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Part III

**Environmental
Protection Agency**

**Announcement of the Drinking Water
Contaminant Candidate List; Notice**

ENVIRONMENTAL PROTECTION AGENCY

[W-97-11; FRL-5972-5]

Announcement of the Drinking Water Contaminant Candidate List

AGENCY: U.S. Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Safe Drinking Water Act (SDWA), as amended in 1996, requires the Environmental Protection Agency (EPA) to publish a list of contaminants which, at the time of publication, are not subject to any proposed or promulgated national primary drinking water regulation (NPDWR), that are known or anticipated to occur in public water systems and which may require regulations under the SDWA [section 1412(b)(1)]. The SDWA, as amended, specifies that EPA must publish the first list of contaminants (Drinking Water Contaminant Candidate List, or CCL) not later than 18 months after the date of enactment, i.e., by February 1998, and every five years thereafter. The SDWA, as amended, also specifies that the CCL must be published after consultation with the scientific community, and after notice and opportunity for public comment.

A draft CCL was published in the October 6, 1997 edition of the Federal Register (62 FR 52193) in order to seek comment from the public. Seventy-one comments were received. The comments have been reviewed and considered in creating the final CCL presented in today's notice. The CCL is divided among contaminants which are identified as priorities for drinking water research, those which need additional occurrence data, and contaminants which are priorities for consideration for the development of future drinking water regulations and guidance. The CCL includes 50 chemical and 10 microbiological contaminants/contaminant groups.

The full record for this notice has been established under docket number W-97-11, and includes supporting documentation as well as all comments received in response to the October 6, 1997 notice. The full record is available for inspection from 9:00 a.m. to 4:00 p.m., Monday through Friday, excluding legal holidays at the Office of Water Docket, East Tower Basement, USEPA Headquarters, 401 M Street, S.W., Washington, D.C. For access to the docket, please call 202-260-3027 to schedule an appointment.

FOR FURTHER INFORMATION CONTACT: For general information, please contact the

EPA Safe Drinking Water Hotline. The toll-free number is 800-426-4791. The Hotline operates from 9:00 a.m. to 5:30 p.m., Monday through Friday, excluding legal holidays. For specific information on the Contaminant Candidate List and the contaminant identification process, please contact Ms. Evelyn Washington, at the U.S. Environmental Protection Agency, Office of Ground Water and Drinking Water, Mailcode 4607, Washington, D.C. 20460, phone: 202-260-3029, fax: 202-260-3762, email: washington.evelyn@epamail.epa.gov.

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SUPPLEMENTARY INFORMATION:

Abbreviations Used in This Notice

AMA—American Medical Association
 AWWARF—American Water Works Association Research Foundation
 CAA—Clean Air Act
 CASRN—Chemical Abstract Services Registry Number
 CCL—Contaminant Candidate List
 CERCLA—Comprehensive Environmental Response, Comprehensive and Liability Act
 CPVC—Chlorinated Polyvinyl Chloride
 DBPR—Microbiological and Disinfection Byproducts Regulations
 DWEL—Drinking Water Equivalent Level
 DWPL—Drinking Water Priority List
 EDSTAC—Endocrine Disruptor Screening and Testing Advisory Committee
 EPA—Environmental Protection Agency

ESWTR—Enhanced Surface Water Treatment Rule
 FIFRA—Federal Insecticide, Fungicide, and Rodenticide Act
 FQPA—Food Quality Protection Act
 FR—Federal Register
 GWDR—Ground Water
 GW—Ground Water Disinfection Rule
 IRIS—Integrated Risk Information System
 MCL—Maximum Contaminant Level
 MCLG—Maximum Contaminant Level Goal
 MTBE—Methyl-t-butyl Ether
 NAS—National Academy of Sciences
 NAWQA—National Water Quality Assessment Program
 NDWAC—National Drinking Water Advisory Council
 NOAEL—No-Observed-Adverse-Effect-Level
 NPDWR—National Primary Drinking Water Regulations
 NPL—National Priority List
 NSF—National Sanitation Foundation
 OPP—EPA's Office of Pesticide Programs
 OPPTS—EPA's Office of Pollution Prevention and Toxic Substances
 PGWDW—Pesticides in Ground Water Database
 PVC—Polyvinyl Chloride
 RfD—Reference Dose
 SAB—EPA's Science Advisory Board
 SAP—Science Advisory Panel
 SDWA—Safe Drinking Water Act
 SWTR—Surface Water Treatment Rule
 TTHM—total trihalomethane
 TSCA—Toxic Substances Control Act
 UCMR—Unregulated Contaminant Monitoring Regulations
 WHO—World Health Organization

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I. Background

The Safe Drinking Water Act (SDWA), as amended in 1996, requires the Environmental Protection Agency (EPA) to publish a list of contaminants that are known or anticipated to occur in public water systems, and which may require regulation under the SDWA [section 1412(b)(1)]. The SDWA, as amended, also specifies that EPA must publish this list of contaminants (Drinking Water Contaminant Candidate List, or CCL) not later than 18 months after the date of enactment (i.e., by February 1998), and publish a new CCL every five years thereafter. The SDWA requires that the list of contaminants include those which, at the time of publication, are not subject to any proposed or promulgated national primary drinking water regulation (NPDWR). The list must be published after consultation with the scientific community, including the Science Advisory Board, after notice and opportunity for public comment, and after consideration of the occurrence database established under section 1445(g). The unregulated contaminants considered for the list must include, but not be limited to, substances referred to in section 101(14) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), and substances registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Today's notice is being published pursuant to the requirements in section

1412(b)(1). The contaminants included are not subject to any proposed or promulgated national primary drinking water regulation, are known or anticipated to occur in public water systems, and may require regulation under the SDWA. During the development of the CCL, the Agency consulted with stakeholders, including the National Drinking Water Advisory Council's (NDWAC) Working Group on Occurrence & Contaminant Selection, which includes microbiologists, toxicologists, public health scientists, and engineers, and consulted with other members of the scientific community including the Science Advisory Board (SAB). A draft CCL was published in the October 6, 1997 edition of the **Federal Register** (62 FR 52193) to seek comment from the public.

Seventy-one comments were received in response to the notice on the draft CCL; 66 comments were received by the due date, and an additional 5 comments were received later. The majority were supportive of the CCL process and the development of this first CCL, and provided suggestions on specific contaminants that should be included on, or excluded from, the CCL. The comments, data, and information provided were taken into consideration in preparing the final CCL presented in today's notice. Modifications to the CCL presented in today's notice were also reviewed by the National Drinking Water Advisory Council (NDWAC), and the NDWAC Working Group on Occurrence & Contaminant Selection.

The Agency believes the CCL presented in today's notice is a first step toward improving risk assessment, strengthening science and data, and achieving better decision-making and future priority setting. The CCL is

designed to be responsive to each of the requirements noted above of the SDWA, as amended, and is consistent with the goals of the Drinking Water Redirection Strategy. The CCL is the result of a concerted effort of screening a larger set of contaminants to a subset of those of most concern.

This final CCL will be the primary source of priority contaminants for the Agency's drinking water program. The list is divided among priorities for drinking water research, priorities for additional occurrence data collection, and those contaminants which are priorities for consideration for Agency determinations of whether or not to regulate specific contaminants by August 2001.

The SDWA does not preclude the Agency from taking action on a contaminant not included on the CCL. The EPA can decide to monitor, develop guidance, or conduct research, for a contaminant not included on the CCL. The Agency can also develop regulations to address an urgent threat to public health under SDWA [section 1412(b)(1)(D)]. The Agency is also not precluded from modifying the CCL prior to the due date of the next CCL, which is February 2003.

II. Drinking Water Contaminant Candidate List

The following table includes the contaminants, microbiological and chemical, presented as the Drinking Water Contaminant Candidate List. The chemical contaminants in the table are identified by name and Chemical Abstracts Service Registry Number (CASRN). The CCL includes 50 chemical and 10 microbiological contaminants/contaminant groups.

TABLE 1.—DRINKING WATER CONTAMINANT CANDIDATE LIST

Microbiological contaminants	
Acanthamoeba (guidance expected for contact lens wearers)	
Adenoviruses	
Aeromonas hydrophila	
Caliciviruses	
Coxsackieviruses	
Cyanobacteria (blue-green algae), other freshwater algae, and their toxins	
Echoviruses	
Helicobacter pylori	
Microsporidia (Enterocytozoon & Septata)	
Mycobacterium avium intracellulare (MAC)	
Chemical contaminants	
	CASRN
1,1,2,2-tetrachloroethane	79-34-5
1,2,4-trimethylbenzene	95-63-6
1,1-dichloroethane	75-34-3
1,1-dichloropropene	563-58-6
1,2-diphenylhydrazine	122-66-7
1,3-dichloropropane	142-28-9
1,3-Dichloropropene	542-75-6

Chemical contaminants	CASRN
2,4,6-Trichlorophenol	88-06-2
2,2-dichloropropane	594-20-7
2,4-dichlorophenol	120-83-2
2,4-dinitrophenol	51-28-5
2,4-dinitrotoluene	121-14-2
2,6-dinitrotoluene	606-20-2
2-methyl-Phenol (o-cresol)	95-48-7
Acetochlor	34256-82-1
Alachlor ESA & other acetanilide pesticide degradation products	N/A
Aldrin	309-00-2
Aluminum	7429-90-5
Boron	7440-42-8
Bromobenzene	108-86-1
DCPA mono-acid degradate	887-54-7
DCPA di-acid degradate	2136-79-0
DDE	72-55-9
Diazinon	333-41-5
Dieldrin	60-57-1
Disulfoton	298-04-4
Diuron	330-54-1
EPTC (s-ethyl-dipropylthiocarbamate)	759-94-4
Fonofos	944-22-9
Hexachlorobutadiene	87-68-3
p-Isopropyltoluene (p-cymene)	99-87-6
Linuron	330-55-2
Manganese	7439-96-5
Methyl bromide	74-83-9
Methyl-t-butyl ether (MTBE)	1634-04-4
Metolachlor	51218-45-2
Metribuzin	21087-64-9
Molinate	2212-67-1
Naphthalene	91-20-3
Nitrobenzene	98-95-3
Organolins	N/A
Perchlorate	N/A
Prometon	1610-18-0
RDX	121-82-4
Sodium	7440-23-5
Sulfate	14808-79-8
Torbacil	5902-51-2
Terbufos	13071-79-9
Triazines & degradation products of triazines (including, but not limited to Cyanazine 21725-46-2, and atrazine-desethyl 6190-65-4).	
Vanadium	7440-62-2

III. Changes Made to Create the Final Contaminant Candidate List Based on Comments Received on the Draft

The criteria which EPA used to select the contaminants for the CCL are described in detail in the October 6, 1997 notice (62 FR 52193) on the draft CCL. In general, the criteria for including a contaminant on the CCL consisted of determinations of whether the occurrence, or anticipated occurrence, of a contaminant was likely at levels of concern to human health. The October notice solicited input from the public and specifically requested comments on (1) the approach EPA used to create the list and suggestions on the process for future lists; (2) contaminants on the list; (3) data needs categories; and (4) whether to include perchlorate on the CCL.

EPA received 71 comments, 66 by the deadline and 5 additional late comments. The majority of comments

were supportive of the CCL process, and the development of this first CCL. Comments were received from a number of segments of the stakeholder community, including equipment manufacturers, consultants, chemical manufacturers, trade associations, environmental groups, state regulatory agencies, water utilities, and private citizens. Commenters provided data and information on specific contaminants and included suggestions on the process for future CCL development, as well as feedback on the data and research needs indicated for the contaminants on the CCL. Roughly 60 issues were raised by the comments, both contaminant-specific and related to the development of a process for identifying contaminants for future CCLs. The comments, data, and information provided were taken into consideration in preparing the final CCL presented in today's notice. Proposed changes to the

CCL were also reviewed by the NDWAC Working Group on Occurrence & Contaminant Selection, and the NDWAC full-Council.

A number of comments indicated that many did not understand the function of the CCL. The CCL is not the list of contaminants for which the Agency has made a determination to regulate. The CCL is a list of priority contaminants (not otherwise addressed) for drinking water program activities which include those for: (1) drinking water research, (2) monitoring, (3) guidance development, as well as those for (4) selection and regulatory determination by the year 2001. The next steps likely to occur with regard to any given contaminant are discussed in more detail in Section V in today's notice.

Despite the support expressed for the development of this first CCL, commenters advised that more robust criteria are needed for future CCL

development and for contaminant selection. The Agency agrees with these commenters and will continue to work to develop a contaminant identification process for chemical and microbiological contaminants to be used to develop future CCLs. Section IV.C. of today's notice provides additional information on how the Agency plans to develop these processes.

The following is a summary of the significant public comments received that led to changes to the CCL. The remainder of this section responds to the more significant comments, and indicates how the CCL was changed in response to these comments. A complete report of responses to all comments received on the notice of the draft CCL can be found in the docket.

A. Acetochlor, Metolachlor, and Alachlor ESA

A number of commenters supported the inclusion of acetochlor, metolachlor, and alachlor ESA (the sulfonic acid degradate of alachlor) on the CCL, while others indicated that they should not be included. Three commenters indicated that acetochlor should have low priority for regulation, and that the Agency should consider deleting it from the CCL. The commenters argued that under the Acetochlor Registration Project, the EPA has established very conservative triggers for its potential cancellation of use as a pesticide. The commenters went on to indicate that in 175 community water systems monitored since March 1995, acetochlor detections have occurred in only 20% of samples, that no system had an average mean concentration exceeding 2 ppb, which is one of the triggers, and that additional monitoring data will indicate that concentrations found in public water systems are far below 140 ppb.

One commenter argued that metolachlor should not be included on the CCL. That although it is detected in water, it is rarely above the lifetime health advisory level of 70 ppb, and the detections in most cases are associated with point sources. The commenter stated that data collected under the Unregulated Contaminant Monitoring Regulations is available on a state-by-state basis, and the results reported from 3 States also indicate no detections above the lifetime health advisory level of 70 ppb. Another commenter suggested that alachlor ESA should not be included on the CCL, as it, too, should have a low priority for regulation based on concentrations in water not exceeding 6370 ppb.

Other commenters argued that metolachlor, acetochlor, and alachlor ESA should be kept on the CCL since

States reported finding these contaminants in water. One commenter added that the metolachlor ESA and metolachlor OA degradation products should be included on the CCL also, since all have been found in ground water.

One commenter also pointed out that metolachlor, acetochlor, and alachlor do not have a common mode of action, and thus cannot be grouped together to develop a single standard to address all acetanilide pesticides.

EPA Response

The Agency disagrees with the commenters who believe it is inappropriate to include acetochlor, metolachlor, and alachlor ESA on the CCL. By including these contaminants on the CCL, the Agency has not yet made a determination with respect to regulating any of them. In light of the reported occurrences of these contaminants in water, the drinking water program needs to determine what action is appropriate to ensure the protection of public health even if the action may be only the development of guidance for States and public water systems. The Office of Water will evaluate further the available toxicity and occurrence information for these pesticides in order to determine appropriate concentration values adequate to protect against risks associated with exposure through drinking water. With respect to metolachlor specifically, the Agency believes it is appropriate to include it on the CCL. The data collected under the Unregulated Contaminant Monitoring Regulations is being collected from all States and will be compiled and evaluated as additional information is collected and evaluated for all contaminants on the CCL.

The Agency agrees that it is appropriate to include other acetanilide pesticide degradation products in addition to alachlor ESA, since they, too, have been found in ground water. However, at this time, the Agency has not yet determined which are the most important to include; therefore, EPA has decided to include alachlor ESA & other acetanilide pesticide degradation products as a group of contaminants on the CCL. The determination of which degradation products are of most concern will be determined as we learn more about these contaminants as a class. The Agency also agrees with the commenter that because alachlor, acetochlor, and metolachlor do not have a common mode of action, they are not at this time appropriate contaminants to be grouped together to develop a single approach addressing all acetanilide

pesticides. Contrary to earlier statements, acetanilide pesticides are not likely candidates for development of "total standards" in the foreseeable future. However, the Agency is interested in the development of "total standards," or standards that address classes of compounds, where appropriate, and as the state of the science improves.

B. Acetone and Cumene

Two commenters remarked that outdated oral reference doses (RfD) from the Integrated Risk Information System (IRIS) for acetone and cumene were used in developing the draft CCL and that analyses should be done with current information. The Chemical Manufacturers Association's Acetone Panel submitted comments about acetone and recommended that it should not be included on the final CCL. The reason given, in addition to the outdated RfD, was that outdated information concerning levels of acetone detected in the environment, including data from old National Priority List (NPL) sites had been used in the Agency's evaluation and that this did not provide a reliable basis for estimating likely levels of acetone in drinking water or sources of drinking water. The Panel believes more relevant information shows that acetone is unlikely to be present in drinking water or sources of drinking water at levels of concern.

The Chemical Manufacturers Association's Cumene Panel submitted comments about cumene and recommended that it should not be included on the final CCL. The reason given, in addition to the outdated RfD, was that concentrations of cumene detected in the environment were not at levels of concern, and it is rarely detected in drinking water or sources of drinking water.

EPA Response

The Agency agrees with the commenters that the current IRIS values should be used in the evaluations for developing the CCL. The updated value for acetone has not been posted on the IRIS database; however, the Agency has acknowledged the new value of 0.9 mg/kg/day previously in a notice concerning section 313 of the Emergency Planning and Community Right-to-Know Act (60 FR 31644). The updated value for cumene has been posted on the IRIS database, and is 0.1 mg/kg/day.

The occurrence data from the U.S. Geological Survey's National Water Quality Assessment Program (NAWQA) indicates that acetone was detected at a

frequency of greater than 10% of the samples collected; however, the concentrations found did not exceed their reporting level of 0.2 µg/l. When the current IRIS values are used for acetone and cumene, and compared to the available occurrence data, neither meets the criteria set forth for identifying contaminants for the CCL, and therefore, acetone and cumene have been removed from the CCL.

C. Aldicarb and Nickel

EPA received a number of comments encouraging the inclusion of aldicarb and nickel on the CCL, while a few commented that it was inappropriate to include these contaminants, despite the Agency's existing statutory obligation with regard to these contaminants.

EPA Response

In the case of aldicarb (aldicarb, aldicarb sulfoxide, aldicarb sulfone) and nickel, the Agency has determined that it is inappropriate to include these contaminants on the CCL. The 1996 Amendments to SDWA explicitly reenacted the requirements for regulation of these contaminants [section 1412 (b)(2)]. 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 aldicarb, and they never became effective. NPDWRs for nickel were promulgated on July 17, 1992, but the MCL was later vacated and remanded in response to a lawsuit from the Nickel Development Institute and other industry parties.

The Agency intends to complete regulatory action for both aldicarb and nickel. The time-frame of completing action for these contaminants is likely to be the same time-frame required by SDWA for regulatory determinations for contaminants on the CCL. When considering the nature and type of work necessary to complete action on these contaminants, the effort for aldicarb is anticipated to be less extensive than that required for nickel; thus, regulations for aldicarb are likely to be completed prior to regulations for nickel.

D. Aluminum

EPA received four comments recommending that aluminum not be included on the CCL. One commenter stated that regulations would be premature at this time, due to the need for additional information on the risk of adverse effects and occurrence in drinking water. Other commenters argued that there was no scientific health basis for the inclusion of aluminum on the CCL, and that the

World Health Organization (WHO) stated in 1995 that there is an inadequate basis for revising existing guidelines for aluminum below the 200 µg/l standard used to control taste and odor effects. The commenters also explained that the source of aluminum in drinking water is primarily linked to the use of alum as a flocculent in water treatment, and the implications of regulating aluminum at lower levels could cause deleterious effects on water quality.

An additional commenter felt that aluminum should be included on the CCL based on new literature on the relationship of aluminum to Alzheimer's Disease, elderly mental impairment, and childhood learning disabilities. The commenter disagreed with the need for additional data on the health impacts of aluminum. The commenter contends that much more is actually known today about how aluminum causes neurological injury than is known for lead, and that there is as much data on the health effects of aluminum as was ever available for lead.

EPA Response

The Agency disagrees with the commenters who indicated that aluminum should not be on the CCL. The Agency believes it is appropriate to include aluminum on the CCL because of the new developments and research on aluminum epidemiology indicating a potential link between aluminum and adverse neurological effects. It is clear that additional studies are needed to characterize the risk of this contaminant from exposure through drinking water.

Due to aluminum's widespread occurrence and the recent studies indicating some association with Alzheimer's like symptoms and other potential neurotoxic effects, the Agency believes aluminum warrants further investigation. It is also EPA's opinion that additional data are needed to determine an adequate no-observed-adverse-effect-level (NOAEL) for potential chronic neurotoxicity. The inclusion of a contaminant on the CCL does not necessarily mean that the contaminant will be regulated. Contaminants on the CCL include those priorities for which the Agency must make a determination of whether or not to regulate by the year 2001, and priority contaminants for which the Agency will gather additional data and conduct research. At this time, the EPA has included aluminum among the contaminants for which additional research is needed.

E. Dimethoate

One commenter suggested that dimethoate be deleted from the CCL. The major reasons given were that dimethoate did not meet the occurrence criteria, because data used in the Agency's analysis from the Pesticides in Ground Water Database (PGWDB) report were recorded erroneously, and that the IRIS values lack critical evaluation and therefore should not be considered in evaluating whether a contaminant should be included on the CCL.

EPA Response

The Agency agrees with the commenter on the point raised about the occurrence data, but not on the point raised about the use of IRIS values. Based on the faulty occurrence data, dimethoate has therefore been removed from the CCL.

In general, the RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The health assessment information and RfD values on a chemical substance are included in IRIS only after a comprehensive review of chronic toxicity data by U.S. EPA health scientists from several program offices and the Office of Research and Development. The Agency believes it is entirely appropriate to use RfD values reported to IRIS in the absence of drinking water health advisory values in the derivation of health levels of concern for determining if a contaminant should be included on the CCL.

However, according to EPA's Office of Pesticide Programs (OPP), the office that prepared the PGWDB report, and the Georgia Department of Natural Resources, the data reported for the State of Georgia are incorrect. The laboratory analysis sheets from the Georgia Ground Water Management Laboratory Program indicate dimethoate was not detected in any samples in the State. By eliminating the occurrence data from the PGWDB report for the State of Georgia and replacing it with this new information, which the Agency feels is appropriate, dimethoate no longer meets the criteria for inclusion on the CCL, and has therefore been removed.

F. DTBB

DTBB, also known as 2,6-di-tert-butyl-p-benzoquinone, is a contaminant that appears to be associated with sewage contamination of ground water, and is

considered by some to be a good indicator of such contamination. DTBB was determined not to meet the criteria for the CCL per se, but was included on the draft list nevertheless, because of the persistent nature of the contaminant, and its potential to serve as an indicator. One commenter stated that coliforms and nitrate already serve the purpose as indicators of contamination, and that it was pointless to include DTBB on the CCL, since it, in fact, did not meet the criteria.

EPA Response

The Agency agrees with the commenter and has removed DTBB from the CCL. DTBB does not meet criteria set forth for identifying contaminants for the CCL, and since there are currently acceptable indicators of sewage contamination in the use of total coliforms, its inclusion is unnecessary.

G. Methyl Bromide

Several commenters supported the inclusion of methyl bromide on the CCL. The principal reason cited by commenters was the widespread use of methyl bromide as a fumigant and its likely occurrence in drinking water sources. One commenter indicated that although the frequency of detection in samples was less than 0.1% in ambient water monitoring conducted by the U.S. Geological Survey, methyl bromide should be considered for inclusion because the environmental significance may warrant it.

EPA Response

Methyl bromide, which is also known as bromomethane, was included on the draft CCL based on input from stakeholders that it was found in drinking water. In response to the comments, EPA has reevaluated the available information on methyl bromide occurrence. Contrary to assertions of likely widespread occurrence in source water due to its use as a fumigant, the U.S. Geological Survey ambient water monitoring indicates it occurs at less than 0.1% frequency, at very low concentrations (less than 0.2 µg/l). However, unregulated contaminant monitoring data collected from States indicates methyl bromide occurred in 0.8% of the public water systems. One explanation for this apparent anomaly could be that the finished water occurrence comes not from its use as a fumigant, but that methyl bromide is associated with the disinfection processes used for drinking water treatment. Nevertheless, methyl bromide met the criteria for inclusion on the CCL; the concentrations reported

(maximum 29 µg/l) in the unregulated contaminants database exceeded the health level of 0.8 µg/l.

Methyl bromide is a gas produced by both manmade and natural sources. Methyl bromide is primarily used for soil fumigation (87%), but its other agricultural uses include: commodity and quarantine treatment (8%), and structural fumigation (5%). When used as a soil fumigant, methyl bromide is injected into the soil at a depth of 12 to 24 inches. About 50 to 95% of the methyl bromide injected in the soil eventually enters the atmosphere. About 80 to 95% of the amount used for commodity treatments, and well over 90% used for structural fumigation eventually enters the atmosphere. A significant quantity of methyl bromide used for agricultural purposes is known to escape to the atmosphere due to its volatile nature. Therefore, the U.S. Geological Survey data indicating less than 0.1% frequency of occurrence is consistent with what would be expected to present in ground water due to methyl bromide's use as a fumigant.

Methyl bromide is also considered a Class I ozone depleting substance, and as such, its use is being phased out around the world by the Montreal Protocol, and in the U.S., by the Clean Air Act (CAA). The Montreal Protocol is an international treaty developed to protect the earth from the detrimental effects of ozone depletion, and to control the production and trade of ozone depleting substances on a global basis. Title VI of the CAA, as amended in 1990, requires that certain ozone depleting substances be phased out in the U.S. within seven years. Under the CAA, the EPA has prohibited the production and importation of methyl bromide starting January 1, 2001. As a result, given methyl bromide's lack of persistence, occurrence in source waters will likely decrease even more.

If methyl bromide is a disinfection byproduct, EPA has a number of rules and activities currently in place and under development to address it. In 1979, EPA issued an NPDWR establishing an MCL for the total trihalomethanes (TTHMs) disinfection byproducts. The Agency is also in the process of updating the disinfection byproducts regulation. In 1994, EPA proposed a revised standard for TTHMs and a new standard for haloacetic acids. The TTHMs were regulated not only to control trihalomethanes, but also to protect against other similar byproducts. Because of structural similarity, steps to reduce formation of TTHMs would also reduce formation of methyl bromide. The treatment technique of enhanced coagulation, included in the 1994

proposed DBPR, will remove disinfection byproduct precursors, thus reducing the levels of disinfection byproducts in finished waters. Although methyl bromide is not a TTHM, for which an MCL is explicitly established, the Agency believes it would be effectively controlled under the DBPR. However, it is not clear whether methyl bromide is being formed due to disinfection.

Because it cannot be determined whether methyl bromide is being formed due to disinfection, and its use as a fumigant cannot be completely dismissed as source of drinking water contamination, the Agency has decided to retain methyl bromide on the CCL. At the January 7, 1998 meeting, the NDWAC Working Group on Occurrence & Contaminant Selection concurred with the EPA recommendation to delete methyl bromide because it was being addressed in ongoing rulemakings for disinfection byproducts. However, at the February 2, 1998 meeting, the full NDWAC recommended the Agency retain methyl bromide on the CCL after receiving comment that because it is a mono-halogenated compound, it was not specifically regulated with the TTHM family which are tri-halogenated compounds, and that it may not turn out to be a disinfection byproduct. At the meeting, EPA was insufficiently lucid in explaining the connection between the TTHM byproducts and the control of similar byproducts. Nonetheless, after further consideration of the NDWAC recommendation, and given the uncertainties about the source, EPA has concluded that methyl bromide should remain on the CCL.

Since methyl bromide is a gas, most health studies have used the inhalation route of exposure, and the effects of oral exposure have received limited attention. In 1989, EPA classified methyl bromide as a Group D carcinogen (not classifiable) due to inadequate bioassay data. At the time of the IRIS assessment, also in 1989, a chronic oral study was not available, therefore an additional uncertainty factor of 10 (total uncertainty of 1,000) was applied to the RfD calculation. However, since the IRIS assessment, a 2-year rat feeding study showed no evidence of carcinogenicity, and a National Toxicology Program inhalation study, conducted in 1992, found no evidence of carcinogenicity. The Agency will also explore the potential sources of drinking water contamination, and the expected impact of the prohibited production and importation of methyl bromide which begins in January 1, 2001. Methyl bromide is listed on the Research Priorities portion of the CCL to

allow the Agency time to better determine the drinking water risk due to this contaminant.

H. Microorganisms

Many commenters stated that the rationale for the inclusion of microorganisms appeared to be inconsistent. They suggested that other microorganisms would have been included had the criteria been used consistently. It was not the intention of EPA, nor the participants of the EPA Drinking Water Microbiology and Public Health Workshop, to develop a comprehensive list of all possible agents of waterborne disease. The intent was to list what were considered the most important agents (or potential agents) of waterborne disease. The Agency recognizes that the Workshop participants could have established different lists of reasonable criteria for selecting pathogens, and believes that the ultimate decisions represent the best (albeit sometimes subjective) judgment of the panel. Nevertheless, the Agency believes that the process for developing the current CCL for microorganisms by this group of nationally recognized experts in the field of microbiology was reasonable and credible.

EPA believes that regulations that are currently in effect [Surface Water Treatment Rule (SWTR), Total Coliform Rule (TCR)] or are now under development [e.g., Groundwater Disinfection Rule (GWDR), Enhanced Surface Water Treatment Rule (ESWTR), and Disinfection Byproducts Regulations (DPBR)] will address a number of the microorganisms that commenters have suggested. Generally, if a microorganism has not caused, or not expected to cause, a waterborne outbreak in the U.S., or if the organism is known to be susceptible to disinfection or filtration required by current or upcoming regulations, the organism has not been included on the CCL.

Protozoa

Several commenters supported the draft CCL, which included *Toxoplasma gondii*, *Cyclospora cayetanensis*, and two microsporidia—*Enterocytozoon* and *Septata*. One commenter suggested the addition of *Entamoeba histolytica* to the CCL, primarily because of its virulence. One commenter suggested that EPA add *Isospora belli* to the final CCL.

EPA Response

After further consideration, EPA has decided to remove *Toxoplasma* and *Cyclospora* from the final CCL. *Toxoplasma gondii* is about the same size as *Giardia*, and *Cyclospora*

cayetanensis is larger than *Cryptosporidium*. The Agency believes that the upcoming M/DBPR to control *Giardia* and *Cryptosporidium* will also control these larger organisms. Microsporidia remains on the CCL for the reasons indicated in the preamble to the draft CCL, including the ineffectiveness of chlorination and filtration.

The Agency recognizes that *Entamoeba histolytica* can be virulent. Even though the commenter cites an article stating that dogs and perhaps pigs may be reservoirs for *E. histolytica* (Benenson 1995), animals are probably not major host reservoirs, in contrast to the situation for *Giardia* and *Cryptosporidium*. Thus, if sewage treatment practices are adequate, the potential for source water contamination is probably low, as suggested by the fact that the organism has not caused a significant waterborne disease outbreak since the early 1950s (the one reported exception in the U.S. was a small outbreak in 1984 associated with untreated well water). Importantly, the cyst is large (10–15µm). It is slightly larger than a *Giardia* cyst, and much larger than microsporidia spores that infect humans (1–5µm) to which the commenter compares *E. histolytica*. Thus, EPA believes that regulations that control for *Giardia* and *Cryptosporidium* should also control *E. histolytica*. For these reasons, *E. histolytica* was not included on the final CCL. The Agency has also decided not to include *Isospora belli* for the reasons given in the preamble of the draft CCL, especially for the fact that its oocysts are 30×12µm, larger than *Giardia* cysts, and any rule to control *Giardia* and *Cryptosporidium* should also control this organism.

Viruses

The draft CCL included the following viruses: caliciviruses, adenoviruses, coxsackieviruses, echoviruses, and the hepatitis A virus. Several commenters suggested that EPA add rotaviruses, hepatitis E virus, and bacteriophage to the final CCL.

EPA Response

The final CCL remains the same as the draft, except that the hepatitis A virus has been removed. Hepatitis A was removed because it is being addressed by current regulations, or regulations under development. As a matter of policy, all viruses are regulated as a class under EPA's SWTR and are going to be regulated as a class under the GWDR, and the Agency does not believe that additional research is needed to demonstrate the efficacy of disinfection for this organism. In contrast, the

Agency believes that additional research is needed on the impact of treatment for the other viruses that remain on the CCL.

EPA did not include rotaviruses on the final CCL, primarily because they are vulnerable to disinfection and should always be associated with fecal contamination. Thus, the Agency believes that EPA's SWTR, plus the upcoming GWDR, should adequately control these viruses.

EPA excluded the hepatitis E virus from the final CCL because the Agency does not regard the virus as a significant public health threat in the U.S. and believes that current sewage treatment practices are sufficient to eliminate significant risk of waterborne transmission. EPA recognizes that hepatitis E is a major problem in some developing countries, especially for pregnant women. However, there is no evidence that the organism is a problem in the U.S. Rare cases have occurred in the U.S., usually among travelers returning from an area where the disease is endemic (Mast and Krawczynski 1996). Structurally, the organism is a small, single-stranded RNA virus similar to the caliciviruses, coxsackieviruses, and echoviruses, all of which remain on the CCL, because of evidence of outbreaks and occurrence in finished waters.

Bacteriophage were excluded from the CCL because they are not pathogenic to humans. However, EPA recognizes that they may be useful as an indicator of fecal contamination. EPA has decided not to include indicators of fecal contamination or of pathogens on the final CCL. However, the Agency will consider indicators in the context of regulations to control pathogens on the CCL. For example, the Agency is considering two bacteriophage—the somatic coliphage and the male-specific coliphage—as an indicator of fecal contamination under the Groundwater Disinfection Rule.

Bacteria

The draft CCL included the following bacteria: *Helicobacter pylori*, *Legionella*, *Mycobacterium avium* complex, and *Aeromonas hydrophila*. Commenters urged EPA to include additional bacteria, including *Pseudomonas aeruginosa*, *Shigella*, *Salmonella*, *Vibrio*, *Arcobacter*, *Campylobacter*, *Yersinia*, and *E. coli* O157:H7, and that if these enteric bacterial pathogens were not included on the CCL, then *H. pylori* and *A. hydrophila* should not be included either, because both are sensitive to disinfection also.

EPA Response

The final CCL does not include the enteric bacterial pathogens that commenters suggested EPA add (*Shigella*, *Salmonella*, *Vibrio*, *Arcobacter*, *Campylobacter*, *Yersinia*, and *E. coli* O157:H7). The Agency's reasons for excluding these organisms are that they are all sensitive to disinfection and are all associated with fecal contamination. Thus, EPA regards total coliforms as an adequate indicator for these organisms. Moreover, the SWTR requires all surface water systems to disinfect, and the forthcoming GWDR is likely to require systems that have wells vulnerable to fecal contamination to disinfect or provide other corrective action. The Agency regards these regulatory tools as sufficient to control for the above pathogens.

With regard to *P. aeruginosa*, the preamble to the draft CCL indicated that the participants of the EPA Drinking Water Microbiology and Public Health Workshop could not agree on whether to include this organism on the draft CCL. There was controversy among participants about its public health significance and its potential health risk via the waterborne route. Therefore, participants recommended that EPA conduct a complete literature search on the topic before deciding whether to include this organism on the final list. The Agency has not yet completed this search. Because of this lack of information, EPA has decided to defer a decision on *P. aeruginosa* and not include it on the CCL. However, should the literature search suggest that regulatory action may be necessary, EPA will increase the priority of research in this area, if appropriate.

With regard to *Helicobacter*, following the meeting of the panel, an article was published indicating that *Helicobacter* is sensitive to chlorine (Johnson, Rice and Reasoner 1997). However, EPA decided not to remove *Helicobacter* from the CCL because of the large number of people in the U.S. affected by peptic ulcers (about 20 million people) and gastritis, the poor survival rate of individuals with gastric cancer, and ignorance about the mode of transmission of the organism. *Helicobacter pylori* has been implicated in the cause of these three diseases. The Agency believes that, in spite of the recent disinfection data, it would be improper to remove *Helicobacter* from the CCL for these reasons.

With regard to *Aeromonas hydrophila*, EPA recognizes that this organism is sensitive to disinfection in source and finished waters. However, unlike the fecal pathogens listed above,

A. hydrophila may enter the distribution system either as a result of inadequate treatment or a break in the water distribution system, and grow as part of the biofilm on the pipes or in the sediment, which may protect it from disinfectants. In addition, *A. hydrophila* is not necessarily associated with fecal contamination. Thus, the total coliforms rule may not be adequate as an indicator for this organism. Moreover, systems which are not required to disinfect (or take other corrective action) under the forthcoming Groundwater Disinfection Rule because they are considered not vulnerable to fecal contamination, may still be vulnerable to *A. hydrophila*. For these reasons, EPA does not believe that this organism can be treated in the same manner as *E. coli* O157:H7 and other fecal bacteria listed by the commenter. Thus, the final CCL includes *A. hydrophila*.

EPA removed *Legionella* in ground water from the final CCL. It was removed because: (1) the Agency intends to address the control of this organism under the Groundwater Disinfection Rule, and (2) the Agency does not believe that high priority research is needed in this area to regulate this organism.

Algae and Their Toxins

Several commenters strongly urged EPA to add algae, especially the blue-green algae, plus their toxins (e.g., mycotoxin) to the CCL. One commenter suggested that *Pfiesteria piscicida* be included on the final CCL, as well.

EPA Response

In the preamble to the draft CCL, EPA stated that certain species of blue-green algae produce toxins that could be harmful if ingested at high enough concentrations, but that algal control was best handled through good watershed management practices. The Agency continues to regard this strategy as reasonable. However, the Agency has decided to add the algae and their toxins to the final CCL because: (1) pathogenic algae and their toxins are not necessarily associated with fecal contamination and thus may not be effectively controlled by the SWTR or ESWTR, and (2) some data suggest that current treatment techniques may be particularly inadequate in controlling algal toxins. Placement of this group of contaminants on the CCL will make them a priority for research to determine what triggers toxic algal growth in source water and the effectiveness of water treatment practices.

EPA is aware that *Pfiesteria piscicida* has been implicated in adverse health effects in humans. Apparently at least

13 researchers who worked with dilute toxic cultures of this organism and 10 fishermen sustained mild to serious health effects by water contact or by inhaling toxic aerosols. Symptoms include skin rashes, reddening of the eyes, severe headaches, blurred vision, nausea/vomiting, breathing difficulties, kidney and liver problems, short-term memory loss, confusion, and other problems. The organism has a complicated life cycle, with about 24 stages. *Pfiesteria*'s habitat is estuarine or brackish water. Current data indicate that, like most other dinoflagellates, the organism grows poorly in fresh water and does not elaborate toxins in this milieu, thus, there is no evidence that *Pfiesteria* occurs or could occur in drinking water. Moreover, the size ranges from 5–450 µm, with the dormant cyst stages 7–60 µm in diameter. Thus filtration that is effective for removing *Cryptosporidium* (4–6 µm) should be effective for removing *Pfiesteria*. For these reasons, EPA believes that *Pfiesteria* does not represent a health threat in drinking water systems, and thus did not include *Pfiesteria* on the final CCL.

I. MTBE

A number of commenters agreed with the inclusion of methyl-t-butyl ether (MTBE) on the CCL, and some indicated that MTBE should be included among the contaminants for which determinations will be made by 2001. Another commenter suggested it should not be included on the CCL but should be included in the forthcoming Unregulated Contaminant Monitoring rulemaking, due in 1999.

EPA Response

The Agency agrees that MTBE should remain on the CCL. However, as with all the contaminants on the list, EPA has not made a determination with respect to regulating MTBE. Although there are serious limitations in the MTBE data, there is some evidence to support a concern for potential human hazard. MTBE has been found in some drinking water wells but it is uncertain whether the concentrations are at levels of health concern. Given the potential health hazard and need for additional data, MTBE meets the criteria for placement on the CCL.

The inclusion of a contaminant on the CCL does not mean that the contaminant will be regulated. As noted earlier, contaminants on the CCL include those for which the Agency must make a determination of whether or not to regulate by 2001 pursuant to the requirements of the SDWA, but it also includes the Agency's research

priorities, contaminants for which monitoring is necessary to gather additional data. MTBE will remain on the CCL since the Agency needs additional occurrence data.

At this time, the EPA has not included MTBE among the contaminants for which determinations will be made by 2001. As stated earlier, MTBE needs additional health and occurrence data, and as such, it will be one of the priority contaminants for which the Agency will gather such data. There are no data on the effects on humans of drinking MTBE contaminated water. Therefore, EPA is continuing to evaluate the available health information and is doing additional research to seek more definitive estimates of potential risks to humans from drinking water. One of the mechanisms for gathering occurrence data is to include a contaminant in the forthcoming Unregulated Contaminant Monitoring rulemaking to be issued in August 1999. The Agency is also not precluded from using other means of gathering occurrence data which may include conducting special studies. The data collection and evaluation efforts will assist in determining what the appropriate action should be with respect to MTBE. Placing MTBE in this category does not prevent the Agency from selecting it to make a determination of whether or not to regulate by 2001; however, at this time, it is not likely that the necessary data will be collected and evaluated in time to make a determination by this date.

To facilitate data collection and evaluation efforts for MTBE, an Agency-wide task force has been formed and has prepared a draft Oxygenates in Water Research Strategy. The Strategy identifies current, or soon to be started, research in areas that include environmental occurrence, source characterization, transport and transformation, exposure, toxicity, and treatment. The Strategy will also identify key areas of research that are still necessary to build a stronger, more informed scientific database to support health risk assessment and risk management decisions with respect to fuel oxygenates, including MTBE.

On October 7, 1997, EPA convened a day-long meeting of over 50 experts—including representatives from industry, academia, consultants, and other government agencies—to review a draft of the Strategy. The information produced in this workshop is being used to help revise the draft of the Strategy, which will serve as a blueprint to assist in coordinating efforts by various organizations, public and private, in addressing the issues related

to oxygenates in water. The Agency will also publish the Strategy in the *Federal Register* this Spring, to seek additional public comment on the research priorities identified.

J. Organotins

Four commenters argued that organotins, specifically the mono- and di-organotins, the only types used as polyvinyl-chloride (PVC) heat stabilizers, should not be included on the CCL. The commenters maintained that, due to evidence of low toxicity and low migration (thus, low risk to consumers), mono- and di-organotins, especially mono- and di-methyltins, should not be of concern to drinking water, particularly in light of the National Sanitation Foundation (NSF) certification program for plumbing materials. Other commenters indicated that it was premature for the Agency to regulate organotins, but thought it prudent that the Agency keep informed of the issue.

EPA Response

EPA disagrees with the commenters who suggest that organotins should be deleted from the CCL. It should be emphasized that retaining organotins on the CCL does not necessarily mean that they will be regulated. The Agency believes that organotins, including mono- and di-organotins which are used as heat stabilizers in PVC and chlorinated polyvinyl-chloride (CPVC) pipes, are of sufficient concern to warrant further investigation. The Agency is aware of the NSF certification program, and has noted that many States require the use of NSF-certified material in the construction of new buildings. The Agency agrees with the NDWAC Working Group recommendation that an assessment of the toxicological data underlying the action levels established by the NSF needs to be made along with assessment of other available information on organotins, before these compounds can be disregarded as of concern. The Agency requested this information from the NSF, and learned that due to confidentiality agreement, NSF cannot disclose this information, therefore we have not yet been able to assess the toxicological data.

There are numerous concerns about the occurrence and toxicological significance of various species of organotins in drinking water. A recent report indicates that unlike PVC systems, new CPVC systems have the potential to contaminate drinking water with organotin compounds for a longer period of time after installation (Forsyth and Jay 1997). There has been a report

concerning tributyltin contamination of drinking water from PVC pipes, and tributyltin is of far more toxicological significance than mono- and di-organotins (Sadiki et al, 1996). There is also concern about the recent reports of teratogenic potential of dibutyltin (Ema et al, 1996). The Canadian Government is concerned about organotin contamination of drinking water and has launched a national survey.

In view of these concerns, the Agency believes that organotins, including mono- and diorganotins, should remain on the CCL until the Agency can perform its own in-depth evaluation of the occurrence and toxicological data of the contaminants of this class.

K. Perchlorate

The majority of comments on perchlorate indicated support for its inclusion on the CCL. Commenters pointed out that the information on the occurrence of perchlorate in drinking water supplies was sufficient to raise concern over the potential impact on public health. A few commenters expressed concern that perchlorate should not be regulated or that there was not sufficient information at present to warrant its regulation, and that a health advisory would be more appropriate.

EPA Response

The Agency agrees with commenters that sufficient information exists to raise concern over the potential health effects and occurrence of perchlorate in drinking water supplies. Despite significant data gaps regarding health effects, occurrence, and treatment technologies, perchlorate has been found in a number of drinking water supplies at levels of health concern, and as a result is included on the final CCL.

The Agency understands that the extent of actual or even potential perchlorate contamination is unclear for many parts of the country, and that for some areas of the country perchlorate contamination may not be an issue. However, perchlorate has been detected in a number of drinking water supplies to date and warrants further evaluation. Placement of perchlorate on the CCL means that the Agency will make it a priority to conduct further investigation and evaluation of the health effects and national occurrence of perchlorate in drinking water supplies.

Perchlorate has been placed in the categories of needing additional health effects, treatment research, and occurrence information. Several toxicological and occurrence studies are planned or are underway, which will assist the Agency in filling these data

gaps on perchlorate. At this time, the Agency has not made a determination to issue a health advisory or to regulate perchlorate. The additional data obtained from these health effects and occurrence studies will provide a sound scientific basis for future EPA decisions of whether to regulate perchlorate or not, to prepare a health advisory or guidance, or to include perchlorate in the Unregulated Contaminant Monitoring rulemaking. Placing perchlorate in these categories does not preclude the Agency from selecting it to make a determination of whether or not to regulate by 2001, but at this time it is unlikely that perchlorate will be included among those for which determinations will be made by 2001.

L. Rhodamine WT

A few commenters argued that Rhodamine WT be removed from the CCL. The commenters stated that Rhodamine WT has a very specialized purpose. They also noted that it is certified by the NSF and that the certification is reviewed by EPA. They also stated that data for including Rhodamine WT were questionable, and that the contaminant had no specific health effect.

EPA Response

EPA agrees with the commenters and has removed Rhodamine WT from the CCL. Rhodamine WT was placed on the draft CCL because it was detected in ground water above the NSF Standard 60 concentration of 0.1 µg/L for drinking water. However, three concentrations have been established under the NSF Standard 60; 0.1 µg/L for drinking water, 10 µg/L for water entering a drinking water plant (prior to treatment and distribution), and 100 µg/L for ground water not associated with drinking water production. These concentration values were developed under the Agency's former Additives Program which was subsequently privatized and turned over to NSF in the 1980's.

The maximum concentration of available occurrence data was 28 µg/L detected in ground water, and, as such, should be compared to the recommended value of 100 µg/L for ground water, not the value for drinking water. Given this comparison, the maximum concentration of 28 µg/L is well below the recommended value for ground water of 100 µg/L. When the NSF guidance regarding the use of Rhodamine WT as a fluorescent tracer in water flow studies is followed the Agency does not anticipate any adverse health effects resulting from the use of Rhodamine WT.

M. Sodium

Many commenters were opposed to including sodium on the CCL, primarily due to their contention that sodium in drinking water is not a public health concern because of its extremely low level in drinking water, and its small contribution to overall sodium intake. Commenters also noted that controlling sodium in public water systems would be cost-prohibitive and produce marginal or nonexistent health benefits. Commenters argued that food, which is the major source of sodium, is allowed to average 440 mg/day under a "salt-restricted" medically-supervised diet, and that controlling sodium content in food would address salt-restriction more directly. Commenters also strongly disagreed with the use of EPA's DWEL of 20 mg/l as the public health criteria for determining whether to include sodium on the CCL. The commenters mentioned a more up-to-date, 1996 report published by the American Medical Association (AMA) showing a lack of association between sodium and blood-pressure, except for older individuals with existing hypertension. Other commenters argued for the inclusion of sodium, citing studies linking it to hypertension and the need to maximize protection of salt-sensitive individuals as a sensitive subpopulation.

EPA Response

The issue of sodium posed a unique challenge for the Agency priority setting and contaminant candidate listing process. Information from commenters on each side made important points. On the one hand, high levels of salt intake can be associated with hypertension in some individuals. On the other hand, sodium levels in drinking water are unlikely to be a significant contribution to adverse health effects.

This low level of concern is compounded by the legitimate criticisms of EPA's 20 mg/l guidance level that was used in this process. EPA believes this guidance level for sodium needs updating, and is probably low. If a health benchmark for drinking water were established using current information and current drinking water health assessment procedures, it would likely be higher. This revision could establish a new level at which sodium occurrence would not meet the criteria for inclusion on the CCL as a drinking water contaminant of concern. There was insufficient time to complete a reassessment of the sodium guidance in advance of the CCL issuance.

Given the state of the data, EPA faced a dilemma on whether or not to list

sodium. A decision not to list would be justified by the fact that much is known about sodium and it does not appear to be a drinking water risk comparable to other priority contaminants. In fact, this was the logic supporting the decision not to include sodium on the previous drinking water priority list in 1991. However, a decision to list sodium would afford EPA the opportunity to address the confusion surrounding the current guidance for sodium in drinking water.

In the end, EPA decided to include sodium on the CCL, primarily as a vehicle to reexamine and correct the current, outdated guidance. Therefore, sodium is listed, not as a Regulatory Determinations Priority, but as a Research Priority to allow time to evaluate and revise the Agency guidance. When this is completed, EPA will reevaluate whether sodium merits retention on the CCL for any further action.

N. Triazines

Many commenters applauded EPA's intention to address triazines and their metabolites as a group a "good first step" to addressing these compounds. A number of commenters indicated that we should include other triazine degradation products such as deisopropyl atrazine and diaminochlorotriazine (same as diaminotriazine) because they too are common degradation products of atrazine as well as simazine, and are found at higher concentrations than atrazine-desethyl. Once commenter expressed concern that additional information was being considered and evaluated by the Agency under the OPP Special Review program, and that these reviews should be completed before triazines are considered for the CCL.

EPA Response

The Agency agrees with the points raised by the commenters regarding the triazine degradation products. As a result, the EPA has decided to include triazines and their degradation products (including but not limited to: cyanazine and atrazine-desethyl) on the CCL as a group to include all potential risks from this class of compounds. Stakeholders, through the regulatory reassessment process in developing the redirection strategy, and through the development of this draft CCL, have requested that the Agency address triazine pesticides as a group, which includes all parent and degradate compounds, as opposed to each triazine as an individual contaminant.

The EPA has been studying the mechanism of carcinogenicity of this

group of analogues along with their degradation products, and will continue to study these chemicals as a group to characterize their risk in drinking water. The Agency regulated atrazine in 1991 and simazine in 1992. The Agency may ultimately develop regulations for the mixtures of triazines either through the revision of existing regulations or the development of new ones.

EPA disagrees with the notion that triazines should be excluded from the CCL until after the completion of the Special Reviews. The triazines are included in the Priority Group 1 of pesticide tolerances that will be examined first under the Food Quality Protection Act (FQPA) tolerance reassessment (62 FR 42020). The work being accomplished by OPP in their review efforts will certainly be factored into EPA's decisions regarding triazines, as with all pesticides on the CCL.

O. Zinc

Two commenters were opposed to the inclusion of zinc on the CCL. The commenters argued that zinc did not meet the criteria for inclusion on the CCL, and is generally non-toxic to animals and humans. They pointed out that zinc is used in a wide variety of products, and is also an essential element. One commenter stated that the Agency had not considered zinc's beneficial qualities when deciding whether it should be included on the CCL, and that the WHO and EPA have both stated that deficiency of zinc is more of a concern than over-exposure. The commenter further argued that the history of the substitution from the 1988 DWPL was not considered, and that the HA value used in the Agency's analysis was from a "7-yr old draft" which was not available for comment and therefore the explanation behind the Agency's HAL of 2,000 µg/l was not available for comment.

EPA Response

The EPA agrees with the commenter on the point raised that zinc does not meet the criteria for inclusion on the CCL, and has removed zinc from the CCL. The Agency has determined that the number of public water systems with zinc levels above 1,000 µg/l is 4, and none had occurrence levels above 2,000 µg/l, and, as a result, zinc doesn't meet the criteria for inclusion on the CCL. The criterion for a contaminant to be included on the CCL was "occurrence at the health level of concern in 10 or more small public water systems." The action of removing zinc from the CCL was due to its lack of occurrence in water systems at health levels of concern, not due to its lack of

toxicity. It is known that daily exposure to zinc of approximately 60 mg/l (60,000 µg/l) or more can effect copper metabolism, and result in deleterious health effects.

IV. Continuing Work in Preparation for Future CCLs

In the Federal Register notice on the draft CCL, the Agency deferred action on a number of pesticides, and contaminants implicated as endocrine disruptors, in anticipation of impending resolution specific to these two groups of contaminants. Action on these contaminants continues to be deferred and these contaminants will be reconsidered when the next CCL is developed. The Agency is also resuming work on a contaminant identification process to be used in the development of future CCLs. Further discussion of these three topics follows.

A. Pesticides Deferred

In developing the CCL, the SDWA requires EPA to consider substances registered as pesticides under FIFRA. During the development of the CCL, the Agency's Office of Ground Water and Drinking Water sought assistance from OPP in determining what pesticides should be priorities for the drinking water program. In response to the request, OPP provided recommendations for a number of pesticides based on physical-chemical properties, occurrence and extent of use, using the Ground Water (GW) Risk score. The GW-Risk score is a calculated potential of pesticides to leach to ground water. Pesticides with a GW-Risk of 2.0 or greater were included for initial consideration in developing the draft CCL.

However, later during the data evaluation and screening phase of the CCL development, the decision was made to defer pesticides identified by the GW-Risk of 2.0 or greater for which no additional information was available. Inclusion on the CCL would be deferred pending further evaluation of the potential of these pesticides to occur at levels of health concern. The Agency is working to develop a tool to estimate concentrations in ground and surface waters based on physical-chemical properties and pesticide use volumes, and will then compare the estimated concentrations with health advisory levels or calculated health levels based on reference doses or cancer potency.

It was anticipated that the tool to estimate concentrations of pesticides in ground and surface waters would be completed and available in time to reevaluate the inclusion of the additional pesticides prior to

completing the CCL. However, the Agency believes it is important to have this tool peer-reviewed prior to its use, which would increase the time necessary for its development beyond the time available. Therefore, EPA did not attempt to complete this work before finalizing the CCL in today's notice. As a result, action on these pesticides remains deferred until the next CCL.

On December 10, 1997, the Science Advisory Panel (SAP) met to discuss drinking water exposure assessment issues with the OPP. The objective of the meeting was to obtain SAP's recommendation on the approaches and models developed by OPP to determine short-term and long-term potential exposures from pesticides in drinking water. The issues of monitoring requirements, and assessing impacts of exposure to mixtures were also part of the discussion. The approaches and models developed by OPP and the forthcoming SAP's recommendations on these issues are of particular importance to the Office of Water in that the outcome will be used in the drinking water program as well.

B. Endocrine Disruptors

During the development of the draft CCL, the Agency initially considered, then later deferred, a number of contaminants implicated or suspected as substances which disrupt the function of the endocrine system. As stated in the notice of the draft CCL, EPA issued an interim assessment in February 1997, pending a more extensive review expected to be issued by the National Academy of Sciences (NAS), determining that, while effects have been found in laboratory animal studies, a causal relationship between exposure to a specific environmental agent and an adverse health effect in humans operating via endocrine disruption has not been established, with a few exceptions. Further research is needed before such effects can be demonstrated.

Under the SDWA, as amended, the Agency is also required to establish a program to screen endocrine disrupting contaminants. Additional authority to assess endocrine disruptors is also provided through the recently enacted FQPA. EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) has the Agency lead on endocrine disruptor screening and testing issues, and is actively engaged in research and regulatory initiatives to respond to the growing scientific and public concern over endocrine disruptors. Also, the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) has

been established to provide advice and counsel to the Agency in implementing a screening and testing strategy required under the FQPA and SDWA. EDSTAC will complete its recommendations for a screening and testing strategy by March 1998. The recommendations will be peer-reviewed jointly by the SAB and the FIFRA SAP.

As a result, pending completion of the EDSTAC's recommendations and the additional review of endocrine disruptors by the NAS, EPA has not included contaminants for inclusion on this first CCL based solely on the possibility of endocrine disruption (although several contaminants implicated as endocrine disruptors were considered for other reasons). As stated in the notice on the draft CCL, the Agency will continue to follow this issue closely and reconsider this category of potential contaminants in the development of future CCLs.

C. Development of the Contaminant Selection Process

This CCL is largely based on knowledge acquired over the last few years and other readily available information, but an enhanced, more robust approach to data collection and evaluation will be developed for future CCLs. The Agency will also resume work on the contaminant identification and the contaminant selection process. The CCL, and the identification and selection process will serve as the cornerstones of the Agency's regulatory development process. In addition to developing the CCL, and the identification and selection process, the Agency intends to obtain resources in order to acquire better data and information, improve analytical capability, and seek additional stakeholder involvement.

The next steps for improving the contaminant identification and selection process include an American Water Works Association Research Foundation (AWWARF) project utilizing a series of workshops in which established decision-making tools would be employed to develop a process to identify emerging pathogens of concern for consideration, regulation, and future research. The work is expected to begin in June/July 1998. A project with the

NAS will also be undertaken to solicit input on criteria for listing and selecting chemical contaminants for future CCLs. A panel is currently being formed and work is expected to begin in summer of 1998. The development of the identification and the selection process will be completed in consultation with the NDWAC and the Working Group on Occurrence & Contaminant Selection, and their future involvement is likely to include reviewing products from AWWARF and NAS in 1999. The CCL is a critical input to shaping the future direction of the drinking water program, and improvements to the process will be made with each successive cycle of publishing the list.

V. Data, Research Needs and Next Steps

Table 2 divides the CCL into categories to represent the next steps and data needs for each contaminant. Sufficient data are needed to conduct analyses on extent of exposure and risk to populations via drinking water in order to determine appropriate Agency action (development of health advisories, or regulations, or no action) for many of these contaminants. If sufficient data are not available, they must be obtained before such an assessment can be made. The data and information required will be gathered by research or monitoring programs, and are not likely to be available for analyses to be completed prior to 2001. Thus, the contaminants for which sufficient data exist at the time of publishing the CCL are likely to be those from which the determinations will be made by 2001.

However, it should be noted that the groupings in Table 2 are based on current information, and some movement of contaminants between categories can be expected as more information is evaluated and analyzed. The Regulatory Determination Priorities category in Table 2 will be used to select 5 or more contaminants for which the Agency must determine, by August 2001, whether or not regulations should be developed. To make these determinations, further analysis of data currently available, or data that will become available within a short period, is required to prepare supporting documents addressing health criteria, cost and benefit assessments, and

analyses of analytical methods, occurrence, and treatment technology and feasibility. For contaminants in the category, there may also be some short-term research needs, such as bench-scale treatability studies, that must also be completed. The next steps for the Agency regarding the contaminants in this category are to determine which contaminants to address first, and outline plans of action to work towards making determinations for five or more by August 2001.

The contaminants in the Research Priorities category have significant data gaps in areas of health, treatment, or analytical methods. For these contaminants, the research, or data gathering, and subsequent analysis needed are not expected to be complete within the 3½ years, by August 2001, in order to make determinations of whether regulation of these contaminants is necessary. These are EPA's priority contaminants for research and data gathering. Some of these research needs are currently being addressed by EPA or other agencies (e.g., Department of Defense for perchlorate), while other needs are newly identified.

The contaminants in the Occurrence Priorities category have significant data gaps in occurrence data. The Unregulated Contaminant Monitoring Regulations (UCMR) will be the primary source for data for most contaminants included in this category; however, some contaminants may be more appropriate for special studies or surveys, or joint data gathering efforts with other Agencies. Also, for some contaminants, suitable analytical methods must be developed prior to obtaining the occurrence data necessary.

The next steps for the Agency are to develop short- and long-term research plans on health, treatment, and methods, to develop the UCMR proposal (expected August 1998) for gathering occurrence data, and to plan for special occurrence studies, where appropriate. The Agency will also use its FIFRA and Toxic Substances Control Act (TSCA) authorities, as appropriate, to conduct studies and obtain data necessary for decision-making.

TABLE 2.—NEXT STEPS FOR THE CCL

Regulatory determination priorities	Research priorities			Occurrence priorities
	Health research	Treatment research	Analytical methods research	
Acanthamoeba (guidance) 1,1,2,2-tetrachloroethane 1,1-dichloroethane 1,2,4-trimethylbenzene 1,3-dichloropropene 2,2-dichloropropane Aldrin Boron Bromobenzene Dieldrin Hexachlorobutadiene p-Isopropyltoluene Manganese Metolachlor Metribuzin Naphthalene Organotins Triazines & degradation products (Incl., but not limited to Cyanazine and atrazine-desethyl) Sulfate Vanadium	Aeromonas hydrophila Cyanobacteria (Blue-green algae), other freshwater algae, and their toxins Caliciviruses Helicobacter pylori Microsporidia Mycobacterium avium intercellulare (MAC) 1,1-dichloropropene 1,3-dichloropropane Aluminum DCPA mono-acid & di-acid degradates Methyl bromide MTBE Perchlorate Sodium (guidance)	Adenoviruses Aeromonas hydrophila Cyanobacteria (Blue-green algae), other freshwater algae, and their toxins Caliciviruses Coxsackieviruses (ICR data) Echoviruses (ICR data) Helicobacter pylori Microsporidia Mycobacterium avium intracellulare (MAC) Aluminum MTBE Perchlorate	Adenoviruses Cyanobacteria (Blue-green algae), other freshwater algae, and their toxins Caliciviruses Helicobacter pylori Microsporidia 1,2-diphenylhydrazine 2,4,6-trichlorophenol 2,4-dichlorophenol 2,4-dinitrophenol 2-methyl-Phenol Acetochlor Alachlor ESA Fonofos Perchlorate RDX	Adenoviruses.* Aeromonas hydrophila. Cyanobacteria (Blue-green algae), other freshwater algae, and their toxins.* Caliciviruses.* Coxsackieviruses (ICR data). Echoviruses (ICR data). Helicobacter pylori.* Microsporidia.* 1,2-diphenylhydrazine.* 2,4,6-trichlorophenol.* 2,4-dichlorophenol.* 2,4-dinitrophenol.* 2,4-dinitrotoluene. 2,6-dinitrotoluene. 2-methyl-phenol.* Alachlor ESA* and Acetochlor.* DCPA mono-acid & di-acid degradates. DDE. Diazinon. Disulfoton. Diuron. EPTC. Fonofos.* Linuron. Molinate. MTBE. Nitrobenzene. Perchlorate.* Prometon. RDX.* Terbacil. Terbufos.

The groupings in Table 2 are based on current information, and some movement of contaminants between categories can be expected as more information is evaluated and analyzed. *Suitable analytical methods must be developed prior to obtaining occurrence data.

VI. Other Requirements

The CCL is a notice and not a regulatory action; therefore, the following statutes and executive orders are not applicable at this time: the Regulatory Flexibility Act, Small Business Regulatory Enforcement Fairness Act, Paperwork Reduction Act, Unfunded Mandates Reform Act; and Executive Order 12866. For any contaminants selected for rule-making, all necessary analysis will be conducted in accordance with the rule-making process.

Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks, requires that Federal Agencies identify and assess health risks and safety risks that disproportionately affect children, and ensure that its policies, programs, activities, and standards address disproportionate health and safety risks to children. The SDWA also requires the

Agency to select priorities for regulation while considering risks to sensitive subpopulations, such as infants and children.

The impact on sensitive populations will be addressed in the contaminant selection process, and will be a component of the Agency's determination of whether or not to regulate a given contaminant. In preparation for addressing the issues of sensitive subpopulations, the Agency is sponsoring several activities to determine water intake by age group, by demographic distribution, and by innate or developed sensitivity to potential drinking water contaminants. The Agency is also collaborating with the Center for Disease Control and Prevention on a study of six major cities to determine the most sensitive populations for drinking water manifested during major outbreaks of illness from incidents of water. Other

research also is underway to determine the extent of vulnerable populations including children and the immunologically impaired.

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