ENVIRONMENTAL PROTECTION AGENCY

[FRL–7529–2]

Announcement of Regulatory Determinations for Priority Contaminants on the Drinking Water Contaminant Candidate List

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: The Safe Drinking Water Act (SDWA), as amended in 1996, directs the United States Environmental Protection Agency (EPA) to publish a list of contaminants (referred to as the Contaminant Candidate List, or CCL) to assist in priority-setting efforts for the Agency's drinking water program. SDWA also directs the Agency to select five or more contaminants every five years from the current CCL and determine whether or not to regulate these contaminants with a National Primary Drinking Water Regulation (NPDWR).

On June 3, 2002, EPA published preliminary regulatory determinations for nine contaminants together with the determination process, rationale, and supporting technical information for each contaminant to seek comment from the public (67 FR 38222). The nine contaminants include three inorganic compounds (IOCs) (manganese, sodium, and sulfate); three synthetic organic compounds (SOCs) (aldrin, dieldrin, and metribuzin); two volatile organic compounds (VOCs) (hexachlorobutadiene and naphthalene); and one microbial contaminant, *Acanthamoeba.* EPA's preliminary determination was that no regulatory action was appropriate for any of the nine contaminants.

EPA received 15 comments from individuals or organizations on the preliminary regulatory determinations for the nine contaminants. The Agency has reviewed these comments and, after careful consideration, decided that no regulatory action is appropriate, at this time, for the nine CCL contaminants published in the June 2002 notice. Regulation of the nine contaminants would not present a meaningful opportunity for health risk reduction for persons served by public water systems (PWSs).

Today's action describes the statutory requirements for the CCL, the analysis EPA used to make the regulatory determinations, a summary of relevant public comments with the Agency's responses, a summary of the nine CCL contaminants, and the Agency's findings for each contaminant.

ADDRESSES: The official public docket for this action is located at EPA's West Building, Room B–102, 1301 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: For copies of, and general information about this document or information about the nine contaminants discussed in this action, contact the Safe Drinking Water Hotline. Callers within the United States may reach the Hotline at (800) 426–4791 or its local number (703) 412–3330. The Hotline is open Monday through Friday, excluding Federal holidays, from 9 a.m. to 5:30 p.m., Eastern Time. For technical inquiries contact: Thomas Carpenter (202) 564–4885, e-mail: *carpenter.thomas@epa.gov* or Harriet Colbert, (202) 564–4698, e-mail: *colbert.harriet@epa.gov.*

SUPPLEMENTARY INFORMATION

I. General Information

A. Does This Notice Apply to My Public Water System?

Today's action does not impose any requirements on anyone. Instead, it notifies interested parties of EPA's responses to comments received on EPA's preliminary determination and of EPA's final determination not to regulate nine CCL contaminants.

B. How Can I Get Copies of Related Information?

1. Docket. EPA has established an official public docket for this action under Docket ID No. OW–2002–0021. The official public docket is the collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center 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 Water Docket is (202) 566–2426.

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/.*

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section I.B.1. Once in the system, select ''search,'' then key in the appropriate docket identification number.

Abbreviations and Acronyms Used in This Action

ATSDR Agency for Toxic Substances and Disease Registry
AWQC Ambient Water Quality Criteria
CASRN Chemical Abstract Services Registry Number
CCL Contaminant Candidate List
CWS Community Water Supply
EPA U.S. Environmental Protection Agency
FDA U.S. Food and Drug Administration
FR Federal Register
g gram
HRL Health reference level
IOC Inorganic compound
kg Kilogram
L Liter
MCL Maximum contaminant level
MCLG Maximum contaminant level goal mg milligram
MTBE Methyl-t-butyl ether
NDWAC National Drinking Water Advisory Council
NIRS National Inorganic and Radionuclide Survey
NPDWR National Primary Drinking Water Regulation
NRC National Research Council
OPP Office of Pesticides Program
ORD Office of Research and Development
PWS Public Water System
RSC Relative Source Contribution
SAB Science Advisory Board
SDWA Safe Drinking Water Act
SOC Synthetic organic compound
TRI Toxic Release Inventory
UCM Unregulated Contaminant Monitoring
USEPA United States Environmental Protection Agency
USGS United States Geological Survey
VOC Volatile organic compound

II. Background

A. What Is the Statutory Requirement for the Contaminant Candidate List?

SDWA, as amended in 1996, directs EPA to publish a list of contaminants (referred to as the Contaminant Candidate List, or CCL) to assist the Agency in priority-setting efforts. The CCL is a list of contaminants which are not subject to any proposed or promulgated NPDWRs, are known or anticipated to occur in PWSs, and may require regulation under SDWA.

The first CCL was developed with considerable input from the scientific community and stakeholders. EPA published a draft CCL requesting public comment on October 6, 1997 (62 FR 52193, USEPA 1997). The first final CCL was published on March 2, 1998 (63 FR 10273, USEPA 1998). The SDWA requires that a new CCL be published every five years. EPA is currently preparing the next CCL. The March 1998 CCL contained 60 contaminants, including 50 chemicals or chemical groups and 10 microbiological contaminants or microbial groups. Many of these contaminants lacked some of the information necessary to support a regulatory determination and were identified in the March 1998 CCL notice (USEPA 1998) as having data needs. The 60 CCL contaminants were divided into categories to represent research and data needs associated with each contaminant. The categories were: (1) Regulatory determination priorities; (2) health effects research priorities; (3) treatment research priorities; (4) analytical methods research priorities; and (5) occurrence priorities.

In 1998, 20 of the 60 contaminants were classified as regulatory determination priorities because EPA believed that, at that time, there was sufficient data for these contaminants to evaluate both exposure and risk to public health and to support a determination of whether or not to proceed to promulgation of a NPDWR. Since the March 1998 CCL, EPA found that there was insufficient information, in the Agency's judgement, to support a regulatory determination for 12 of the 20 priority contaminants. In addition, the CCL-contaminant, sodium, was reclassified and added to the list of regulatory determination priorities as a means of reassessing the current guidance level for sodium. Thus, EPA is now presenting regulatory determinations for nine priority contaminants that have sufficient information to support a regulatory determination at this time.

The Agency however, continues to conduct research and/or to collect occurrence information on the remaining 51 CCL contaminants. EPA has been aggressively conducting research to fill in the data gaps and recognizes that stakeholders may have a particular interest in the timing of future regulatory determinations for other contaminants on the CCL. Stakeholders may be concerned that regulatory determinations for such contaminants should not necessarily wait until the end of the next regulatory determination cycle. In this regard, it is important to recognize that the Agency is not precluded from monitoring, conducting research, developing guidance, or regulating contaminants not included on the CCL as necessary and appropriate (see SDWA sections 1412(b)(1)(B)(ii)(III) and 1412(b)(1)(F)), or from taking action on CCL contaminants when information becomes available. Thus, some regulatory determinations may be made before the end of the next regulatory determination cycle (*i.e.,* August 2006).

B. What Contaminants Did EPA Consider for Regulation?

EPA published preliminary regulatory determinations in the June 3, 2002, edition of the **Federal Register** (67 FR 38222, USEPA 2002a) for nine priority contaminants that have sufficient information to support a regulatory determination at this time. The nine contaminants include three IOCs (manganese, sodium, and sulfate); three SOCs (aldrin, dieldrin, and metribuzin); two VOCs (hexachlorobutadiene and naphthalene); and one microbial contaminant, Acanthamoeba. Information for each of the nine CCL contaminants is available in the EPA Fact Sheet (USEPA 2002b), in the Health Effects Support Documents or Drinking Water Advisories for each of the nine CCL contaminants (2003a–h), and in the regulatory determination support documents (USEPA 2001a–g). This information is available at the Water Docket (No. OW–2002–021) and is also available on EPA's Safe Drinking Water Regulatory Determination website at *http://www.epa.gov/safewater/ccl/cclregdetermine.html.* Brief descriptions of each of the nine CCL contaminants considered for regulatory determinations are included in section V of this notice.

III. What Analyses Did EPA Use To Make the Regulatory Determinations?

The precepts for guiding EPA in making regulatory determinations for a drinking water contaminant are included in Section 1412(b)(1)(A) of SDWA. This section of SDWA requires EPA to consider the following three evaluation criteria prior to making a regulatory decision: (1) Potential adverse health effects from the contaminant; (2) occurrence of the contaminant in PWSs with a frequency and at levels of public health concern; and (3) whether regulation of the contaminant would present a meaningful opportunity for health risk reduction for persons served by PWSs.

EPA developed a comprehensive approach for making regulatory determinations with significant expert input and recommendations suggested by the National Research Council (NRC), National Drinking Water Advisory Council (NDWAC), and stakeholders. The regulatory determination approach is largely based on the NDWAC recommendations. For each of the nine contaminants, EPA evaluated the best available peer reviewed data on health effects, and approximately seven million analytical data points on contaminant occurrence. For those contaminants with adequate monitoring methods, as well as health effects and occurrence data, EPA applied an approach in making regulatory determinations that followed the NDWAC recommendations and complies with the SDWA requirements under Section 1412(b)(1)(A). In June 2002, EPA consulted with the Science Advisory Board (SAB) Drinking Water Committee and requested its review and comment on whether the protocol EPA developed, based on the NDWAC recommendations, was consistently applied and appropriately documented. The SAB provided verbal feedback regarding the use of the NRC and NDWAC recommendations in EPA's decision criteria for making its regulatory determinations, as well as its interest in remaining involved in future regulatory determinations. SAB recommended that the Agency provide a transparent and clear explanation of the process for making regulatory determinations. In today's announcement and in the documentation supporting this announcement, the Agency has taken the SAB recommendation into consideration in explaining the evaluation process used to make today's regulatory determinations.

EPA characterized the human health effects that may result from exposure to a contaminant found in drinking water. Based on this characterization, EPA estimated a health reference level (HRL) or benchmark value for each contaminant. EPA has prepared Health Effects Support Documents or Drinking Water Advisories (USEPA 2002c and 2003a–g) for each contaminant, which are available at the EPA Water Docket and on-line at *http://www.epa.gov/edocket/.* The support documents address the following: Exposure from drinking water and other media; toxicokinetics; hazard identification; dose-response assessment; and an overall characterization of risk from drinking water.

Using the Agency's Unregulated Contaminant Monitoring (UCM) program data and National Inorganic and Radionuclide Survey (NIRS) data, EPA estimated the number of PWSs and the population served by the PWSs at the benchmark values, and the

geographic distribution, using a large amount of State occurrence data that are generally indicative of national occurrence. The UCM data form part of the Agency's basis for its estimates of national occurrence since these data provide occurrence information for several unregulated contaminants. The NIRS data provide a statistically representative sample of the national occurrence of many other unregulated and regulated inorganic contaminants in ground water community water supplies (CWSs).

EPA also employed other State drinking water data, use and environmental release information (*e.g.*, EPA's Toxic Release Inventory (TRI), academic and private sector publications), as well as ambient water quality data (*i.e.*, source water existing in surface waters and aquifers before extraction and treatment as drinking water), to augment the UCM drinking water data and to evaluate the likelihood of contaminant occurrence. EPA included, when available, data from the U.S. Geological Survey's (USGS) National Water Quality Assessment program.

A detailed discussion of the data collected and analyses for each contaminant can be found in the respective regulatory determination support document. The regulatory determination support documents (USEPA 2001a–g) are available in the EPA Water Docket.

The underlying data and analysis supporting the findings used by the Agency to make the regulatory determinations are summarized in the June 2002 notice (USEPA 2002a).

IV. Summary of Public Comments and the Agency's Responses on the CCL Regulatory Determination Process

The comment period on the June 3, 2002, notice ended on August 2, 2002. EPA received 15 comments on the preliminary regulatory determinations for the nine CCL contaminants published by EPA in the June 2002 notice (USEPA 2002a). Four comments were received from water systems and related associations, seven from industry groups, two from environmental advocacy groups, one from a State agency and one from a State-related association. Although most commenters generally approved of EPA's determination not to regulate any new contaminants at this time, some commenters expressed concerns about the process associated with EPA's regulatory determinations for these nine contaminants, as well as with CCL activities not specifically related to the preliminary determinations.

A majority of the comments were focused on five over-arching topic areas:

1. Some commenters expressed concern over the transparency of the CCL decision-making process.

2. Several industry groups expressed a concern that the health effects assessments were too conservative.

3. Several commenters expressed concern with EPA's progress in filling research gaps related to the CCL and encouraged EPA to publicly track research needs and progress on remaining CCL contaminants.

4. The majority of commenters generally approved of EPA's determination not to regulate any new contaminants at this time. However, one commenter questioned the appropriateness of EPA's decisions not to regulate any of the nine priority contaminants.

5. Several comments were received regarding contaminants on the CCL for which draft regulatory determinations were not included in the June 2002 notice, including perchlorate and methyl-t-butyl ether (MTBE).

A complete copy of the public comments and the Agency's responses are included in the Docket for today's action. The remainder of this section discusses the five key topic areas identified by commenters in response to the June 2002 CCL regulatory determination notice (USEPA 2002a).

1. Lack of Transparency of Regulatory Determination Approach

Comment Summary: Several commenters expressed a concern about the ''lack of transparency'' in the regulatory determination approach used by the Agency for the June 2002 notice. Most of those commenters suggested that EPA did not provide an adequate explanation for the reduction in the number of the priority contaminants from twenty to nine since the publication of the first CCL in March 1998 (USEPA 1998). These commenters suggested that the Agency needs to provide better justification regarding the reasons for excluding the twelve contaminants listed in the March 1998 CCL from the regulatory determination process.

Several commenters suggested that this regulatory determination process approach does not provide for enough participation from outside groups for the development of non-regulatory strategies. These commenters suggested that the Agency should allow for more meaningful public involvement in the regulatory determination process. One commenter stated that, given the Agency's analysis of occurrence and health effects data over several years, the 60-day comment period was not adequate to allow ''detailed analysis by interested stakeholders.''

Other commenters, however, observed that the CCL regulatory determination approach taken by EPA was ''reliably consistent'' with the basic charge of the SDWA and the NDWAC workgroup recommendations. Several commenters noted that, by EPA following the protocol recommended by the NDWAC Work Group, stakeholders were assured that the Agency used the ''best-available, peer-reviewed science'' in these determinations.

Agency Response: EPA developed a consistent regulatory determination approach for evaluating CCL contaminants that followed NDWAC's recommended protocol for health effects and occurrence analysis. The regulatory determination approach for each contaminant on the list included an evaluation of the adequacy of current analytical and treatment methods, the best available peer-reviewed data on health effects, and an occurrence data set of about seven million contaminant occurrence data points.

By using this approach, EPA determined that, at the time of the June 2002 notice (USEPA 2002a) of preliminary regulatory determinations there was not sufficient information to support a regulatory determination on twelve of the twenty priority contaminants. As noted previously, the CCL-contaminant, sodium, was moved to the list of regulatory determination priorities to allow an update of the Agency's position on the issue of sodium in drinking water.

The NDWAC, which is comprised of representatives from the general public, State and local agencies, and private groups concerned with drinking water safety, was convened to provide input during the regulatory determination process. Throughout the regulatory determination process, EPA's approach has been to maintain a strong partnership with stakeholders and involve them to the maximum extent possible, thereby helping to ensure that stakeholders understand the regulatory determination process and provide valuable input.

The Agency agrees that a meaningful opportunity for discussions with stakeholders is an important component of the CCL Regulatory Determination process. The Agency utilized a variety of mechanisms to involve stakeholders in the process. These included two broad-based stakeholder meetings, one in November 1999 and one in July 2002. Members of the public also were invited to attend the three sessions of the NDWAC Work Group in the Spring/

Summer of 2000, which focused on protocol recommendations to the Agency. In addition, EPA representatives delivered presentations at a variety of meetings held by other organizations. Moreover, EPA did ask for and considered comments made on the sodium and sulfate Drinking Water Advisories during the comment period on the June 2002 notice (USEPA 2002a).

The Agency believes the 60-day public comment period for the June 2002 notice (USEPA 2002a) was sufficient. The Agency took steps to facilitate public review of its preliminary decisions, as well as supporting documentation. In addition to the July 2002 stakeholder meeting, these steps included making key materials available on the Agency's website and providing hard copies of materials upon request.

2. Health Effects Assessments

Comment Summary: Some commenters suggested that EPA's analysis of adverse health effects and calculation of the HRLs were too conservative. On the other hand, one commenter questioned how the Agency's analysis underlying the regulatory determination approach incorporated appropriate safety factors and exposure assessments relative to children's health concerns.

Commenters recommended that EPA use the revised Office of Water methodology for deriving ambient water quality criteria (AWQC), (USEPA 2000), in an effort to protect human health in the final health effects support documents. According to the comments, this revised methodology establishes five different consumption rates and body weight classifications as a means to make the human health exposure assessments. One commenter specified that EPA needs to use more accurate consumption data for sodium rather than simply incorporating U.S. Food and Drug Administration (FDA) assertions.

Agency Response: EPA believes it is appropriate to use a conservative approach to assessing the health effects of an unregulated contaminant in the context of a determination of whether it should be considered for NPDWR regulation. In order to determine whether to propose an NPDWR for an unregulated contaminant, SDWA requires EPA to determine whether the contaminant ''may have an adverse effect on the health of the persons,'' Section 1412(b)(1)(A)(i), which is a very broad criterion. As a result, EPA believes that a conservative health effects analysis is appropriate.

The HRL used by EPA in these determinations is a conservative health-based value and is different depending on whether a contaminant is considered a carcinogen or a noncarcinogen. For carcinogens, a 10–6 risk was chosen as the HRL since the maximum contaminant level goal (MCLG) for such contaminants will generally be zero. For noncarcinogens, the reference dose and a 20 percent relative source contribution (RSC) factor was used in conjunction with a 70 kilogram (kg) adult body weight and a 2 liter (L) water intake for the HRL calculation. EPA uses these standard regulatory assumptions for determining the MCLG of a noncarcinogen that lacks specific data on the RSC. EPA used best available peer reviewed data and analyses in evaluating adverse health effects. Accordingly, EPA disagrees with those commenters that felt that EPA was too conservative in establishing the HRL. EPA followed practices and policies that are similar to those used to establish an NPDWR and that are consistent with the SDWA section 1412(b)(1)(A)(i) criterion. If such a conservative approach does not result in EPA deciding to initiate a regulatory process for a contaminant, the Agency may decide to use a non-regulatory approach in addressing the issue, such as issuing a Drinking Water Advisory.

Children's health issues were considered in making regulatory determinations for each of the nine contaminants included in this final notice. The details of the individual assessments are included in the Health Effects Support Documents or Drinking Water Advisories for each contaminant. These documents are available for review at the EPA Water Docket and on-line at *http://www.epa.gov/edocket/.*

The AWQC (USEPA 2000) methodology continues to recommend the use of 70 kg for adult body weight and 2 liters per day for water intake for risk calculations. These are the same parameters used by EPA to derive an MCLG. EPA believes that its current methodology, based on adult exposures, for the derivation of MCLGs, and for making regulatory determinations under SDWA section 1412, remains generally appropriate. EPA has not yet determined a protocol for making a regulatory determination for a chemical for which an infant's or a particular childhood age grouping's body weight and drinking water intake would be the basis of a regulatory action. A decision for such a contaminant would be made on the basis of the toxicity and exposure data, and could utilize the age groupings and body weight information from the AWQC human health methodology if it were appropriate.

EPA did not use FDA's sodium consumption data of 4 to 6 grams/day (g/day) in establishing a benchmark value for sodium. EPA decided to use a benchmark value for sodium instead of an HRL because sodium lacks suitable dose-response data and there is considerable controversy regarding the role of sodium in the etiology of hypertension. EPA derived the benchmark value for sodium of 120 mg/L in drinking water from the National Institutes of Health, National Academy of Sciences, American Heart Association, and the U.S. Department of Agriculture recommended daily dietary intake of 2.4 g/day.

3. EPA Research Agenda

Comment Summary: Several commenters expressed concern that, in their view, there is a lack of progress by EPA in filling research gaps related to the CCL. In particular, commenters focused on high visibility contaminants, such as the microbiological contaminants, MTBE, and other ''emerging contaminants.'' Commenters also stressed the need to establish a vehicle for publicly tracking research needs and progress made in research areas.

Agency Response: Before EPA can determine whether to regulate contaminants, additional data on health, treatment technologies, and analytical methods, are needed for contaminants on the Research Priorities portion of the CCL, and occurrence data is needed for contaminants on the Occurrence Data Needs portion of the CCL. The remaining 51 CCL contaminants for which decisions are not being made today do not have sufficient data to support a regulatory determination. The Agency considers obtaining this data to be the priority of its research and occurrence monitoring programs. The Agency continues to actively conduct research and/or to collect occurrence information on these 51 CCL contaminants and other emerging contaminants. Because these research issues are broader than those that EPA can address alone, it is anticipated that other entities will be involved in conducting much of the needed research to support this process. For example, EPA already is jointly undertaking research efforts, and encourages stakeholders, through close and regular consultation, to be partners in filling many of the research gaps. The EPA continues to identify and develop new collaborations to conduct research and gather the additional data to characterize occurrence and adverse

health effects to support future regulatory determinations of CCL contaminants. EPA is also engaged with our stakeholders in a NDWAC work group to refine the CCL listing process to address emerging contaminants for future efforts.

EPA agrees with the comment concerning the importance of establishing a vehicle that will allow stakeholders to track the status of drinking water research projects. EPA is committed to providing a means for stakeholders to track research needs and progress made in research areas, and is developing a web-based research inventory that is expected to be available to the public in 2003. This website will serve as a repository of information on drinking water research projects currently funded or performed by the EPA.

4. Criticism of Regulatory Decisions Made

Comment Summary: One commenter expressed concern that EPA's decision not to regulate any of the nine priority contaminants was not appropriate. A comment submitted and co-signed by 22 environmental organizations disagreed with the regulatory determinations for four contaminants, hexachlorobutadiene, manganese, sodium and sulfate. The commenters believe that EPA's monitoring data presented in the June 2002 notice shows that over 22,000 people were exposed to hexachlorobutadiene at concentrations above the HRL. The commenters assert that although EPA says manganese has low toxicity, EPA finds that nearly 3% of the population exceeded EPA's HRL. The commenters also disagreed with the Agency determination that regulation is not warranted because food sources of sodium are a more significant contribution to sodium in the diet than drinking water. The commenters also assert that EPA should regulate sulfate because EPA's monitoring data shows that millions of Americans are likely to have sulfate levels above the HRL in their drinking water, which puts infants and other subpopulations at risk.

Agency Response: The preliminary regulatory determinations on whether or not to regulate the nine priority contaminants were based on the three SDWA statutory requirements, and the contaminants were evaluated in terms of national significance. EPA's assessment of the health effects and national occurrence were discussed in detail in the June 2002 notice. EPA disagrees that each of the contaminants identified by the commenters should be regulated. The rationale supporting the regulatory determination is provided below.

EPA found that hexachlorobutadiene occurs in systems, but not at a frequency or level of public health concern. The commenter has misinterpreted the monitoring data presented in the June 2002 notice. The number 22,736 in the notice refers to the number of reporting PWSs in the monitoring data set and does not reflect the number of people exposed to hexachlorobutadiene concentrations above the HRL. The June 2002 notice states that 0.02% (4 out of 22,736) reporting systems detected hexachlorobutadiene above the HRL affecting 0.005% (3,350 out of the 67 million) of the population served by these systems (67 FR 38235). Because of this low frequency, EPA believes it is most appropriate at this time to address occurrence of hexachlorobutadiene at the State level rather than at the national level.

EPA disagrees with the commenter's criticism of the decision not to regulate manganese. Manganese is an essential trace element needed for the normal healthy growth and function of animals as well as human beings. Therefore, the decision whether or not to regulate manganese needs to balance the concern for the potential toxic effects from high oral exposure with the concern for adverse effects from manganese deficiency. In 2001, the Institute of Medicine (IOM) set an adequate level for manganese at 2.3 mg/day for men and 1.8 mg/day for woman.

Furthermore, in 2001, the IOM set a tolerable upper intake level for manganese at 11 mg/day. While 3% of the population may be exposed to manganese at levels above the 0.30 mg/L HRL for drinking water, this level is well below the IOM tolerable level. For example, assuming a daily intake of 2 liters of drinking water with manganese at the HRL of 0.30 mg/L, the daily intake of manganese from drinking water at the HRL would only expose a person to 0.6 mg/day. This value is well below IOM's 11 mg/L adequate level for manganese and represents only 5.5% of IOM's upper limit for manganese. Public drinking water accounts for a relatively small proportion of a person's manganese intake, even at the HRL. Therefore, the Agency concludes that regulation of drinking water for manganese does not provide a meaningful opportunity to reduce the risk of adverse health effects. The commenter is referred to the *CCL Preliminary Regulatory Determination Support Document for Manganese* (EPA 815–R–01–013) for a more detailed discussion of this issue.

EPA disagrees with the commenter's criticism of the decision not to regulate sodium. Because sodium in drinking water is a very small contributor to daily dietary intake and because the levels at which sodium intake can contribute to increasing the blood pressure of individuals with normal blood pressures is not clearly established, EPA does not believe that a NPDWR for sodium presents a meaningful opportunity for public health protection at this time.

EPA disagrees with the commenter's criticism of the decision not to regulate sulfate. EPA used current data (Round 2 of the UCM program) that indicate that about 1.8% of the reporting systems serving approximately 2 million people from a 20-state cross section of the unregulated contaminant monitoring study exceeded 500 mg/L. Although additional data from six states had very similar results, EPA found that the weight of evidence suggests that the adverse health effect is generally mild, of short duration, and generally occurs at concentrations considerably greater than 500 mg/L, except in very limited circumstances when contaminants that exacerbate the effects of sulfate are also present in the water. Therefore, EPA has made the determination not to regulate sulfate with a NPDWR at this time because regulation would not present a meaningful opportunity for health risk reduction for persons served by public drinking water systems. However, EPA prepared a Drinking Water Advisory to provide guidance to communities that may be exposed to drinking water with high sulfate concentrations. This advisory contains information of use to sensitive sub-populations, such as infants and travelers.

5. Stakeholder's Highest Priority for Future Regulatory Determinations

Comment Summary: Commenters encouraged EPA to be aggressive and consider an expedited regulatory determination for several CCL contaminants including MTBE and perchlorate.

Agency Response: For this regulatory determination, EPA developed a comprehensive evaluation approach based on the recommendations from NRC and NDWAC. As explained in the June 2002 notice (USEPA 2002a), this evaluation satisfies the three SDWA requirements under section 1412(b)(1)(A)(i)–(iii). For each of the contaminants, the Agency evaluated the adequacy of current analytical and treatment methods, the best available peer-reviewed data on health effects, and an occurrence data set of approximately seven million analytical data points. At this time, EPA does not believe adequate data exists in these key areas to make a regulatory

determination either for perchlorate or MTBE. EPA is gathering information to fill the data gaps for these contaminants.

With respect to perchlorate, EPA is gathering national occurrence data on perchlorate in drinking water through the Unregulated Contaminant Monitoring (UCM) Rule. The Agency is also completing a rigorous peer review of health effects studies and is developing a final toxicity review and risk characterization. As part of this effort, EPA has asked the National Academy of Sciences to review science issues related to the 2002 draft EPA risk assessment for perchlorate. In addition, the Agency is funding research studies on treatability of perchlorate for PWSs. Some of the technology currently in use at hazardous waste sites is being evaluated for the feasibility of using it in water treatment at community water systems. At the same time, EPA is seeking to improve the analytical method sensitivity that would allow concentrations of perchlorate to be quantified at lower levels than are presently possible. The Agency is moving concurrently in each of these areas to meet data and research needs as quickly as possible. When the necessary information is collected, we plan to move forward with a regulatory determination. In this regard, it should be emphasized that where EPA determines there is sufficient information on this or any other unregulated contaminant, the Agency is prepared to act in advance of the next five year regulatory determination cycle.

Regarding MTBE, on-going activities will provide the Agency with improved health effects and occurrence data. At this time, EPA is preparing its revised risk assessment for MTBE for peer review. The Agency established the 1997 Drinking Water Advisory for MTBE at 20–40 micrograms per liter (µg/L, or parts per billion, ppb) to avoid unacceptable taste and odor and provide a protective margin of exposure for adverse health effects. The 20–40 ppb level was not based on the possible cancer risks. As a result of the UCM Rule, data from PWSs required to monitor for MTBE will be available in the middle of 2004.

V. Summary of the Agency's Findings on the Nine CCL Contaminants

A. Acanthamoeba

Description: Acanthamoeba is a free-living protozoa commonly found in water, soil, and air. Species of this microbe have been isolated worldwide from brackish and sea water, tap water, bottled water, airborne dust, swimming pools, hot springs, thermal effluents of power plants, ocean sediments, vegetables, and hot tubs. *Acanthamoeba* species have been associated with human infections affecting the eye, lung, brain, and skin. *Acanthamoeba* has been recovered from the nose and throat of humans with impaired respiratory function and from apparently healthy persons, suggesting that the amoeba is commonly inhaled.

Agency Findings: After reviewing the best available public health and occurrence information, EPA has made the determination not to regulate *Acanthamoeba* with a NPDWR at this time, because regulation would not present a meaningful opportunity for health risk reduction for the people served by public drinking water systems (PWSs). As noted in the June 2002 notice (USEPA 2002a), EPA has no national monitoring data to indicate occurrence of *Acanthamoeba* cysts in drinking water, and filtration practices commonly used to treat drinking water remove *Acanthamoeba* cysts.

A complete review of EPA's analysis of the health effects, occurrence, and exposure for *Acanthamoeba* were presented in the June 2002 notice (USEPA 2002a) and in the health effects support document for *Acanthamoeba* (USEPA 2003h). EPA intends to release a guidance document for *Acanthamoeba* that will be directed mainly to contact lens wearers and will address the risks of *Acanthamoeba* eye infection associated with improper care of contact lenses.

B. Aldrin and Dieldrin

Description: Aldrin and dieldrin (Chemical Abstract Services Registry Number (CASRN) 309–00–2 and 60–57–1, respectively) are the common names of two structurally similar insecticides. They are discussed together because aldrin readily changes to dieldrin in the body and in the environment, and they cause similar adverse health effects. From 1950–1970, aldrin and dieldrin were popular pesticides used for crops, such as corn and cotton. Because of concerns about damage to the environment and the potential harm to human health, EPA banned most uses of aldrin and dieldrin in 1974, except for the control of termites, and banned all uses outright since 1987. According to the Agency for Toxic Substances and Disease Registry (ATSDR), aldrin and dieldrin have not been produced in the United States since 1974 (ATSDR 1993).

Agency Findings: After reviewing the best available public health and occurrence information, EPA has made the determination not to regulate aldrin or dieldrin with a NPDWR at this time, because regulation would not present a meaningful opportunity for health risk reduction for the people served by PWSs. EPA recognizes that aldrin and dieldrin are probable human carcinogens, but the chemicals have been banned for most uses since 1974, and have a low frequency and low level of occurrence in drinking water supplies.

A complete review of EPA's analysis of the health effects, occurrence, and exposure for aldrin and dieldrin were presented in the June 2002 notice (USEPA 2002a) and in the regulatory determination (USEPA 2001a) and health effects (USEPA 2003a) support documents for aldrin and dieldrin.

C. Hexachlorobutadiene

Description: Hexachlorobutadiene (CASRN 87–68–3) is a VOC that is relatively insoluble in water (solubility of 2–2.55 mg/L). Hexachlorobutadiene is mainly used to make rubber compounds. It is also used in gyroscopes, as a heat transfer liquid, as a hydraulic fluid, as a solvent, and to make lubricants. It has never been manufactured as a commercial product in the United States, however, it is imported and significant quantities of the chemical are generated in the United States as a waste by-product from the chlorination of hydrocarbons.

Most exposure to hexachlorobutadiene comes from breathing contaminated air in the workplace environment. People living near hazardous waste sites containing hexachlorobutadiene may be exposed to it by breathing air or by drinking contaminated water.

Agency Findings: After reviewing the best available public health and occurrence information, EPA has made the determination not to regulate hexachlorobutadiene with a NPDWR at this time, because it would not present a meaningful opportunity for health risk reduction for persons served by PWSs. Hexachlorobutadiene occurs in PWSs, but not at a frequency or level of public health concern.

A complete review of EPA's analysis of the health effects, occurrence, and exposure for hexachlorobutadiene were presented in the June 2002 notice (USEPA 2002a) and in the regulatory determination (USEPA 2001b) and health effects (USEPA 2003b) support documents for hexachlorobutadiene.

D. Manganese

Description: Manganese (CASRN 7439–96–5) is a naturally occurring element found at low levels in soil, water, and food. It is an essential trace element for humans and all animal species. It constitutes approximately 0.1

percent of the earth's crust, however, it does not occur in the environment in its pure metal form, but is ubiquitous as a component of more than 100 minerals including many silicates, carbonates, sulfides, oxides, phosphates, and borates (ATSDR 2000).

Manganese is generally considered to have low toxicity when ingested orally. The major source of manganese intake in humans (with the exception of possible occupational exposure) is dietary ingestion; manganese is a nutrient and is not considered to be very toxic when ingested with food. Reports of adverse effects following oral exposure are rare.

Agency Findings: After reviewing the best available public health and occurrence information, EPA has made the determination not to regulate manganese with a NPDWR at this time, because it would not present a meaningful opportunity for health risk reduction for persons served by PWSs. Manganese is generally not considered to be very toxic when ingested with the diet and drinking water accounts for a relatively small proportion of manganese intake.

A complete review of EPA's analysis of the health effects, occurrence, and exposure for manganese were presented in the June 2002 notice (USEPA 2002a) and in the regulatory determination (USEPA 2001c) and health effects (USEPA 2003c) support documents for manganese. EPA is developing a Drinking Water Advisory for manganese to provide guidance to communities that might be exposed to elevated concentrations of manganese in their drinking water.

E. Metribuzin

Description: Metribuzin (CASRN 21087–64–9) is a pesticide that does not volatilize readily, yet is relatively soluble in water. It is relatively persistent in the environment and degrades primarily through exposure to sunlight. Metribuzin is used as an herbicide on soybeans, potatoes, alfalfa, sugar cane, lentils, asparagus, tomatoes, carrots, peas, barley, wheat, range grasses, and Christmas trees. Metribuzin has limited non-agricultural utility. Metribuzin is not classifiable as a human carcinogen, but there may be effects on the liver and body weight from chronic exposure to high doses.

Agency Findings: After reviewing the best available public health and occurrence information, EPA has made the determination not to regulate metribuzin with a NPDWR at this time, because it would not present a meaningful opportunity for health risk reduction for persons served by PWSs. Metribuzin is not known to occur in PWSs at levels of public health concern. National monitoring data indicate that metribuzin is infrequently detected in public water supplies.

A complete review of EPA's analysis of the health effects, occurrence, and exposure for metribuzin were presented in the June 2002 notice (USEPA 2002a) and in the regulatory determination (USEPA 2001d) and health effects (USEPA 2003d) support documents for metribuzin.

F. Naphthalene

Description: Naphthalene (CASRN 91–20–3) is a VOC that is naturally present in fossil fuels, such as petroleum and coal, and is formed when wood or tobacco are burned. Naphthalene is produced in commercial quantities from either coal tar or petroleum. Most naphthalene use (60%) is as an intermediary in the production of phthalate plasticizers, resins, phthaleins, dyes, pharmaceuticals, and insect repellents. Crystalline naphthalene is used as a moth repellent and as a solid block deodorizer for diaper pails and toilets.

The major source of human exposure to naphthalene is through the use of moth-balls containing naphthalene. This exposure can be from breathing the vapors or handling the mothballs. People also may be exposed by breathing tobacco smoke and air near industries that use or produce naphthalene. Usually naphthalene is not found in water because it evaporates or biodegrades quickly. When it is found in water, it is usually at levels lower than 0.01 mg/L (ATSDR 1995).

Agency Findings: After reviewing the best available public health and occurrence information, EPA has made the determination not to regulate naphthalene with a NPDWR at this time, because it would not present a meaningful opportunity for health risk reduction for persons served by PWSs. Naphthalene is not known to occur in PWSs at levels of public health concern. National monitoring data indicate that naphthalene is infrequently detected in public water supplies.

A complete review of EPA's analysis of the health effects, occurrence, and exposure for naphthalene were presented in the June 2002 notice (USEPA 2002a) and in the regulatory determination (USEPA 2001e) and health effects (USEPA 2003e) support documents for naphthalene.

G. Sodium

Description: Sodium (CASRN 7440–23–5) is the sixth most abundant element on earth and is widely distributed in soils, plants, water, and foods. Ground water typically contains higher concentrations of minerals including sodium salts than do surface waters. In addition to naturally occurring sources of sodium, sodium compounds are used in deicing roads, as water treatment chemicals, and in domestic water softeners. Sewage effluents can also contribute significant quantities of sodium to water.

Sodium is an essential trace element, and adequate levels of sodium are required for good health. Food is the main source of daily human exposure to sodium, primarily in the form of sodium chloride (table salt). Most of the sodium in our diet is added during food processing and preparation.

Agency Findings: After reviewing the best available public health and occurrence information, EPA has made the determination not to regulate sodium with a NPDWR at this time, because it would not present a meaningful opportunity for health risk reduction for persons served by PWSs. The contribution of drinking water to daily sodium intake is very small when compared to the total dietary intake. Short-term excursions beyond the benchmark values pose no adverse health risk for most individuals, including the majority of persons with hypertension. Sodium in drinking water is a very small contributor to daily dietary intake and the levels at which sodium intake can contribute to increasing the blood pressure of individuals with normal blood pressures are not clearly established. The Agency currently does, however, require monitoring for sodium at the entry point to the distribution system and that results be reported annually to public health officials for surface water systems, and every three years for ground water systems (as defined in 40 CFR 141.41). The water supplier must report sodium test results to local and State public health officials, unless this responsibility is assumed by the State. This requirement is intended to provide the public health community with information on sodium levels in drinking water to be used in counseling patients and is the most direct route for gaining the attention of the affected population.

A complete review of EPA's analysis of the health effects, occurrence, and exposure for sodium were presented in the June 2002 notice (USEPA 2002a) as well as in the regulatory determination (USEPA 2001f) support document for sodium. EPA is issuing a final Drinking Water Advisory for sodium concurrent with today's action (USEPA 2003f). The sodium advisory provides guidance to

communities that might be exposed to elevated concentrations of sodium chloride or other sodium salts in their drinking water. This sodium advisory also provides appropriate cautions for individuals on low-sodium or sodium-restricted diets.

H. Sulfate

Description: Sulfate (SO_4^{-2}, CASRN 14808–79–8) exists in a variety of inorganic salts. Sulfate salts such as sodium, potassium, and magnesium are very water soluble and are often found in natural waters. Sulfate salts of metals such as barium, iron, or lead have very low water solubility. Sulfate is found in soil, sediments, and rocks and occurs in the environment as a result of both natural processes and human activities. Sulfate compounds are used for a variety of commercial and industrial purposes.

Sulfate may enter surface or ground water as a result of discharge or disposal of sulfate-containing wastes. In addition, sulfur oxides produced during the combustion of fossil fuels are transformed to sulfuric acid in the atmosphere. Through precipitation (acid rain), sulfuric acid can enter surface waters, lowering the pH and raising sulfate levels.

Sulfate is present in the diet. A number of food additives are sulfate salts and most (such as copper sulfate and zinc sulfate) are approved for use as nutritional supplements.

Sulfate may have adverse health affects on persons, primarily through its laxative effect following high-level, acute exposures. The adverse health effect from ingesting high levels of sulfate is increased water in the fecal matter (diarrhea), possibly contributing to dehydration. Because local populations usually acclimate to high sulfate levels, the impact is primarily on infants, transient populations (*e.g.*, business travelers, visitors, and vacationers), and new residents.

Agency Finding: After reviewing the best available public health and occurrence information, EPA has made the determination not to regulate sulfate with a NPDWR at this time, because it would not present a meaningful opportunity for health risk reduction for persons served by PWSs. Although sulfate occurs in many PWSs nationally, the weight of evidence suggests that the adverse health effect is generally mild, of short duration, and generally occurs at concentrations considerably greater than 500 mg/L, except in very limited circumstances when sulfate co-occurs with magnesium and high total dissolved solids, which exacerbate its laxative effects. EPA is issuing a final Drinking Water Advisory to provide guidance to communities that may be exposed to drinking water with high sulfate concentrations.

A complete review of EPA's analysis of the health effects, occurrence, and exposure for sulfate were presented in the June 2002 notice (USEPA 2002a) as well as in the regulatory determination (USEPA 2001g) support document for sulfate. EPA will issue a final Drinking Water Advisory for sulfate concurrent with today's action (USEPA 2003g). The advisory for sulfate provides guidance to communities that may be exposed to drinking water contaminated with high sulfate concentrations. This advisory contains information of use to sensitive sub-populations, such as infants and travelers.

VI. How Will EPA Address the Data Needs of the Remaining 51 CCL Contaminants?

The Agency continues to conduct research and/or to collect occurrence information on the remaining CCL contaminants. EPA has been conducting research to fill identified data gaps. The Agency will take action as appropriate when information becomes available and will not necessarily wait until the end of the next regulatory determination cycle before making other regulatory determinations.

To support decisions on CCL contaminants, the Agency is required to evaluate when and where these contaminants occur, the extent of exposure, and their risk to public health. EPA must also determine if regulating the contaminant presents a meaningful opportunity for reducing public health risk. Contaminants deemed ready for regulatory determination, which include those that are the subject of today's decisions, are determined to have sufficient data to support a decision as to whether or not to regulate based on evaluation of both exposure and risk to public health.

The remaining 51 CCL contaminants for which decisions are not being made today do not have sufficient data to support regulatory decisions. The Agency continues to conduct research and/or collect occurrence information on these remaining contaminants. The research issues are broader than those that EPA can address alone. It is anticipated that other entities will be involved in conducting much of the needed research to support this process. EPA continues to identify and develop new collaborations to conduct research and gather the additional data to characterize occurrence and adverse health effects to support future regulatory determinations of CCL contaminants. EPA is also engaged with our stakeholders in a NDWAC work group to refine the CCL listing process to address emerging contaminants for future efforts

EPA is committed to providing a means for our stakeholders to track progress of research on remaining CCL contaminants. The Agency is currently developing a web-based system that will be available to the public in 2003. This website will serve as a repository of information on drinking water research projects currently funded or performed by EPA.

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Dated: July 11, 2003.

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[FR Doc. 03–18151 Filed 7–17–03; 8:45 am]

BILLING CODE 6560–50–P