipients, individuals undergoing potent cytoreductive treatments) are not included in this health effects scoring. While such populations are considered sensitive subpopulations, immunosuppressed individuals often have a higher standard of ongoing health care and protection required than the other sensitive populations under medical care. More importantly, nearly all pathogens have very high health effect scores for the markedly immunosuppressed individuals; therefore there is little differentiation between pathogens based on health effects for the immunosuppressed subpopulation.

This protocol scores the representative or common clinical presentation for the specific pathogen for the population category under consideration. EPA used recently published clinical microbiology manuals as the primary data source for the common clinical presentation. These manuals take a broad epidemiological view of health effects rather than focusing on narrow research investigations. The one exception to this approach was EPA's scoring of health effects for *Helicobacter pylori*. *H. pylori* is discussed in greater detail in section IV.C as well as in the support document, ''CCL 3 Microbes: PCCL to CCL Process'' (USEPA, 2008 f).

To obtain a representative characterization of health effects in all populations, EPA evaluated separately the general population and these four sensitive populations as to the common clinical presentation of illness for that population. EPA added the general population score to the highest score among the four sensitive subpopulations for an overall health effects score. The resulting score acknowledges that sensitive populations have increased risk for waterborne diseases.

EXHIBIT 17.—HEALTH EFFECTS SCORING PROTOCOL FOR PATHOGENS

Outcome category	Score	Manifestation in population class				
		General population	Children/ infants	Elderly	Pregnant women	Chronic disease
Does the organism cause significant mortality (> 1/1,000 cases)?.	7					
Does the organism cause pneumonia, meningitis, hepatitis, encephalitis, endocarditis, cancer, or other severe manifestations of illness necessitating long term hospitalization (> week)?.	6					
Does the illness result in long term or permanent dysfunction or disability (e.g., sequelae)?.	5					
Does the illness require short term hospitalization? (< week)?	4					
Does the illness require physician intervention?	3					
Is the illness self-limiting within 72 hours (without requiring medical intervention)?.	2					
Does the illness result in mild symptoms with minimal or no impact on daily activities?.	1					

d. Combining Protocol Scores to Rank Pathogens

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

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

The CCL selection process considered pathogens causing recent waterborne outbreaks more important than pathogens detected in drinking water without documented disease from that exposure. Direct detection of pathogens indicates the potential for waterborne transmission of disease. Documented waterborne disease outbreaks provide an additional weight of evidence that illness was transmitted and that there was a waterborne route of exposure. EPA developed protocols to define a hierarchy of the relevance that each of these types of data provide in evaluating microbes for the CCL. Combining these two sources of occurrence information enabled EPA to consider both emerging pathogens, which are detected in water and should be considered, yet are not tracked by public health surveillance programs, and those pathogens with WBDO data. This hierarchy also acknowledges that organisms identified as agents in WBDO are a higher priority for the CCL.

Next, pathogens were scored using the Health Effects Protocol. All five population categories were scored for each pathogen using the most common clinical presentation for the specific pathogen for the population category under consideration. Because it is recognized that pathogens may produce a range of illness from asymptomatic infection to fulminate illness progressing rapidly to death, scoring decisions are based upon the more common clinical presentation and clinical course for the population under consideration, rather than the extremes. The pathogen's score for the general population is added to the highest score among the four sensitive populations to produce a sum score between 2 and 14.

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

Exhibit 18 presents the scores for all the PCCL pathogens with the exception of *Giardia* and *Cryptosporidium.* These two protozoan pathogens made it through the screening protocol, however, EPA chose not to score or include them on the PCCL because EPA has recently published a national primary drinking water regulation that specifically addresses these pathogens (January 4, 2006, 71 FR 388 (USEPA, 2006 a) and is discussed in more detail later.

EXHIBIT 18.—PATHOGENS ON THE PCCL

Pathogen	WBDO	Occurrence	Normalized health score	Total[1] score
Naegleria fowleri	4	3	5.0	9.0
Legionella pneumophila	5	3	3.6	8.6
Escherichia coli (0157)	5	3	3.2	8.2

EXHIBIT 18.—PATHOGENS ON THE PCCL—Continued

Pathogen	WBDO	Occurrence	Normalized health score	Total[1] score
Hepatitis A virus	5	2	3.2	8.2
Shigella sonnei	5	3	3.2	8.2
Helicobacter pylori	1	3	5.0	8.0
Campylobacter jejuni	5	3	2.5	7.5
Salmonella enterica	5	3	2.5	7.5
Caliciviruses	5	3	2.1	7.1
Entamoeba histolytica	5	3	2.1	7.1
Vibrio cholerae	5	3	2.1	7.1
Adenovirus	2	3	3.6	6.6
Enterovirus	2	3	3.6	6.6
Cyclospora cayetanensis	4	1	2.5	6.5
Mycobacterium avium	4	3	2.5	6.5
Rotavirus	4	2	2.5	6.5
Yersinia enterocolitica	5	3	1.4	6.4
Arcobacter butzleri	4	3	2.1	6.1
Fusarium solani	1	3	2.9	5.9
Plesiomonas shigelloides	4	3	1.8	5.8
Hepatitis E virus	2	1	3.6	5.6
Toxoplasma gondii	2	1	3.2	5.2
Aspergillus fumigatus group	1	3	2.1	5.1
Exophiala jeanselmei	1	3	2.1	5.1
Aeromonas hydrophila	1	3	1.8	4.8
Astrovirus	2	2	1.4	3.4
Microsporidia	1	2	1.4	3.4
Isospora belli	2	0	1.1	3.1
Blastocystis hominis	1	0	0.7	1.7

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

e. Other Criteria Considered for Listing and Scoring Microbes on the Draft CCL 3

i. Organisms Covered by Existing Regulations

EPA considered an additional screening criterion based upon contaminants that might be controlled through drinking water monitoring requirements under the Total Coliform Rule (TCR) (54 FR 27544, June 29, 1989 (USEPA, 1989b)). Many of the bacteria in the CCL Universe, including the *Enterobacteriaceae* and members of the genera *Campylobacter* and *Vibrio,* are associated with fecal contamination and as such their presence could be signaled by the total coliform monitoring requirements under current drinking water regulations. In the TCR, EPA chose to require monitoring for *Escherichia coli* or fecal coliform (and total coliforms) in finished drinking water because it provides a broad indication of the potential presence of fecal pathogens in drinking water, though more so for bacteria than for viruses and protozoa.

EPA chose not to exclude common enteric bacterial pathogens from the PCCL even though they may be indicated by the TCR. Numerous waterborne disease outbreaks have occurred in systems that were in compliance with drinking water monitoring requirements under the TCR. EPA recognizes the frequency of total coliform monitoring under the TCR may be limited, especially for smaller systems, thus transitory fecal contamination could go undetected. The recognition of these bacterial pathogens on the CCL list will provide additional understanding of the risks posed by distribution systems.

The Agency is currently revising the TCR and considering distribution water quality issues (because of the pathways of potential fecal contamination). Including these pathogens on the CCL emphasizes their importance in protecting public health. EPA believes that enteric pathogens should be included for further specific regulatory consideration in the CCL.

ii. Organisms Covered by Treatment Technique Regulations

According to SDWA (section 1412(b)(1), as amended in 1996), EPA must select CCL contaminants that ''at the time of publication, are not subject to any proposed or promulgated national primary drinking water regulation * * *.'' In promulgating regulations for contaminants in drinking water, EPA can set either a legal limit (MCL) and require monitoring for the contaminant in drinking water or, for those contaminants that are difficult to measure, EPA can establish a treatment technique requirement. The Surface Water Treatment Rule (SWTR) (54 FR 27486, June 29, 1989 (USEPA, 1989a)) included MCLGs for *Legionella, Giardia,* and viruses at zero because any amount of exposure to these contaminants represents some public health risk. Since measuring disease-causing microbes in drinking water is not considered to be feasible, EPA established treatment technique requirements for these contaminants. The purpose of subsequent treatment technique requirements (Interim Enhanced Surface Water Treatment Rule (63 FR 69478; USEPA 1998a), Long Term Surface Water Treatment Rule 1 (67 FR 1813; USEPA, 2002a) and the Long Term Surface Water Treatment Rule 2 (71 FR 654; USEPA, 2006a)) which included an MCLG of zero for *Cryptosporidium,* is to reduce disease incidence associated with *Cryptosporidium* and other pathogenic microorganisms in drinking water. These rules apply to all public water systems that use surface water or ground water under the direct influence of surface water.

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

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

While *Cryptosporidium* and *Giardia* have been implicated in WBDOs, there is a substantial amount of research regarding health effects and sensitivity to various treatment control measures. More importantly, as noted above, EPA has recently published a National Primary Drinking Water Regulation, The Long Term 2 Surface Water Treatment Rule that specifically addresses these pathogens (71 FR 654 (USEPA, 2006a)). Therefore, they are excluded from the CCL.

EPA did not exclude specific viruses and *Legionella* from consideration for the CCL even though they have broad category MCLGs and treatment technique requirements. Viruses include a wide range of taxa. The treatment and health effects information for different viral taxa was very limited when setting the treatment technique requirements for surface water and ground water systems. Also, different viral taxa have been implicated in various waterborne disease outbreaks for which EPA did not have dose response or treatment data when promulgating its treatment technique requirements. *Legionella* has recently been identified in numerous WBDOs (e.g., CDC *MMWR* reports, 2006). Additionally EPA received additional information on the occurrence of *Legionella* in distribution systems as part of the nominations process (USEPA 2008g). Therefore EPA included viruses and *Legionella* on the draft CCL 3.

iii. Applying Genomic and Proteomic Data to Microbes

The Agency and NDWAC workgroup evaluated the possibility of using genomics and proteomics as data to identify emerging waterborne pathogens, opportunistic microorganisms, and other newly identified microorganisms. While the application of these data in identifying genetic properties that may be pathogenic is a powerful tool for the elucidation of pathogenic mechanisms, the technology is yet largely unproven and the Agency has decided at this time not to use these techniques for CCL application. However, the Agency is monitoring the progress of these technologies and as the data improve and genomics progresses the Agency may consider them for future CCL development.

4. Selection of the Draft CCL 3 Microbes From the PCCL

The 29 PCCL pathogens in Exhibit 18 are ranked according to an equal weighting of their summed scores for normalized health effects and the higher of the individual scores for WBDO and occurrence in drinking water. EPA believes this ranking indicates the most important pathogens to consider for the draft CCL 3. To determine which of the 29 PCCL pathogens should be the highest priority for EPA's drinking water program and included on the draft CCL 3, the Agency considered both scientific and policy factors. The factors included the PCCL scores for WBDO, occurrence, and health effects; comments and recommendations from the various expert panels; the specific intent of SDWA; and the need to focus Agency resources on pathogens to provide the most effective opportunities to advance public health protection. After consideration of these factors, EPA has determined that the draft CCL 3 will include the 11 highest ranked pathogens shown in Exhibit 18.

Additionally, the Agency notes that, and as can be observed in Exhibit 18, there are a few ''natural'' break points in the ranked scores for the 29 pathogens, with the top 11 forming the highest ranked group of pathogens. EPA does believe that the overall rankings strongly reflect the best available scientific data and high quality expert input employed in the CCL selection process, and therefore should be important factors in helping to identify the top priority pathogens for the draft CCL 3.

C. Public Input

1. Nominations and Surveillance

On October 16, 2006, EPA published a **Federal Register** notice (71 FR 60704 (USEPA, 2006 b)) requesting the public to submit chemical and microbial contaminant nominations that should be considered for CCL 3. EPA evaluated nominated contaminants to identify the data supporting their nomination. This section describes EPA's request for contaminants and summarizes the nominations received by EPA. A more detailed discussion of the contaminants, including a list of the specific contaminants nominated, can be found in the CCL 3 Nominations Summary in EPA's Water Docket (USEPA, 2008 g).

The Agency sought CCL nominations for contaminants by framing the SDWA requirements in a series of questions to document the anticipated or known occurrence in PWS(s) and adverse health effects of potential contaminants. The Agency requested that the public respond to these questions and provide the documentation and rationale for including a contaminant for consideration in the CCL process. The questions posed to the public were:

—What are the contaminant's name, CAS number, and/or common synonym (if applicable)?

—What factors make this contaminant a priority for the CCL 3 process (e.g., widespread occurrence; anticipated toxicity to humans; potentially harmful effects to susceptible populations (e.g., children, elderly and immunocompromised); potentially contaminated source water (surface or ground water), and/or finished water; releases to air, land, and/or water; contaminants manufactured in large quantities with a potential to occur in source waters)?

—What are the significant health effects and occurrence data available, which you believe supports the CCL requirement(s) that a contaminant may have an adverse effect on the health of persons and is known or anticipated to occur in public water systems?

The Agency compiled the information from the nominations process to identify the contaminants nominated and the rationale for the nomination and to compare the supporting data to information already gathered by EPA.

The nominations process identified 150 chemical and 24 microbial contaminants from 11 organizations and individuals. The organizations that nominated contaminants are:

—American Society of Microbiology (ASM),

—American Water Works Association (AWWA),

—Association of Metropolitan Water Agencies (AMWA),

—Association of State Drinking Water Administrators (ASDWA),

—Mothers Against *Acanthamoeba* Disease,

—Natural Resources Defense Council, (NRDC),

—Riverkeepers,

—State of New Jersey Department of Environmental Protection,

—State of New York Department of Health, and

—State of Texas Commission on Environmental Quality.

Exhibit 19 summarizes the types of nominated contaminants and who nominated them. The complete list of chemical and microbial contaminants nominated can be found in EPA's Water Docket. Some of the nominations identified categories of contaminants that the Agency should consider for the CCL. There were 23 chemical groups identified from the 150 chemical contaminants that were nominated. For

example, several organizations identified pesticides that are not currently regulated under the SDWA as candidates for consideration. Other groups identified by the public are listed in Exhibit 19.

EXHIBIT 19.—SUMMARY OF CCL 3 NOMINATIONS

Nominator	Number of individual contaminants or specific examples from nominated groups	Types and groups of contaminants
ASM	2	Mimivirus, *Naegleria fowleri*.
AMWA	3	Nitrosoamines and other DBPs.
ASDWA	14	Disinfection byproducts (DBPs), unregulated pesticides, solvents, total petroleum hydrocarbons, cyanotoxins, 3 perfluorinated contaminants (PFCs), viruses, phthalates, nitrite, nitrate; endocrine disruptors.
AWWA	38	DBPs, pesticides, 16 specific microbes, cyanotoxins, radium, 1,4-dioxane.
Mothers Against *Acanthamoeba* Disease	1	*Acanthamoeba*.
New Jersey DEP	4	PFOS, PFOA, trichloropropane, tertiary butyl alcohol.
New York DOH	24	Pharmaceuticals, personal care products, DBPs, fuel oxygenates, 1,4-dioxane, herbicides, bio-monitoring data.
NRDC	26	Alkylphenolpolyethoxylates (APEs that may be endocrine disrupter compounds (EDC)), all unregulated pesticides, perchlorate, Mycobacterium avium complex (MAC), phthalates, managanese, bisphenol A.
Riverkeeper	52	Pharmaceuticals, sodium, chloride.
Texas DEQ	3	Viruses, nitrite, nitrate.

The Agency evaluated the nominations to identify contaminants not previously considered for the CCL and new pertinent information provided by the public. Nominated contaminants were evaluated to identify and compare supporting information provided to that used in the CCL process. Of the 174 chemical and microbial contaminants nominated, 152 contaminants were already being considered by the Agency. Seven of the nominated contaminants are currently regulated in PWSs and will not be included in the CCL 3 process. Most of the data sources cited in the nominations process were already identified for the CCL 3 process. The nominations process did identify recently published specialized studies from scientific literature that were subsequently incorporated in the CCL 3 evaluation process.

Where new supplemental data was provided for contaminants that had not been identified for the draft CCL 3, EPA used the supplemental data to screen the nominated chemicals and score the attributes for those that passed the screen. EPA then processed the nominated contaminants through the models and the post-model evaluations. Twenty of the contaminants identified in the nominations process are on the draft CCL 3.

2. External Expert Review and Input

EPA actively sought external advice and expert input for the draft CCL 3. In addition to their own recommendations, the NRC and NDWAC recommended that the Agency seek opportunities to incorporate additional expert input in the development of the draft CCL 3. EPA convened several external expert panels at integral stages during the development of the draft CCL 3. EPA incorporated expert judgment and input from the scientific community into the CCL process for both chemicals and microbes. The Agency has requested a consultation with the Science Advisory Board that will take place in 2008.

For each expert panel, EPA sought panel members that provided a variety of disciplines and expertise. Panel members were encouraged to provide comments as individuals based upon their expertise and background, not as representatives of their respective organizational affiliations. Expert panel members were also encouraged to present individual comments if consensus comments were not developed. Separate panels were convened to review the draft chemical and microbial CCL 3 lists and the processes used to develop them. A more detailed discussion of the chemical and microbial expert review and input is provided in the support documents in the EPA Water Docket. A brief overview of the chemical and microbial expert review and stakeholder involvement follows.

a. Chemical Expert Input Panels

In September of 2006, EPA formed two external expert panels to provide specific input into the chemical CCL 3 process. In the first panel, experts reviewed the data sources and the process used to identify the chemical universe. EPA convened the second panel for a 3-day workshop to review the data and information used to develop screening criteria, the data and methodology for the classification approach, and to provide overall input into the CCL process. In summary, the panels recommended that EPA consider additional data sources in the process. They also commented on ways to improve and clarify the presentation of EPA efforts, thereby ensuring that the CCL 3 process for chemicals is more transparent. The expert panel reviewing the classification approach identified additional analyses and approaches to train and validate the models. The panel specifically commented on the varied nature of data elements and sources considered in the classification process. The panel recommended that to account for these varied data sources, contaminants be flagged based upon data certainty, and that uncertainty be considered in making a listing decision. The Agency applied their recommendations in the development of the draft CCL 3. In addition, the expert panels acknowledged the Agency's efforts to transparently present a complex process and noted that many of the questions posed by the panels were previously considered by EPA. They recommended that additional discussion and information in the support documents would add to the clarity of the process.

In March 2007, EPA convened a panel to review the preliminary draft CCL 3 list for the chemical contaminants in a two-day workshop. Panelists provided

comments on a preliminary draft list of contaminants after receiving supporting materials and presentations from EPA staff. The panel's review focused mainly on the chemicals on the draft CCL 3. They provided comments on contaminants considered for the draft CCL 3 and commented on the supporting data and methods EPA used to identify the contaminants selected. They also provided general comments on the classification model output and the processes used to select chemical contaminants for CCL 3. In addition, they recommended EPA consider a strong outreach process to highlight the significant modeling and decision making processes used in its development.

The panel recognized the level of effort and detail that went into the development of the modeling process used to create the draft list and complimented EPA on these efforts. Comments from all the panels were considered by EPA and appropriate changes were incorporated into the process/protocols to formulate the draft CCL 3. (Specific recommendations and comments are further described in USEPA, 2008h.)

b. Microbial Expert Input Panels

EPA convened three workshops to review, discuss, and comment on the microbes considered and selected for the draft CCL 3. In December 2005, a group of expert microbiologists reviewed and commented on the universe of human pathogens and the screening criteria used to develop the PCCL. This panel agreed that focusing on human pathogens is a reasonable and pragmatic way to identify potential drinking water contaminants. While the panel suggested that animal pathogens may develop the ability to infect humans, they noted that these emerging contaminants should not be listed on the CCL based on the theoretical potential to become zoonotic pathogens. They also identified additional criteria and methods to apply those criteria to the Microbial Universe, which EPA incorporated into the CCL process.

In June 2006, a panel of experts met for three days to review EPA's implementation of recommendations by NRC and NDWAC to select microbes for the CCL. EPA implemented the NDWAC recommendation to develop a process that paralleled the chemical process yet still accounted for the different types of data and information that are uniquely available for microbial contaminants. Panel members agreed that health effects and occurrence of microbes should be evaluated to identify pathogens of the greatest health importance. The panel recommended that EPA use a decision tree approach for microbes rather than the classification approach suggested by NRC and NDWAC.

The panel further recommended that the Agency consider a different selection process than the one used for chemical contaminants, related to the different information available for microbes. Based on this recommendation, the Agency evaluated options to consolidate the potency and severity attributes for microbes into a single health effect attribute, developed a waterborne disease outbreak protocol, and considered occurrence as a single attribute. The Agency considered these and other recommendations as it developed the current three attribute selection process discussed in Section III.B. The panel also recommended that the Agency consider drinking water treatment and removing microbes from further consideration if conventional drinking water treatment protects public health. The Agency's considerations of these and other recommendations are discussed in the Microbial Expert Review support document (USEPA, 2008i).

In March 2007, EPA convened a third workshop to review the preliminary draft CCL 3 list of microbial contaminants. EPA provided the panel with background materials and staff presentations. The panel's review focused mainly on the draft CCL 3 for microbes. The panel also provided comments on the processes used to select the microbial contaminants. Panel members commented on specific microbes considered for the draft CCL 3 and commented on the data and processes EPA used to identify the contaminants selected. The panel noted that the Agency considered a comprehensive list of microbes and thought the draft CCL 3 was reasonable. The panel also recommended that the Agency consider adding a frequency of disease parameter to the health effects scoring protocol for future CCLs. For example, while the panel agreed with EPA that the health effects for *Naegleria fowleri* are severe, the health effects scoring protocol should consider the limited occurrence of disease. The panel also noted that this would help balance the consideration of less severe adverse health effects such as gastrointestinal illness that are more prevalent with consideration of more severe responses that are less prevalent, such as *N. fowleri.* The panel recommended that EPA provide further discussion of the rationale to evaluate waterborne disease and health effects equally in the protocol. The discussion of the Agency's rationale is included in Section III.B and addresses the importance of documented waterborne disease outbreaks to identify potential microbial contaminants for the CCL. (A more detailed summary of the expert comments is provided in USEPA, 2008 i.)

3. How are the CCL and UCMR Interrelated for Specific Chemicals and Groups?

EPA promulgated UCMR 2 on January 4, 2007 (72 FR 367 (USEPA, 2007 a; see also USEPA, 2007 b and c)). The UCMR program was developed in coordination with the CCL. Both programs consider the adverse health effects a contaminant may pose through drinking water exposures. Sixteen contaminants on the UCMR 2 monitoring list are also on the draft CCL 3. The draft CCL 3 includes acetochlor and its degradates, alachlor degradates, dimethoate, 1,3-dinitrobenzene, metolachlor and its degradates, RDX, terbufos sulfone, and four of the nitrosamines. In addition to the health effects data and potential occurrence, the UCMR 2 also considers analytical methods, availability of analytical standards, and laboratory capacity to conduct a nationwide monitoring program in selecting contaminants. The UCMR 2 includes nine contaminants that are not on draft CCL 3. The five polybrominated flame retardants can be measured by the same analytical method used for terbufos sulfone. The polybrominated flame retardants lacked sufficient occurrence information to be listed on draft CCL 3 (USEPA 2008 b). The polybrominated flame retardants are listed on UCMR2 because of recent concern that these have become more widespread environmental contaminants (e.g., Darnerud *et al.*, 2001) and this monitoring data will provide information for future CCLs. Similarly, 2,4,6-trinitrotoluene (TNT) and two of the nitrosamines also use an analytical method in the UCMR 2. The Agency will also use the results from UCMR 2 as a source of occurrence information during the selection of CCL 4, as well as for CCL 3 regulatory determinations. Alachor was listed on UCMR 2, but was removed from consideration for CCL 3 because there is an existing MCL.

IV. Request for Comment

The purpose of this notice is to present the draft CCL 3 and seek comment on various aspects of its development. The Agency requests comment on the approach used to develop the draft CCL 3 and also requests comments on the contaminants selected, including any supporting data

that can be utilized in developing the final CCL 3. A number of contaminants considered for the draft CCL 3 may be of particular current interest. The following sections provide information for a few of the contaminants that are of most interest. Data obtained and evaluated for developing the draft CCL 3 and referred to in the following sections may be found in the docket for this notice. Specifically, the Agency is also asking for public comments on pharmaceuticals and perfluorinated compounds to identify any additional data and information on their concentrations in finished or ambient water and requests comment on how they have been considered in the CCL 3 process. The Agency is also seeking additional data and information on the occurrence and health effects of *H. pylori* and how this pathogen was considered in the CCL 3 process. Information and comments submitted will be considered in determining the final CCL 3, as well as in the development of future CCLs and in the Agency's efforts to set drinking water priorities in the future.

A. Pharmaceuticals

The Agency evaluated data sources to identify pharmaceuticals and personal care products that have the potential to occur in PWSs. The primary source of health effects information on pharmaceuticals in the universe was the Food and Drug Administration Database on Maximum Recommended Daily Doses (MRDD). This database includes the recommended adult doses for over 1,200 pharmaceutical agents. Occurrence information from USGS Toxics Substances Hydrology program's National Reconnaissance of Emerging Contaminants, and related efforts, provided ambient water concentration data for 123 contaminants, which include pharmaceuticals. Other data sources included TRI and high production volume chemical data. From this analysis, EPA included 287 pharmaceuticals in the Chemical Universe. These pharmaceuticals had maximum recommended daily dose information that EPA used to evaluate adverse health effects. EPA considered those pharmaceuticals for which MRDD values and occurrence information were available and pharmaceuticals that were in Toxicity Category 1, using the same criteria discussed in Section III.A.2.a. EPA found that less than two percent of the pharmaceuticals included in the MRDD database fell into this category.

EPA applied the LOAEL screening protocols to contaminants with MRDD values. The LOAEL protocol was used because pharmaceutical agents, although used for their beneficial effects, have associated side-effects that may be adverse. Chemicals evaluated with these data had similar modal values and distributions to the toxicity values from IRIS. The range of toxicity values in this database covered 9 orders of magnitude when evaluated based on their rounded logs. They had the same modal value as the LOAELs from IRIS and a very similar distribution. Thirty-five percent of the IRIS LOAELS and 38 percent of the MRDDs had the modal rounded log. Thirty-three percent of the LOAELs and 19 percent MRDDs had rounded logs that were lower than the mode, while 31 percent of the LOAELs and 44% of the MRDDs had rounded logs that were above the modal log value.

The screening process moved approximately 10 percent of the pharmaceuticals in the Universe to the PCCL. All toxicity data on those chemicals were included in the screening with the most serious qualitative or quantitative measure of toxicity determining placement in a toxicity category. Only one of the PCCL chemicals (diazinon, a veterinary product as well as a pesticide) had water concentration data. Two other pharmaceuticals: phenytoin (an anticonvulsant) and nitroglycerin (treatment of angina), had release data. The remainder were scored for occurrence based on production information, which meant that they fell into the low certainty bin for their occurrence parameters. Nitroglycerin is the only pharmaceutical that is included on the draft CCL 3. EPA is aware of concerns regarding the potential presence of pharmaceuticals in water supplies. The Agency is seeking additional data and information on the concentrations of pharmaceuticals in finished or ambient water and requests comment on how pharmaceuticals have been considered in the CCL 3 process.

B. Perfluorooctanoic Acid and Perfluorooctane Sulfonic Acid

EPA evaluated perfluorinated compounds in the CCL 3 process and requests comment on its decisions to include perfluorooctanoic acid (PFOA) and not to include perfluorooctane sulfonic acid (PFOS) on the draft CCL 3. EPA identified potential health effects and occurrence information for these compounds from the data sources discussed in Section III. The data used for these compounds are discussed in the support documents in more detail. Available analytic methods for these chemicals limited the occurrence data for these compounds. The Agency identified data on the annual production from CUS/IUR indicating limited production and possible release to the environment. Several organizations nominated PFOS and PFOA for consideration in the CCL process. The nominations noted that these chemicals are persistent in the environment and have been detected at varying levels in drinking water and ambient water in smaller specialized studies. EPA collected the information cited in the nominations and evaluated each of these chemicals. The Agency included PFOA on the draft CCL 3 because it met the criteria for inclusion on draft CCL 3 based on drinking water occurrence studies in Ohio and West Virginia (Emmett, *et al.*, 2006) and on health effects data indicated through animal studies (USEPA, 2005 a).

The Agency did not include PFOS on the draft CCL 3. Occurrence data for PFOS characterized detections in several States (Boulanger, *et al.*, 2004, Hansen, *et al.*, 2002, Goeden and Kelly, 2006). These data showed that levels of detection for PFOS in ambient water ranged from 20 to approximately 100 parts per trillion. Data identified in the nominations process detected PFOS at higher concentrations in areas surrounding landfills known to be contaminated with industrial waste containing PFOS. The CCL process did not consider occurrence data from targeted studies of contaminated waste sites, however. Such studies are usually developed to identify and characterize hazardous waste cleanup efforts and may not be representative of occurrence in drinking water not in close proximity to the study site. PFOS was phased out of production in the U.S. between 2000 and 2002, and regulation limits its importation to a very small number of controlled, very low release uses, (67 FR 72854; December 9, 2002 (USEPA, 2002 c)). Based on the general absence of occurrence data, combined with the phase out, effectively eliminating most future releases, PFOS did not meet the criteria for CCL 3.

The Agency is evaluating data related to PFOA in a formal risk assessment process under the Toxic Substance Control Act. EPA's Science Advisory Board (SAB) completed a review of a draft risk assessment in 2006 and SAB made recommendations for the further development of the risk assessment. A final risk assessment may not be completed for several years, as a number of important studies are underway. The Agency is also participating in additional research regarding the toxicity and persistence of related perfluorochemicals, as well as research to help identify where these chemicals

are coming from and how people may be exposed to them.

C. Helicobacter pylori

Helicobacter pylori is a pathogen that causes gastric cancer in addition to acute gastric ulcers. EPA placed this pathogen on the draft CCL. However, the analysis for *H. pylori* differs from the other pathogens due to the long term and/or chronic nature of its health effects rather than the more common acute effects of most waterborne pathogens. This organism is an emerging pathogen whose impact has only recently begun to be understood. Given the slow development of adverse health effects due to infection by *H. pylori*, it is more difficult to link contamination of drinking water and show a waterborne disease outbreak. Therefore, given the long timeframe of cancer and ulcer development (as opposed to the commonly acute gastrointestinal illness of nearly all the other pathogens on the PCCL) as well as the ongoing nature of the research, EPA used peer-reviewed scientific papers to score the health effects of *Helicobacter pylori.* EPA request comment on the process of selection of microbial contaminants that cause chronic rather than acute health effects.

V. EPA's Next Steps

Between now and the publication of the final CCL, the Agency will evaluate comments received during the comment period for this notice, consult with the SAB, and re-evaluate the criteria used to develop the draft CCL and revise the CCL, as appropriate.

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