



Request for Nominations of Drinking Water Contaminants for the Contaminant Candidate List

October 16, 2006

**ENVIRONMENTAL PROTECTION
AGENCY**

[EPA-HQ-OW-2005-0039; FRL-8231-3]

**Request for Nominations of Drinking
Water Contaminants for the
Contaminant Candidate List**

AGENCY: Environmental Protection
Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is requesting nominations of chemical and microbial contaminants for possible inclusion in the third drinking water Contaminant Candidate List (CCL 3). EPA is also requesting information that shows the nominated contaminant may have an adverse health effect on people and the contaminant occurs or is likely to occur in public water systems.

DATES: Nominations must be received on or before December 15, 2006.

ADDRESSES: Submit your nominations to the CCL3 Nominations Web site <http://www.epa.gov/safewater/ccl/ccl3.html> by following the on-line instructions for submitting nominations or mail to CCL Nominations, Environmental Protection Agency, Mail Code: 4607M, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: For general information contact the EPA Safe Drinking Water Hotline at (800) 426-4791 or e-mail: hotline-sdwa@epa.gov. For technical questions about this notice contact Clifton Townsend, Standards and Risk Management Division, Office of Ground Water and Drinking Water, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 564-1576; e-mail address: townsend.clifton@epa.gov. For technical inquiries regarding EPA's CCL 3 Nominations Web site, please contact Zeno Bain at (202) 564-5970 or e-mail: bain.zeno@epa.gov.

SUPPLEMENTARY INFORMATION

I. General Information

A. Does This Action Apply to Me

This action requests drinking water contaminant candidate nominations and provides information on how the public can submit nominations to the Agency.

B. How Can I Get Copies of This Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under Docket ID No. EPA-HQ-OW-2005-0039. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the Water Docket in the EPA Docket Center.

or the EPA Web site at <http://www.epa.gov/epahome/dockets.htm> for current information on docket status, locations and telephone numbers.

2. *Electronic Access.* You may access this Federal Register document electronically through the EPA Internet under the Federal Register listings at <http://www.epa.gov/fedrgstr/>.

II. Background

A. What Is the CCL?

There are thousands of naturally occurring and man-made contaminants that have the potential to enter sources of drinking water (e.g., pesticides, pharmaceuticals, personal care products, industrial chemicals). Some of these contaminants may pose no risk to human health, but others may cause cancer or have endocrine disrupting, reproductive, or developmental effects. Naturally occurring microbial contaminants may also cause acute illness. To ensure that public health is protected, EPA must assess the universe of unregulated drinking water contaminants to determine if they may require regulation under the Safe Drinking Water Act (SDWA).

The CCL is the primary vehicle used by EPA to target and prioritize unregulated contaminants in drinking water for research and analysis to determine which new contaminants should be regulated. SDWA requires that EPA publish, every five years, a list of unregulated chemical and microbial contaminants that are known or anticipated to occur in public water systems and which may require regulation under the Safe Drinking Water Act (SDWA Section 1412(b)(1)). EPA is also required to consult with the scientific community and provide notice and opportunity for public comment prior to publication of the CCL.

SDWA also requires EPA to determine whether to regulate at least five contaminants from the CCL every five years. In making regulatory determinations, the Agency must consider the following three statutory criteria:

1. Is the contaminant likely to cause an adverse effect on the health of persons?
2. Is the contaminant known or likely to occur in public water systems at a frequency and level of concern?
3. Does regulation of the contaminant present a meaningful opportunity for health risk reduction for persons served by public water systems?

B. How Did EPA Develop Previous Contaminant Candidate Lists?

The first CCL (CCL 1) was published on March 2, 1998 (63 FR 10273). The contaminants were categorized based on four priority areas in drinking water research: occurrence, health effects, treatment, and analytical methods. CCL 1 was developed based on a review by technical experts of readily available information and contained 50 chemicals and 10 microbial contaminants. EPA consulted with the scientific community and the National Drinking Water Advisory Council (NDWAC) on a process for developing the first CCL. Based on the NDWAC recommendations, the Agency developed and used screening and evaluation criteria to develop a list of chemical contaminants for CCL 1. For microbiological contaminants, the Agency followed NDWAC recommendations and sought external expertise to identify and select potential waterborne pathogens. The Agency convened a workshop of microbiologists and public health experts who developed criteria for screening and evaluation and subsequently developed an initial list of potential microbiological contaminants.

On July 18, 2003 (68 FR 42897), EPA announced its final regulatory determination for nine contaminants from CCL 1, which concluded that sufficient data and information was available to make the determination not to regulate nine contaminants (eight chemicals and one microbial).

The second CCL (CCL2) was published on February 24, 2005 (70 FR 9071) and carried forward the remaining 51 chemical and microbial contaminants listed on CCL 1. Currently, the Agency is evaluating data and research on these chemicals and microbes to make regulatory determinations as it continues work to develop the CCL 3.

C. How Is EPA Developing Future CCLs?

After publication of CCL 1, the Agency recognized the need for a more robust and transparent process for identifying and narrowing the list of potential contaminants for future CCLs and sought advice from the National Academies of Science (NAS) on how to improve the CCL process. The 2001 NAS report, *Classifying Drinking Water Contaminants for Regulatory Consideration* (NAS 2001), proposed a broader, more comprehensive screening process to assist EPA in identifying those contaminants for the CCL. The NAS recommended that EPA develop and use a process for creating 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 that indicate public health risk and the likelihood of occurrence in drinking water. All of the contaminants on the PCCL would then be assessed in more detail using a classification approach and tools along with expert judgment to evaluate the likelihood that specific contaminants could occur in drinking water at levels and at frequencies that pose a public health risk. The outcome of the detailed classification approach results in the draft CCL.

The contaminants initially considered for the CCL (i.e. CCL Universe) include naturally occurring substances, emerging waterborne pathogens, chemical agents, byproducts and degradants of chemical agents, and biological toxins. The PCCL will include contaminants that occur, or have the potential to occur, in drinking water and cause, or may cause adverse health effects.

In 2002, EPA consulted with NDWAC and received advice for implementing the 2001 NAS recommendations. NDWAC recommended that EPA move forward with the NAS recommendations using an adaptive management approach. This approach provides a framework to implement recommendations in phases and refine and adjust the CCL process as more

information and experience are attained. NDWAC provided specific recommendations on eliciting public participation and suggested that EPA seek contaminant nominations from the public for inclusion on the CCL. Implementing the nominations process provides a mechanism for early public participation in the CCL process and allows the Agency to obtain suggestions for contaminants that should be on the CCL (NDWAC 2004).

D. How Will EPA Use Data Sources To Identify Contaminants for the CCL Universe?

Based upon recommendations from NAS and NDWAC, the Agency is using the following guiding principles to construct the CCL Universe: (1) The universe should include those contaminants that have demonstrated or have potential occurrence in drinking water, and (2) the universe should include those contaminants that have demonstrated or have potential adverse health effects. These inclusionary principles apply to the selection of CCL contaminants for initial consideration in the CCL Universe.

EPA has evaluated over 280 resources (referred to as "data sources") to determine whether they are appropriate for use in identifying potential drinking water contaminants for the CCL. The data sources vary widely in their development and use (e.g., research, surveys, and compliance monitoring); type of data (e.g., concentrations, health

effects, microbiological occurrence, and environmental fate); data format; availability; and possible applicability to the universe of contaminants for consideration.

The Agency recognizes that there are 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.

To identify chemical contaminants, consistent with recommendations for developing the Universe, the Agency recognizes that the most appropriate data sources for use in the CCL classification process will provide information in a number of areas including concentrations, health effects, occurrence, and environmental fate. EPA has identified four factors that should be met for data sources to be considered useable. Sources are screened for relevance, completeness, redundancy (those sources with the most comprehensive sources are selected, while less comprehensive sources with the same information are rejected), and retrievability to determine use in the CCL classification process. Table 1 provides a list of the data sources that EPA will use in compiling the Chemical CCL Universe.

TABLE 1.—INITIAL CLASSIFICATION OF CHEMICAL DATA SOURCES

Data source name	Organizations
ATSDR CERCLA Priority List	Agency for Toxic Substances and Disease Registry.
ATSDR Minimal Risk Levels (MRLs)	Agency for Toxic Substances and Disease Registry.
Chemical Toxicity Database—Ministry of Health and Welfare, Japan	Ministry of Health and Welfare, Japan.
Chemical Update System/Inventory Update Rule (CUS/UR)	EPA.
Cumulative Estimated Daily Intake/Acceptable Daily Intake (CEDI/ADI) Database	U.S. Food and Drug Administration (FDA).
Database of Sources of Environmental Releases of Dioxin-Like Compounds in the United States.	EPA.
Distributed Structure Searchable Toxicity Public Database Network (DSSTox)	EPA.
Everything Added to Food in the United States (EAFUS) Database	FDA.
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) List	EPA.
Generally Regarded As Safe (GRAS) Substance List	FDA.
Guidelines for Canadian Drinking Water Quality (CADW). Summary of Guidelines	Health Canada.
World Health Organization (WHO) Guidelines for Drinking Water Quality: Summary Tables	WHO.
Health Advisories (HA) Summary Tables	EPA.
High Production Volume (HPV) Chemical List	EPA.
Hazardous Substances Data Bank (HSDB)	National Library of Medicine.
Indirect Additives Database	FDA.
International Agency for Research on Cancer (IARC) Monographs	International Agency for Research on Cancer.
International Toxicity Estimates for Risk (ITER) Database	Toxicology Excellence for Risk Assessment (TERA).
Integrated Risk Information System (IRIS)	EPA.
Joint Meeting On Pesticide Residues (JMPR)—2001. Inventory of Pesticide Evaluations	World Health Organization, Food and Agriculture Organization
National Drinking Water Contaminant Occurrence Database (NCOD)—Round 1 & 2	EPA.
National Drinking Water Contaminant Occurrence Database (NCOD)—Unregulated Contaminant Monitoring Rule (UCMR).	EPA.

TABLE 1.—INITIAL CLASSIFICATION OF CHEMICAL DATA SOURCES—Continued

Data source name	Organizations
National Inorganics and Radionuclides Survey (NIRS)	EPA.
National Pesticide Use Database	National Center for Food and Agricultural Policy.
National Reconnaissance of Emerging Contaminants (NREC)—USGS Toxic Substances Hydrology Program.	U.S. Geological Survey (USGS).
National Toxicology Program (NTP) Studies	National Cancer Institute.
National Water Quality Assessment (NAWQA)	USGS.
OSHA 1988 Permissible Exposure Limits (PELs)	National Institute for Occupational Safety and Health (NIOSH).
Pesticide Data Program	USDA.
Pesticides Pilot Monitoring Program	USGS/EPA.
Risk Assessment Information System (RAIS)—Department of Energy—Chemical Factors	U.S. Department of Energy.
Risk Assessment Information System (RAIS)—Health Effects Data	Department of Energy.
State of California EPA Chemicals Known to the State to Cause Cancer or Reproductive Toxicity.	State of California.
Storage and Retrieval (STORET)	EPA.
Substance Registry System (SRS)	EPA.
Syracuse Research Corporation (SRC)—BIODEG	Syracuse Research Corporation.
The Toxics Release Inventory (TRI)	EPA.
Toxic Substances Control Act (TSCA) List	EPA.
Toxicity Criteria Database—California Office of Environmental Health Hazard Assessment (OEHHA).	California Office of Environmental Health Hazard Assessment.
University of Maryland—Partial List of Acute Toxins/Partial List of Teratogens	University of Maryland.

For microbes, the adverse health effects from exposure are characterized by clinical or epidemiological data and there are few analytical methods to estimate or model the occurrence of microbes. Limited sources of tabular data for microbes may require evaluation of primary literature, technical reports, monographs and reference books to identify the universe of microbes for consideration. The Agency is using human pathogens as the starting point for identifying microorganisms considered for inclusion in the CCL Universe. The primary source of information on human pathogens is *Risk Factors for Human Disease Emergence* (Taylor *et al.* 2001), which provides a list of 1,415 human pathogens. In addition to the Taylor *et al.* study, the Agency will use the nominations process to ensure that the CCL universe captures emerging pathogens.

E. Why Is EPA Soliciting Contaminant Nominations?

EPA is requesting contaminant nominations from the public to ensure that contaminants that may not be identified for consideration as part of the recommended CCL process are considered. The Agency is making significant progress in developing a contaminant classification approach and continues to implement the NAS and NDWAC recommendations.

While NAS and NDWAC recommended a data driven step-wise approach to classifying contaminants, these experts also recognized the importance of providing an additional

pathway for the public to identify new and emerging contaminants that may not be identified in an evaluation of the data sources. A public nominations process allows the Agency to consider new and emerging contaminants that might not otherwise be considered because new information has not been widely reported or recorded.

Following the recommendations of NAS and NDWAC, the Agency has compiled a universe of contaminants and will add nominated contaminants from the public to the CCL Universe. The nominees will be considered as EPA evaluates NAS and NDWAC recommendations to screen the CCL universe and develops criteria to classify contaminants for the draft CCL.

III. EPA CCL Nominations Process

This contaminant nominations process is the first opportunity to make nominations to the new CCL (CCL 3). The Agency will also accept nominations during the notice and comment period following EPA's publication of the draft CCL 3.

A. How can Stakeholders, Agencies, Industry, and the Public Nominate Contaminants for the CCL?

EPA's preferred method for submission of contaminant nominations is through the EPA CCL 3 Nomination Web site. Interested parties can nominate chemicals, microbes, or other materials for consideration on the new CCL by sending information electronically, or in hard copy to EPA. Do not submit confidential business information (CBI) through e-mail. If you

wish to submit CBI, first contact EPA (see ADDRESSES section) for instructions on how to submit CBI. When submitting a nomination, it is preferred that the nominators include a name, affiliation, phone number, mailing address, and e-mail address; however, this information is not required and nominations can be submitted anonymously. The nominator should also address the following questions for each contaminant nominated to the CCL:

1. What is the contaminant's name, CAS number, and/or common synonym (if applicable)?
2. 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; released to air, land, and/or water; contaminants manufactured in large quantities with a potential to occur in source waters)?
3. 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? Please provide complete citations, including author(s), title, journal and date. Contact information for the primary investigator would also be helpful.

B. How Do I Submit Nominations Through EPA's Nominations Web Site?

The Web site is designed to provide key information to the Agency, as described in Section III. A of this notice, for each contaminant nominated to the CCL process.

The Web address to nominate a contaminant can be found at <http://www.epa.gov/safewater/ccl/ccl3.html>.

C. How do I Submit Nominations in Hard Copy?

You may submit nominations by mail. To allow full Agency consideration of your nomination, please ensure that your nominations are received or postmarked by midnight December 15, 2006. The addresses for submittal of nominations by mail are listed in the ADDRESSES section of this document

D. What Will Happen to My Nominations After I Submit Them?

The Agency will include nominated contaminants into the CCL Universe EPA will evaluate the information available for the nominated contaminants to determine the

appropriateness of inclusion on the PCCL and finally the CCL. While EPA does not intend to respond to the nominations directly or individually, the Agency will fully explain nominated contaminants for the CCL3.

IV. References

Copies of these documents are found at <http://www.regulations.gov>, Docket ID No. EPA-OW-2005-0039.

NAS 2001. National Academy of Sciences, National Research Council. 2001. Classifying Drinking Water Contaminants for Regulatory Consideration. National Academy Press. Washington, DC. Available at <http://books.nap.edu/books/0309074088/html/index.html> NDWAC 2004. National Drinking Water Advisory Council. National Drinking Water Advisory Council Report on the CCL Classification Process to the U.S. Environmental Protection Agency, May 18, 2004. Available at http://www.epa.gov/safewater/ndwac/pdfs/report_ccl_ndwac_07-06-04.pdf.

Taylor, Latham, and Woolhouse. 2001. Risk factors for human disease emergence (Appendix A). Philosophical Transactions of the Royal Society of London Biology: 256:983-98.

Dated: October 6, 2006.

Benjamin H. Grumbles,
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Note: The EPA Docket Center suffered damage due to flooding during the last week of June 2006. The Docket Center is continuing to operate. However, during the cleanup, there will be temporary changes to Docket Center telephone numbers, addresses, and hours of operation for people who wish to visit the Public Reading Room to view documents. Consult EPA's **Federal Register** notice at 71 FR 54815 (September 19, 2006)