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**SUPPLEMENTARY INFORMATION:** EPA has previously transferred to its contractor, ERG (located in Chantilly, Virginia and Lexington, Massachusetts), information, including CBI, that was collected under the authority of section 308 of the CWA. Notice of the transfer was provided to the affected industries (see, for example, 59 FR 58840, November 15, 1994). EPA determined that this transfer was necessary to enable the contractors and subcontractors to perform their work in supporting EPA in planning, developing, and reviewing effluent guidelines and standards for certain industries.

Today, EPA is giving notice that it has entered into additional contracts, numbers 68-C-02-095 and 68-C-01-073, with ERG. The reason for these contracts is to secure additional contractor support in engineering analysis, survey and database development, economic analyses, and ecological analyses. To obtain assistance in responding to these contracts, ERG has entered into contracts with their subcontractors. In particular, ERG has obtained the services of the following subcontractors: Abt Associates (located in Cambridge, Massachusetts); AH Environmental Consultants, Inc. (located in Newport News and Springfield, Virginia); AmDyne Corporation (located in Glen Burnie, Maryland); Amendola Engineering, Inc. (located in Westlake, Ohio); Analytica Alaska, Inc. (located in Juneau, Alaska); Applied Geographics, Inc. (located in Boston, Massachusetts); Avanti Corporation (located in Annandale, Virginia); CK Environmental (located in Atlanta, Georgia); DRPA, Inc. (located in Rosslyn, Virginia); GeoLogics Corporation (located in Alexandria, Virginia); Hydraulic and Water Resources Engineers, Inc. (located in Waltham, Massachusetts); N. McCubbin Consultants, Inc. (located in Foster, Quebec, Canada); Stratus Consulting, Inc. (located in Boulder, Colorado); Tetra Tech, Inc. (located in Fairfax, Virginia); Versar, Inc. (located in Springfield, Virginia); and independent consultant Danforth Bodien.

All EPA contractor, subcontractor, and consultant personnel are bound by the requirements and sanctions contained in their contracts with EPA and in EPA's confidentiality regulations found at 40 CFR Part 2, Subpart B. ERG and its subcontractors adhere to EPA-

approved security plans which describe procedures to protect CBI. The procedures in these plans are applied to CBI previously gathered by EPA for the industries identified below and to CBI that may be gathered in the future for these industries. The security plans specify that contractor and subcontractor personnel are required to sign non-disclosure agreements and are briefed on appropriate security procedures before they are permitted access to CBI. No person is automatically granted access to CBI; a need to know must exist.

The information that will be transferred to ERG and its subcontractors consists primarily of information previously collected by EPA to support the development and review of effluent limitations guidelines and standards under the CWA and the development of discharge standards under Title XIV. In particular, information, including CBI, collected for the planning, development, and review of effluent limitations guidelines and standards for the following industries may be transferred: Airport deicing; aquaculture; concentrated animal feeding operations; centralized waste treatment; coal mining; drinking water; industrial laundries; waste combustors; iron and steel manufacturing; landfills; meat and poultry products; metal finishing; metal products and manufacturing; nonferrous metals manufacturing; oil and gas extraction (including coalbed methane); ore mining and dressing; organic chemicals, plastics, and synthetic fibers; pesticide chemicals; pharmaceutical manufacturing; petroleum refining; pulp, paper, and paperboard manufacturing; steam electric power generation; textile mills; timber products processing; tobacco; and transportation equipment cleaning. In addition, for the development of standards under Title XIV, EPA may transfer information, including CBI, about large cruise ships that operate in the waters around Alaska.

EPA also intends to transfer to ERG and its subcontractors all information listed in this notice, of the type described above (including CBI) that may be collected in the future under the authority of section 308 of the CWA or voluntarily submitted (e.g., in comments in response to a **Federal Register** notice), as is necessary to enable ERG and its subcontractors to carry out the work required by their contracts to support EPA's effluent guidelines planning process; development of effluent limitations guidelines and standards; and discharge standards from cruise ships.

Dated: February 15, 2005.

**Geoffrey H. Grubbs,**

*Director, Office of Science and Technology.*

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## ENVIRONMENTAL PROTECTION AGENCY

[OW-2003-0028; FRL-7876-9]

RIN 2060-AD86

### Drinking Water Contaminant Candidate List 2; Final Notice

**AGENCY:** Environmental Protection Agency.

**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 that, at the time of publication, are not subject to any proposed or promulgated national primary drinking water regulations, that are known or anticipated to occur in public water systems, and that may require regulations under SDWA (section 1412 (b)(1)). SDWA, as amended, specifies that EPA must publish the first list of drinking water contaminants no later than 18 months after the date of enactment, i.e., by February 1998, and every five years thereafter.

The EPA published the first Candidate Contaminant List (CCL) in March of 1998 (63 FR 10273). The second draft CCL (CCL 2) was published on April 2, 2004 (69 FR 17406) and announced EPA's preliminary decision to carry forward the remaining 51 contaminants on the 1998 CCL as the draft CCL 2, provided information on EPA's efforts to expand and strengthen the underlying CCL listing process to be used for future CCL listings, and sought comment on the draft list as well as EPA's efforts to improve the contaminant selection process for future CCLs. Today's final CCL 2 carries forward the remaining 51 contaminants proposed on April 2, 2004.

**ADDRESSES:** EPA has established a docket for this action under Docket ID No. OW-2003-0028. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publically available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publically available only in hard copy form. Publically available docket materials are

available either electronically in EDOCKET or in hard copy at the Water Docket, EPA/DC, EPA West, Room B102, 1301 Constitution Avenue, NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the Water Docket is (202) 566-2426. For access to docket material, please call (202) 566-2426 to schedule an appointment.

**FOR FURTHER INFORMATION CONTACT:** For questions about this notice contact Dan Olson, Standards and Risk Management Division, Office of Ground Water and Drinking Water (MC-4607M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 202-564-5239; fax number: 202-564-3752; e-mail address: *olson.daniel@epa.gov*. For general information contact the EPA Safe Drinking Water Hotline at (800) 426-4791 or e-mail: *hotline-sdwa@epa.gov*. The Safe Drinking Water Hotline is open Monday through Friday, excluding legal holidays, from 9 a.m. to 5 p.m.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

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

Today's action does not impose any requirements on anyone. Instead, it notifies interested parties of EPA's final CCL 2 as well as EPA's efforts to improve the contaminant selection process for future CCLs. Contaminants on the list will be considered under the regulatory determination provision of SDWA (see section 1412(b)(1)(B)(ii)), which directs EPA to select at least five contaminants from the CCL every five years to determine if regulating the contaminants through National Primary Drinking Water Regulations would present a meaningful opportunity to reduce health risk.

**II. Background and Summary of Today's Action**

*A. What Is the Purpose of Today's Action?*

The CCL is the primary source of priority contaminants for evaluation by EPA's drinking water program. Contaminants on the CCL are currently not subject to any proposed or promulgated national primary drinking water regulation, but are known or anticipated to occur in public water systems, and may require regulation

under SDWA. The EPA conducts research on health effects, analytical methods, contaminant occurrence, treatment technologies, and treatment effectiveness for priority drinking water contaminants on the CCL. The Agency also develops drinking water guidance and health advisories, and makes regulatory determinations for priority contaminants on the CCL.

Today's action informs interested parties of EPA's final CCL 2 as well as EPA's efforts to improve the contaminant selection process for future CCLs.

*B. The Background of the CCL*

The SDWA is the core statute protecting drinking water at the Federal level. Under SDWA, EPA sets public health goals and enforceable standards for drinking water quality. In 1996, Congress amended SDWA to emphasize sound science and risk-based priority-setting. Congress also changed the way drinking water regulatory priorities are set by establishing the CCL requirements. The 1996 SDWA amendments require EPA to (1) publish every five years a list of currently unregulated contaminants in drinking water that may pose risks (the CCL), and (2) make determinations on whether or not to regulate at least five of these contaminants on a five year cycle, or three and a half years after each CCL is published (SDWA section (b)(1)).

Today's action is being published pursuant to the requirements in section 1412(b)(1). The contaminants included are not subject to any proposed or promulgated national primary drinking water regulation, are known or anticipated to occur in public water systems, and may require regulation under the SDWA. A draft CCL 2 was published in the April 2, 2004 edition of the **Federal Register** (69 FR 17406) to announce EPA's preliminary decision to carry forward the remaining 51 contaminants on the 1998 CCL as the CCL 2, to provide information on EPA's efforts to expand and strengthen the underlying CCL listing process to be used for future CCL listings, and to seek comment on the draft list as well as EPA's efforts to improve the contaminant selection process for future CCLs.

Today's action establishes the final CCL 2 which includes 42 chemicals or chemical groups and nine microbiological contaminants. This list continues to be an important tool under the SDWA to help prioritize research and serves as the central focus of the regulatory determination process noted previously. It is important to note, however, that under the SDWA, the EPA

may also make regulatory determinations for any unregulated contaminant not on today's CCL (see SDWA section 1412(b)(1)(B)(ii)(III)). Thus, the Agency has the authority to act as necessary to protect public health as new information becomes available.

**III. Drinking Water Contaminant Candidate List 2**

Table III-1 lists the contaminants on the final CCL 2. These contaminants are identified by name and, where available, the Chemical Abstracts Service Registry Number (CASRN). The final CCL 2 consists of nine microbiological contaminants and 42 chemical contaminants or contaminant groups.

**TABLE III-1.—FINAL DRINKING WATER CONTAMINANT CANDIDATE LIST 2**

Microbiological contaminant candidates	
Adenoviruses	Aeromonas hydrophila
Caliciviruses	Coxsackieviruses
Cyanobacteria (blue-green algae), other	freshwater algae, and their toxins
Echoviruses	Helicobacter pylori
Mycosporidia (Enterocytozoon and Septata)	Mycobacterium avium intracellulare (MAC)
Chemical contaminant candidates	
CASRN	
1,1,2,2-tetrachloroethane.	79-34-5
1,2,4-trimethylbenzene.	95-63-6
1,1-dichloroethane ...	75-34-3
1,1-dichloropropene ..	563-58-6
1,2-diphenylhydrazine ..	122-66-7
1,3-dichloropropane ..	142-28-9
1,3-dichloropropene ..	542-75-6
2,4,6-trichlorophenol	88-06-2
2,2-dichloropropane ..	594-20-7
2,4-dichlorophenol .....	120-83-2
2,4-dinitrophenol .....	51-28-5
2,4-dinitrotoluene .....	121-14-2
2,6-dinitrotoluene .....	606-20-2
2-methyl-Phenol (o-cresol).	95-48-7
Acetochlor .....	34256-82-1
Alachlor ESA & other acetanilide pesticide degradation products.	N/A
Aluminum .....	7429-90-5
Boron .....	7440-42-8
Bromobenzene .....	108-86-1
DCPA mono-acid degradate.	887-54-7
DCPA di-acid degradate.	2136-79-0
DDE .....	72-55-9
Diazinon .....	333-41-5
Disulfoton .....	298-04-4
Diuron .....	330-54-1
EPTC (s-ethyl-dipropylthiocarbamate).	759-14-4

Fonofos .....	944-22-9
p-Isopropyltoluene (p-cymene) .....	99-87-6
Linuron .....	330-55-2
Methyl bromide .....	74-83-9
Methyl-t-butyl ether (MTBE) .....	1634-04-4
Metolachlor .....	51218-45-2
Molinate .....	2212-67-1
Nitrobenzene .....	98-95-3
Organotins .....	N/A
Perchlorate .....	14797-73-0
Prometon .....	1610-18-0
RDX .....	121-82-4
Terbacil .....	5902-51-2
Terbufos .....	13071-79-9
Triazines and degradation products of triazines .....	including, but not limited to Cyanazine 21725-46-2 and atrazine-desethyl 6190-65-4
Vanadium .....	7440-62-2

#### IV. Summary of Comments

The comment period on the April 2, 2004, **Federal Register** notice, "Drinking Water Contaminant Candidate List 2; Notice" (69 FR 17406) ended on June 1, 2004. EPA received a total of seven comments that focused on EPA's draft CCL 2 and EPA's efforts to improve the contaminant selection process for future CCLs. EPA received two comments from associations representing water utilities, one comment from a State-related association, one comment from a water utility, one comment from a State agency, one comment from an individual, and one anonymous comment. A summary of these comments and EPA's response to these comments follow. A complete copy of the public comments and the Agency's responses are included in the Docket for today's action and can be obtained at <http://www.epa.gov/edocket/>.

The majority of comments were supportive of the CCL process. The comments on development of the draft CCL 2 focused on two key topic areas: (1) Reassembling the CCL taking new available information into account; suggestions on information that should be considered, and contaminants that should be included or deleted from the CCL; and (2) requests for information on the status of CCL-related research. Comments on the development of future CCLs focused on four key topic areas: (1) Expert judgement and transparency, (2) the role of data quality, (3) a simplified approach with adaptive management for future CCLs, and (4) the role of virulence factor activity relationships (VFARs). The remainder of this section discusses these key areas in turn.

#### A. Developing the draft CCL 2

1. Suggestions on new information and contaminants that should be included or deleted from the CCL.

*Comment Summary:* Two commenters believe that EPA should create a new CCL taking new available information into account. One commenter recommended that EPA not carry forward five chemicals (1,1,2,2-tetrachloroethane, 1,1-dichloropropene, 1,3-dichloropropane, 1,3-dichloropropene, and 2,2, dichloropropane) currently on CCL 1 to CCL 2, two commenters recommended that N-nitrosodimethylamine (NDMA) should be added to the CCL, and one commenter recommended that enterotoxigenic *Escherichia coli* (*E. coli*) be included on the final CCL 2.

*Agency Response:* In response to commenters who recommended that EPA create a new CCL to take new available information into account, and the suggestion that EPA remove five chemicals (1,1,2,2-tetrachloroethane, 1,1-dichloropropene, 1,3-dichloropropane, 1,3-dichloropropene, and 2,2, dichloropropane) from the CCL, EPA does not believe that it is appropriate to create a new CCL, or remove any contaminants from the CCL, at this time. Where there is adequate information about a particular contaminant, EPA plans to make a regulatory determination which will either remove that contaminant from the CCL or start a national rule making process to set a national primary drinking water regulation. With regard to future CCLs, EPA is developing an expanded comprehensive system for evaluating a wider range of existing information, identifying new data, and applying revised screening criteria to generate the CCL 3 in response to extensive recommendations from the National Academy of Sciences National Research Council (NRC) and National Drinking Water Advisory Council (NDWAC).

With specific regard to NDMA, there is already a substantive body of health effects research that the Agency has relied upon to classify it as a "probable human carcinogen" (USEPA, 1993). The key information gap for this contaminant relates to occurrence in public water system distribution systems. Some initial research has been conducted in this area and the Agency plans to collect more comprehensive occurrence information as part of the upcoming national survey of key unregulated contaminants under section 1445(a)(2).

Regarding enterotoxigenic *E. coli*, EPA will be considering this microbe as part

of the revised and expanded CCL 3 review process. The Agency believes that this will be a more appropriate and effective approach for evaluating this bacteria in comparison to a wide range of other microbes that will be considered under the broader analytical approach recommended by the NRC and NDWAC.

2. Provide the status of CCL-related research, data collection, and pending initiatives that have been undertaken since CCL 1.

*Comment Summary:* Commenters identified several CCL-related research activities that have been undertaken since CCL 1 and requested that EPA provide the status of CCL-related research, data collection, and pending initiatives that have been undertaken since CCL 1.

Two commenters also requested information about the Agency's progress to date and the intended future path for integrating the 35 deferred pesticides and 21 contaminants (suspected of having adverse effects on endocrine function) into the CCL process.

*Agency Response:* EPA agrees that the status of CCL-related research should be publically available. The Agency has taken a number of steps to provide this information through its Web sites and in documents it has published.

EPA Web sites addressing CCL-related research information include the following:

- EPA's Office of Ground Water and Drinking Water Drinking Water Research Information Network (DRINK), found at <http://www.epa.gov/safewater/drink/intro.html>, is a publicly accessible, Web based system that tracks over 1,000 ongoing research projects conducted by EPA and other research partners from national, regional, and international research agencies and organizations. The DRINK system stores, manages, and delivers descriptive summary data on drinking water-related projects, including abstracts, status of projects, uniform resource locators to datasets and reports, and contact information on projects.

- EPA's Office of Ground Water and Drinking Water Web site at <http://www.epa.gov/safewater/ccl/cclfs.html> has information on the NDWAC (e.g., reports, meeting announcements, and meeting summaries which includes meetings of the NDWAC CCL Work Group), monitoring of unregulated contaminants from public water systems, the National Contaminant Occurrence Database, analytical methods for compliance monitoring, and treatment technologies.

- EPA's Office of Research and Development (ORD) environmental

information management system Web site at <http://www.epa.gov/eims/> maintains information on EPA research projects, including project title, abstract, start and end dates, principal investigator, funding, results and publications, and related technical documents.

- EPA's Office of Science and Technology Web site at <http://www.epa.gov/waterscience/humanhealth/> has information on EPA's drinking water standards, health and consumer advisories, criteria documents, and related technical documents.

A key document addressing CCL-related research and information is EPA's Draft Multi-Year Plan (MYP) for the drinking water research program. The Draft MYP describes the Agency's drinking water research program activities and plans for fiscal years 2003—2010 (see <http://www.epa.gov/osp/myp/dw.pdf>). As a tool for planning and communication, the MYP provides: (1) A context for annual planning decisions and a basis for describing the impacts of these decisions; (2) a framework for integrating research on common issues across the EPA's ORD laboratories and centers, as well as across the various Agency Goals established under the Government Performance and Results Act; and (3) a resource for communicating research plans and products within ORD and with EPA programs, the regions and interested parties outside of EPA. MYPs are updated on a biennial basis to provide opportunities for making the necessary adjustments to the research program.

As discussed in the draft CCL 2 notice (69 FR 17406), EPA plans to consider the deferred pesticides in the context of an improved approach for selecting contaminants for future CCLs (CCL 3). This will enable the Agency to consider these contaminants in a consistent, reproducible manner with a wide range of other contaminants. In this regard, it is important to note that EPA may conduct research, and make regulatory determinations for any unregulated contaminant not on today's CCL (see SDWA section 1412(b)(1)(B)(ii)(III)). Thus, the Agency has the authority to act as necessary to protect public health as new information becomes available.

As with pesticides, EPA believes that suspected endocrine disruptors should be considered when the next CCL is developed. This enables the Agency to use a more refined and improved approach in evaluating these contaminants. As previously stated, EPA is not restricted to the

contaminants on this CCL for making regulatory determinations.

#### B. Developing a Process for Future CCLs

There were four key issues identified by commenters on developing a process for future CCLs. They are:

1. Expert judgement and transparency
2. The Role of Data Quality.
3. Simplified approach with adaptive management applied for future CCLs.
4. The role of virulence factor activity relationships.

Each of these issues is discussed in turn below.

##### 1. Expert Judgement and Transparency

*Comment Summary:* Two commenters stated that there is a need for the CCL process to be a transparent process. The commenters stated that they view the transparency of the CCL process as being critical to its success so that both the regulated community and the public can understand it. One commenter also recommended that the Agency combine expert judgement and classification algorithms (a formula or set of steps for solving a particular problem) in developing the CCL. Classification algorithms or automated processes should serve as mechanisms for screening down the number of contaminants that the experts must then evaluate in greater depth.

Both commenters believe that the use of expert judgement can be transparent and is an essential component to any future CCL process. They urged EPA to clearly define the role of expert judgement including the specific parts of the listing process where it would be used.

One commenter also suggested that the CCL process should be an ongoing process within the Office of Water and that the Agency should actively monitor appropriate peer-reviewed literature for new contaminants, new methods, and new health effects data. In addition, the Agency should also increase its involvement in ongoing symposia, professional meetings, and workshops on topics relevant to the CCL.

*Agency's Response:* The Agency agrees with the commenters that transparency and use of expert judgement should be important components of the CCL process. These recommendations were included in both the NRC report (NRC, 2001) and in the NDWAC Report on the CCL Classification Process to the U.S. Environmental Protection Agency (NDWAC, 2004). The Agency received the NDWAC report in May of 2004 and is currently evaluating the recommendations.

The NRC and NDWAC reports recommend that the EPA conduct the CCL process so that interested stakeholders have an opportunity to participate at key steps in developing the CCL. Additionally the reports recommend greater use of expert judgment and critical review of the CCL classification process. While the reports did not provide specific advice on how to accomplish these recommendations they did identify key milestones, such as selecting sources of data and developing criteria to select contaminants. Structuring the process around such milestones should enhance transparency and facilitate expert review.

The Agency continues to evaluate the NDWAC recommendation on how to include expert judgment and conduct the CCL process in a transparent manner and will consider these comments as future CCLs are developed.

##### 2. The Role of Data Quality

*Comment Summary:* Two commenters stressed the importance of data quality in the CCL process. Both commenters support the use of high quality data and sound science in the CCL process.

The commenters expressed some concern about the current quality of data used for the CCL process. The commenters suggested that EPA should focus on using high quality data that are appropriate to support valid characterization of a contaminant and that EPA maintains a focus on data quality at each stage of the CCL process.

One commenter expressed an interest in participating in the ongoing development and application of a viable data quality assurance system that would support the data objectives for each step in the CCL process.

*Agency's Response:* The NDWAC recommendations also discussed the nature and type of data and information used in the CCL process. In discussing information quality considerations, the Council noted that data and information on contaminants considered in the CCL process will consist of different types of data and that some contaminants will not be robustly characterized. The report also recommends that while the Agency should be explicit about how it selects data for the CCL process, the process must have some flexibility to adequately consider emerging contaminants. As the Agency develops the CCL process and evaluates the NDWAC recommendations, it will consider the commenters' recommendations as well as the SDWA data quality requirements.

### 3. Simplified Approach

*Comment Summary:* One commenter expressed concern over the NAS and NDWAC recommendations, characterizing them as “a theoretical and esoteric process and not a pragmatic process.” The commenter believes that there is a need for the Agency to develop a simpler, more streamlined approach that uses only the attributes of occurrence and health effects and that potentially eliminates some of the major complications associated with the NRC three-step, five-attribute CCL process, thereby making the process more effective in the near term. The NRC approach can serve as a useful guide for the Agency’s long-term CCL development effort; however, the details and logistics of the approach require additional work.

One commenter was concerned about the resources and time needed to develop the CCL using a new approach. The commenter suggested that convening a series of workshops with external experts would be an efficient way of addressing issues related to data quality, contaminant attributes, training sets, process performance, and protocols for classification algorithms.

*Agency’s Response:* The NDWAC report provides a series of recommendations for the Agency to consider as it develops the CCL process. The NDWAC report also noted that the NRC three-step approach using five attributes has merit, but identified practical limitations or difficulties the Agency would need to address. For example, the NDWAC report recommends that the Agency should consider classification approaches but “should use another approach for selecting contaminants for the near term (*i.e.*, for CCL 3) if there are difficulties that cannot be overcome.” The NDWAC report also identifies issues that the Agency should consider in the NRC’s recommendation on classification approaches and emphasizes that the Agency should consider practical constraints. The NDWAC report specifically recommended that the screening step be as simple as possible, which would require fewer resources and less time while adequately identifying those contaminants of greatest significance. The report further encouraged the Agency to consider whether fewer than the five attributes used in the NRC example of a classification approach are adequate for a new CCL process. The NDWAC report recognizes that the Agency will learn more about the CCL process in each iterative step and recommended an adaptive management approach to

develop the CCL process. As the Agency evaluates the NDWAC recommendations, it will consider the need for a pragmatic approach using available resources for development of the next CCL and the most efficient ways to incorporate expert involvement in the CCL process.

### 4. The Role of Virulence Factor Activity Relationship.

*Comment Summary:* A variety of comments were received on the proposed role of genomic data and the VFAR concept for the CCL process. Most of the commenters acknowledged that VFAR appears to be a powerful and useful tool that shows great promise for future CCL development, but felt that the Agency had not made clear how it proposes to use VFAR technology.

The commenters suggested that the Agency is placing too much emphasis on VFAR. One commenter stated that the Agency appears to be relying too heavily on an advanced genomic technology. The commenter expressed concerns that the technology’s applications to environmental samples are unproven and recommended that it not be used in the next CCL process.

One commenter suggested that there are many unknown variables associated with the VFAR concept and it should therefore be treated with extreme caution. Two commenters are concerned that VFAR may not offer practical solutions to immediate concerns regarding waterborne disease and would require a multi-year commitment and collaboration by EPA and other participating organizations before it would be useful.

*Agency Response:* The NRC (NRC, 2001) recommendations provided a detailed discussion of the potential and proposed role of VFARs in the CCL process. The VFAR principle can be described as comparing the gene structure of newly identified waterborne pathogens to pathogens with known genetic structures that have been associated with human disease.

Virulence factors are defined broadly by the NRC as the ability of a pathogen to persist in the environment, gain entry into a host (*e.g.*, humans), reproduce, and cause disease or other health problems either because of its architecture or because of its biochemical compounds. A number of virulence factors are known, including the ability of a microbe to move within a host under its own power, the ability of mechanisms to protect the microbe against the body’s defenses (*e.g.*, anti-phagocytosis mechanisms), the ability of a microbe to adhere or attach to the surface of a host cell, and the ability of

microbes to produce toxins that injure host cells. The NDWAC was specifically charged to provide an evaluation of the VFAR approach and to identify studies that explore the feasibility of the approach. While the Agency recognizes VFAR as a potential tool for future CCLs, EPA is not planning to solely rely on the approach in the near term for CCLs. In its deliberation, the NDWAC conducted several explorations and literature reviews on the nature and type of genomic data available to characterize genes that may be associated with virulence factors and an organism’s potential to cause harm. The reviews and analyses showed that the technology, although powerful, still has serious limitations for near term CCLs. The NDWAC provided a series of pragmatic recommendations for considering pathogens for near term CCLs and several recommendations for improving this process as genomic technology and reporting improve. As the Agency develops the CCL process for microbes it will take these comments under consideration.

## V. Developing Future CCLs—NDWAC Recommendations and Next Steps

### A. NDWAC Recommendations

In the **Federal Register** notice of April 2, 2004 (69 FR 17406), EPA discussed the activities of the NRC and the NDWAC related to the CCL. The EPA sought the advice of the NRC in response to comments received during the development of the 1998 CCL, which advocated a broader, more comprehensive approach for selecting contaminants.

The Agency asked the NRC to address three key topics related to drinking water contaminant selection and prioritization:

1. What approach should be used to develop future CCLs?

2. How best should EPA assess emerging drinking water contaminants and related databases to support future CCL efforts?

3. What approach should EPA use to set priorities for contaminants on the CCL?

The NRC’s findings and recommendations on these topics were published in three reports: Setting Priorities for Drinking Water Contaminants (NRC, 1999a), Identifying Future Drinking Water Contaminants (NRC, 1999b), and Classifying Drinking Water Contaminants for Regulatory Consideration (NRC, 2001).

The NRC recommendations provided a framework for evaluating a larger number of contaminants and making decisions about contaminants for which

data are limited through the use of innovative technologies and expert advice. The EPA requested the assistance of NDWAC to evaluate and provide advice on implementing the NRC's recommended classification process.

The NDWAC formed the CCL Classification Process Work Group (the Work Group) and charged it with reviewing the NRC 2001 report. The Work Group was asked to advise the NDWAC on development and application of the classification approach suggested by the NRC, including evaluating proposed and alternative methodologies. The Work Group met 10 times from September of 2002 to March of 2004. All Work Group meetings were open to the public and announced in the **Federal Register**. In conducting its review, the Work Group considered the large and growing number of agents that might become candidates for scrutiny in the CCL process, and the rapid expansion of information on these agents. Based on this review, the Work Group provided the following recommendations:

1. There is merit in the three-step selection process proposed by NRC for classifying chemical and microbial contaminants. The NDWAC believes the three-step process should involve identification of the CCL universe, screening the universe to a preliminary CCL, and selecting the CCL from the Preliminary CCL.

2. The NDWAC recommends that the Agency should move forward with the NRC recommendation to develop and evaluate some form of prototype classification approach. (A prototype classification uses computer-based computational tools to weigh selected contaminant characteristics against the characteristics of various classes of drinking water contaminants whose occurrence and health effects are relatively well understood.)

3. The NDWAC believes that expert judgment plays an important role throughout the three-step selection process, particularly in reviewing the prototype model and the output of the new classification approach.

4. The NDWAC recommended enhancing the surveillance for emerging chemical and microbial contaminants and also soliciting information from the public via a nomination process to assure a full consideration of potential contaminants.

The NDWAC also identified a number of practical limitations or difficulties in developing and applying the recommended approach and provided advice on how these might be addressed.

The NDWAC presented the final report to the Administrator on May 19, 2004. The report, entitled National Drinking Water Advisory Council Report on the CCL Classification Process to the U.S. Environmental Protection Agency provides a detailed summary of the questions considered by the NDWAC, the analyses conducted to explore the questions, key points discussed, and the NDWAC's recommendations and rationale for the recommendations. The report is available at <http://www.epa.gov/safewater/ndwac/council.html>.

#### *B. Next Steps*

The Agency is working to evaluate the NDWAC recommendations and to meet the statutory deadline to issue the next CCL. The NDWAC recommendations encourage the Agency to consider the practical limitations identified in their report and to use an adaptive management approach to develop CCLs. This adaptive management approach will enable the Agency to identify which recommendations can be implemented for the next CCL while learning from and improving upon each successive listing process and at the same time protecting public health. In its development of a new CCL process, the Agency will focus on several areas in the near future and continue to seek input and advice from experts and interested stakeholders. Some of the key areas to be explored in developing the new CCL process are discussed below.

The NDWAC recommended that microbial and chemical contaminants be evaluated by parallel processes that meet in the formation of a single CCL. The Agency is developing parallel processes for microbial and chemical contaminants that take into account the systematic differences in how these contaminants are characterized and take the best advantage of the information available for microbial and chemical contaminants.

The Agency is also considering approaches and opportunities to seek out and incorporate input from experts and interested stakeholders as the CCL process is developed. EPA held a public meeting on September 15, 2004, to provide an update on its efforts to improve upon the CCL process. The Agency is also consulting with interested stakeholders on how to increase expert involvement in the process and on opportunities to gather information on new and emerging contaminants through professional conferences, focused workshops, and coordination with other Federal and State agencies. The Agency will provide additional opportunities for the

exchange of information with the public before the next CCL is proposed in the **Federal Register**.

The Agency is evaluating data sources that characterize a contaminant's potential to occur in drinking water and produce adverse health effect. The evaluation will consider the NRC and NDWAC recommendations as well as SDWA requirements in selecting information and data to consider for the next CCL. This evaluation will identify the best available data that for use in the CCL process and result in a process to compile information for a significantly larger group of chemical and microbial contaminants than initially considered for CCL 1.

The Agency anticipates conducting analyses to identify specific criteria related to occurrence and health effects associated with contaminants that could be used to select contaminants for the CCL. The Agency is evaluating the NDWAC recommendation to develop a series of screening criteria that would identify contaminants for additional scrutiny and prioritization. The NDWAC recommendations provide insight on the occurrence and health effects data that the Agency could use to identify a smaller set of contaminants for additional evaluation but does not recommend specific levels or criteria to implement the screening process.

The NDWAC also recommended that the Agency explore the use of classification approaches to identify contaminants for consideration for the CCL. The Agency is evaluating the requirements for a classification approach for the next CCL and anticipates seeking additional advice from experts and stakeholders. EPA will need to evaluate various classification approaches, consider the range of potential performance indicators, conduct calibration and validation analyses, and engage experts in the evaluation of the selected approach(es) and associated validation results.

As a new CCL process is developed and implemented for the next list, the Agency will provide updates and information on the process. The CCL process is a critical input to shaping the future direction of the drinking water program. The Agency anticipates that improvements to the process will result in a more comprehensive approach to developing the CCL.

#### **VI. References**

**Federal Register**, Vol. 63, No. 40.

Announcement of the Drinking Water Contaminant Candidate List; Notice. March 2, 1998. 10273. (63 FR 10273).

**Federal Register**, Vol. 69, No. 64. Drinking Water Contaminant Candidate List 2;

Notice. April 2, 2004. 17406. (69 FR 17406).

National Drinking Water Advisory Council (NDWAC). 2004. National Drinking Water Advisory Council Report on the CCL Classification Process to the U.S. Environmental Protection Agency. Available at <http://www.epa.gov/safewater/ndwac/council.html>.

National Research Council (NRC). 1999a. Setting Priorities for Drinking Water Contaminants. National Academy Press, Washington, DC <http://www.nap.edu/catalog/6294.html>.

National Research Council (NRC). 1999b. Identifying Future Drinking Water Contaminants. National Academy Press, Washington, DC <http://www.nap.edu/catalog/9595.html>.

NRC. 2001. Classifying Drinking Water Contaminants for Regulatory Considerations. National Academy Press, Washington, DC <http://books.nap.edu/books/0309074088/html/index.html>.

USEPA. 1993. N-nitrosodimethylamine; CASRN 62-75-9, Integrated Risk Information Service (IRIS). Carcinogenicity assessment last updated July 1, 1993.

Dated: February 17, 2005.

**Benjamin H. Grumbles,**

*Assistant Administrator, Office of Water.*

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BILLING CODE 6560-50-P

## FEDERAL COMMUNICATIONS COMMISSION

### Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission

February 15, 2005.

**SUMMARY:** The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act (PRA) of 1995, Public Law 104-13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimate; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to

minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology.

**DATES:** Written Paperwork Reduction Act (PRA) comments should be submitted on or before March 28, 2005. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

**ADDRESSES:** Direct all Paperwork Reduction Act (PRA) comments to Judith B. Herman, Federal Communications Commission, Room 1-C804, 445 12th Street, SW., Washington, DC 20554 or via the Internet to [Judith-B.Herman@fcc.gov](mailto:Judith-B.Herman@fcc.gov).

**FOR FURTHER INFORMATION CONTACT:** For additional information or copies of the information collection(s), contact Judith B. Herman at 202-418-0214 or via the Internet at [Judith-B.Herman@fcc.gov](mailto:Judith-B.Herman@fcc.gov).

**SUPPLEMENTARY INFORMATION:**

*OMB Control No.:* 3060-0823.

*Title:* Pay Telephone Reclassification, Memorandum Opinion and Order, CC Docket No. 96-128.

*Form No.:* N/A.

*Type of Review:* Extension of a currently approved collection.

*Respondents:* Business or other for-profit.

*Number of Respondents:* 400.

*Estimated Time Per Response:* 2-35 hours.

*Frequency of Response:*

Recordkeeping requirement, third party disclosure requirement, and on occasion, monthly, and quarterly reporting requirements.

*Total Annual Burden:* 44,700 hours.

*Total Annual Cost:* \$480,000.

*Privacy Act Impact Assessment:* No.

*Needs and Uses:* The Commission is seeking extension (no change in requirements) for this information collection. The Commission is submitting this information collection to the OMB in order to obtain the full three-year clearance from them. For background, the Commission adopted and released a Memorandum Opinion and Order in March 1998, which clarified the requirements established in the Payphones Orders for the provision of payphone-specific coding digits and for tariffs that local exchange carriers (LECs) must file pursuant to the Payphone Orders. The Commission also granted a waiver of Part 69 of the Commission's rules so that LECs can establish rate elements to recover the costs of implementing FLEX-ANI (a type of switch software) to provide

payphone specific coding digits for per-call compensation. The Commission is required in the Payphone Orders to implement section 276 of the Act.

*OMB Control No.:* 3060-0986.

*Title:* Competitive Carrier Line Count Report.

*Form No.:* FCC Form 525.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Business or other for-profit.

*Number of Respondents:* 1,300 respondents; 4,753 responses.

*Estimated Time Per Response:* .5-6 hours.

*Frequency of Response:* On occasion, quarterly and annual reporting requirements and third party disclosure requirement.

*Total Annual Burden:* 3,707 hours.

*Total Annual Cost:* N/A.

*Privacy Act Impact Assessment:* N/A.

*Needs and Uses:* The Commission has revised this information collection. The information collection has been revised as a result of: (1) Certain collections associated with the election of a disaggregation path were one-time in nature and have been eliminated and removed from this burden estimate; and (2) the Commission has created a new FCC Form 525 to collect line count data required by Competitive Eligible Telecommunications Carriers (CETCs) pursuant to this and other OMB control numbers, as well as line count data related to lines provided by CETCs using unbundled network elements (UNEs). The UNE data are necessary for Universal Service Administrative Company (USAC) to implement section 54.307 of the Commission's rules. It is anticipated that the implementation of FCC Form 525 will reduce burdens in several collections by standardizing the information submission format. As collections 3060-0972, 3060-0774 and 3060-0942 are renewed, the information provided in FCC Form 525 will be eliminated from the burden estimates for these collections. The Commission will use the information requirements to determine whether and to what extent rural telecommunications carriers providing the data are eligible to receive universal service support.

*OMB Control No.:* 3060-0298.

*Title:* Competitive Carrier Line Count Report.

*Form No.:* FCC Form 525.

*Type of Review:* Revision of a currently approved collection.

*Respondents:* Business or other for-profit.

*Number of Respondents:* 1,300 respondents; 4,753 responses.

*Estimated Time Per Response:* 57 hours.