Forest, Lincoln Ranger District, Lewis and Clark County, MT, Comment Period Ends: May 17, 2004, Contact: Dan Seaforth (406) 362–4265.

EIS No. 040137, Draft EIS, AFS, OR

Diamond Lake Restoration Project, Improve Water Quality and the Recreational Fishery, Umpqua National Forest, Diamond Lake Ranger District, Umpqua River Basin, Douglas County, OR, Comment Period Ends: May 17, 2004, Contact: Sherrie Chambers (541) 496–3532. This document is available on the Internet at: *http://www.fs.fed.us/r6/umpqua.*

EIS No. 040138, Final EIS, FHW, AR, MS, I–69

Mississippi River Crossing, Construction from a western terminus at US 65 near McGehee, AR, to an eastern terminus at State Highway 1 near Benoit, MS, US Coast Guard Bridge Permit, US Army Corps Section 10 and 404 Permits, NPDES Permit, Desha County, AR and Bolivar County, MS, Wait Period Ends: May 3, 2004, Contact: Randal Looney (501) 324–6430.

EIS No. 030139, Draft EIS, FHW, WI

Wisconsin Highway Project, Enhance the Mobility of Motorized and Nonmotorized Travel, US 18/151 (Verona Road) and the US 12/14 (Beltine) Corridors, Dane County, WI, Comment Period Ends: May 17, 2004, Contact: Johnny M. Gerbitz (608) 829–7500.

EIS No. 040140, Draft EIS, DOI, UT

Utah Lake Drainage Basin Water Delivery System (ULS), Construction and Operation, Bonneville Unit of the Central Utah Project (CUP), Utah, Salt Lake, Wasatch and Juab Counties, UT, Comment Period Ends: June 11, 2004, Contact: Reed Murray (801) 379–1237.

EIS No. 040141, Draft EIS, AFS, ID

Clearwater National Forest, Proposes to Approve Plans-of-Operation for Small-Scale Suction Dredging in Lolo Creek and Moose Creek, Clearwater National Forest, North Fork Ranger District, Clearwater and Idaho Counties, ID, Comment Period Ends: May 17, 2004, Contact: Vern Bretz (208) 476–4541.

EIS No. 040142, Final EIS, NPS, WI

Apostle Islands National Lakeshore Wilderness Study, Wilderness Designation or Nondesignation, Ashland and Bayfield Counties, WI, Wait Period Ends: May 4, 2004, Contact: Robert Krumenaker (715) 779–3397.

EIS No. 040143, Draft EIS, NPS, OH

Fallen Timbers Battlefield and Fort Miamis National Historic Site, General Management Plan, Implementation, Lucas County, OH, Comment Period Ends: June 1, 2004, Contact: James Speck (419) 535–3050.

EIS No. 040144, Draft EIS, AFS, NV

Martin Basin Rangeland Project, Authorize Continued Livestock Grazing in Eight Allotments: Martin Basin, Indian, West Side Flat Creek, Buffalo, Bradshaw, Buttermilk, Granite Peak and Rebel Creek Cattle and Horse Allotments, Humboldt-Toiyable National Forest, Santa Rosa Ranger District, Humboldt County, NV, Comment Period Ends: May 17, 2004, Contact: Steve Williams Ext 112 (775) 623–5025.

EIS No. 040145, Draft EIS, AFS, MT

Grasshopper Fuels Management Project, Modify Vegetation Conditions, Reduce Fuel Loads and Break up Fuel Continuity, Beaverhead-Deerlodge National Forest, Dillon Ranger District, Beaverhead County, MT, Comment Period Ends: May 17, 2004, Contact: Great Clark (406) 683–3935.

EIS No. 040146, Draft EIS, NPS, WI

Arrowhead-Weston Transmission Line Right-of-Way Crossing of the St. Croix National Scenic Riverway, US Army COE Section 10 and 404 Permits, Washburn County, WI, Comment Period Ends: May 17, 2004, Contact: Jill Medland (715) 483–3284.

EIS No. 040147, Draft Supplement, AFS, OR

Rimrock Ecosystem Restoration Projects, New Information on the Commercial and Non-commercial Thinning Treatments in the C3 Management Area, Umatilla National Forest, Heppner Ranger District, Grant, Morrow and Wheeler Counties, OR, Comment Period Ends: May 17, 2004, Contact: David Centrex (541) 676–9187. This document is available on the Internet. at: *http://www.fs.fed/us/r6/uma/projects/readroom/.*

EIS No. 040148, Final EIS, FTA, CA

Transbay Terminal/Caltrain Development Downtown Extension/Redevelopment Project, New Multi-Modal Terminal Construction, Peninsula Corridor Service Extension and Establishment of a Redevelopment Plan, Funding, San Francisco, San Mateo and Santa Clara Counties, CA, Wait Period Ends: May 3, 2004, Contact: Jerome Wiggins (415) 744–3115.

Amended Notices

EIS No. 040027, Draft EIS, IBR, NB, CO, WY

Programmatic ES—Platte River Recovery Implementation Program, Assessing Alternatives, Cooperative, Endangered Species Recovery Program, The Four Target Species are Whooping Crane, Interior Least Tern, Piping Plover and Pallid Sturgeon, NB, WY and CO, Comment Period Ends: June 2, 2004, Contact: Curt Brown (303) 445–2096. Revision of FR Notice Published on 1/30/2004: CEQ Comment Period Ending 4/2/2004 has been Extended to 6/2/2004.

Dated: March 30, 2004.

Ken Mittlelholtz,

Environmental Protection Specialist, Office of Federal Activities.

[FR Doc. 04–7482 Filed 4–1–04; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7641–5]

Drinking Water Contaminant Candidate List 2; 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 which, 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 which 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 (henceforth referred to as the 1998 Contaminant Candidate List or the 1998 CCL), and every five years thereafter. Today's notice announces EPA's preliminary decision to carry over the remaining 51 contaminants on the 1998 CCL as the draft CCL 2, provides information on EPA's efforts to expand and strengthen the underlying CCL listing process to be used for future CCL listings, and requests comment on CCL-related activities to improve the drinking water contaminant listing process. Today's draft CCL includes 42 chemicals or chemical groups and nine microbiological contaminants. The

Agency's approach to the draft CCL 2 is to continue using the remaining contaminants on the 1998 CCL for prioritizing research and making regulatory determinations while working with the National Drinking Water Advisory Council (NDWAC) and stakeholders to complete a review of the National Research Council (NRC) recommendations for developing a more comprehensive and transparent CCL listing process. The EPA seeks comment on the range of CCL issues and activities addressed in this notice.

DATES: The Agency requests comment on today's notice. Comments must be received or postmarked by midnight June 1, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in section I.C of the Supplementary Information section. The official public docket for this action is located at EPA West Building, Room B102, 1301 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: For questions about this notice contact Dan Olson at (202) 564–5239 or e-mail *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 5:30 p.m.

SUPPLEMENTARY INFORMATION:

I. General Information

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

Neither this draft CCL 2 nor the final CCL 2, when published, imposes any requirements on anyone. Instead, it notifies interested parties of the availability of EPA's Draft CCL 2 and seeks comment on this draft list as well as EPA's efforts to improve the contaminant selection process for future CCLs. Contaminants on the list may become the subject of future regulations. At that time, the public would be provided additional opportunities to comment as part of the rule making process.

B. How Can I Get Copies of Related Information?

1. *Docket.* EPA has established an official public docket for this action under Docket ID No. OW–2003–0028. The official public docket is a collection of materials that is available for public viewing at the Water Docket in the EPA Docket Center, (EPA/DC) EPA West, Room B102, 1301 Constitution Avenue, NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the Water Docket is (202) 566–2426. For access to docket material, please call (202) 566–2426 to schedule an appointment.

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

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket identification number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as confidential business information (CBI) and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in section I.B.1.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the Docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and To Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' The EPA is not required to consider these late comments.

1. *Electronically.* If you submit an electronic comment as prescribed below, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

a. EPA Dockets. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket,* and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in Docket ID No. OW–2003–0028. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or

other contact information unless you provide it in the body of your comment.

b. E-mail. Comments may be sent by electronic mail (e-mail) to *OW-Docket@epa.gov*, Attention Docket ID No. OW–2003–0028. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the Docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

c. Disk or CD ROM. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in section I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send an original and three copies of your comments to: Water Docket, Environmental Protection Agency, Mail Code: 4101T, 1200 Pennsylvania Ave., NW., Washington DC, 20460, Attention Docket ID number OW–2003–0028.

3. *By hand delivery or courier.* Deliver your comments to: Water Docket, Environmental Protection Agency, EPA West Building, Room B102, 1301 Constitution Avenue, NW., Washington, DC, Attention Docket ID number OW–2003–0028. Such deliveries are only accepted during the Docket's normal hours of operation as identified in section I.B.1.

D. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at your estimate.

5. Provide specific examples to illustrate your concerns.

6. Offer alternatives.

7. Make sure to submit your comments by the comment period deadline identified.

8. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

II. Background and Summary of Today's Notice

This section summarizes the purpose of today's notice and provides a brief background on the CCL requirements and prior activities related to the CCL.

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

The drinking water 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, analytical methods, treatment technologies and effectiveness, and contaminant occurrence 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 **Federal Register** notice explains why EPA is carrying over the remaining 51 contaminants on the 1998 CCL as the draft CCL 2 and provides background information on the list. Additionally, this notice describes efforts to improve on the CCL selection process, the NRC recommendations to EPA on developing future CCLs, and related issues being evaluated by EPA and NDWAC to implement the NRC recommendations. (The NDWAC provides independent advice, consultations, and recommendations to EPA on matters related to the activities, function, and policies of the Agency under the SDWA, as amended. See section V for further discussion on NDWAC.) The EPA requests comment on the draft CCL 2 and on the process for developing future CCLs.

B. The Background of the CCL

The SDWA is the core statute addressing 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, and (2) make determinations on whether or not to regulate at least five contaminants on a five year cycle, or three and a half years after each CCL (SDWA section 1412(b)(1)).

Following the 1996 SDWA Amendments, EPA sought NDWAC's recommendations on the process that should be used to identify contaminants for inclusion on the CCL. For chemical contaminants, the Agency developed screening and evaluation criteria based on recommendations from NDWAC and identified 262 potential chemical contaminants. For microbiological contaminants, NDWAC recommended that the Agency seek external expertise to identify and select potential waterborne pathogens. As a result, the Agency convened a workshop of microbiologists and public health experts, developed screening and evaluation criteria based on workshop recommendations, and evaluated an initial list of 25 potential microbiological contaminants.

The 1998 CCL process benefitted from considerable input from the scientific community and the public through stakeholder meetings and the public comments received on the draft CCL published in 1997. The EPA published the final CCL containing 50 chemical and 10 microbiological contaminants in March of 1998 (63 FR 10273). A detailed discussion of how EPA developed the 1998 CCL is presented in section III of this notice.

After publication of the final 1998 CCL, EPA began collecting occurrence data and conducting research on the CCL contaminants. Data collection efforts include assessing the occurrence of contaminants in public water systems through the Unregulated Contaminant Monitoring Regulation (64 FR 50556), as well as evaluating occurrence data from national surveys and considering State-level contaminant occurrence information. Research efforts focused on obtaining the information needed to characterize the adverse health effects of contaminants, drinking water treatment options, and the development of analytical methods to detect contaminants in drinking water.

As noted above, the 1996 SDWA also directs EPA to select at least five contaminants from the CCL every five years to determine if regulating the contaminants with a national primary drinking water regulation would present a meaningful opportunity for health risk reduction (SDWA section 1412 (b)(1)). In order to make regulatory determinations on contaminants, EPA must have sufficient data to evaluate

when and where contaminants occur, human exposure, and the risk to public health.

On July 18, 2003, EPA announced its final determinations for a subset of contaminants on the 1998 CCL (68 FR 42898), which concluded that sufficient data and information were available to make the determination that a regulation was not appropriate for the following nine contaminants: Acanthamoeba, aldrin, dieldrin, hexachlorobutadiene, manganese, metribuzin, naphthalene, sodium, and sulfate.

III. Developing Today's Draft Drinking Water Contaminant Candidate List

This section provides the approach EPA used to develop the draft CCL 2, explains the rationale to support the approach, and presents the draft CCL 2.

A. Approach and Rationale for the Draft CCL 2

The EPA's approach for the draft CCL 2 is to continue to use contaminants identified on the 1998 CCL to set drinking water research priorities and make regulatory determinations. The EPA believes that it is appropriate for the draft CCL 2 to be based on the 1998 CCL because (1) in developing the 1998 CCL, the Agency used peer-reviewed data and information to evaluate contaminants; (2) EPA relied on significant input from experts and stakeholders to develop a high quality process for selecting the contaminants on the CCL; (3) the Agency has invested in research and data collection activities related to the CCL, and is preparing to make regulatory determinations in the 2006 time-frame using the data collected from these activities; and (4) continued reliance on high priority contaminants remaining from the 1998 CCL allows the Agency to focus resources on completing ongoing work on an expanded process for classifying drinking water contaminants based on recent recommendations of the National Research Council (NRC, 2001). A more detailed discussion of this approach follows.

1. Organizing and Extracting Data

a. *Evaluating available chemical contaminant listings.* The EPA reviewed contaminants from seven well-known lists, as well as contaminants recommended by stakeholders, to develop the 1998 CCL (Table III–1). These lists contained chemicals that could be of potential concern in drinking water. In addition, EPA evaluated a number of other contaminants identified by stakeholders during the December 2–3, 1996, stakeholder meeting for potential inclusion on the CCL. In the process of creating the final list, EPA removed from consideration 23 contaminants suspected of being endocrine disruptors and 35 pesticides, because both groups of chemicals were the focus of additional data collection efforts under other programs in the Agency. The EPA intends to consider both groups of chemicals as part of the next CCL screening and evaluation process.

TABLE III.—I INITIAL CHEMICAL LISTS CONSIDERED FOR DEVELOPMENT OF THE 1998 CCL

List	Description
1991 Drinking water priority list (DWPL, EPA, 1991)	56 contaminants.
Health advisories (HAs)	108 contaminants, (included all contaminants with HAs or HAs under development).
EPA's Integrated Risk Information System database	48 contaminants, based on a risk-based screen developed by EPA for the 1994 DWPL.
Contaminants identified by public water systems	22 ''non-target'' contaminants identified by public water systems for the 1994 DWPL.
Agency for Toxic Substances and Disease Registry's list of contaminants found at Comprehensive Environmental Response, Compensation and Liability Act sites.	Top 50 contaminants from the 1995 list of 275 prioritized hazardous substances.
Stakeholder summary list	59 contaminants proposed as candidates by participants in a December 2–3, 1997 stakeholder meeting.
Toxic Release Inventory (TRI) list	51 contaminants that met the criteria for assessing the potential to occur in public water; derived from an original 1994 TRI list of 343 chemicals.

b. *Screening chemical contaminants.* In 1997, EPA developed screening criteria to evaluate the potential occurrence and health effects of chemical contaminants gathered from the lists based on the recommendation of experts in the drinking water field, including NDWAC. These screening criteria focused on the following two questions:

1. Is a given contaminant found in water at levels of health concern?

2. If no data exists on contaminant occurrence, is the contaminant likely to be found in water based on surrogates for occurrence?

An affirmative answer to either question moved the contaminant to the health effects phase of the evaluation. Contaminants met the criteria if the available data indicated occurrence in a drinking water system serving a population of 100,000 or more, occurrence in two or more States, or occurrence in 10 or more small public water systems at levels that would trigger concern for human health. If a contaminant did not have specific occurrence data, EPA assessed the potential for a contaminant to occur in drinking water based on surrogates for occurrence. Surrogates for occurrence included: TRI release estimates, production amounts from industry data, and physical-chemical properties. A contaminant was considered to have the potential to occur if, using the TRI, the release to surface water was in excess of 400,000 pounds per year and the physical-chemical properties indicated persistence and mobility of the contaminant. A contaminant was also considered to have the potential to occur if the production volume exceeded 10 billion pounds per year, and physical-chemical properties indicated persistence and mobility of the contaminant.

If a pollutant met the occurrence screening criteria, EPA then screened it for potential health effects. The health effects phase of the evaluation had one major criterion: Was there evidence, or was there suggestion, that the contaminant causes adverse human health effects? This criterion was met if a contaminant had one or more of the following elements: (1) Listed by California Proposition 65, (2) addressed by an EPA Health Advisory, (3)

considered a likely (based on animal data) or known (based on human data) carcinogen by EPA or the International Agency for Research on Cancer, (4) evaluated by more than one human epidemiological study (indicating adverse effects), (5) received an oral value in EPA's Integrated Risk Information System, (6) regulated in drinking water by another industrial country, (7) identified as a member of a chemical family of known toxicity, or (8) characterized by a structural activity relationship indicating toxicity. If a contaminant had none of these elements, then EPA did not include it in the 1998 CCL.

A contaminant that met both the occurrence screening criteria and received an affirmative response to any of the above health effects screening elements resulted in that contaminant's inclusion into the draft 1998 CCL.

c. *Selecting microbiological contaminants.* In May of 1997, at the recommendation of NDWAC, EPA convened a workshop on microbiology and public health to develop a list of pathogens for possible inclusion in the 1998 CCL (62 FR 52193). Participants included experts from academia, the drinking water industry, EPA, and other Federal agencies. The EPA prepared and distributed a list of 25 microorganisms (6 protozoa, 8 viruses, 7 bacteria, and 4 algal toxins) for initial consideration by workshop members. Microorganisms were included on this initial list if they were identified in disease outbreak data, if published literature documented the occurrence of known or suspected pathogens in water, or if other information suggested the possibility of a public health risk. The workshop participants established screening 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.

All of the microorganisms included on the initial EPA list, as well as other organisms that arose during the discussions, were evaluated against these criteria. The results of the deliberations of the microbiology workshop were adopted by NDWAC and subsequently utilized by the Agency to select 13 microbiological contaminants placed on the draft 1998 CCL.

2. Input From Stakeholders, Experts, and the Public

The EPA relied on significant input from experts and stakeholders to develop a high quality process for selecting the contaminants on the 1998 CCL. The Agency sought stakeholder input from a number of sources and at several different junctures in the CCL development process. First, EPA convened a day-long meeting of over 50 experts, including representatives from industry, academia, consultants, and other government agencies to review a draft of the strategy for developing the CCL. The EPA also convened NDWAC to review the strategy and make recommendations on the development of the CCL. Experts on the NDWAC met numerous times to discuss the CCL process and data on potential contaminants.

As mentioned in the prior section, EPA also relied on the advice of nationally recognized experts in the field of microbiology, during a separate meeting, to classify microbiological contaminants. These experts identified and selected the microbiological contaminants for initial consideration.

Additionally, EPA consulted with the Agency's Science Advisory Board which is a public advisory group that provides extramural scientific information and advice to EPA.

The draft CCL containing 58 chemical and 13 microbiological contaminants was published on October 6, 1997 (62 FR 52193). The EPA requested comment on the approach used to develop the CCL, and on whether specific contaminants should be on the list. The EPA received 71 comments from many segments of the drinking water community including trade associations, environmental groups, industries, chemical manufacturers, State and local health regulatory agencies, water utilities, and private citizens. Commenters provided data and information on specific contaminants and included suggestions on the process for future CCL development. Based on these comments, EPA removed 10 chemical and 4 microbiological contaminants, and added 2 chemical and 1 microbiological contaminant to the final list. The final 1998 CCL contained 50 chemical and 10 microbiological contaminants and was published on March 2, 1998 (63 FR 10273).

3. Research and Data Collection for Contaminants on the 1998 CCL

The EPA has made data collection and research on the CCL contaminants a priority and continues to collect information and conduct research in the areas of health effects, analytical methods, treatment, and occurrence. As noted previously, the Agency is preparing to make regulatory determinations in the 2006 time-frame using the data collected from these activities.

a. *Research on health effects, treatment, and analytical methods.* The Drinking Water Research Program's Multi-Year Plan identifies over 50 projects for contaminants on the CCL. These projects are scheduled for completion in the next two years and span three research areas: health effects, treatment, and analytical methods. The results of these activities will provide the information needed to characterize potential health impacts, assess the ability to detect selected contaminants in drinking water, and verify treatment capability and cost.

b. *Data collection on occurrence.* To assess whether the CCL contaminants are occurring in drinking water systems, EPA identified occurrence priorities and determined whether analytical methods were available to monitor for priority CCL contaminants. Because SDWA requires EPA to limit monitoring requirements to 30 contaminants in any 5-year cycle, only a subset of the CCL contaminants were monitored in the first round of data collection. Data will be available for use from the first five-year cycle of monitoring in mid-2004. The second cycle of data collection is expected to begin in 2006 and will be completed in mid-2010, after EPA proposes and promulgates a new list of contaminants for monitoring. Research is also underway to develop methods for contaminants currently without adequate analytical methods, or where the current analytical method detection limit was above the known adverse health effect level of concentration. Completion of these methods will allow EPA to make regulatory determinations in the future.

Because data from ongoing research and data collection activities will become available in the next few years, EPA believes that it is appropriate to maintain current focus on gathering this information in preparation for making regulatory determinations in 2006.

4. Development of an Improved Classification Process for Future CCLs

Continued focus on many of the priority contaminants from the 1998 CCL allows the Agency to target resources to complete its ongoing work on an expanded process for classifying drinking water contaminants, so that contaminants identified in many more sources can be effectively screened.

After the 1998 CCL was published, the Agency asked the National Research Council, the operating arm of the National Academy of Sciences, to review the 1998 CCL selection process and provide recommendations on how

the process could be improved. These recommendations were developed over several years and provided to the Agency in late 2001 (see section IV). On balance, the NRC found the 1998 CCL to be an important first step and noteworthy effort to identify and select unregulated chemical and microbiological drinking water contaminants. As with any new initiative, the NRC identified a number of opportunities to strengthen and expand the analytical process upon which the 1998 CCL was based. The NRC recommendations focused on developing a larger initial list (universe) and on identifying new approaches for screening larger numbers of potential CCL contaminants. While the NRC recommendations greatly expand the universe of contaminants and suggest a change in the manner in which contaminants are selected for the CCL, they are based on the same fundamental principles used in developing the 1998 CCL—a focus on health impacts and occurrence. The NRC approach addresses the expansion of the universe of contaminants and recommends a process that combines expert judgement with the use of computerized data sources and classification processes to screen contaminants (see section IV.C for more information). The use of automated classification processes would allow EPA to evaluate many more contaminants than experts alone can evaluate in the absence of these processes. The much broader and more complex approach recommended by the NRC may enable EPA to gather information from sources that were not used to develop the 1998 CCL, and thus strengthen the Agency's ability to identify emerging contaminants.

The EPA agrees that an approach that combines expert judgement with automated classification processes should be explored. The Agency is continuing to assess and refine the approach recommended by the NRC. The Agency believes that the CCL proposed today is sound, and should continue to be the source of contaminants for making additional regulatory determinations in the near term. This, however, should not be interpreted to mean that EPA is restricted to the contaminants on this CCL for making regulatory determinations. The EPA may add contaminants to this list and make regulatory determinations for any unregulated contaminant not on today's CCL, as necessary, to address an urgent threat to public health.

B. The Draft CCL 2

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

TABLE III–2.—DRAFT DRINKING WATER CCL 2

Microbiological contaminant candidates
Adenoviruses
Aeromonas hydrophila
Caliciviruses
Coxsackieviruses
Cyanobacteria (blue-green algae), other freshwater algae, and their toxins
Echoviruses
Helicobacter pylori
Microsporidia (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)	759–94–4
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 [1].	
Vanadium	7440–62–2

[1] Including, but not limited to Cyanazine 21725–46–2 and atrazine-desethyl 6190–65–4.

IV. The National Research Council's Recommended Approach for Developing Future CCLs

This section summarizes the NRC recommendations to EPA for developing future CCLs and discusses other issues related to contaminant selection and prioritization.

The EPA sought the advice of the NRC in response to comments received during the development of the 1998 CCL, which indicated a need for a broader, more systematic 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 the following three NRC 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 discussion in today's notice focuses on the 2001 report, which synthesizes key findings from the prior reports.

In its report entitled Classifying Drinking Water Contaminants for Regulatory Consideration, the NRC recommended that EPA use a two-step process for generating future CCLs. The first step in the process is to select contaminants from a broad universe of chemical, microbiological, and other types of potential drinking water contaminants for inclusion on a preliminary CCL (PCCL), based on a screening assessment of human health impacts, occurrence data, and expert judgement (NRC, 2001). The second step in the process is to use a classification algorithm (a formula or set of steps for solving a particular problem), in conjunction with expert judgement, to select from the PCCL contaminants to be included on the CCL. The NRC believes that this process of selecting

contaminants for future CCLs will result in a more systematic, transparent, and comprehensive approach to classifying drinking water contaminants.

A. Screening the Universe of Contaminants

The NRC suggests that the universe of potential drinking water contaminants could contain tens of thousands contaminants and recommends that EPA consider a range of contaminants including naturally occurring substances, emerging waterborne pathogens, chemical agents, byproducts, degradates of chemical agents, radionuclides, and biological toxins as part of the universe. The NRC's approach to assembling the universe is to begin with data sources that are currently available and to work with the public, the drinking water industry, and the scientific community to develop a strategy for assessing contaminants that are not found in existing databases or lists (NRC, 2001). This approach could greatly expand on the number of contaminants to be reviewed and the number of databases and lists to be searched.

B. Compiling the PCCL

The NRC further suggested that EPA develop a well-conceived set of screening criteria that can be applied rapidly and routinely, in conjunction with expert judgement, to screen the universe of potential drinking water contaminants to a much smaller PCCL.

To compile the PCCL, the NRC recommends an approach that relies on health effects and occurrence information. The NRC suggests a screening process that selects contaminants from a hierarchy of information based on the following criteria related to both health effects and occurrence:

1. Contaminants that are demonstrated to cause adverse health effects and are demonstrated to occur in drinking water.
2. Contaminants that have the potential to cause adverse health effects and are demonstrated to occur in drinking water.
3. Contaminants that are demonstrated to cause adverse health effects and that have the potential to occur in drinking water.
4. Contaminants that have the potential to cause adverse health effects and that have the potential to occur in drinking water.

The NRC advises EPA to acquire input from the public and other ''stakeholders'' on the PCCL. This approach will assist EPA in making any policy judgements about the PCCL and will encourage transparency in the process.

C. Contaminant Selection From the PCCL to the CCL

The second step is the selection of drinking water contaminants on the PCCL for inclusion on the CCL.

The NRC evaluated a number of screening and assessment processes and recommended that EPA consider the prototype classification method, combined with expert judgement, as an effective approach for selecting contaminants. Prototype classification uses computer-based computational tools to weigh selected contaminant characteristics (also called attributes) against the characteristics of drinking water contaminants that are known to occur in drinking water and are recognized as having negative health impacts. These attributes could include various measures of toxicity, occurrence, and surrogates for these measures where primary data do not exist. A prototype classification algorithm would need to be ''trained'' to recognize features of contaminants that should be on the CCL by inputting key information about contaminants that we know should and should not be on the CCL.

For demonstration purposes, the NRC used a prototype classification approach known as a ''neural network.'' Neural networks are being used in investment analysis to predict foreign exchange rates, credit worthiness, and signature analysis. The approach relies on expert judgement to determine which attributes should be used to characterize the contaminants and the relative importance of the attributes. The neural network then uses mathematical formulas to evaluate attributes of contaminants against those of known contaminants and makes a prediction based on the importance placed on the contaminants' attributes.

In addition to suggesting a sample prototype classification method, the NRC also identified possible attributes for use in comparing the characteristics of potential contaminants. They suggested the following attributes: potency, severity, prevalence, magnitude, and persistence-mobility. The NRC considered these attributes because of their applicability to both chemicals and microbes, and noted that, after additional analysis and advice, EPA might well determine that other attributes were more appropriate for developing the CCL.

D. Virulence Factor Activity Relationships for Assessing Emerging Waterborne Pathogens

The NRC also addressed the issue of how best to examine emerging waterborne pathogens, opportunistic microorganisms, and other newly identified microorganisms in Classifying Drinking Water Contaminants for Regulatory Consideration (NRC, 2001). The panel recognized several difficulties in classifying microbiological drinking water contaminants. These include difficulties in characterizing microbiological contamination of drinking water, identifying the organism responsible for outbreaks, and developing databases for emerging pathogens. The NRC recommended that EPA explore virulence factor activity relationships (VFARs) to address this problem. The VFAR principle can be described as comparing the gene structure of newly identified waterborne pathogens to pathogens with known genetic structures which 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.

Genetic information in the form of gene sequences has been stored in several computerized ''libraries'' or ''gene banks'' for the use of the research community. The NRC described several of these gene banks and provides a list of microorganisms whose genomes have already been studied. The NRC noted that the genetic information of additional microbes are being added to gene banks at a rapid pace (NRC, 2001).

The NRC also recommended that EPA explore the use of gene chip technology (also referred to as biochips, deoxyribonucleic acid (DNA) chips, DNA microarrays, and gene arrays) to assist in classifying drinking water contaminants. Gene chips are devices not much larger than postage stamps. Thousands of tiny cells are typically placed on a glass wafer. Each holds deoxyribonucleic acid, or DNA, from a different human or microbiological

gene. The array of cells on a gene chip makes it possible to carry out a large number of genetic tests on a sample at one time. At the moment, the devices are used in pharmaceutical laboratories to investigate which genes are involved in various normal and disease processes and to speed up the process of finding new drugs.

The NRC believed that this approach has major and far reaching potential and indicated that, in the near future, microarrays could be developed that are labeled with genes for a variety of virulence factors and could be used to assay drinking water samples for the presence of genetic virulence factors of concern.

The NRC recognized that use of the VFAR approach to identify potential waterborne pathogens would require a multi-year commitment and significant cooperation and collaboration by EPA and other participating organizations before the technology can be used to develop the CCL.

V. Implementation of the National Research Council Recommendations

The NRC recommendations provided a possible 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. In making these recommendations, the NRC stressed that more work is needed in the area of research and encouraged EPA to explore different approaches for effective implementation.

The EPA has requested the assistance of NDWAC to evaluate and provide advice on the NRC's recommended classification process. This section describes the role played by NDWAC in assisting EPA's evaluation and implementation of the NRC recommendations and the development of the classification approach.

A. The National Drinking Water Advisory Council Background and Charge

As previously noted, the 1974 SDWA established NDWAC to provide independent advice, consultations, and recommendations to EPA on matters related to the activities, functions, and policies of the Agency under SDWA. To assist in this process, the NDWAC forms work groups of experts to perform assessments of specific drinking water issues. The work groups prepare reports and recommendations that the NDWAC considers when making its recommendations to EPA. The NDWAC CCL Work Group began its deliberations in September 2002. The Work Group is comprised of 21 recognized technical and public health experts representing an array of backgrounds and perspectives.

The NDWAC CCL Work Group is charged with discussing, evaluating, and providing advice to the Agency on methodologies, activities, and analysis needed to implement the NRC recommendations on an expanded approach for the CCL listing process. The EPA is working with the NDWAC CCL Work Group to explore issues related to a contaminant classification approach including (1) collecting and organizing the data, (2) screening the contaminants in the universe to compile the PCCL, (3) classifying contaminants from the PCCL to the CCL, and (4) developing the VFAR concept and classifying microorganisms. The NDWAC CCL Work Group is currently discussing and evaluating the issues related to implementing the NRC recommendations. EPA is assisting the NDWAC CCL Work Group by conducting analyses and investigations that inform the Work Group discussions. The NDWAC CCL Work Group expects to present its recommendations to the NDWAC in 2004.

The NDWAC CCL Work Group and EPA have made great progress in evaluating the NRC recommendations. The EPA recognizes that the recommended approach would require a significant, sustained effort to screen many more data sources for potential CCL contaminants and to adapt computer programs for environmental contaminant selection. The efforts to date have provided substantial information about the scope of the effort and the challenges ahead.

B. Ongoing Analysis of the Classification Approach

1. Organizing and Extracting Data

The NRC recommended that EPA begin by considering a broad universe of chemical, microbiological, and other types of potential drinking water contaminants and contaminant groups. The NRC projects that the scope of the universe could be on the order of tens of thousands of contaminants, which represent a dramatically larger set of substances to be initially considered in terms of types and numbers of contaminants than that used for the creation of the 1998 CCL (262 contaminants from 8 data sources). Considering that there is no comprehensive list of potential drinking water contaminants, and limited data on health effects, occurrence, and other related data for many of the potential contaminants, EPA is challenged with defining the universe of potential drinking water contaminants, determining how it will identify data sources, and identifying what approach it will use for extracting information.

Based on the NRC recommendations, EPA is considering two guiding principles for construction of the CCL universe: (1) The universe should include those contaminants that have demonstrated or potential occurrence in drinking water, and (2) the universe should include those contaminants that have demonstrated or potential adverse health effects. These inclusionary principles apply to selection of contaminants to be included in the CCL universe. The proposed process involves the identification of information and data sources and the development of a means of extracting data to be merged into a CCL universe data set.

The NDWAC CCL Work Group and EPA have identified a number of data sources as potentially useful resources. The data sources vary widely in their intended use (*e.g.*, research, survey, and compliance monitoring); type of data (*e.g.*, concentrations, health effects, chemical information, microbiological occurrence, environmental fate, and genetic sequences); data format; availability; and possible applicability to the universe of contaminants. The data sources include the following:

- Databases recommended by the NRC (NRC 1999a, 1999b, and 2001)
- Databases required by SDWA 1412(b)
- Chemical structure databases (*e.g.*, molecular structure information used for predictive toxicology)
- Chemical property databases (*e.g.*, chemical boiling point and solubility)
- Bibliographic databases (*i.e.*, references to published literature)
- Subscription/commercial databases
- Genomic sequence databases
- International databases
- Other sources of information recommended by NDWAC and other organizations

In addition to data availability and extraction issues, EPA must also address data quality concerns. The Agency is required under SDWA to use the best available peer-reviewed science and data collected by accepted methods or best available methods. While the standards of quality depend on the use to which the data is put, and screening level analyses require less rigorous standards than some other uses (*e.g.*, rule development), the data used to define the CCL universe of contaminants must nonetheless be accurately characterized and its quality

clearly understood. To satisfy these quality assurance objectives, EPA is in the process of developing a Quality Assurance Project Plan to cover all phases of the CCL process, from defining the universe of contaminants to making regulatory determinations.

2. Compiling the PCCL

The NRC recommended that EPA develop a set of screening criteria that could be applied rapidly and routinely, in conjunction with expert judgement, to screen the universe of potential drinking water contaminants for inclusion on the PCCL. The NRC considered this a significant challenge, but did not deliberate extensively on the criteria to be used for this screening. Thus, this screening step has become an area of significant analysis by EPA and the NDWAC CCL Work Group. Work to develop a process and criteria for screening is ongoing, as is the analysis of methods that would enable the screening of contaminants with little or no primary data or information.

In addition to exploring screening criteria, EPA is evaluating how expert judgement could be used to quickly reduce a broad universe to a manageable set of contaminants for the PCCL. While the NRC reports only provided a conceptual recommendation for screening the universe to a PCCL, the NRC indicated that the process should not involve an extensive analysis of data. The NRC suggested that EPA develop coarse screening criteria that can eliminate chemicals with low production volume and low potential for adverse health effects, unless expert judgement of health effects would place a chemical on the PCCL.

As previously described, EPA is coordinating efforts with the NDWAC CCL Work Group to develop a list of occurrence databases to be used in the analysis and will evaluate available human exposure or potential human exposure databases such as production and use databases, environmental release databases, and environmental media and biological tissues monitoring databases. The toxicological or health effects databases being evaluated include health assessment databases and waterborne disease outbreak databases as well as other information.

For health effects screening, EPA is focusing on contaminants that may be potent at levels near those found in drinking water and substances with irreversible or life threatening health effects. The NDWAC CCL Work Group is considering a number of options for processing data and information in order to examine the relationship between adverse health effects and occurrence in drinking water to make decisions on movement to the PCCL.

3. Classifying Contaminants From the PCCL to the CCL

The challenge of classifying a potentially large number of contaminants for movement from the PCCL to the CCL raises the question of what kind of process or method is best suited for performing this task. The NRC panel recommended the use of a prototype classification approach combined with expert judgement. The EPA has asked NDWAC for advice in this area and is exploring several alternative models including: artificial neural networks, classification and regression trees, logistic regression (a specific form of a generalized linear model), and multivariate adaptive regression splines. Work is ongoing to identify and test models and conduct trial classifications using a subset of the contaminants that will be in the universe.

Use of the prototype classification approach necessitates assigning a score to each attribute for a given contaminant. Attributes are descriptive properties which allow different types of contaminants to be compared in a consistent manner. The NRC recommended the following attributes: potency (*i.e.*, the amount of a contaminant that is needed to cause illness); severity (*i.e.*, the seriousness of the health effect); prevalence (*i.e.*, how common does or would a contaminant occur in water); magnitude (*i.e.*, the concentration or expected concentration of a contaminant relative to a level that causes a perceived health effect); and persistence-mobility (*i.e.*, a surrogate for occurrence when occurrence information is unavailable). The EPA and NDWAC CCL Work Group are examining the five attributes recommended by the NRC, as well as exploring other possible attributes.

The EPA and NDWAC CCL Work Group are also exploring how attributes (*e.g.*, potency) for a given contaminant might be scored using differing data elements (*e.g.*, the reference dose (RfD), the no observable adverse effect level (NOAEL), and the lowest observable adverse effect level (LOAEL)), so that the score for an attribute would reflect the degree of the health effect or occurrence relative to other contaminants.

The NDWAC CCL Work Group and EPA have undertaken significant analysis with regard to the severity attribute. For example, the following range of scores was used by the NRC to represent the severity of a given contaminant for health effects as follows:

0. No effect
1. Changes in organ weights with minimal clinical significance
2. Biochemical changes with minimal clinical significance
3. Pathology of minimal clinical significance
4. Cellular changes that could lead to disease; minimal functional change
5. Significant functional changes that are reversible
6. Irreversible changes, treatable disease
7. Single organ system pathology and function loss
8. Multiple organ system pathology and function loss
9. Disease likely leading to death
10. Death

The EPA and NDWAC CCL Work Group are exploring ways that the severity scale provided by the NRC might be modified so that effects in the middle of the scale (*e.g.*, 4–8) would be more easily differentiated and to allow for appropriate scoring of reproductive and developmental effects. The EPA and NDWAC CCL Work Group are also examining possible approaches to scoring chemicals that lack information on a critical effect for severity.

Similarly, EPA is engaged in substantial technical analysis with the NDWAC CCL Work Group of a possible scoring methodology for the attribute potency. The NRC suggested that potency could be measured in terms of the RfD, the NOAEL, the LOAEL, or by other measures.

Additional issues and challenges the NDWAC CCL Work Group is considering include:

1. Which data elements are best suited to estimate the score for an attribute? For example, for the attribute potency, values exist for RfDs, NOAELs, and LOAELs.

2. In what order should data for a given contaminant be considered given the quality, confidence, and certainty of data sources? For example, should EPA score a contaminant using an RfD over an oral LOAEL if both are available?

3. If no RfD or LOAEL is available, then which value should be used to score a contaminant?

4. Should EPA review all types of data elements even when an RfD exists?

5. How should contaminants be scored when data from different sources suggest conflicting scores?

6. When should surrogates be used in place of the preferred data elements? For example, using production and release data to estimate the potential for occurrence may be a better approximation than limited sampling in one location.

7. How should surrogates be expressed and scored?

8. For the health effects attributes, which populations should be targeted in scoring (*e.g.*, adults, children, or sensitive subpopulations)? Is it possible to make that distinction given the data that are available?

9. Should an assessment of certainty and confidence be incorporated into the scoring process to reflect the quality of the data?

10. How should scoring for occurrence data elements be addressed?

11. How should subjectivity of severity scoring process be addressed? For example, some disorders are treatable depending upon when treatment is initiated. How should treatability be accounted for without subjectively referring to a person's ability to obtain medical treatment?

12. What data quality guidelines would be appropriate for classifying contaminants from a PCCL to the CCL? Would different guidelines for screening contaminants be appropriate from a CCL universe to a PCCL?

13. Which models or other approaches would be best suited for classification given the scoring approach?

4. The Virulence Factor Activity Relationship Concept and Classifying Microorganisms

The VFAR process offers a possible alternative to identifying and characterizing microbiological contaminants that lack information. As previously discussed, the VFAR concept 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. The NRC recommends the use of the VFAR approach for assessing emerging waterborne pathogens, opportunistic microorganisms, and other newly identified microorganisms. While this approach may offer significant improvements for the future, it may not be sufficiently developed in time for the next CCL (*i.e.*, the 2008 CCL). Some of the challenges to overcome include the ability of microbiological genes to exhibit considerable adaptability by frequently gaining or losing genetic elements. The presence of multiple genetic elements, together with the relative frequency of chromosomal recombinations, results in highly dynamic genes that make predictability difficult.

Researchers have mapped about 100 entire genomes of bacteria and viruses, and the number of mapped genomes, especially of pathogens, is growing rapidly. Researchers store the information in several computerized libraries, or gene banks. Sophisticated computer software programs can sort and match genetic information in these libraries, which can allow researchers to predict the ability of a microbe to produce virulence factors, and compare a microbe to known pathogens. Some waterborne pathogens have similar toxins, surface proteins, and mechanisms of infection, and some of the genes for these factors have been identified.

The NDWAC CCL Work Group and EPA are exploring a means of using gene banks for drinking water applications. For example, EPA searched for genetic sequences associated with virulence using the National Center for Biotechnology Information's GenBank database. The database contains a large list of such sequences, most of which are associated with pathogens or microbes used in laboratory studies. Initial findings indicate that some relevant sequence data are available, however, the data were in a form that proved difficult to use for this purpose.

The EPA is also coordinating efforts with the NDWAC CCL Work Group to evaluate an approach based on bioinformatics to extract relevant information from databases and literature sources on known waterborne pathogen gene sequences. The information could provide the gene sequences needed to demonstrate the potential use of gene chip technology in performing VFAR analysis.

The EPA is also exploring alternative approaches to screen microbes for the next CCL, given the uncertainty surrounding the time frame for a fully developed VFAR approach. For example, EPA is exploring an approach that would construct a microbiological universe, define microbiological attributes, and score the attributes.

The EPA believes that the NRC recommendations hold substantial promise and is exploring ways to take the recommendations beyond the conceptual framework to development and implementation. Additionally, EPA is working with the NDWAC CCL Work Group to define the dimensions of the microbiological universe as part of a step-wise process for defining the CCL. The EPA welcomes comments on these and other relevant microbiological issues to assist the Agency in addressing the NRC recommendations.

VI. Request for Comment

The EPA seeks comments on the range of CCL issues and activities addressed in this notice. EPA is also requesting comment on its decision to carry over the remaining contaminants on the 1998 CCL as the draft CCL 2. The Agency is asking for public comments on the following questions related to the process for developing the 2008 CCL:

1. Which data sources should the Agency use to assemble the universe of potential CCL contaminants?

2. Should the Agency adopt the general framework of moving from a broad universe of potential candidates to a PCCL and finely to a CCL?

3. If so, what criteria should be used for inclusion of a contaminant on the PCCL, and in selecting contaminants from the PCCL to the CCL?

4. How should EPA address contaminants that lack data on toxicity, occurrence, and exposure?

In addition, the Agency welcomes comments on other aspects of the approach recommended by the NRC.

The EPA expects that public comments on these and other relevant issues will assist the Agency in addressing remaining questions posed by the NRC and the NDWAC and welcomes comments from the public. The Agency recognizes that, while the draft CCL 2 has not been compiled using the new approach recommended by the NRC, many of the underlying principles and objectives remain the same. Information and comments submitted on this notice will be considered in determining the final CCL 2 list, as well as in the development of future CCLs and in the Agency's efforts to set drinking water priorities in the future.

VII. References

NRC. 1999a. Setting Priorities for Drinking Water Contaminants. National Academy Press, Washington, DC *http://www.nap.edu/catalog/6294.html*.

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*.

EPA. 1991. Priority List of Substances Which May Require Regulation Under the Safe Drinking Water Act. Notice. **Federal Register** Vol 56, No. 9, p. 1470. January 14, 1991.

EPA. 1997a. EPA Drinking Water Microbiology and Public Health Workshop. Washington, DC, EPA, Office of Ground Water and Drinking Water, May 20–21, 1997.

Dated: March 16, 2004.

Benjamin H. Grumbles,

Acting Assistant Administrator, Office of Water.

[FR Doc. 04–7416 Filed 4–1–04; 8:45 am]

BILLING CODE 6560–50–P