

ENVIRONMENTAL PROTECTION AGENCY

[FRL-5904-7]

Announcement of the Draft Drinking Water Contaminant Candidate List**AGENCY:** 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 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. Today's notice announces the draft CCL, provides background on how it was developed, and seeks comment on various aspects of developing the final CCL. The CCL will be the source of priority contaminants for drinking water research, monitoring, guidance development, and for selection of candidates for drinking water regulation. The draft CCL includes 58 chemical and 13 microbiological contaminants.

DATES: Submit comments on or before December 5, 1997.

ADDRESSES: Send written comments to the Comment Clerk, docket number W-97-11, Water Docket (MC4101), USEPA, 401 M. St., SW, Washington, DC 20460. Please submit an original and three copies of your comments and enclosures (including references). Comments must be received or postmarked by midnight December 5, 1997.

Commenters who want EPA to acknowledge receipt of their comments should enclose a self-addressed, stamped envelope. No facsimiles (faxes) will be accepted. Comments may also be submitted electronically to ow-docket@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Electronic comments must be identified

by the docket number W-97-11. Comments and data will also be accepted on disks in WordPerfect in 5.1 format or ASCII file format. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

The full record for this notice has been established under docket number W-97-11, and includes supporting documentation as well as printed, paper versions of electronic comments. The full record is available for inspection from 9 to 4 p.m. Monday through Friday, excluding legal holidays at the Water Docket, Room M2616, Headquarters, USEPA, 401 M. Street, SW, Washington, DC. For access to docket materials, please call 202/260-3027 to schedule an appointment. Additionally, a few critical pieces of the record have been made available at each Regional Office.

FOR FURTHER INFORMATION CONTACT: For general information, please contact the EPA Safe Drinking Water Hotline. The toll-free number is 800-426-4791. For specific information on the CCL 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, DC 20460, phone: 202-260-3029, fax: 202-260-3762, email: washington.evelyn@epamail.epa.gov.

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Abbreviations Used in this Notice

ACWA—Association of California Water Agencies
 ATSDR—Agency of Toxic Substances and Disease Registry
 AWWARF—American Water Works Association Research Foundation
 CASRN—Chemical Abstract Services Registry Number
 CCL—Contaminant Candidate List
 CDC—Center for Disease Control and Prevention
 CERCLA—Comprehensive Environmental Response, Comprehensive and Liability Act
 CIM—Contaminant Identification Method
 D/DBP—Disinfectants and Disinfection Byproducts
 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
 GW—Ground Water
 HA—Health Advisory
 HSDB—Hazardous Substances Data Base
 IARC—International Agency for Research on Cancer
 ICR—Information Collection Request
 IESWTR—Interim Enhanced Surface Water Treatment Rule
 IRIS—Integrated Risk Information System
 LTESWTR—Long-term Enhanced Surface Water Treatment Rule
 MCL—Maximum Contaminant Level
 MCLG—Maximum Contaminant Level Goal
 NAS—National Academy of Sciences
 NCOB—National Contaminant Occurrence Database
 NDWAC—National Drinking Water Advisory Council
 NIPDWR—National Interim Primary Drinking Water Regulations
 NPDWR—National Primary Drinking Water Regulations
 NPL—National Priority List
 NRC—National Research Council
 OGWWD—EPA's Office of Ground Water and Drinking Water

OPP—EPA's Office of Pesticide Programs
 OPPTS—EPA's Office of Pollution Prevention and Toxic Substances
 PWS—Public Water Systems
 RDA—Recommended Daily Allowance
 RfD—Reference Dose
 RQ—Reportable Quantity
 SAB—EPA's Science Advisory Board
 SDWA—Safe Drinking Water Act
 STORET—Storage and Retrieval Database
 SWTR—Surface Water Treatment Rule
 TRI—Toxic Release Inventory
 WHO—World Health Organization

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 regulations under the SDWA (section 1412(b)(1)). The SDWA, as amended, specifies that EPA must publish this 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 publish a CCL every five years thereafter. The SDWA also 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).

Prior to the 1996 Amendments, the SDWA required the EPA to publish a drinking water priority list (DWPL) of contaminants every three years which were known or anticipated to occur in drinking water and which may have required regulation under the SDWA. In response to these previous amendments, EPA published two DWPLs which served as candidates for regulation. The first DWPL was published on January 22, 1988 (53 FR 1892), and the second was published on January 14, 1991 (56 FR 1470).

The 1996 Amendments to the SDWA were developed and enacted during the time of the Presidential initiative intended to substantially improve the

existing regulatory system to move the Nation toward a new and better environmental management system for the 21st century. During the two-year period prior to the 1996 Amendments, EPA developed a National Drinking Water Program Redirection Strategy (EPA, 1996a) to (1) establish priorities for setting safety standards based on health risks and sound science; (2) support strong, flexible partnerships among EPA, States, local governments and other stakeholders to protect public health; and (3) promote effective community-based source water protection. The Redirection Strategy provides an overall framework for the development of the CCL, as well as for other drinking water program activities.

The Agency believes the draft CCL presented in today's notice is the result of a commendable effort of screening a larger set of contaminants to the subset of those of most concern. The draft CCL is a first step toward improving risk assessment, strengthening science and data, and achieving better decision-making and future priority setting. Today's notice announces the draft CCL, provides background on how it was developed, summarizes detailed material available in the docket and used to develop the list, seeks comment on the methods used to develop the draft CCL, and seeks comment on developing the final CCL. The draft 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 redirection strategy.

Today's notice is being published pursuant to the requirement in section 1412(b)(1) that the CCL be subjected to prior notice and opportunity for public comment. The contaminants included are not subject to any proposed or promulgated national primary drinking water regulation,¹ are known or anticipated to occur in public water systems, and may require regulations under the SDWA. During the development of the draft CCL, the Agency consulted with stakeholders, including the National Drinking Water Advisory Council's Working Group on Occurrence & Contaminant Selection, which includes microbiologists, toxicologists, public health scientists, and engineers, and with other members of the scientific community including the Science Advisory Board (SAB). The Agency plans for a more in-depth consultation with the SAB during the

¹ With the exception of nickel, aldicarb and its degradates, and sulfate, which are considered special cases. Refer to later sections of this notice for rationale for inclusion.

fall of 1997. The occurrence database, which is to be established under section 1445(g) by August 1999, was not considered since it is currently under development; however, occurrence data from other sources was considered.

The final CCL, after publication in February 1998, will be the source of priority contaminants for the Agency's drinking water program. Priorities for drinking water research, occurrence monitoring, guidance development, including the development of health advisories, will be drawn from the CCL. The CCL will also serve as the list of contaminants from which the Agency will make determinations of whether or not to regulate specific contaminants. This first 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.

II. Draft Drinking Water Contaminant Candidate List

The following table includes the contaminants, microbiological and chemical, presented as the draft Drinking Water Contaminant Candidate List. The contaminants were identified as described by Section III of today's notice. The contaminants in the table are identified by name and Chemical Abstracts Service Registry Number (CASRN). The draft CCL includes 58 chemical contaminants/contaminant groups and 13 microbiological contaminants.

TABLE 1.—DRAFT DRINKING WATER CONTAMINANT CANDIDATE LIST

Chemical contaminants	CASRN
1,1,2,2-tetra-chloroethane	79-34-5
1,2,4-trimethylbenzene	95-63-6
1,1-dichloro-ethane	75-34-3
1,1-dichloro-propene	563-58-6
1,2-diphenylhydrazine	122-66-7
1,3-dichloropropane	142-28-9

TABLE 1.—DRAFT DRINKING WATER CONTAMINANT CANDIDATE LIST—Continued

Chemical contaminants	CASRN
1,3-Dichloropropene (telone or 1,3-D)	542-75-6
2,4,6-trichlorophenol	88-06-2
2,2-dichloro-propane	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
2,6-di-tert-butyl-p-benzoquinone (DTBB)	719-22-2
2-methyl-Phenol (o-cresol)	95-48-7
Acetochlor	34256-82-1
Acetone	67-64-1
Alachlor ESA (a degradation product of alachlor)	
Aldicarb*	
Aldrin	309-00-2
Aluminum	7429-90-5
Atrazine-desethyl, a degradation product of triazines	6190-65-4
Boron	7440-42-8
Bromobenzene	108-86-1
Cyanazine	21725-46-2
p-Cymene (p-isopropyltoluene)	
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
Dimethoate	60-51-5
Disulfoton	298-04-4
Diuron	330-54-1
EPTC (s-ethyl-dipropylthiocarbamate)	759-94-4
Fonofos	944-22-9
Hexachloro-butadiene	87-68-3
Isopropylbenzene (cumene)	98-82-8
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
Nickel*	
Nitrobenzene	98-95-3
Organotins	
Prometon	1610-18-0
RDX	121-82-4

TABLE 1.—DRAFT DRINKING WATER CONTAMINANT CANDIDATE LIST—Continued

Chemical contaminants	CASRN
Rhodamine WT	
Sodium	7440-23-5
Sulfate*	
Terbacil	5902-51-2
Terbufos	13071-79-9
Vanadium	7440-62-2
Zinc	7440-66-6
Microbiological Contaminants:	
Acanthamoeba (guidance expected for contact lens wearers)	
Adenoviruses	
Aeromonas hydrophila	
Caliciviruses	
Coxsackieviruses	
Cyclospora cayetanensis	
Echoviruses	
Helicobacter pylori	
Hepatitis A virus	
Legionella (in ground water)	
Microsporidia (Enterocytozoon & Septata)	
Mycobacterium avium intracellulare (MAC)	
Toxoplasma gondii	

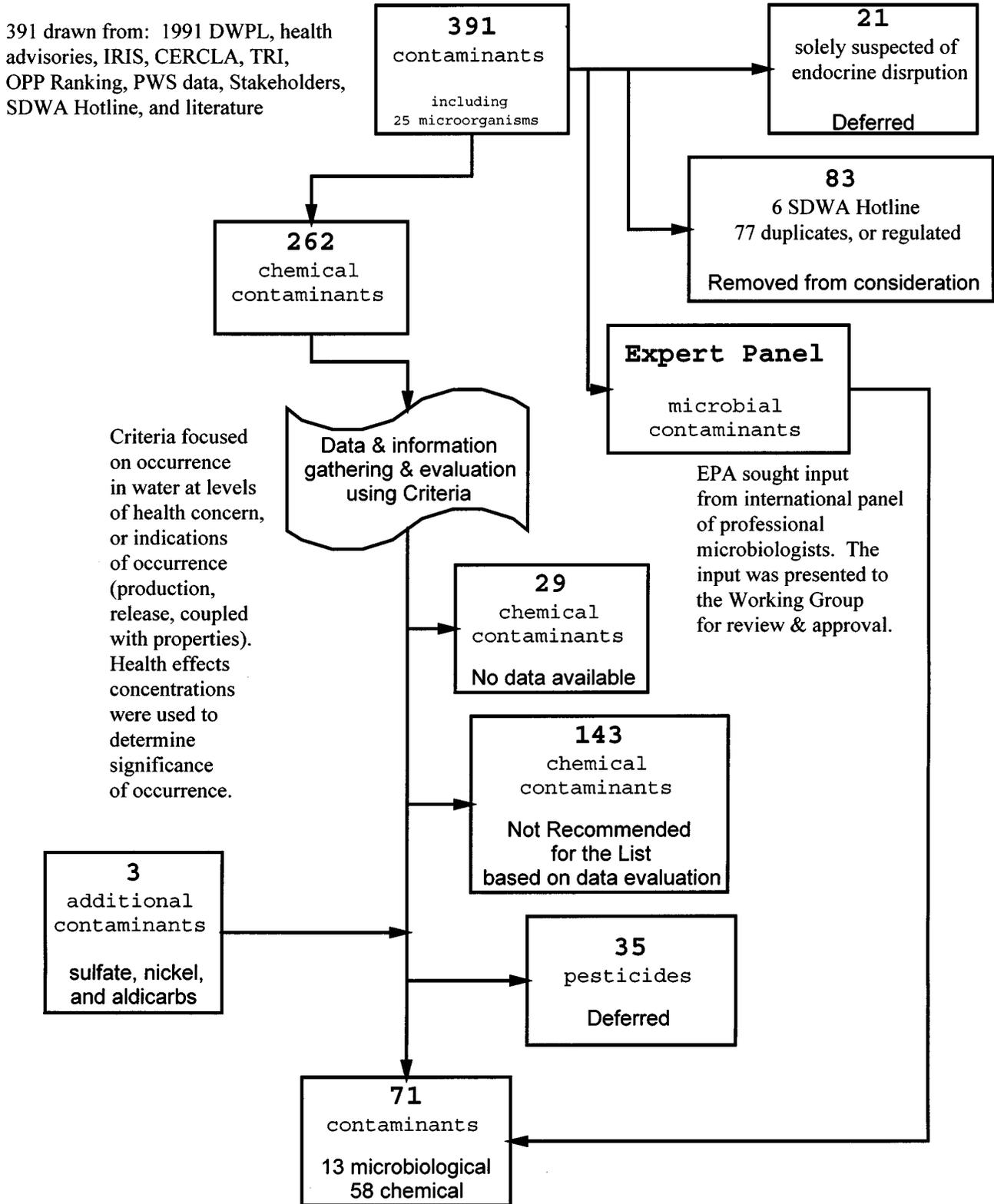
*Included on the CCL as special cases, not subject to the criteria used to identify other contaminants.

III. Identification of Contaminants for the Draft Drinking Water Contaminant Candidate List

Drinking water contamination generally occurs from: (1) Contaminants that find their way into drinking water sources from industrial waste releases, agricultural runoff, atmospheric deposition, and other pollution sources; (2) contaminants formed during the treatment of water supplies (e.g., disinfection by-products); and (3) materials used for treatment, storage, and distribution of water. EPA has considered all of these sources in identifying microbiological and chemical contaminants for this draft CCL. Figure 1 provides a graphical representation of how today's draft CCL was developed.

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Figure 1. Illustration of Decision Tool Used to Develop the Draft Contaminant Candidate List



The National Drinking Water Advisory Council's (NDWAC) Working Group on Occurrence & Contaminant Selection played an integral part in the development of the CCL by providing recommendations for the criteria, and the contaminants for initial consideration. Also, during the development of the CCL, the Agency sought the expertise of microbiologists for input on microorganisms to include on the CCL. The following sections describe the role of the NDWAC Working Group and describe the approach used to develop the CCL for microorganisms and chemical contaminants.

A. Role of NDWAC Working Group

After enactment of the recent SDWA amendments, and in keeping with the redirection strategy, EPA held its first stakeholder meeting on approaches to developing CCLs on December 2 and 3, 1996 in Washington, D.C. Participants, including public water system professionals, state regulatory officials, public health officials, environmental groups and other stakeholders, with a range of interests, explored issues concerning the identification of potential drinking water contaminants for consideration for the first CCL as well as the factors to consider for future CCL development. One result of the meeting was the recommendation that the February 1998 CCL be the first topic addressed by the NDWAC Working Group on Occurrence & Contaminant Selection.

In 1975, pursuant to the SDWA [Section 1446(a)], NDWAC was established under the Federal Advisory Committee Act to provide practical and independent advice, consultation, and recommendations to EPA on the activities, functions and policies related to the SDWA. At its meeting held on November 13 and 14, 1996, NDWAC decided that working groups should be formed on the following subjects: Small Systems Capacity Building; Operator Certification; Source Water Protection; Consumer Confidence Reports; Drinking Water State Revolving Fund; and Occurrence & Contaminant Selection. The NDWAC Occurrence & Contaminant Selection Working Group has been integral to developing the criteria and identifying contaminants for the draft CCL published today.

At the recommendation of the Working Group, the Agency sought expertise on microbiological contaminants and convened a workshop of microbiologists. The input from the workshop was adopted by the Working Group for use in developing the draft CCL. The approach used to identify

microorganisms for the CCL is explained in more detail in section III.B.

In addition to microorganisms, the Working Group developed recommendations on chemical contaminants. The recommendations addressed which contaminants to include for initial consideration, and the criteria for use in determining which contaminants should be included on the draft CCL. The recommendations were developed over a series of meetings with the Working Group followed by the endorsement by the full NDWAC. The details concerning the contaminants included for initial consideration, and development and use the identification criteria are contained in section III.C.

B. Microbiological Contaminants Identified for the Draft CCL

On May 20–21, 1997, EPA utilized a workshop on microbiology and public health to develop a list of pathogens for possible inclusion on the first CCL. Taking part in this workshop were invited experts representing academia, EPA and other federal agencies, and the water industry. In preparation, EPA scientists prepared and distributed a list of microorganisms for initial consideration by workshop members (see Table 2.). Inclusion of organisms on this initial list was based on disease outbreak data, published literature documenting the occurrence of known or suspected pathogens in water, and other information. A summary of the workshop proceedings is in the docket.

Table 2. Initial List of Microorganisms Developed by EPA for Consideration by the Workshop on Microbiology and Public Health

Protozoa

Microsporidia
Toxoplasma
Cyclospora
Acanthamoeba
Naegleria
Isospora

Viruses

Hepatitis E
Astroviruses
Coxsackie/Echo viruses
Adenovirus 40/41
Norwalk virus and other caliciviruses
Rotavirus

Bacteria

Helicobacter pylori
Mycobacterium (MAC)
E. coli O157:H7
Aeromonas hydrophila
Pseudomonas aeruginosa
Acrobacter
Campylobacter

Algal Toxins

Anaebaena flos-aquae
Aphanizomenon flos-aquae
Microcystis aeruginosa
Schizothrix calcicola

Workshop participants established a set of baseline criteria for deciding whether an organism should appear on the CCL. These criteria were (1) public health significance, (2) known waterborne transmission, (3) occurrence in source water, (4) effectiveness of current water treatment, and (5) adequacy of analytical methods. Organisms on the EPA list mentioned above, as well as other organisms that arose during the discussions, were evaluated against these criteria.

The CCL published today includes the list of pathogens identified by the workshop and subsequently adopted by the NDWAC as recommendations for the CCL. Algal toxins were considered to be of minimal public health significance, and therefore were not included on the draft CCL. The following sections identify the organisms selected, the rationale for why a pathogen was included on the CCL, and the rationale why certain pathogens were not included.

1. Protozoa

The following protozoa are included on the CCL: *Cyclospora cayetanensis*, *Toxoplasma gondii*, the two microsporidia—*Enterocytozoon* and *Septata*, and *Acanthamoeba*. It is recommended that EPA develop guidance for controlling *Acanthamoeba*, for individuals who wear contact lenses. The rationale for their selection follows.

C. cayetanensis has caused waterborne outbreaks in other countries and one documented outbreak in the U.S. Thus, it may be a significant public health risk. Disease symptoms include watery diarrhea, abdominal cramping, decreased appetite, and low-grade fever (Huang et al., 1995). In HIV-infected persons, the disease may be chronic and constant (Soave and Johnson, 1995). The occurrence of this organism in natural waters and its animal host range are unknown. However, *C. cayetanensis* is transmitted by the fecal-oral route, and so its presence in water is likely. The morphology of *C. cayetanensis* suggests that the organism is relatively resistant to disinfectants, but due to its large size (7–10µm in diameter) it may be removed satisfactorily by filtration. *Cyclospora* is included on the CCL because it has caused waterborne disease outbreaks in the U.S. and other countries.

Toxoplasma gondii causes a common infection of mammals and birds, but the complete life cycle only occurs in wild

and domestic cats. The organism infects a high percentage of the human population (50 percent in some areas of the U.S.) but, while subclinical infections are prevalent, illness is rare (Fishback, 1992). However, illness may be severe in fetuses and AIDS patients. Symptoms include fever, swelling of lymph glands in the neck, blindness and mental retardation in fetuses, and encephalitis in AIDS patients (Fishback, 1992). There have been two documented outbreaks of toxoplasmosis—in Panama and British Columbia—both linked epidemiologically to drinking water. Chlorination of unfiltered surface waters is not effective against *Toxoplasma* (Benenson et al., 1982). However, due to their large size (11x12µm), filtration may be effective in controlling this organism. *Toxoplasma* is included on the CCL because it poses a significant public health risk, can be transmitted via the waterborne route, and because a reasonable potential exists for completing the needed research in the next few years for controlling this organism.

Microsporidia are a large group of protozoan parasites that are common in the environment and multiply only inside cells (Cali, 1991). Five species of microsporidia have been reported to cause disease in humans, but only two are significant in water: *Enterocytozoon bieneusi* and *Septata intestinalis*. Both are common in people with AIDS (Goodgame, 1996) and occur chiefly in AIDS patients (Bryan, 1995), although infections have been reported in otherwise healthy persons (Weber et al., 1994). Symptoms may include diarrhea (sometimes severe and chronic), and illness involving the respiratory tract, urogenital tract, eyes, kidney, liver or muscles (Bryan, 1995; Goodgame, 1996; Cali, 1991).

Microsporidia that infect humans produce small (1–5µm), very resistant spores (Waller, 1979; Cali, 1991). They are shed in bodily fluids, including urine and feces, and thus have a strong potential to enter water sources. However, no waterborne outbreak has yet been reported and there is no published evidence of waterborne transmission. Chlorine is probably not effective against microsporidia, given that other protozoan spores (cysts, oocysts) are resistant to chlorine. Thus, effective filtration and watershed control may be needed to control this organism in drinking water. *E. bieneusi* and *S. intestinalis* are included on the CCL because they pose a significant risk to immuno-compromised individuals and may not be removed effectively by filtration because of their small size (the

spores are somewhat smaller than *Cryptosporidium* oocysts).

Acanthamoeba are a group of free-living amoeba that are common in soil and water, including drinking water (Sawyer, 1989; Gonzalez de la Cuesta et al., 1987). Some *Acanthamoeba* species are pathogenic and can cause inflammation of the eye's cornea (especially in individuals who wear soft or disposable contact lenses (Seal et al., 1992)), and chronic encephalitis in the immuno-compromised population (Kilvington, 1990). To date, no case of waterborne disease has been reported. However, *Acanthamoeba* cysts are relatively resistant to chlorine (De Jonkheere and Van der Voorde, 1976). Because drinking water is not a suspected route of transmission, workshop members did not include *Acanthamoeba* on their list. However, as stated above, the Workshop participants and the NDWAC recommend that EPA issue guidance to educate the public about the potential problem with contact lenses.

Two protozoa that were on the initial list for consideration developed by EPA (*Naegleria fowleri*, *Isospora belli*), and two that were not (*Entamoeba histolytica*, *Blastocystis hominis*) were also considered by the workshop, but were not included on the CCL. The reasons for excluding them follow.

N. fowleri is a free-living amoeba, about 8–15µm in size, found in soil, water, and decaying vegetation. Although it is common in many surface waters, it rarely causes disease. All disease incidents have been associated with swimming in natural or manmade, warm fresh waters; drinking water is not a suspected route of transmission. The route of infection is via inhalation rather than by ingestion. For this reason, it was not included on the CCL.

I. belli causes gastrointestinal illness, primarily in AIDS patients and children. There have been no documented cases of waterborne transmission. However, the organism is transmitted by the fecal-oral route, so its presence in water is possible. Filtration is probably effective in removing *I. belli* oocysts, given their large size (30x12µm). This organism was not included on the CCL because of the lack of documentation on waterborne transmission and the belief that not enough is known about the organism for developing potential regulations within a three-year time-frame.

E. histolytica is not considered to be a significant health problem in the U.S. In contrast to the situation for *Giardia* and *Cryptosporidium*, animals are not host reservoirs for *E. histolytica*. Thus, the potential for source water

contamination is relatively low, especially if sewage treatment practices are adequate. Moreover, the organism has not caused a significant waterborne disease outbreak since the early 1950s. Thirdly, the cyst is large (10–15µm), slightly larger than a *Giardia* cyst; thus, filtration should be effective for removing this organism. For these reasons, this organism was not included on the CCL.

B. hominis was not included on the CCL because its clinical significance has not been determined and very little is known about its potential for waterborne transmission or its occurrence in water.

2. Viruses

The following viruses are included on the CCL: caliciviruses, adenoviruses, coxsackieviruses, echoviruses, and the hepatitis A virus. The rationale for their inclusion follows.

The caliciviruses are a common cause of acute, but mild, gastrointestinal illness in the U.S. Between 1980 and 1994, 14 waterborne disease outbreaks with more than 9,000 associated cases caused by the Norwalk virus and other caliciviruses were reported. Thus, their public health significance is high. However, because adequate recovery and assay methods for the caliciviruses are not yet available, information about the occurrence of these viruses in water or the effectiveness of water treatment is lacking. It is believed that current research programs might fill the research gap in the near-term to allow development of regulations, if necessary, to control this group of organisms.

Most of the adenoviruses are respiratory pathogens. However, serotypes 40 and 41 are important causes of gastrointestinal illness, especially in children. However, all types may be shed in the feces, and may be spread by the fecal-oral route. Although adenoviruses have been detected in water, data on their occurrence in water are meager. No drinking water outbreaks implicating these viruses have been reported. Both the respiratory and gastrointestinal adenoviruses are recommended for the CCL because of their high public health significance and data which suggest that adenoviruses are relatively resistant to disinfectants.

The coxsackieviruses are readily found in wastewater and surface water, and sometimes in drinking water (Hurst, 1991). Although they have not caused a documented outbreak of waterborne disease, coxsackieviruses produce a variety of illnesses in humans, including the common cold, heart

disease, fever, aseptic meningitis, gastrointestinal problems, and many more, some of which can be serious (Melnick, 1992). Coxsackieviruses are included on the CCL because they are found more frequently in water than other viruses and are associated with a number of illnesses.

The echoviruses, like the coxsackieviruses, are readily detected in water, including treated drinking water. They are associated with milder illnesses than the coxsackieviruses, and have not caused a documented outbreak. Echoviruses are included on the CCL because, like the coxsackieviruses, they are found more frequently in water than other viruses and are associated with a number of illnesses.

The hepatitis A virus has caused at least 11 waterborne disease outbreaks of infectious hepatitis since 1980. Therefore, it has a high public health significance. The virus has been found in contaminated drinking water, and is somewhat resistant to chlorination (Peterson et al., 1983). For these reasons, it is also included on the CCL.

Three viruses that were on the initial list for consideration developed by EPA (rotaviruses, hepatitis E virus, and astroviruses) and two that were not (picobirna and picotrivirna) were also considered by the workshop participants, but were not included on the CCL. The reasons for not including them follow.

Rotaviruses cause acute gastroenteritis, primarily in children. Almost all children have been infected at least once by the age of five years (Parsonnet, 1992), and in developing countries, rotavirus infections are a major cause of infant mortality. Rotaviruses are spread by fecal-oral transmission and have been found in ambient water, ground water, and tap water (Gerba et al., 1985; Gerba, 1996). However, only a single waterborne disease outbreak has been reported in the U.S. and only several have been documented outside the U.S. (Gerba et al., 1985). Rotaviruses are readily inactivated by chlorine, chlorine dioxide, and ozone, but apparently not by monochloramine (Berman and Hoff, 1984; Chen and Vaughn, 1990, Vaughn et al., 1986; 1987). Rotaviruses were not included on the CCL because they are not regarded as an important public health problem in the U.S., and because of their vulnerability to disinfectants.

Hepatitis E virus is an important agent of hepatitis in underdeveloped countries, but apparently not in the U.S. The virus is transmitted by the fecal-oral route (Dreesman and Reyes, 1992) and probably a majority of cases are

waterborne. Even though the disease is apparently not a health concern in the U.S., one investigation found that 21.3% of blood donors in Baltimore were seropositive (Thomas et al., 1997), suggesting previous exposure to the organism. Infections are mild and self-limiting except for pregnant women, who have a fatality rate of up to 39%. No data from disinfection studies have been published. Hepatitis E virus was not included on the CCL because it is not regarded as a significant public health threat in the U.S., and because current sewage treatment practices are judged sufficient to eliminate risk of waterborne transmission.

Astroviruses are found throughout the world and cause illness in 1–3 year old children and in AIDS patients, but rarely in healthy adults (Kurtz and Lee, 1987; Grohmann et al., 1993). Symptoms are mild and typical of gastrointestinal illness, but the disease is more severe and persistent in the severely immuno-compromised. Astroviruses are transmitted by the fecal-oral route and have been detected in water and have been associated anecdotally with waterborne disease outbreaks (Cubitt, 1991; Pinto et al., 1996). The astroviruses were not included on the CCL because of the mildness of the illness and the lack of adequate documentation about the occurrence in water and potential as a waterborne disease agent.

The picobirna and picotrivirna viruses are of public health significance outside the U.S., and are not regarded as being a waterborne problem in the U.S. and are adequately removed from effluent water by current sewage treatment practices. Picobirna and picotrivirna viruses were not included on the CCL for these reasons.

3. Bacteria

The following bacteria are included on the CCL: *Helicobacter pylori*, *Legionella*, *Mycobacterium avium* complex, and *Aeromonas hydrophila*. The rationale for their identification follows.

H. pylori has been closely associated with peptic ulcers, gastric carcinoma, and gastritis (Peterson, 1991; Nomura et al., 1991; Parsonnet et al., 1991, Cover and Blaser, 1995). Data about its distribution in the environment are scarce, but the organism has been found in sewage (Sutton et al., 1995) and has been linked to ambient water and drinking water by epidemiological tests and other means (Klein et al., 1991; Shahamat et al., 1992; Shahamat et al., 1993; Hulten et al., 1996). The number of people in the U.S. that have antibodies against *H. pylori*, and thus

have been exposed to the organism, is high. *Helicobacter* is thought to be vulnerable to disinfectants. *H. pylori* is included on the CCL because of its public health significance in the U.S. and the possibility of waterborne transmission.

Legionella pneumophila and other *Legionella* species cause Legionnaires Disease (a type of pneumonia) and Pontiac Fever (a mild, nonpneumonic illness). Legionnaires Disease, which has a 15% mortality rate, typically results from the inhalation of aerosols of water containing the organism. *Legionella* are abundant and naturally occurring in surface water; thus they are not necessarily associated with fecal contamination. They have also been detected in ground water. Small numbers can occur in the finished waters of systems employing full treatment (U.S. EPA, 1989b) and can colonize plumbing systems, especially warm ones. Aerosols from fixtures, such as showerheads, may cause the disease via inhalation. Aerosols from cooling towers, hot tubs, and pools have also caused a number of outbreaks. Direct person-to-person spread has not been documented (Yu et al., 1983). Ozone, chlorine dioxide, and ultraviolet light are effective in controlling *Legionella*, but data for chlorine are inconsistent (States et al., 1990). *Legionella* in surface water are already regulated under EPA's Surface Water Treatment Regulations (40 CFR part 141, subpart H). *Legionella* in ground water is included on the CCL because of their public health significance in the U.S. and the possibility of waterborne transmission via ground water.

Mycobacterium avium complex (MAC; also known as the *Mycobacterium avium intracellulare* complex) is common in the environment and can colonize water systems and plumbing systems (du Moulin and Stottmeier, 1986; du Moulin et al., 1988). It is known to cause pulmonary disease and other diseases, especially in individuals with a weakened immune system (e.g., AIDS patients). Drinking water has been epidemiologically linked to infections in hospital patients (du Moulin and Stottmeier, 1986). MAC is relatively resistant to chlorine disinfection (Pelletier et al., 1988). MAC is included on the CCL because of its high public health significance, its ability to colonize on pipes, and its relative resistance to chlorine.

Aeromonas hydrophila can cause wound infections and septicemia in people with a weakened immune system, and some evidence suggests that it causes gastrointestinal disease in

healthy people. The organism is common in water and is not necessarily associated with fecal contamination. It is vulnerable to disinfectants. *A. hydrophila* is included on the CCL primarily because it is common in source water.

Pseudomonas aeruginosa is a free-living bacterium that is common in water. People at risk include patients with profound neutropenia, cystic fibrosis, severe burns, and those with foreign devices installed (Hardalo and Edberg, 1997). The organism has also caused numerous outbreaks of dermatitis in recreational waters, e.g., pools, whirlpools, and hot tubs (Kramer et al., 1996). Because of differing opinions among the microbiologists who participated in the workshop about its public health significance and its potential health risk via the waterborne route, a decision could not reach on whether to include *P. aeruginosa* on their list. Rather, it was recommended that EPA conduct a complete literature search on the topic before the Agency decides whether to include this organism on the final list. The literature search will be conducted prior to publishing the final CCL.

Four bacteria that were on the initial list for consideration developed by EPA (*Escherichia coli* O157:H7, *Campylobacter*, *Arcobacter*, and the cyanobacteria) and four that were not (*Salmonella*, *Shigella*, *Vibrio cholerae* and other *Vibrio* species, and *Yersinia enterocolitica*) were also considered by the workshop, but were not included on the CCL. The reasons for excluding them follow.

E. coli O157:H7, *Campylobacter*, *Salmonella*, *Shigella*, *V. cholerae*, and *Y. enterocolitica* have all caused waterborne disease in the U.S. and are regarded as significant health risks. They were not included on the CCL because current treatment practices were deemed to be adequate in controlling these organisms. *Arcobacter* was not included on the CCL because its health significance and the possibility of waterborne transmission are unknown, and because current treatment practices were judged likely in controlling this organism.

Cyanobacteria (also known as blue-green algae) are generally not considered an important health risk. However, certain species may produce neurotoxins (which affects the nervous system), hepatotoxins (which affects the

liver), and other types of toxins which, if ingested at high enough concentrations, may be harmful. High concentrations of toxins associated with a bloom of *Schizothrix calcicola* may have been responsible for an outbreak of gastroenteritis in 1975 (Lippy and Erb, 1976). However, little evidence exists that ambient levels found in most water supplies pose a health risk to the normal population. The cyanobacteria was not included on the CCL because the problem is thought to be best handled through good watershed management practices to prevent algal growth in source waters.

4. Microbiological Indicators

Indicators of fecal contamination or of pathogens were not addressed at the workshop. EPA is involved, however, in a project with the International Life Sciences Institute to begin an evaluation of which microbiological indicators are most appropriate for various types of environmental waters. Currently, the Agency uses total coliform bacteria as the sole indicator of microbiological drinking water quality.

5. Future Activities Planned for Microbiological Contaminants and the CCL

EPA is attempting to develop a more formal framework for identifying, selecting and prioritizing pathogens (and their indicators) for research and possible regulation, and for future CCLs. To date, the identification of pathogens for the CCL has been relatively informal. In contrast, a more objective approach for contaminant identification and selection in the future may be based on a numerical scoring procedure such that contaminants with higher scores would have greater priority for regulation, research and guidance development than those that have lower scores.

6. Possible Impacts From Other Regulatory Activity

Pathogens that are included on the final CCL, will be candidates for regulatory control, guidance development, and additional research over the next five years. These organisms may be controlled, however, by regulations currently under development such as the Enhanced Surface Water Treatment Rule, the Ground Water Disinfection Rule. If pathogens on the CCL are determined to be controlled by these regulations, they will be withdrawn from the CCL.

C. Chemical Contaminants Identified for the Draft CCL

As stated earlier, the NDWAC Working Group on Occurrence & Contaminant Selection played an integral part in developing the draft CCL presented in today's notice. At the initial Working Group meeting held on April 3-4, 1997, the Agency proposed a number of lists of contaminants as a logical starting point for developing the draft CCL. Some lists originate from other Agency programs, while others were developed in anticipation of future DWPLs. The Agency also proposed that the initial list would need to be reduced to a smaller list of priority contaminants that would become the CCL.

In April, the Working Group identified 32 contaminants thought to be those most important for inclusion on the first CCL, other contaminants for initial consideration, and criteria to be used to evaluate and screen all contaminants initially considered. During this April meeting, and two subsequent meetings, held on June 23 and July 17, 1997, the Working Group developed these recommendations which were approved by the full NDWAC, and subsequently adopted by the Agency, to use in screening the initial list to the contaminants to today's draft CCL. Summaries of the meetings are provided in the docket. The following sections provide the rationale for the initial list of contaminants considered and a summary of the development and application of the criteria used to evaluate the contaminants on the initial list to develop the draft CCL.

1. The Initial List of Chemical Contaminants Considered

Ten lists of chemical contaminants were considered to be logical starting points for developing the first CCL. Of the ten, eight lists were ultimately combined to serve as the initial list of contaminants to be considered for the CCL. Some contaminants appear on more than one of the eight lists. The initial list of contaminants considered, as well as those eliminated or deferred from consideration, are in Table 3. The following sections provide a description of each of the lists and the rationale behind including it with, or excluding it from, the initial list of contaminants considered.

TABLE 3.—INITIAL LIST OF CHEMICAL CONTAMINANTS CONSIDERED DURING DEVELOPMENT OF THE DRAFT CCL

Contaminant	CAS No.	Contaminant lists considered							
		1991 DWPL (1)	Health advisories (2)	IRIS (3)	PWS (4)	CERCLA (5)	Stakeholder summary list (6)	TRI list (7)	OPP ranking (8)
Contaminants Identified as Initial Candidates for the CCL during April 3–4, 1997 Working Group Meeting									
Inorganics:									
Aluminum	7429–90–5	✓	✓				✓	✓	
Zinc	7440–66–6	✓	✓					✓	
Pesticides:									
Acetochlor	34256–82–1		✓				✓		✓
Alachlor ESA			✓				✓		✓
Butylate	2008–41–5		✓	✓					✓
Chlorpyrifos	2921–88–2		✓	✓			✓		
DCPA (Dacthal)	1861–32–1	✓	✓				✓		
DCPA di-acid degradate	2136–79–0	✓							✓
DCPA mono-acid degradate	887–54–7	✓							
DDE	72–55–9			✓		✓			
Diazinon	333–41–5		✓						✓
Diuron	330–54–1		✓				✓		✓
Endosulfan	115–29–7			✓			✓		✓
EPTC (s-ethyl-dipropylthio-carbamate)	759–94–4			✓					✓
Malathion	121–75–5		✓	✓					
Methyl parathion	298–00–0		✓	✓					
Metolachlor	51218–45–2	✓	✓	✓			✓		✓
Metribuzin	21087–64–9	✓	✓	✓			✓		✓
Prometon	1610–18–0	✓	✓	✓					✓
Propanil	709–98–8			✓					
Tebuthiuron	34014–18–1		✓						✓
Terbacil	5902–51–2		✓						✓
Triazines (total) (9)							✓		
Triazine degradation products (9), atrazine-desethyl	6190–65–4						✓		✓
Triazines (unregulated) (9)							✓		
Trifluralin	1582–09–8	✓	✓	✓					✓
Organics:									
2-methyl-Phenol (o-cresol)	95–48–7			✓					
Acetone	67–64–1			✓					
Ethylene glycol	107–21–1		✓	✓				✓	
Methyl ethyl ketone (MEK)	78–93–3	✓	✓				✓	✓	
Methyl-t-butyl ether (MTBE)	1634–04–4	✓	✓				✓	✓	
Nitrobenzene	98–95–3	✓		✓					
Phenol	108–95–2		✓	✓				✓	
Additional Contaminants Considered for the CCL									
Inorganics:									
Ammonia	7664–41–7		✓				✓	✓	
Ammonium nitrate	6484–52–2		✓					✓	
Ammonium sulfamate	7773–06–0		✓					✓	
Ammonium sulfate	7783–20–2		✓					✓	
Boron	7440–42–8	✓	✓						
Carbon disulfide	75–15–0							✓	
Carbonyl sulfide	463–58–1							✓	
Cobalt	7440–48–4							✓	
Hydrochloric acid	7647–01–0							✓	
Hydrogen fluoride	7664–39–3							✓	
Manganese	7439–96–5	✓				✓	✓	✓	
Metam-sodium	137–42–8			✓					
Molybdenum	7439–98–7	✓	✓						
Phosphoric acid	7664–38–2							✓	
Phosphorous	7723–14–0		✓			✓		✓	
Sodium	7440–23–5		✓						
Strontium	7440–24–6		✓						
Vanadium	7440–62–2	✓	✓						
Pesticides:									
1,3-Dichloropropene (telone or 1,3-D)	542–75–6	✓	✓	✓			✓		✓
2,4,5-T	93–76–5	✓	✓						
2,4-DB	94–82–6								✓
2,4-DP	120–36–5						✓		

TABLE 3.—INITIAL LIST OF CHEMICAL CONTAMINANTS CONSIDERED DURING DEVELOPMENT OF THE DRAFT CCL—
Continued

Contaminant	CAS No.	Contaminant lists considered							
		1991 DWPL (1)	Health advisories (2)	IRIS (3)	PWS (4)	CERCLA (5)	Stakeholder summary list (6)	TRI list (7)	OPP ranking (8)
4-Nitrophenol (p-Nitrophenol) ..	100-02-7	✓	✓						
Acephate	30560-19-1		✓				✓		
Acifluofen	50594-66-6	✓	✓				✓		✓
Aldrin	309-00-2		✓			✓			
Ametryn	834-12-8		✓				✓		✓
Amitraz	33089-61-1						✓		
Asulam	3337-71-1	✓							✓
Bensulfuron methyl									✓
Bentazon	25057-89-0	✓	✓						✓
Benzidine	92-87-5					✓			
Bromacil	314-40-9	✓	✓				✓		✓
Bromoxynil	1689-84-5			✓					✓
Cadre									✓
Caprolactum	105-60-2			✓					
Captan	133-06-2			✓					
Carbaryl	63-25-2		✓	✓					
Carboxin	5234-68-4		✓						
Chloramben	133-90-4		✓				✓		
Chlorimuron ethyl	90982-32-4								✓
Chlorothalonil	1897-45-6		✓	✓					
Chlorsulfuron	64902-72-3								✓
Clopyralid	1702-17-6						✓		
Cyanazine	21725-46-2	✓	✓	✓			✓		✓
Cyromazine	66215-27-8	✓					✓		
DDD	72-54-8					✓			
DDT	50-29-3			✓		✓			
Diazinon—oxyprymidine									✓
Dicamba	1918-00-9	✓	✓				✓		✓
Dichlobenil	1194-65-6		✓				✓		
Dieldrin	60-57-1		✓			✓	✓		
Dimethoate	60-51-5			✓			✓		
Dimethrin	70-38-2		✓				✓		
Diphenamid	957-51-7		✓						
Disulfoton	298-04-4		✓				✓		
Endosulfan sulfate	1031-07-8					✓			
Ethalfuralin	55283-68-6								✓
Ethofumesate	26225-79-6						✓		
Ethoprop	13194-48-4						✓		
Ethylenethiourea (ETU)	96-45-7	✓	✓				✓		✓
Fenamiphos	22224-92-6		✓				✓		✓
Fluazifop-p-butyl									✓
Fluometuron	2164-17-2		✓						✓
Fomesafen	72178-02-0	✓							
Fonofos	944-22-9		✓	✓			✓		
Halofenozide									✓
Halosulfuron									✓
Hexazinone	51235-04-2						✓		✓
Imazamethabenz	81405-85-8								✓
Imazapyr									✓
Imazaquin	81335-37-7								✓
Imazethapyr	81335-77-5								✓
Imidacloprid							✓		
Lactofen	77501-63-4	✓							
Linuron	330-55-2			✓					
Maneb (ETU precursor)	12427-38-2			✓					
MCPA	94-74-6		✓				✓		
MCPP	93-65-2						✓		
Metalaxyl	57837-19-1	✓							
Methazole	20354-26-1								✓
Methomyl	16752-77-5	✓		✓			✓		
Metsulfuron methyl	74223-64-6						✓		✓
Molinate	2212-67-1			✓					
MSMA	2163-80-6								✓
Napropamide	15299-99-7						✓		
Nicosulfuron									✓
Norflurazon	27314-13-2						✓		✓

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Continued

Contaminant	CAS No.	Contaminant lists considered							
		1991 DWPL (1)	Health advisories (2)	IRIS (3)	PWS (4)	CERCLA (5)	Stake- holder summary list (6)	TRI list (7)	OPP rank- ing (8)
Paraquat	4685-14-7		✓	✓					✓
Pendimethalin	40487-42-1			✓					✓
Primisulfuron methyl									✓
Prometryn	7287-19-6								✓
Pronamide	23950-58-5		✓						
Propachlor	1918-16-7		✓				✓		✓
Propargite	2312-35-8			✓					
Propazine	139-40-2		✓	✓					✓
Propham	122-42-9		✓						
Propiconazole	60207-90-1						✓		
Propoxur (Baygon)	114-26-1		✓						
Prosulfuron									✓
Pyrazon	1698-60-8						✓		
Pyriithiobac-Na									✓
Rimsulfuron									✓
Sethoxydim	74051-80-2								✓
Sulfentrazone									✓
Sulfometuron methyl	74222-97-2								✓
Tebufenozide									✓
Terbufos	13071-79-9		✓	✓			✓		
Terbufos sulfone									✓
Thiazopyr									✓
Thifensulfuron methyl	79277-27-3								✓
Thiodicarb	59669-26-0	✓							
Triallate	2303-17-5			✓					
Triasulfuron	82097-50-5						✓		✓
Triberuron methyl									✓
Vernolate	1929-77-7								✓
Organics:									
1,1,1,2-tetra-chloroethane	630-20-6	✓	✓						
1,1,1-trichloropropane			✓						
1,1,2,2-tetra-chloroethane	79-34-5	✓	✓						
1,1-dichloro-ethane	75-34-3	✓							
1,1-dichloro-propene	563-58-6	✓	✓						
1,2,3-trichloro-propane	96-18-4	✓	✓						
1,2,4-trimethylbenzene	95-63-6							✓	
1,2-diphenyl-hydrazine	122-66-7	✓							
1,3,5-trichlorobenzene	108-70-3		✓						
1,3-butadiene	106-99-0							✓	
1,3-dichloro-benzene	541-73-1	✓							
1,3-dichloropropane	142-28-9	✓	✓						
1,3-dichloropetan-3-OL					✓				
1,3-dinitrobenzene	99-65-0		✓						
1,4-dioxane	123-91-1		✓	✓			✓	✓	
1,4-dithiane	505-29-3		✓						
1-methyl -2-Pyrrolidinone	872-50-4				✓				
2,2-dichloro-propane	594-20-7	✓	✓						
2,4,6-trichlorophenol	88-06-2		✓						
2,4-dichlorophenol	120-83-2		✓						
2,4-dinitrophenol	51-28-5	✓							
2,4-dinitrotoluene	121-14-2	✓	✓						
2,6-dinitrotoluene	606-20-2	✓	✓						
2,6-di-tert-butyl-p- benzoquinone (DTBB), (2,6- bis(1,1-dimethylethyl)2,5- cyclohexadiene-1,4-dione) ...	719-22-2				✓				
2-methanoxy ethanol	109-86-4							✓	
3-chloro-1-propene	107-05-1				✓				
4,4'-isopropylidenediphenol (bisphenol A)	80-05-7							✓	
4-methyl-Phenol (p-cresol)	106-44-5				✓				
Acetaldehyde	75-07-0							✓	
Acetamide	60-35-5				✓				
Acetonitrile	75-05-8							✓	
Acrylic acid	79-10-7							✓	
Acrylonitrile	107-13-1	✓	✓					✓	

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Continued

Contaminant	CAS No.	Contaminant lists considered							
		1991 DWPL (1)	Health advisories (2)	IRIS (3)	PWS (4)	CERCLA (5)	Stakeholder summary list (6)	TRI list (7)	OPP ranking (8)
Other fuel oxygenates (TAME, DIPE, ETBE)	na						✓		
n-Butanol	71-36-3			✓				✓	
n-Hexane	110-54-3		✓						
Naphthalene	91-20-3	✓	✓				✓	✓	
nitro-Cyclopentane				✓				
Nitrocellulose	9004-70-0		✓						
Nitroglycerine	55-63-0							✓	
Nitroguanidine		✓						
o-Chlorotoluene	95-49-8	✓	✓						
Octatriene, 3,7-dimethyl-1,3,6-Organotins (tributyl, methyl tin, etc.)	13877-91-3				✓				
P-Chlorotoluene	106-43-4	✓	✓				✓		
Pentachloroethane	76-01-7		✓						
Propylbenzene n-	103-65-1		✓						
Propylene glycol	57-55-6						✓		
Propylene oxide	75-56-9							✓	
Rhodamine WT						✓		
RDX (cyclo trimethylene trinitramine)	121-82-4		✓						
Terbutylazine	5915-41-3				✓				
Tetrahydrofuran	109-99-9	✓					✓		
Tetranitromethane (TNM)	509-14-8		✓						
Trichlorofluoromethane	75-69-4		✓						
Triethylbenzene	25340-18-5		✓						
Trinitrotoluene (TNT)	118-96-7		✓						
Vinyl acetate	108-05-4							✓	

1. 1991 Drinking Water Priority List, but does not include disinfection by-products or cryptosporidium for which regulations are being under the M/DBP rules.
2. Health Advisories developed under EPA's Health Advisory Program. Does not include contaminants regulated under the SDWA.
3. Contaminants from IRIS based on a risk-based screen developed by EPA.
4. Contaminants identified in public water systems samples as non-targets.
5. First 50 contaminants of the 1995 ATSDR Ranked CERCLA priority chemicals list.
6. Stakeholder Summary List consists of specific contaminants proposed as candidates by participants of EPA's December 2-3, 1997 Stakeholder Meeting on the Contaminant Identification Method.
7. The TRI List was derived from chemicals with significant health effects as found in IRIS.
8. The OPP Ranking is a ranking of pesticides from highest to lowest potential to leach to ground water.
9. Stakeholders requested that the Agency address tirazines as a class of contaminants including their degradates, as opposed to addressing them as individual contaminants.

a. 1991 Drinking Water Priority List. The SDWA, as amended in 1986, required EPA to publish a triennial list of priority contaminants, the DWPL, which may require regulation. The first list containing 53 contaminants/contaminant group was published on January 2, 1988 (53 FR 1892). Since none of the contaminants had been selected for regulation, EPA revised and updated the 1988 list three years later. The revised and updated list, published on January 14, 1991 (56 FR 1470), contained 50 substances carried over from the 1988 list and 27 new substances, bringing the total number of contaminants/contaminant groups to 77, including one microorganism.

In consideration of the statutory requirements and the time frame for rulemaking in the SDWA at the time, EPA used the following criteria to select

contaminants for the DWPL: (1) occurrence or the potential occurrence of the substance in public water systems; (2) documented or suspected adverse health effects; and (3) the availability of sufficient information on the substance so that a regulation could be developed within the statutory time frame. The contaminants were selected from the following groups: disinfectants and their byproducts, the first group of 100 contaminants on the 1987 CERCLA priority list of hazardous substances (52 FR 12866), design analytes of the EPA National Pesticide Survey conducted between 1987-1990, pesticides with high potential for leaching in groundwater, substances recommended by the States and EPA regions, unregulated contaminants monitored under Section 1445 of the SDWA, and certain substances reported frequently

and at high concentrations in drinking water. The selection of contaminants was made with the assistance of the DWPL workgroup which consisted of representatives from various programs within the Agency, the National Toxicology Program, the U.S. Geological Survey, and the Agency for Toxic Substances and Disease Registry.

For development of the draft CCL, the Agency selected contaminants from the 1991 DWPL that were not specifically addressed by other regulations under development. Thus, all contaminants specifically addressed by the disinfectants and disinfection byproducts regulation were eliminated from consideration.

b. Health advisories. The Health Advisories (HAs) are prepared for contaminants that have the potential to cause adverse human health effects and

which are known or anticipated to occur in drinking water, but for which no national regulations currently exist. Each HA contains information on the nature of the adverse health effects of the contaminant and the concentrations that would not be anticipated to cause an adverse effect following various periods of exposure. HAs also summarize available data on occurrence, pharmacokinetics, environmental fate, health effects, available analytical methods, and treatment techniques for the contaminant. HA concentration levels include a margin of safety to protect sensitive members of the population (e.g., children, the elderly, pregnant women).

The Office of Water Health Advisory Program was initiated to provide information and guidance to individuals and agencies concerned with potential risk from drinking water contaminants. HAs are used only for guidance and are not legally enforceable, and are subject to change as new information becomes available. For purposes of developing the draft CCL, all contaminants with HAs, or HAs under development, were considered.

c. Integrated Risk Information System. The Integrated Risk Information System (IRIS) is an EPA on-line database containing health risk and EPA regulatory information. IRIS lists chemicals of interest or concern for which the Agency has reached consensus regarding adverse health effects. When available, a reference dose (RfD) for non-cancer health effect resulting from oral exposure is reported with information about how the RfD was derived and any uncertainty regarding the source studies. An RfD is an estimate of a daily exposure to the human population that is likely to be without appreciable risk of adverse effect over a lifetime of exposure. For carcinogens, a carcinogenic assessment, or cancer potency factor, is reported for both oral and inhalation exposure. The cancer potency factor is the estimated risk to the human population of cancer effects over a lifetime of exposure.

In 1992, in anticipation of the next DWPL, the Agency developed a list of chemicals based on a risk-based screen of chemicals in IRIS. There were approximately 600 chemicals in the IRIS database in 1992, and 312 were selected for further screening. The 312 were chosen because they had defined toxicity via the oral route of exposure and did not have NPDWRs. The 312 chemicals were screened using the following categories: (1) using Storage and Retrieval (STORET) data, chemicals were identified with concentration in

water that exceeded the drinking water equivalent level (DWEL) which was derived from the reference dose or cancer potency; (2) chemicals were identified that were produced in quantities exceeding one billion pounds per year; (3) pesticides were identified with use exceeding 1000 tons per year; and (4) chemicals were identified that were reported in the Toxic Release Inventory (TRI) database as discharged to surface water in excess of 100 tons per year. Sixteen chemicals met the STORET criteria; nine, the production criteria; 31, the pesticides criteria; and 6, the TRI criteria. A total of 48 individual chemicals were identified, and some were identified by more than one screen. All 48 contaminants were included on the initial list for consideration.

d. Non-Target Analytes in Public Water Supply Samples. In anticipation of the 1994 DWPL, the Agency consulted with analytical laboratories that routinely analyze samples for public water systems to determine what contaminants were occurring that were not currently regulated. A list of contaminants tentatively identified in 1991 from drinking water samples collected for compliance monitoring was developed. These contaminants, also referred to as non-targets analytes, are compounds identified by the spikes found on the chromatograph. The concentrations for these compounds were not measured. These non-target analytes represent the monitoring experience of several water systems with operations in various states. The contaminants included on the initial list for consideration are a subset of 23 contaminants chosen from the larger list of non-targets analytes. The 23 contaminants were chosen because they were considered to be related to possible anthropogenic sources.

e. CERCLA Priority List. In developing the CCL, the SDWA requires EPA to consider substances referred to in section 101(14) of the CERCLA. CERCLA requires the Agency for Toxic Substances and Disease Registry (ATSDR) to prepare a list in the order of priority of hazardous substances which are most commonly found at facilities on the CERCLA National Priority List (NPL).

In 1995, ATSDR developed a list of 275 hazardous substances ranked by the order of priority. (ATSDR, 1996) To develop this list, ATSDR considered 750 of 2800 substances present at NPL sites and ranked them based on the following three criteria, which were combined to result in a total score. These criteria were: (1) Frequency of occurrence at NPL sites, (2) toxicity, and (3) potential

for human exposure. The number of NPL sites at which a substance was identified in any medium was used to indicate the frequency of occurrence. EPA's Reportable Quantity (RQ) was used to assess the toxicity of candidate substance. If a RQ was not available, the RQ methodology was applied to candidate substances to establish a Toxicity/Environmental Score. The human exposure component was based on two parts: the concentration of the substance in the environmental media and the exposure status of population. EPA included the top 50 substances from the 1995 CERCLA prioritized list of 275 substances for consideration for the draft CCL.

f. Stakeholder responses. In December 1996, the EPA convened its first stakeholder meeting on the contaminant identification process. At that meeting, EPA requested input on what contaminants to include on its first CCL. At the December meeting, and following, participants have provided input to the Agency on contaminants for inclusion on, or exclusion from, the CCL. Some stakeholders provided information on health effects or occurrence, or both, while others listed contaminants. All contaminants suggested by stakeholders were included for initial consideration except those which already had NPDWRs, or which were included under other regulatory activity mentioned in section VIII of this notice.

g. Toxic Release Inventory. Another source of available information which could serve as a predictor of anticipated occurrence in drinking water, is the TRI. This data base, established under the Emergency Planning and Community Right-to-Know Act of 1986, contains information from manufacturing facilities in the United States regarding transfers and releases of toxic and hazardous materials to air, ground and water. The most recent report analyzed data gathered for calendar year 1994 from 22 chemical categories and included 343 separate chemicals from 23,000 facilities which met certain thresholds requiring submission of data. (U.S. EPA, 1997c).

In order to assess the potential for a chemical to be a contaminant in public water systems, EPA conducted an analysis of the release and emissions data. Each of the four categories of emissions or discharges were assigned a threshold value above which the contaminant was deemed to fit within the criteria of the SDWA, as a contaminant anticipated to occur in public water systems. The threshold did not attempt to attribute differences in reactivity, solubility, mobility or

toxicity of the pollutants at this stage of the contaminant evaluation process, but involved simply determining a gross anticipation factor. If a contaminant was released via an on-site discharge to the environment, EPA judged that it was reasonable to anticipate it as a contaminant in public water systems to varying degrees, depending upon the media receiving the discharge.

The overall analysis of the above TRI criteria resulted in 58 chemicals from the various discharges meeting the criteria. Where a release was close to the threshold, it was included in the tally. Several chemicals met the criteria but were excluded because there is an existing standard (e.g., hydrofluoric acid—fluoride is regulated) or a standard under consideration (sulfuric acid—there is regulatory activity currently underway regarding sulfate). Other contaminants such as ammonia, hydrochloric acid, or methanol were not believed to represent a significant threat to drinking water due to limited persistence, leaving 51 contaminants. Of the 51 contaminants, 49 met the criteria for air release, 21 from stack emissions, 38 for fugitive emissions, 11 via underground injection, 13 from land release, and 30 for surface water releases. All 51 were included for initial consideration in Table 3.

h. Pesticides identified by Office of Pesticide Programs. In developing the CCL, the SDWA requires EPA to consider substances referred to in the FIFRA. During the development of the draft CCL, the Agency's Office of Ground Water and Drinking Water sought assistance from the Office of Pesticide Programs (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. (U.S. EPA, 1997b) The list of pesticides, based on physical-chemical properties, occurrence and extent of use, was ranked using the Ground Water (GW) Risk score, a calculated potential to leach to ground water. Pesticides with a GW Risk of 2.0 or greater were included for initial consideration in developing the CCL (see Table 3).

However, later during the data evaluation and screening phase of the draft CCL development, the decision was made to defer some of the pesticides identified by the OPP GW Risk of 2.0 or greater. The pesticides in Table 4 include those where the GW Risk value of 2.0 or greater was the only factor for inclusion on the CCL. The decision was made, that for these cases, inclusion on the CCL would be deferred pending further evaluation of the

potential of these pesticides to occur at levels of health concern. Many new pesticides for which no other data exists are included in Table 4.

Table 4. Pesticides Deferred

Asulam
bensulfuron methyl
bentazon
bromacil
Cadre
chlorimuron ethyl
chlorsulfuron
Diazinon—oxypyrimidine
Dicamba
Ethylenethiourea (ETU)
Fenamiphos
Fluometuron
Halofenozide
Halosulfuron
Hexazinone
Imazamethabenz
Imazapyr
Imazaquin
Imazethapyr
MCPA (Methoxone)
Methsulfuron methyl
Nicosulfuron
Norflurazon
Primisulfuron methyl
Prometryn
Propazine
Prosulfuron
Pyriithiobac-Na
Rimsulfuron
Sulfentrazone
Sulfometuron methyl
Tebufenozide
Terbufos sulfone
Thiazopyr
Triasulfuron

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 then compare the estimated concentrations with health advisory levels or calculated health levels based on reference doses or cancer potency. The model is expected to be completed and available for use at the end of 1997, and at that time the Agency will reevaluate the inclusion for the additional pesticides on Table 4 on the CCL.

On August 4, 1997, EPA announced its schedule for reassessing tolerances for pesticide residues on raw and processed foods (62 FR 42020). Publication of this schedule was pursuant to the requirements, as established by the Food Quality Protection Act of 1996 (FQPA). Under this new law, EPA is required to reassess all existing tolerances and exemptions from tolerances for both active and inert ingredients. EPA is directed to give priority review to pesticides that appear to present risk

concerns based on current data. Many of the pesticides included in today's notice are included among the first group of reassessments.

In reassessing tolerances, EPA must consider the aggregate exposure to the pesticide, including drinking water; cumulative effects from other pesticides with a common mode of toxicity; whether there is an increased susceptibility from exposure to the pesticide to infants and children; and whether the pesticide produces an effect in humans similar to an effect produced by a naturally occurring estrogen or other endocrine effects.

i. Safe Drinking Water Hotline. The Hotline provides information about EPA's drinking water regulations and other related drinking water and ground water topics to the public, the regulated community, and State and local officials. The Hotline assists callers with questions on the regulations and programs developed in response to the Safe Drinking Water Act, and inquiries about the levels and health effects of specific contaminants found in or suspected to be in drinking water from public water systems and private wells, and handles requests for drinking water publications (fact sheets, pamphlets, health advisories, etc.). The Safe Drinking Water Hotline receives hundreds of calls each week, and a large percentage of the calls come from private citizens, consultants, educators, researchers, and health care professionals from across the country. The Hotline provided a list of contaminants that were not currently regulated or proposed for regulation for which callers had expressed concern or interest (see Table 5).

Table 5. Contaminants Identified by the Safe Drinking Water Hotline

Calcium
Phosphates
1,1,1-dichloroethane
Gasoline
Perchlorate
Total Petroleum Hydrocarbons

The Hotline did not ascertain if the calls were due to a general question or inquiry, or if they were related to a contamination incident. At the April 3-4, 1997 Working Group meeting, the decision was made not to include the Hotline list for initial consideration, and that a list from the Hotline would only be useful if it captured concerns or reports of contamination.

The Agency will attempt to capture Hotline inquiries concerning contamination incidents for future CCL development. Perchlorate, a contaminant discussed later in this notice, probably should have been

included for initial consideration. The fact that perchlorate was on the Hotline list, and no other, may indicate that such a list from the Hotline could be useful if the nature of the inquiry can be recorded.

j. Endocrine disruptors. A list of contaminants was developed which included those suspected of having adverse effects on endocrine function (see Table 6). For several years, the Agency has been concerned that chemicals may be disrupting the endocrine (i.e., hormonal) systems of humans and wildlife. It has also been hypothesized that endocrine disruption might result in cancer, harm to male and female reproductive systems, thyroid damage, or other adverse consequences. In February 1997, EPA issued an assessment and analysis of this concern (U.S. EPA, 1997a). The report represents an interim assessment pending a more extensive review expected to be issued by the National Academy of Sciences (NAS) later this year.

Table 6. Contaminants Identified as Suspected of Endocrine Disruption

Amitrole
Benomyl
Dicofol (Kelthane)
Esfenvalerate
Ethylparathion
Fenvalerate
Kepone
Mancozeb
Metiram
Mirex
Nitrofen
Oxychlorthane
Parathion
Permethrin
Synthetic pyrethroids
Transnonachlor
Tributyltin oxide
Vinclozolin
Zineb
Ziram
Octachlorostyrene
PBBs
Penta- to nonyl-phenols

In brief, the report found 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. The exceptions include incidents of chemical exposure in the workplace and exposure to the drug DES. 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. OPPTS is actively engaged in research and regulatory initiatives to respond to the growing scientific and public concern over endocrine disruptors.

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 is composed of a balanced representation from industry, government, environmental and public health groups, labor, academia, and other interested stakeholders. During its deliberations, the Committee will consider human health, ecological, estrogenic, androgenic, anti-estrogenic, anti-androgenic, and thyroid effects of pesticides, industrial chemicals, and important mixtures. 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 Scientific Advisory Panel.

EPA is also involved in concurrent effort to coordinate activities with the European Union, the Organization of Economic and Community Development, and the United Nations Environmental Program concerning global research programs, and international harmonization of endocrine disruptor screening and testing methods for chemicals and pesticides.

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 initial consideration for the draft CCL based solely on the possibility of endocrine disruption (although several contaminants implicated as endocrine disruptors were considered for other reasons). The Agency will continue to follow this issue closely and reconsider this category of potential contaminants in the development of future CCLs.

2. Development and Application of the Criteria

Criteria were developed by the NDWAC Working Group for use in screening and evaluating chemical contaminants for the draft CCL, with the exception of aldicarb, nickel, and sulfate which are discussed in section III.C.3. The general premises of the

criteria were: (1) The contaminants included for initial consideration be those on EPA's initial list, without NPDWRs, and (2) that occurrence, or anticipated occurrence, of the contaminant be evaluated first, before evaluating its health effects information. The criteria, presented below, were used to screen and evaluate chemical contaminants for the purpose of developing today's draft CCL. Data used to evaluate and screen contaminants were obtained from STORET, the Hazardous Substances Database (HSDB), IRIS, published literature, and various EPA reports and documents. The data used in the evaluation and screening are included in the docket for today's notice.

These criteria, as well as the conceptual approach to the Contaminant Identification Method (CIM) presented in the December 2-3, 1996 Stakeholders meeting, will serve as the basis for developing a more robust contaminant identification method for future CCL development. The search results on each element of the criteria for contaminants considered during the development of the CCL can be found by using the Occurrence Table, the Health Table, and the Comments Table included in the docket for today's notice.

a. Criteria for occurrence. For the occurrence portion of the criteria, an affirmative response to any of the following elements would result in moving to the health portion of the criteria for further consideration. If all of the occurrence elements had a negative response, the contaminant was eliminated from further consideration. The two main elements to the occurrence portion of the criteria were as follows: (1) Was the contaminant looked for and found in drinking water, or in a major drinking water source, or in ambient water at levels that would trigger concern about human health? (2) if the contaminant was not looked for, is it likely to be found in water based on surrogates for occurrence?

To judge whether a contaminant was looked for and found in drinking water, according to the criteria, it would need to be included in a major survey which was defined as one which included a population of 100,000 or more, 2 or more states, or 10 or more small public water systems, or a data set such as EPA's Unregulated Contaminants Database. To judge whether a contaminant was looked for and found in a major drinking water source, or in ambient water, any source of occurrence data could be used. A source of drinking water was considered to be major if it supplied a population of 100,000 or

more, or 2 or more states. Levels that would trigger concern about human health were defined as concentrations in samples within an order of magnitude of the level that is likely to cause health effects, or at least 1/2 of samples at 50% of level that is likely to cause health effects. Contaminants were considered to have met the criteria if the data available indicated occurrence at a population of 100,000 or more; or in 2 or more states; or in 10 or more small public water systems at levels that would trigger concern about human health.

If the contaminant was not looked for using the data available, it was evaluated to determine if it was likely to be found in water based on surrogates for occurrence. The elements considered as surrogates for occurrence included: TRI releases, or production volumes, coupled with physical-chemical properties, or the OPP GW Risk value. In order for a contaminant to meet this criterion as likely to be found in water using TRI, the release to surface water was in excess of 400,000 pounds per year, and the physical-chemical properties indicated persistence & mobility of the contaminant. The quantity of 400,000 pound per year was based on the top 15 TRI chemicals with the largest discharges to surface water as reported in 1995. In order for a contaminant to meet this criterion as likely to be found in water using production, the volume was in excess of 10 billion pounds per year, and physical-chemical properties indicated persistence and mobility.

For a contaminant to meet this criteria as likely to be found in water using OPP GW Risk, the value was 2.0 or greater. However, late during the data evaluation and screening phase of the CCL development, the decision was made to defer contaminants identified under this element until a more in-depth analysis could be performed that would include risk to both surface and ground water, and a component to address health.

b. Criteria for health. For the health portion of the criteria, an affirmative response to any of the following elements resulted in including the contaminant on the first CCL, if it also met the occurrence criteria. A negative response to every question resulted in the contaminant being eliminated from consideration for the CCL. The health portion of the criteria had one major component; was there evidence, or suspicion, that the contaminant causes adverse human health effects? This portion of the criteria was met if a contaminant had one or more of the following elements: (1) Listed by

California Proposition 65, (2) an EPA Health Advisory, (3) a likely (based on animal data) or known (based on human data) carcinogen by EPA or International Agency for Research on Cancer (IARC), (4) more than one human epidemiological study (indicating adverse effects), (5) an oral value in IRIS, (6) regulated in drinking water by another industrial country, (7) a member of a chemical family of known toxicity, or (8) structural activity relationship indicating toxicity.

As the contaminants were being screened and evaluated, the factors for health which proved to be the most useful were those that provided a health level of concern as a concentration that could be compared to the levels of occurrence found in water, such as an EPA Health Advisory, an oral value in IRIS, or a regulatory level from another industrial country. Being listed by California Proposition 65, or a member of a chemical family of known toxicity had limited utility in determining which contaminants to include on the CCL.

3. Additional Specific Contaminants Included

Aldicarb, nickel, and sulfate are also on the draft CCL. The SDWA, as amended, did not specifically mention aldicarb and nickel, but since the Agency has existing obligations for completing regulatory action on these contaminants pursuant to the SDWA, as amended 1986, it was thought to be prudent to include them on the CCL to make clear the intention to address these responsibilities. Sulfate is included on the CCL, since the Agency must make a determination to regulate or not by August 2001, along with at least four more contaminants. The following sections provide the rationale for the inclusion of aldicarb, nickel, and sulfate on the draft CCL.

a. Aldicarb, aldicarb sulfoxide, and aldicarb sulfone. EPA promulgated a final NPDWR for aldicarb, aldicarb sulfoxide and aldicarb sulfone on July 1, 1991 (56 FR 30266). EPA set the maximum contaminant level goal (MCLG) at 0.001 mg/l and maximum contaminant levels (MCLs) of 0.003 mg/l for aldicarb, 0.004 mg/l for aldicarb sulfoxide, and 0.002 mg/l for aldicarb sulfone. In response to an administrative petition from the manufacturer Rhone-Poulenc, the Agency issued an administrative stay of the effective date of the MCLs, i.e., the MCLs never became effective, but monitoring is required. Rhone-Poulenc also filed a petition for judicial review, and the court stayed its proceedings while EPA proceeded administratively,

but required quarterly reports. On agreement of the parties, the judicial proceedings have been dismissed. An updated health advisory was issued in 1995 incorporating data from a human study conducted in 1992 by Rhone Poulenc. The aldicarbs were not subject to the criteria used to identify other chemical contaminants and are being included on the CCL to signify the Agency's intention to complete the regulatory activity for these contaminants. At this point, however, the time frame of completing action relative to aldicarbs has not been determined.

b. Nickel. NPDWRs for nickel including an MCLG and an MCL of 0.1 mg/l were proposed on July 25, 1990 (55 FR 30370) and finalized on July 17, 1992 (57 FR 31776). In September, 1992, the Nickel Development Institute and other industry parties filed a petition for review in the U.S. Court of Appeals for the D.C. Circuit challenging the MCLG and MCL for nickel. The petitioners raised objections over EPA's methodology for determining the MCLG for nickel. Specifically, they raised questions concerning the derivation of the relative source contribution factor and the need for a 3-fold uncertainty factor that EPA applied due to the lack of adequate data on the effects of nickel ingestion on reproductive systems. Because the MCL for nickel was based directly on the MCLG, the petitioners also challenged the nickel MCL.

EPA and the petitioners entered into discussions in an attempt to settle this litigation but could not agree on the merits of the petitioners' challenges. Nevertheless, EPA agreed that it did not fully address in the public record the petitioner's comments on the proposed methodology for deriving the MCLG for nickel, and agreed to take a remand of the MCLG and MCL for nickel. Accordingly, on February 9, 1995, EPA and the nickel industry petitioners filed a joint motion for a voluntary remand of the nickel MCL and MCLG. By orders of February 23, 1995 and March 6, 1995, the court granted this motion and vacated and remanded the nickel MCLG and MCL (and dismissed the lawsuit). No other aspects of the NPDWRs for nickel were vacated, including monitoring requirements and identification of best available technologies for nickel. A notice of this action was published in June 1995 (60 FR 33929).

To provide guidance for the period prior to new regulations for nickel, the EPA updated and issued a health advisory for nickel. Nickel was not subject to the criteria used to identify other chemical contaminants and is

being included on the CCL to signify the Agency's intention to complete regulatory action for this contaminant. The time frame of completing action on nickel has not yet been determined.

c. *Sulfate*. As noted above, by August, 2001 the Agency must decide whether or not to regulate sulfate. The date for making a determination about sulfate coincides with the date by when determinations must be made for 5 or more contaminants from the first CCL. Sulfate was not subject to the criteria used to identify other contaminants; however, it has been included, given these special circumstances.

IV. Contaminants on the CCL Which Are of Specific Interest

A number of contaminants included on the draft CCL may be of particular interest. The following sections attempt to provide additional information for a few of the contaminants that seem to be of most interest. Data obtained and evaluated for developing the draft CCL and referred to in the following discussion can be found in the docket for this notice.

A. Aluminum

There is intense interest from some for development of drinking water regulations for aluminum. Aluminum currently has a secondary MCL of 50 to 200 $\mu\text{g}/\text{l}$ based on organoleptic properties. There have been a few epidemiological studies in Canada that emphasize the need to determine if regulations for this contaminant should be developed based on health effects. At present, based on the work in Canada, it appears that the most sensitive population is the elderly. To determine if aluminum is of health concern to the elderly and to other possible sensitive groups like children, the EPA collaborated with Health Canada on a workshop on aluminum held September 3 and 4, 1997. This workshop was planned to help define the need for chronic animal studies and the use of appropriate animal models to better characterize the risk of this contaminant in drinking water. The Agency will continue to work to determine if aluminum is of health concern, and the appropriate action to address this concern.

B. MTBE

MTBE (methyl-t-butyl ether) is a fuel additive used in many locations throughout the United States to reduce carbon monoxide and ozone forming precursors associated with the combustion of fossil fuels. There is evidence of contamination of drinking water; however the extent of

contamination of drinking water supplies on a national scale is unclear at this time (IAOF, 1997). The Agency is in the process of revising the HA for MTBE that will incorporate updated health effects information, and has completed a research strategy to guide efforts at improving the understanding of the occurrence and health effects of MTBE (U.S. EPA, 1997e). As more PWSs across the country voluntarily monitor for MTBE, and if it is found at levels of concern nationally, the Agency does have the capacity to make a determination to develop regulations to monitor and/or control MTBE prior to the 2001, SDWA deadline for selecting at least 5 contaminants for determination.

C. Organotins

Organotins represent a class of contaminants which include, methyl tin, tributyltin, and others. The organotins of concern are those that result from use in heat stabilizing PVC piping for the in-home distribution of water. There are a few cases of tributyltin contamination of drinking water in the U.S. (Sadiki, 1996). It has been reported that the Canadian government is concerned about organotin contamination and has planned a national survey of drinking water in Canada to assess the danger to human health.

The concentrations of concern for human health are not known at this time, however tributyl tin and other organotins are known to be toxic to aquatic life. On August 7, 1997, the Agency published a notice of ambient water quality criteria document for tributyltin (TBT) and a request for comments (62 FR 42554). Ambient water quality criteria are for the protection of aquatic organisms and guidance to States and others, and may form the basis for enforceable State water quality standards developed pursuant to Section 304(a)(1) of the Clean Water Act.

D. Rhodamine WT

Rhodamine WT is a fluorescent dye widely used as a tracer to measure ground water flow. Rhodamine WT has been certified by the National Sanitation Foundation for use in tracing water under the conditions that it not exceed concentrations in drinking water of 0.1 $\mu\text{g}/\text{l}$ and that exposure be infrequent. Rhodamine WT was detected in ground water above the 0.1 $\mu\text{g}/\text{l}$ value; however the conditions under which the detections occurred are unclear. Rhodamine WT appears to be a contaminant that the Agency may need to observe more closely in terms of its

health effects, and possible occurrence in drinking water.

E. Sodium

At present, the Agency has no NPDWR or HA value for sodium. All that is currently available is a guidance DWEL of 20 mg/l. DWELs are unenforceable guidance levels describing a lifetime exposure concentration of a contaminant that is considered protective of adverse non-cancer health effects, and it also assumes that all of the exposure to a contaminant is from a drinking water source. In addition, EPA has a non-enforceable criterion for dissolved solids and salinity for ambient waters of 250 mg/l.

The DWEL is based on a 1965 American Heart Association recommendation of a 20 mg/l sodium level to protect genetically susceptible people on low sodium diets, assuming a total dietary intake of 500 mg/day. Naturally occurring sodium in food with no salt added averages about 440 mg/day. The additional 60 mg that would increase the intake to the typical level for a restricted diet of 500 mg/day must take into account all other non-food sources, such as drugs, water, etc. A concentration in drinking water of up to 20 mg/l of sodium is compatible with this diet.

Since a significant percentage of the U.S. population is attempting to reduce their sodium intake, the Agency believes that sodium levels in drinking water could be an important issue. This is particularly true for locations where many of the residents using the water may be susceptible to adverse health effects from exposure to this contaminant. The Agency believes that all consumers are able to use water for drinking if the sodium concentration is maintained at or below 20 mg/l, but nearly half of the nation's water supplies have natural or added sodium above these levels.

The inclusion of sodium on the CCL is controversial, but it is expected that guidance will be developed for those who need it, and that including it on the CCL will be a mechanism to develop an Agency position on the issue of sodium in drinking water.

F. Zinc

Zinc is used as a dietary supplement, main ingredient in lozenges, and corrosion inhibitor. There is intense interest over including zinc on the CCL, but there are also indications of health effects associated with increased levels of zinc consumption.

The Agency is aware that zinc is an essential element for which the Food

and Nutrition Board of the National Research Council has established a Recommended Dietary Allowance (RDA). Zinc can also cause adverse health effects at high doses and the zinc RfD (0.3 mg/kg/day) is higher than the RDA for adult men and women. While deriving RfDs, EPA must also keep in mind the fact that excess exposure to an essential trace element, such as zinc, can also cause adverse health effects. The present RfD for zinc represents a balance between the essential requirement for zinc and the toxic effects of too much zinc; however, the Agency is currently working on revising the risk assessment procedures for essential elements. The World Health Organization (WHO) is also in the process of developing a document on the risk assessment of essential trace elements, and EPA will consider the WHO document when it is available.

G. 2,6-di-tert-butyl-p-benzoquinone (DTBB)

DTBB is a contaminant that appears to be associated with sewage contamination of ground water. A ground water study concluded that DTBB was a good indicator of such contamination because, among other reasons, it does not biodegrade readily (Barber, 1988). DTBB was determined not to meet the criteria for the draft CCL per se, but was included nevertheless, because of the recalcitrant nature of the contaminant, its association with sewage contamination, its potential health impacts, and its potential to serve as an indicator of other contamination.

H. Contaminants to be Considered as Groups

Stakeholders, through the regulatory reassessment process and the development of this draft CCL, have requested that the Agency, address triazine pesticides as a group which includes all parent and degradates compounds as opposed to each triazine as an individual contaminant. The triazine pesticides include; cyanazine, propazine, etc., and atrazine and simazine (which are both currently regulated), and are often substituted for one another for similar agricultural use.

The USEPA regulated atrazine in 1991 and simazine in 1992. Cyanazine and atrazine-desethyl, a degradation product of triazines, were identified for the draft CCL using the criteria discussed earlier, and because of the common effect of triazine pesticides and degradates, Office of Ground Water and Drinking Water (OGWDW) and OPP are coordinating to have atrazine and simazine, and possibly other triazines, if warranted, addressed as a group. A

triazine special review was initiated by OPP which will culminate in a proposed decision on the labeling and agricultural use triazine. The proposal is expected during the summer of 1998. The triazines are also included in the Priority Group 1 of pesticide tolerances that will be examined first under the FQPA tolerance reassessment (62 FR 42020).

The Agency is concerned about triazines in water and the exposure of sensitive populations, including children, and OGWDW will work closely with OPP to characterize the risk of triazines in food and water. 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 may ultimately develop regulations for the mixtures of triazines either through the revision of existing regulations or the development of new ones. The same may occur for other families of pesticides, such as the acetanilide pesticides, which include acetochlor, metolachlor, alachlor (which is currently regulated), given their common effects and agricultural uses.

I. Contaminants for Which Unregulated Contaminant Data Are or Will Be Available

Unregulated contaminant monitoring data which have been collected a number of contaminants during 1988–1991, and additional monitoring data collected during 1993–1995 (see Table 7). These monitoring data can serve in evaluating whether these contaminants should be included on the CCL. The data collected during 1988–1991 have been preliminarily evaluated by the Agency; however, further analysis is necessary to determine if a contaminant in fact meets the criteria used to develop the draft CCL. The data collected during 1993–1995, are not yet available; however, during the comment period, and prior to publishing the CCL by February 1998, the Agency will attempt to obtain and evaluate this data to determine if the contaminant should remain on the CCL. Contaminants that do not meet the criteria as presented in today's notice, or as modified subsequent to the comment period of the notice, will not be included on the final CCL to be published by February 1998.

Table 7. Contaminants with Unregulated Contaminant Monitoring Data

1,3-dichloro-benzene
1,2,4-trimethyl-benzene
1,3-dichloropropene

1,3-dichloro-propane
1,1,2,2-tetrachloro-ethane
1,1-di-chloro-ethane
1,1-dichloro-propene
1,2,3-trichloro-propane
2,2-dichloro-propane
bromobenzene
bromomethane
carbaryl
o-chlorotoluene
p-chlorotoluene
cumene
cymene
dichloro-difluoromethane
hexachlorobutadiene
metolachlor
metribuzan
naphthalene
n-propylbenzene
trichlorofluoro-methane

V. Request for Comment

The purpose of today's notice is to present the draft CCL and seek comment on various aspects of its development. The Agency requests comment on the approach used to develop the CCL, and on the contaminants included. The Agency also requests comment on the data and research needs categories the contaminants have been divided into, in Table 8. Any data supporting comments or that can be used by the Agency in developing the final CCL are also requested. In addition to comments on contaminants considered for the draft CCL, the Agency seeks comment on the inclusion of perchlorate on the final CCL. The following sections provide more detail on the data and research needs and the issue of perchlorate.

A. Data and Research Needs

The microbiological contaminants included on the CCL all have research needs of one sort or another in the area of analytical methods. The meeting summary of the Workshop on Microbiology and Public Health, held May 20–21, 1997, provided more detail of the research needed for microorganisms.

For the chemical contaminants on the draft CCL, Table 8 divides them into categories to represent the 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 a given contaminant. 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 exists at the time of publishing the CCL, are likely to

the those from which the determinations will be made by 2001.

TABLE 8.—DATA NEEDS FOR CHEMICAL CONTAMINANTS INCLUDED ON THE DRAFT CCL

Sufficient health effects and occurrence data exist	Need additional health effects data, but not occurrence data	Need additional occurrence data, but not health effects data	Need both health effects and occurrence data
1,1,2,2-tetrachloroethane; 79–34–5	Aluminum; 7429–90–5	1,2-diphenylhydrazine; 122–66–7 ...	2,6-di-tert-butyl-p-benzoquinone (DTBB); 719–22–2
1,2,4-trimethylbenzene; 95–63–6 1,1-dichloro-ethane; 75–34–3	Vanadium; 7440–62–2	2,4,6-trichlorophenol; 88–06–2 2,2-dichloro-propane; 594–20–7	DCPA mono-acid degradate; 887–54–7 DCPA di-acid degradate; 2136–79–0
1,1-dichloro-propene; 563–58–6		2,4-dichlorophenol; 120–83–2	Organotins
1,3-dichloropropane; 142–28–9 1,3-Dichloropropene; 542–75–6 Boron; 7440–42–8 Bromobenzene; 108–86–1 Cyanazine; 21725–46–2 atrazine-desethyl (a triazine degradation product); 6190–65–4. p-Cymene; 99–87–6		2,4-dinitrophenol; 51–28–5 2,4-dinitrotoluene; 121–14–2 2,6-dinitrotoluene; 606–20–2 2-methyl-phenol; 95–48–7 Acetochlor; 34256–82–1 Acetone 67–64–1	
Hexachloro-butadiene; 87–68–3 cumene; 98–82–8 Manganese; 7439–96–5 Methyl bromide; 74–83–9 Metolachlor; 51218–45–2 Metribuzin; 21087–64–9 Naphthalene; 91–20–3 Sodium; 7440–23–5 Zinc; 7440–66–6		Alachlor ESA (an alachlor degradation product). Aldrin; 309–00–2 DDE; 72–55–9 Diazinon; 333–41–5 Dieldrin; 60–57–1 Dimethoate; 60–51–5 Disulfoton, 298–04–4 Diuron; 330–54–1 Fonofos; 944–22–9 Linuron; 330–55–2 MTBE; 1634–04–4. Molinate; 2212–67–1. Nitrobenzene; 98–95–3. Prometon; 1610–18–0. RDX; 121–82–4. Rhodamine WT. Terbacil; 5902–51–2. Terbufos; 13071–79–9. EPTC; 759–94–4.	

B. Perchlorate

Additional information and comment is sought on the inclusion of perchlorate on the final CCL. Perchlorate is being mentioned in this notice because EPA received information that it had been detected in water in the Colorado River and in wells in California, but the information came too late in the process of developing the draft CCL to evaluate it as had been done for the other contaminants. The information the Agency has received regarding perchlorate's occurrence, health effects, source of contamination and treatment that has been included in the docket. This information, and any other submitted in response to comments, as well as additional data that the Agency may obtain, will be considered to determine whether perchlorate should be included on the final CCL.

VI. Development of the Final Drinking Water Contaminant Candidate List, the Contaminant Identification Method, and the Contaminant Selection Process

Between now and the publication of the final CCL, the Agency will evaluate comments received during the comment period for this notice and re-evaluate the criteria used to develop the draft CCL and revise the CCL, as appropriate. The final CCL will be published by February 1998.

In addition to publishing the final CCL, the Agency will also resume work on the CIM and the contaminant selection process. The development of the CIM and the selection process will be completed in consultation with the NDWAC Working Group on Occurrence & Contaminant Selection. The next meeting of the Working Group will likely be later this fall. The CCL, CIM and the selection process will serve as the cornerstones of the Agency's regulatory development process. In addition to developing the CCL, CIM and the selection process with the

Administration policy in mind, the Agency intends to obtain resources to improve the screening process in order to acquire better information, improve analytical capability, and seek additional stakeholder involvement. The CCL is a critical input to shaping the future direction of the drinking water program, and improvements will be made with each successive cycle of publishing the list.

VII. Summary of Other Related Activity Required by the SDWA

After the CCL is developed and in accordance with the SDWA, as amended, the Agency will determine whether or not regulation is needed for at least five contaminants. This step of *contaminant selection* is then followed by proposal and ultimate promulgation of regulations for those contaminants for which a determination has been made to regulate. Two tools provided for in the SDWA, as amended, that relate to development of the CCL, are the

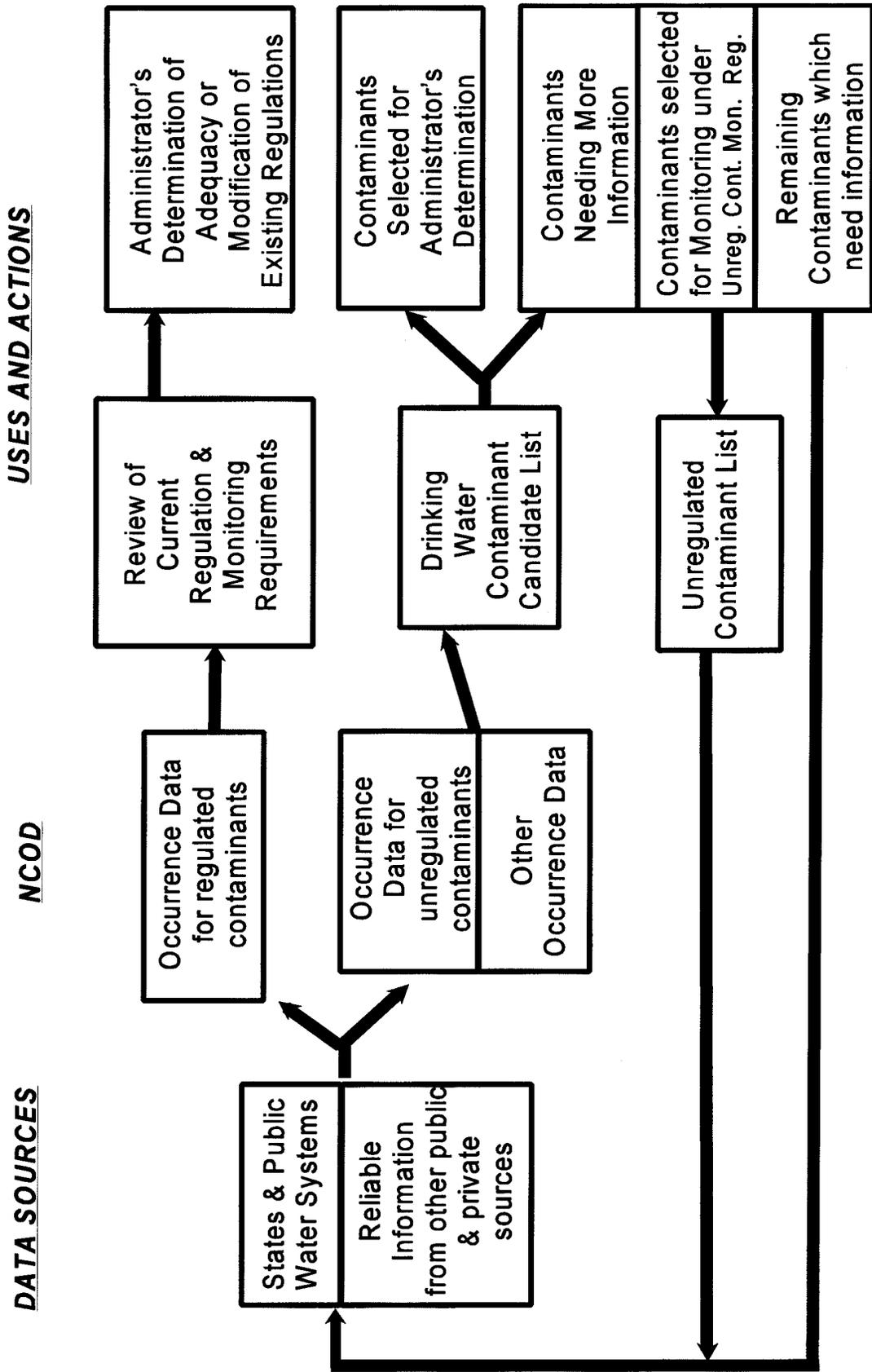
occurrence database and unregulated contaminant monitoring. In *identifying* contaminants for inclusion on the CCL, and *selecting* contaminants for determination, the National Drinking Water Contaminant Occurrence Database must be considered. The

primary mechanism for obtaining the occurrence data for the database is the Unregulated Contaminant Monitoring Requirements provision. Figure 2 provides a representation of the relationship among these various elements. The SDWA requirements for

contaminant selection, the occurrence database and unregulated contaminant monitoring are presented below to give the reader a sense of what these requirements entail and how they relate to the CCL and to each other.

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Figure 2. THE RELATIONSHIP OF THE CCL, THE ADMINISTRATOR'S DETERMINATIONS, THE UNREGULATED MONITORING REQUIREMENTS, AND THE NCOD



A. Contaminant Selection and Regulatory Determination

The SDWA, as amended in 1996, requires EPA to make determinations of whether or not to regulate no fewer than five contaminants from the CCL five years after enactment (i.e., by August 2001), and every five years thereafter (section 1412(b)(1)); which is also three and a half years following each CCL. Any of the contaminants from the CCL that the Agency decides to regulate are subject to proposed NPDWRs within 24 months of this decision to regulate, and final NPDWRs within 18 months of the proposal. The SDWA also requires that EPA give priority to selecting contaminants for regulation that present the greatest public health concern, including vulnerable populations such as infants, the elderly, and those with serious illness. Three criteria must be considered when deciding whether or not to regulate a contaminant: (1) Could the contaminant adversely affect public health, (2) is it known or substantially likely to occur in public water systems with a frequency and at levels posing a threat to public health, and (3) will regulation of the contaminant present a meaningful opportunity for health risk reduction.

The Agency will be developing a contaminant selection process that will address the criteria mentioned above in concert with the contaminant identification method. The contaminant selection process will be used to select contaminants from the CCL for which determinations will be made, while the CIM will be used to develop the CCL. A conceptual approach for the CIM was presented on December 2-3, 1996, at an EPA sponsored stakeholders meeting (U.S. EPA, 1996b) However, in order to meet the February 1998 deadline for finalizing the CCL, further work on the CIM was delayed in favor of developing the draft CCL presented in today's notice. The Agency, in collaboration with the NDWAC Working Group on Occurrence & Contaminant Selection, will resume work on the CIM and the contaminant selection process during the fall of 1997. Knowledge gained during the development of this draft CCL, as well as the feedback received since the December 1996 stakeholders meeting, will be factored into the development.

B. The National Contaminant Occurrence Database

The SDWA, as amended in 1996, requires EPA to establish a national drinking water contaminant occurrence database (NCOD) to be assembled by August 1999 [section 1445(g)]. The

database is to include the occurrence of both regulated and unregulated contaminants, and, once established, is to be used to support the Administrator's determinations for future regulations. The requirements for developing the CCL also include consulting the occurrence database. Since the database is currently under development, and will not be available for the development of this first CCL, the Agency consulted other sources of occurrence data. Once available, however, the NCOD will be used not only to develop future CCLs and support future determinations of the need for regulations, but to develop future regulations.

A Stakeholder meeting was held on May 21-22, 1997, in Washington, D.C., on the NCOD to discuss and obtain input from the public, states, and the scientific community on database design and structure, input parameters and requirements, and the uses and interpretation of the data. This meeting was the first of several expected to take place in the near future regarding the NCOD development.

C. Unregulated Contaminant Monitoring Regulation

The SDWA, as amended, requires EPA to list and develop regulations for monitoring of certain unregulated contaminants by August 1999, and every 5 years thereafter (section 1445(a)(2)). This provision was first introduced with the 1986 amendments to the SDWA and has been substantially modified by the 1996 amendments. The SDWA requires that the list of unregulated contaminants not exceed 30, and that the monitoring data be collected and maintained in the NCOD. Criteria for determining which contaminants on the CCL will be chosen for the unregulated contaminant monitoring list will be developed as part of this regulation.

Contaminants on the CCL that need additional occurrence data will be used as the principal source of contaminants for the list of unregulated contaminants. The unregulated contaminant monitoring provision of the SDWA will be used as a tool to gather the contaminant occurrence data necessary for determining the need for drinking water regulations.

VIII. Summary of Concurrent Regulatory Activity Required by the SDWA

In addition to the requirements for the CCL and contaminant selection, the SDWA, as amended 1996, also contain specific provisions with regard to radon, arsenic, sulfate, and disinfectants and

disinfection byproducts. The SDWA, as amended, did not specify a new time frame for finalizing rulemaking for other radionuclides, however, EPA and the Bull Run Coalition have entered into a consent decree with the court establishing timetables to finalize this rulemaking. Regulatory activity for radon, other radionuclides, arsenic, sulfate, and disinfectants and disinfection byproducts are not affected by today's notice, but are summarized below to provide the reader with an update on the status these specific activities.

A. Radon

The SDWA, as amended in 1996, contains specific provisions for regulating radon in drinking water (section 1412(b) (13)). First, EPA is required to withdraw the proposed rule for radon which was published in 1991 and to re-propose a drinking water regulation for radon by August 6, 1999, and issue final regulations by August 6, 2000. The SDWA, as amended, also requires EPA to: (1) Arrange for the NAS to prepare a peer reviewed risk assessment for radon that evaluates the health effects of radon in drinking water under conditions likely to be experienced through residential exposure and to assess the risk reduction benefits from various mitigation measures to reduce radon levels in indoor air; (2) make available for public comment a health risk reduction and cost analysis comparing costs and benefits of various possible MCL in advance of proposing a radon regulation; and (3) establish an alternative-MCL, if the MCL is set at a level that is more stringent than necessary to reduce the contribution of radon in indoor air originating from drinking water to a level equal to the national average concentration of radon in outdoor air. States will have the option to comply with the less stringent alternative-MCL if they implement a multi-media radon risk reduction program that accomplishes greater health protection than would be achieved by complying with the more stringent MCL alone.

A notice was published in the **Federal Register** on August 6, 1997, to withdraw the radon proposed rule. (62 FR 42221) The NAS risk assessment is scheduled to be complete by July 1998, and the HRRCA is due by February 1998. In addition, EPA held stakeholder meetings on June 26, 1997, in Washington, D.C., and on September 2, 1997, in San Francisco, and has scheduled an additional stakeholder meeting in Boston later this fall to obtain input from the public.

B. Other Radionuclides

On July 18, 1991, EPA proposed NPDWRs for radionuclides in public water supplies (56 FR 33050). EPA proposed MCLs for Radium-228 at 20 pCi/l, Radium-226 at 20 pCi/l, Uranium at 30 pCi/l (20 µg/l), adjusted gross alpha at 15 pCi/l (excluding Ra-226, U, and Rn-222), and beta and photon emitters (excluding Ra-228) at 4 mrem/yr; MCLGs were proposed at zero.

Comments on the proposed rule were received from approximately 600 individuals and organizations. Due to concerns by commenters and Congress over the most effective way to regulate radon and other radionuclides together, the proposed rule was put on hold, pending passage of amendments to the SDWA, so that EPA could gain further clarification of Congress' intent.

The SDWA, as amended in 1996, did not specify a new time frame for finalizing rulemaking for radionuclides, as it did for radon. However, an existing consent decree providing deadlines for regulating radionuclides was amended in 1996 to provide that EPA would, by November 2000, finalize a rule for Uranium; and finalize a rule for Ra-226, Ra-228, alpha and beta/photon emitters, or publish its reasons for not taking final action as to these contaminants. An Agency Workgroup has been formed and is process of evaluating all current data and information, which will lead to finalizing elements of the proposed rule or to re-proposing NPDWRs for radionuclides.

C. Arsenic

In 1975, EPA established National Interim Primary Drinking Water Regulations (NIPDWR), setting an MCL for Arsenic at 50 µg/l. In 1985, EPA proposed an MCLG of 50 µg/l, requesting comment on alternate MCLGs of 100 µg/l and 0 µg/l. However, the SDWA, as amended in 1986, converted the interim standard into a NPDWR, subject to revision by 1989. When the Agency failed to meet the statutory deadline for promulgating an arsenic regulation, a citizen's group filed suit to compel EPA to do so. EPA entered into a consent decree to, in part, issue the arsenic regulation. The consent decree was amended several times to extend the deadlines and with passage of the 1996 Amendments was dismissed as to arsenic.

The SDWA, as amended, requires EPA to conduct additional research on arsenic in order to reduce the uncertainty in assessing the health effects of low exposure levels; to propose a NPDWR for arsenic by January 1, 2000; and to issue a final

regulation by January 1, 2001. (Sec. 1412(b)(12)) EPA developed a research plan, made it available for public comment, and had it peer reviewed in January 1997. The revised research plan will be available this fall. In addition, EPA issued a joint request for research proposals with the American Water Works Association Research Foundation (AWWARF) and the Association of California Water Agencies (ACWA). EPA, AWWARF and ACWA awarded almost \$3 million in grants and contracts this summer, for up to three years. This spring, EPA also funded an Interagency Agreement, with the National Research Council (NRC) of the NAS to review EPA's risk assessment, determine the adequacy of EPA's current MCL for protecting human health and surface water quality criteria, and identify priorities for research to fill data gaps. The NRC report will be submitted to EPA in mid-to-late 1998. In May, 1997, EPA convened an expert panel to evaluate the scientific literature on the genetic and carcinogenic effects of arsenic in order to comment on arsenic's mode of action and the data supporting models extrapolating to low dose arsenic exposures. The final report is now being considered by EPA's IRIS Update Group.

D. Sulfate

A December 20, 1994 proposed sulfate regulation contained both MCLG and MCL levels for sulfate of 500 mg/l and included 4 alternative compliance options designed to allow flexible implementation. Thereafter, the Agency's drinking water redirection effort concluded that sulfate was a relatively low risk contaminant, and further regulatory activity was suspended. The SDWA, as amended, requires completion of a study to resolve risk questions and requires the Agency to make a determination within 5 years of enactment of the Amendments, by August 6, 2001, of whether or not to regulate sulfate. Any of the contaminants from the CCL that the Agency decides to regulate are subject to proposed NPDWRs within 24 months of this decision to regulate, and final NPDWRs within 18 months of the proposal. In 1997 the Agency entered into an Interagency Agreement with the Center for Disease Control and Prevention (CDC). EPA and CDC are currently waiting for completion of the peer review of the jointly planned health risk study for sulfate. The study results, due in February 1999, will serve as input for EPA's contaminant identification and selection protocol to decide whether or not to regulate sulfate, and will be publicly available.

In addition, prior to deciding on the need to regulate sulfate, the Agency would need to make a determination on the adequacy of existing occurrence data for sulfate and, if inadequate, consider approaches for filling data gaps.

E. Disinfectants and Disinfection Byproducts

Microorganisms identified for the CCL are not specifically targeted by the following regulations, however they may be indirectly controlled. Any microorganism identified for the CCL which is determined later to be adequately, although indirectly, controlled by the following regulations, will be subsequently withdrawn from the CCL.

Under the Surface Water Treatment Rule (SWTR) promulgated on June 29, 1989, (54 FR 27486), EPA set MCLGs of zero for *Giardia lamblia*, viruses and *Legionella*; and promulgated NPDWRs for all public water systems (PWSs) using surface water sources or groundwater sources under the direct influence of surface water. The SWTR includes treatment technique requirements for filtered and unfiltered systems that are intended to protect against the adverse health effects of exposure to *Giardia lamblia*, viruses, and *Legionella*, as well as many other pathogenic organisms.

In 1992, EPA initiated a negotiated rulemaking to develop disinfectant and disinfection byproducts regulations. The Regulatory Negotiating Committee met from November 1992 through June 1993 and included representatives of State and local health and regulatory agencies, public water systems, elected officials, consumer groups and environmental groups. One of the major goals addressed by the Committee was to develop an approach that would reduce the level of exposure from disinfectants and disinfection byproducts without undermining the control of microbiological pathogens. To accomplish this, the Committee agreed to the development of three sets of regulations: a two-staged Disinfectant/Disinfection Byproducts Rule (D/DBP), an Enhanced Surface Water Treatment Rule (ESWTR), and an Information Collection Rule (ICR). The purpose of the ICR is to collect occurrence and treatment information to evaluate the need for possible changes to the current SWTR, existing microbial treatment practices, and also evaluate the need for future regulation for disinfectants and disinfection byproducts.

EPA would first develop an *Interim-ESWTR* (IESWTR) that would only apply to systems serving 10,000 people or more, the committee agreed that a

Long-Term-ESWTR (LTESWTR) may be needed for systems serving fewer than 10,000 people when the results of more research and water quality monitoring became available. The LTESWTR could include additional refinements for larger systems.

The ICR was proposed on February 10, 1994 (59 FR 6332) and promulgated on May 14, 1996 (61 FR 24354). The D/DBP regulations and the IESWTR were proposed on July 29, 1994 (59 FR 38668, 59 FR 38832). The SDWA, as amended, requires EPA to promulgate an IESWTR and a Stage I D/DBP Rule by November 1998. In addition, the SDWA requires EPA to promulgate a final ESWTR and a Stage II D/DBP rule by November 2000 and May 2002, respectively [section 1412(b)(2)(C)].

In light of new information that has become available in several key areas related to issues put forth in the D/DBP Stage 1 proposal, the Agency initiated a series of public meetings in May 1996. These meetings were designed to exchange information on issues related to the development of the IESWTR and the Stage 1 D/DBP rule and the impact of the ICR data not being available. In order to facilitate moving in an expedited fashion to meet the deadlines in the 1996 Amendments, and to maximize stakeholder participation, the Agency subsequently established an advisory committee to collect, share, and analyze new information and data as well as to build consensus on the regulatory implications of this new information. After evaluation of the new data and information, the committee made recommendations on a number of major issues. These recommendations and a discussion of the pertinent issues will be published in a **Federal Register** Notice planned for later this fall.

IX. 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. As contaminants are selected for rulemaking, all necessary analysis will be conducted in accordance with the rulemaking 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 risk 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 CDC 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 contamination. Other research also is underway to determine the extent of vulnerable populations including children and the immunologically impaired.

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