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DRINKING WATER
RESEARCH

Better Planning Needed to
Link Needs and Resources

Statement of Peter F. Guerrero, Director,
Environmental Protection Issues,
Resources, Community, and Economic
Development Division



Mr. Chairman and Members of the Subcommittee:

We are here today to discuss our report, which is being released today, on the Environmental Protection Agency's (EPA) drinking water research program.¹ In the Safe Drinking Water Act Amendments of 1996,² the Congress made significant changes to the way that EPA is required to set drinking water quality standards in its regulations governing public water systems. Among other things, the regulations must be based on the best available peer-reviewed science and must consider health risks, risk reduction, and implementation costs. The statute also authorized increased funding for the scientific research needed to support the regulations.

Concerned about whether EPA's drinking water research will be sufficient to support the agency's forthcoming regulations, the Committee asked us to

- compare EPA's budget requests for drinking water research during fiscal years 1997 through 2000 with (1) the amounts authorized for such purposes by the Safe Drinking Water Act Amendments of 1996 and (2) the amounts estimated by EPA to be needed to support the regulations and regulatory determinations required under the amendments;
- obtain the views of stakeholders—those involved with supplying and ensuring the safety of drinking water—regarding the likelihood that EPA will be able to complete the research necessary to support new regulations and regulatory decisions over the next 10 years and the potential consequences if the research is not completed;³ and
- assess EPA's drinking water research plans, including the tasks, projected funding, and anticipated accomplishments, to support the development of new regulations and regulatory decisions over the next 10 years.

In summary, Mr. Chairman, we found the following:

¹Drinking Water Research: Better Planning Needed to Link Needs and Resources (GAO/RCED-99-273, Sept. 24, 1999).

²P.L. 104-182, 110 Stat. 1613 (1996).

³To obtain stakeholders' views, we interviewed officials with the American Water Works Association, American Water Works Association Research Foundation, Association of Metropolitan Water Agencies, Association of State Drinking Water Administrators, National Association of Water Companies, National Drinking Water Advisory Council, and Natural Resources Defense Council. We also contacted officials associated with the National Research Council and the Science Advisory Board.

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- For fiscal years 1997 through 2000, EPA annually requested millions of dollars less than the Congress authorized for drinking water research and regulatory development in the 1996 amendments; however, the gap has narrowed recently. According to EPA officials, the agency's annual budget requests reflect the level of resources that agency officials believe is needed to fulfill EPA's mission and program responsibilities, within the planning ceilings and policy directives provided by the Office of Management and Budget. But there is no overall estimate of resource needs for drinking water with which to compare EPA's annual budget requests because the agency does not generally prepare estimates of the total resources needed to carry out multiyear research programs.
 - Stakeholders expressed concerns about the adequacy of the research for the upcoming regulations on (1) arsenic and (2) microbial pathogens, disinfectants (used to treat drinking water), and disinfection by-products, particularly the adequacy of research regarding health effects and the analytical methods used to detect contaminants. While EPA officials acknowledge that some high-priority research projects will not be completed in time for these regulations, they believe that the available research will be sufficient to support the regulations with sound science. According to the stakeholders, the potential consequences of not having adequate research to support upcoming regulations could be significant. For example, if EPA issues regulations that are more stringent than can be justified by the available science, water utilities could bear unnecessarily high treatment costs. On the other hand, if EPA decides to set a less stringent standard because some scientific data are not available, consumers could be exposed to harmful contaminants longer than necessary.
 - EPA has prepared detailed research plans that identify the specific tasks it needs to complete in order to support upcoming regulations on arsenic and microbial pathogens, disinfectants, and disinfection by-products. However, EPA has not completed research plans for other significant portions of its regulatory workload, including determinations on contaminants that are candidates for regulation and the review and revision of existing drinking water standards. Moreover, while the plans it has prepared specify research tasks, projected accomplishments, and expected completion dates, EPA has not identified the resources that are required to implement the plans and does not have an effective system for tracking the progress of ongoing research in relation to the plans. As a result, it is difficult to ascertain whether the research has been adequately funded or will be available in time to support the development of new regulations and regulatory determinations.

On the basis of these findings, we recommended that EPA take steps to improve the link between research needs and resources and to better ensure that limited research funds within EPA and other organizations are most efficiently targeted. We also recommended that EPA improve the tracking of ongoing research in relation to existing research plans and communicate the agency's progress so that the Office of Research and Development's key customers can obtain timely and accurate reports on the status, timing, and funding of individual research projects.

Background

EPA's responsibility for conducting drinking water research and developing the applicable regulations is split between its Office of Research and Development and Office of Water. The Office of Research and Development's five laboratories and centers are responsible for conducting research on health effects, exposure, treatment technologies, and analytical methods. In addition, its National Center for Environmental Assessment develops risk assessments for some contaminants.⁴ Within the Office of Water, the Office of Science and Technology also does some risk assessments, and the Office of Ground Water and Drinking Water collects data on the occurrence of contaminants in drinking water; prepares the economic assessments, including cost-benefit analyses, and makes the risk management decisions necessary to support the regulatory decisions; and writes the regulations.

Among other things, the 1996 amendments to the Safe Drinking Water Act required EPA to finish developing most of the regulations that were in process at the time of the act's reauthorization, such as standards for arsenic; microbial pathogens, such as cryptosporidium; disinfection by-products; and radon. The amendments also created a new process for identifying contaminants that may warrant regulation on the basis of their adverse health effects, their frequency of occurrence in public water systems, and the projected risk reduction to be achieved by regulating them. EPA was required to publish, by February 1998, a list of high-priority contaminants not currently regulated. (This list is known as the Contaminant Candidate List.) Beginning in August 2001 (and in 5-year cycles thereafter), the amendments require EPA to determine whether to regulate at least five of the contaminants on the list. A determination to regulate them must be based on the best available public health

⁴A risk assessment typically involves an evaluation of (1) the likelihood that a contaminant will cause an adverse health effect, (2) the extent to which the population is exposed to the contaminant through drinking water and other sources, and (3) the relationship between the level of exposure and the adverse health effect.

information and data concerning the occurrence of the contaminant. In addition to regulating new contaminants, EPA must review and revise, as appropriate, existing drinking water standards at least once every 6 years.

The 1996 amendments also modified EPA's standard-setting authority so that health risks, risk reduction, and costs must be considered when drinking water quality standards are established. When proposing a regulation, EPA is required to publish an analysis of, among other things, the effects of the contaminant on the general population and on subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population.⁵ In addition, EPA is required to publish a determination of whether the benefits do or do not justify the costs. To the degree that its actions are based on science, EPA must use the best available peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices.

EPA's Annual Budget Requests for Drinking Water Research and Regulatory Development Are Less Than the Legislatively Authorized Amounts

For fiscal years 1997 through 2000, EPA annually requested millions of dollars less than the amounts the Congress authorized for drinking water research and regulatory development in the 1996 amendments to the Safe Drinking Water Act. Beginning with fiscal year 1998, the gap between the authorized funding levels and annual budget requests was much larger for drinking water research than for regulatory development, but this gap has narrowed recently for both areas. For example, in fiscal year 1999, EPA requested \$35.5 million for drinking water research, or 35 percent less than the \$54.6 million that was authorized for that year. In fiscal year 2000, when EPA requested \$41.5 million of the \$54.6 million authorized for drinking water research, the difference between the authorized and requested funding was 24 percent. To support regulatory development activities, EPA requested \$40.9 million in fiscal year 1999, or about 13 percent less than the \$47 million that was authorized. This gap was reduced to about 3 percent in fiscal year 2000, when EPA requested \$45.5 million of the \$47 million authorized for regulatory development that year.

According to officials within both the Office of Water and the Office of Research and Development, EPA does not prepare its annual budget requests on the basis of the specific funding authorizations in environmental statutes. Instead, the budget requests reflect (1) the level of

⁵These "sensitive subpopulations" may include infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other groups.

resources that agency officials believe is needed to fulfill EPA's mission and program responsibilities and (2) the planning ceilings and policy directives provided by the Office of Management and Budget. Officials from the Office of Research and Development told us that the amount of funding to be requested annually for research on drinking water and other areas is determined through an extensive planning process in which research coordination teams—each responsible for a broad area of research—determine the Office's research priorities for the upcoming budget year. The teams consider several factors, including the Office's overall research strategy, the status of ongoing research, program offices' priorities, and statutory and budgetary constraints. Next, the Office of Research and Development's top management and EPA's Research Coordinating Council, comprising Deputy Assistant Administrators from across the agency, review the teams' recommendations and modify them as appropriate to ensure that the Office's annual budget request focuses on the highest research priorities across the agency.

Using this process, EPA estimates only the resources needed for drinking water (and other) research for a specific budget year, rather than the total resources needed to carry out a multiyear research program for any given research area. In effect, the agency determines—on an annual basis—what research can be accomplished within the targets provided by the Office of Management and Budget. Therefore, there is no overall estimate of resource needs for drinking water research with which to compare the annual budget requests for drinking water research.

In fiscal year 1998, EPA did attempt to do an unconstrained needs assessment that would identify the activities and resources necessary to meet the new statutory mandates of the 1996 amendments, including requirements for drinking water research, and to achieve public health objectives. As we reported earlier this year, EPA concluded that the shortfall in research and data collection funding was in the range of \$10 million to \$20 million annually for fiscal years 1999 through 2005.⁶ The results of the assessment were presented to the National Drinking Water Advisory Council and other stakeholders in April 1998.

EPA officials subsequently explained that the intent of the needs assessment was not to calculate exact budget requirements but to develop a "ballpark" estimate. In March 1999, EPA officials testified that the level of funding received in fiscal year 1999 and requested for fiscal 2000 is

⁶Safe Drinking Water Act: Progress and Future Challenges in Implementing the 1996 Amendments (GAO/RCED-99-31, Jan. 14, 1999).

sufficient to provide the resources needed to (1) meet all near-term requirements of the act's amendments in a timely manner and (2) base regulatory decisions on sound science.⁷ Officials from the Office of Water and Office of Research and Development are currently conducting a comprehensive evaluation of resource needs for the drinking water research program for fiscal year 2001 and beyond.

Officials from the Office of Research and Development pointed out that drinking water research as a percentage of the total research budget has more than doubled—from 3.3 percent in fiscal year 1995 to 7.8 percent in EPA's fiscal 2000 budget request. While the officials acknowledge that it is beyond EPA's capacity to address all drinking water research needs, they said that they have worked to establish partnerships with federal and nonfederal research entities, such as the National Institute of Environmental Health Sciences, the Centers for Disease Control and Prevention, and the American Water Works Association Research Foundation, to leverage additional resources.

Stakeholders Believe Some Research Will Not Be Available in Time to Support Upcoming Regulations

Several stakeholders were concerned about the adequacy of EPA's budget requests for drinking water research and the proportion of the Office of Research and Development's research budget that is devoted to drinking water. They believe that funding for drinking water research should receive a higher priority within EPA, considering its potential impact on public health, and they cited specific areas, such as certain health effects studies, in which they believe that funding constraints caused the research to be started too late to be available when needed.

Beyond the questions surrounding the funding of drinking water research, stakeholders expressed concerns about the adequacy of the research that will be available to support the regulations on arsenic and microbial pathogens, disinfectants, and disinfection by-products.⁸ In the case of arsenic, for example, several stakeholders told us that some of the epidemiological studies,⁹ which will provide information on health effects,

⁷Implementation of the 1996 Safe Drinking Water Act Amendments: Hearing Before Subcommittee on Fisheries, Wildlife and Drinking Water of the Senate Committee on Environment and Public Works, 106th Cong. 13-14 (1999) (Internet, GPO Access).

⁸Conventional water treatment practices require the addition of disinfectant chemicals to the water, that, while effective in controlling many harmful microorganisms, combine with organic and inorganic compounds in the water and form potentially harmful disinfection by-products.

⁹In general, environmental epidemiological studies are used to determine whether an association exists between an adverse health effect and the exposure of a population to a contaminant. Further studies are often needed to confirm the epidemiological association and determine the relationship between the level of exposure and the adverse health effect.

will not be completed in time, in part, because the research was started too late for the results to be available when needed. While some stakeholders, such as the National Drinking Water Advisory Council and the Association of Metropolitan Water Agencies, agree that there will be gaps in the health effects research, they believe that sufficient information exists to take some interim action on arsenic. They expect EPA to lower the existing standard by the statutory deadline of January 2001, and, when the longer-term research is completed, to consider revising the standard again.

Regarding the regulations on microbial pathogens, disinfectants, and disinfection by-products, many stakeholders commented that some of the health effects research—including epidemiological studies and research on sensitive subpopulations, such as children and pregnant women—will not be completed in time for the regulations. Both the Chairman of the National Drinking Water Advisory Council and the Executive Director of the National Association of Water Companies, among others, also expressed concern about whether researchers will be able to identify reliable analytical methods for detecting microbial contaminants, such as cryptosporidium, that will be included in the upcoming regulations.

EPA officials acknowledge that some high-priority research projects will not be completed in time for the upcoming regulations on arsenic and microbial pathogens, disinfectants, and disinfection by-products. For example, in the case of arsenic, EPA has testified that a significant investment in health effects research must continue for several years to address priority research needs. In the case of research on disinfection by-products, officials from the Office of Research and Development told us that the importance of studying certain noncancer health effects has only recently been recognized as EPA's understanding of the science has evolved. Even so, EPA officials believe that the available research will be sufficient to support the regulations with sound science. They told us that they will issue regulations using the best available science and, when additional research results become available, will modify the regulations, if appropriate, as part of the review and revision of existing standards that are required every 6 years.

Some stakeholders questioned EPA's approach. For example, the Executive Director of the American Water Works Association Research Foundation sees EPA's regulatory approach as a compromise that became necessary because some research was started too late to be available when needed. In addition, using a two-stage approach to regulate contaminants could increase costs to utilities in some instances. According to the Executive

Director of the National Association of Water Companies, it is often not cost-effective to make incremental changes in treatment technologies.

The consensus among stakeholders is that the availability of research for contaminants on the Contaminant Candidate List may be the most serious concern because relatively little research has been initiated so far and EPA does not expect to have a research plan until May 2000. According to a variety of stakeholders and officials within the Office of Water, EPA should be conducting research on these contaminants now so that the regulatory determinations and rulemakings associated with these contaminants will be supported by sound science. However, for the most part, this research is just now beginning. In a March 1999 hearing before the House Committee on Science, the Assistant Administrator for the Office of Research and Development testified that in its fiscal year 2000 budget, EPA redirected approximately \$6 million from the funding that had been dedicated to research on microbial pathogens, disinfectants, and disinfection by-products to fill key data gaps and develop analytical methods for chemicals and microbial pathogens on the Contaminant Candidate List. Although the Office of Research and Development has already initiated research in the areas of health effects, exposure, and treatment for selected high-priority contaminants on the list, the fiscal year 2000 funding represents the first major reallocation of resources within the drinking water research budget to address these research needs.

Some stakeholders believe that EPA may have sufficient information for the first set of regulatory determinations, which is due in August 2001. However, stakeholders point out that the contaminants selected for the first determinations may simply represent those for which the most information is available—and not those that pose the most significant health risks. Greater concerns were raised about whether EPA will have sufficient information for the next round of determinations, which must be made by August 2006. A number of stakeholders were particularly concerned that little or no health effects research has been initiated for contaminants on the Contaminant Candidate List, and some noted that epidemiological studies can take 4 or more years to plan and conduct. Consequently, they believe it is important to begin the work now so the results will be available when needed.

According to stakeholders, the potential consequences of not having adequate science to support the regulations could be significant. If EPA issues regulations that are more stringent than what is justified by the

available research, water utilities could bear unnecessarily high treatment costs. In the case of arsenic, for example, under both EPA's and industry's projections, annual compliance costs could increase dramatically, depending on how much the existing standard of 50 parts per billion is lowered. Specifically, EPA has estimated that lowering the arsenic standard to 10 parts per billion would result in annual compliance costs of \$270 million, but found that these costs would be much higher—reaching an estimated \$2.1 billion—if the standard were lowered to 2 parts per billion. Similarly, estimates by the American Water Works Association range from \$708 million, at a level of 10 parts per billion, to \$4.2 billion, at a level of 2 parts per billion.

On the other hand, not having adequate research could have an impact on public health. If EPA decides to set a less-stringent standard or defers regulation of a contaminant because some scientific data are not available, this could mean that consumers would be exposed to harmful contaminants for an additional 6 or more years.¹⁰ The Natural Resources Defense Council and other organizations have expressed concern about the relatively limited research on the impact of drinking water contaminants on sensitive subpopulations, such as pregnant women, children, the elderly, and people with compromised immune systems. An official with the Office of Ground Water and Drinking Water acknowledged that the study of human reproductive and developmental effects, in particular, is an area in which more research is needed. He told us that some earlier studies indicated a possible association between exposure to drinking water treated with disinfectants and these effects but that additional long-term studies are needed to determine if there is any basis for concern.

EPA Has Not Completed Some Research Plans and Does Not Identify or Track the Resources Needed to Implement Existing Plans

EPA has not yet completed research plans for its anticipated work on the Contaminant Candidate List and the review and revision of existing standards, and has not developed a comprehensive research plan that integrates both near-term and long-term research needs. EPA started work on a research strategy for the Contaminant Candidate List after the first list was published in 1998. Although EPA will be required to make a regulatory determination on at least five contaminants from the first list by August 2001, the agency does not expect to complete its strategy until May 2000. Similarly, although EPA must complete the review and revision of about 80 existing standards by August 2002, EPA only recently began the

¹⁰Under section 102(a) of the 1996 amendments, the EPA Administrator has authority to take action more quickly (i.e., promulgate an interim national primary drinking water regulation) whenever contaminants are determined to pose urgent threats to public health.

initial work associated with identifying the research needs for this effort. EPA officials explained that at this point, they do not expect the review of existing standards to require a significant research effort, and, consequently, this work will be incorporated into EPA's comprehensive research plan, which is targeted for completion by December 2000.¹¹

A number of stakeholders were concerned that EPA does not yet have a comprehensive research plan. As illustrated in appendix I, EPA is required to promulgate a number of important regulations over the next few years and, at the same time, must begin the research necessary to support future regulatory determinations on the Contaminant Candidate lists. Stakeholders believe that developing a comprehensive plan would require EPA to lay out an integrated approach for supporting ongoing regulatory efforts and identifying and conducting research on emerging concerns, such as the presence of pharmaceuticals in some sources of drinking water. In addition, a long-term plan would allow the agency to be more anticipatory and less reactive; EPA would thus be able to break the cycle in which the research lags behind regulatory needs. Moreover, with a comprehensive plan, stakeholders can avoid duplicating research that EPA already plans to fund and, instead, sponsor research that complements EPA's efforts.

EPA has prepared detailed research plans in two significant areas—(1) arsenic and (2) microbial pathogens, disinfectants, and disinfection by-products. Although the plans identify the specific research tasks that will be performed and provide information on the anticipated accomplishments, they do not include estimates of the resources needed to fund the planned research. As a result, it is not possible to make a link between the estimated cost of the research laid out in the plans and the funds requested for drinking water research in EPA's budget—and, thus, determine whether the research is adequately funded.

Not only do existing research plans lack key information on resource requirements, but EPA also does not have an effective system for tracking the progress and funding of ongoing research in relation to the plans. The Office of Research and Development makes efforts to communicate the status and results of its work to the Office of Water (e.g., through regular staff-level contacts, special briefings, and status reports) and to interested groups outside the agency through stakeholder meetings and other means. However, officials from both the Office of Water and outside stakeholder

¹¹EPA is required to develop a long-term research plan under section 202(a) of the 1996 amendments. The statute does not impose a deadline on the plan's completion.

groups indicated that they would like to receive regular reports that contain more detailed information on the status of projects in the research plans, including the estimated and actual start and completion dates and the funding for individual projects.

Because the program office needed better information to monitor the status of the work laid out in the research plan and to track project-level resource expenditures, the Office of Water developed its own tracking system for the research on microbial pathogens, disinfectants, and disinfection by-products. Since 1997, the Office of Water has paid a contractor over \$148,000 to develop and maintain the tracking system and input data on the status of individual projects.

Better planning and a more explicit link between research needs and resources would improve the transparency of the budget development process. The Science Advisory Board, which annually reviews the Office of Research and Development's budget requests, has noted improvements in the Office's efforts to link research priorities with specific environmental goals and in the coordination between the Office and the needs of EPA's program offices. However, in commenting on the Office's fiscal year 2000 budget, the Board's Research Strategies Advisory Committee indicated that the lack of transparency in the process used to set research priorities made it difficult for the Committee to evaluate the adequacy of the proposed budget. The Committee recommended that EPA make available information on high-ranking programs that it entertained during the budget-making process but could not fund because of overall budget constraints and competition with other programs. In addition, the Committee found that the criteria that EPA used to emphasize or de-emphasize programs in the proposed budget were unclear and recommended that EPA develop explicit criteria that can be used for setting research priorities during the budget development process. The Committee concluded that such an exercise would not only improve communication and understanding of the budget process for those outside the agency, but would also assist EPA in making its internal decision process more efficient.

In closing, Mr. Chairman, key stakeholders in the drinking water community have concerns about whether EPA's research is on track to meet the demanding regulatory agenda mandated by the Congress in the 1996 amendments to the Safe Drinking Water Act. We believe that more detailed and better-communicated information on planned and ongoing research would help EPA to deal with these concerns and that providing

such information is warranted on the grounds of both accountability and efficiency. Identifying the nature, timing, and estimated cost of needed research over the multiyear research plans—and linking these needs to the annual budget request—will make the funding process more transparent.

In addition, providing information on which projects will be funded in a given year will give stakeholders within and outside EPA a clear basis for assessing the impact of the agency's budget decisions. EPA's reliance on outside research entities to fill the gaps that are beyond the agency's capacity to meet makes it all the more important for EPA to identify high-priority projects that may be deferred or abandoned because of funding constraints. Similarly, having a more effective system for tracking ongoing research will both enhance the budget development process and allow stakeholders to make informed judgments about whether the research is adequately funded and will be available when needed.

Our report being released today recommends a number of actions to improve the transparency of the budget development process and the effectiveness of the system used to track the progress and funding of research projects. First, to improve the link between research needs and resources and to better ensure that limited research funds within EPA and other organizations are most efficiently targeted, we recommended that EPA (1) identify the specific research that must be accomplished, (2) establish time frames showing when the results must be available, (3) estimate the resources that will be required to support the needed research, and (4) use these data to develop budget requests and inform stakeholders about what research will be funded. Second, we recommended that EPA improve the tracking of ongoing research in relation to existing research plans and communicate the agency's progress so that the Office of Research and Development's key customers, including the Office of Water and outside stakeholders, can obtain timely and accurate reports on the status, timing, and funding of individual research projects.

EPA agreed that an adequate investment in drinking water research is critical to provide a sound scientific basis for drinking water regulations. The agency also noted the importance of linking multiyear research planning to the yearly budget cycle and using effective tracking systems for monitoring and communicating the status of research activities and resource requirements.

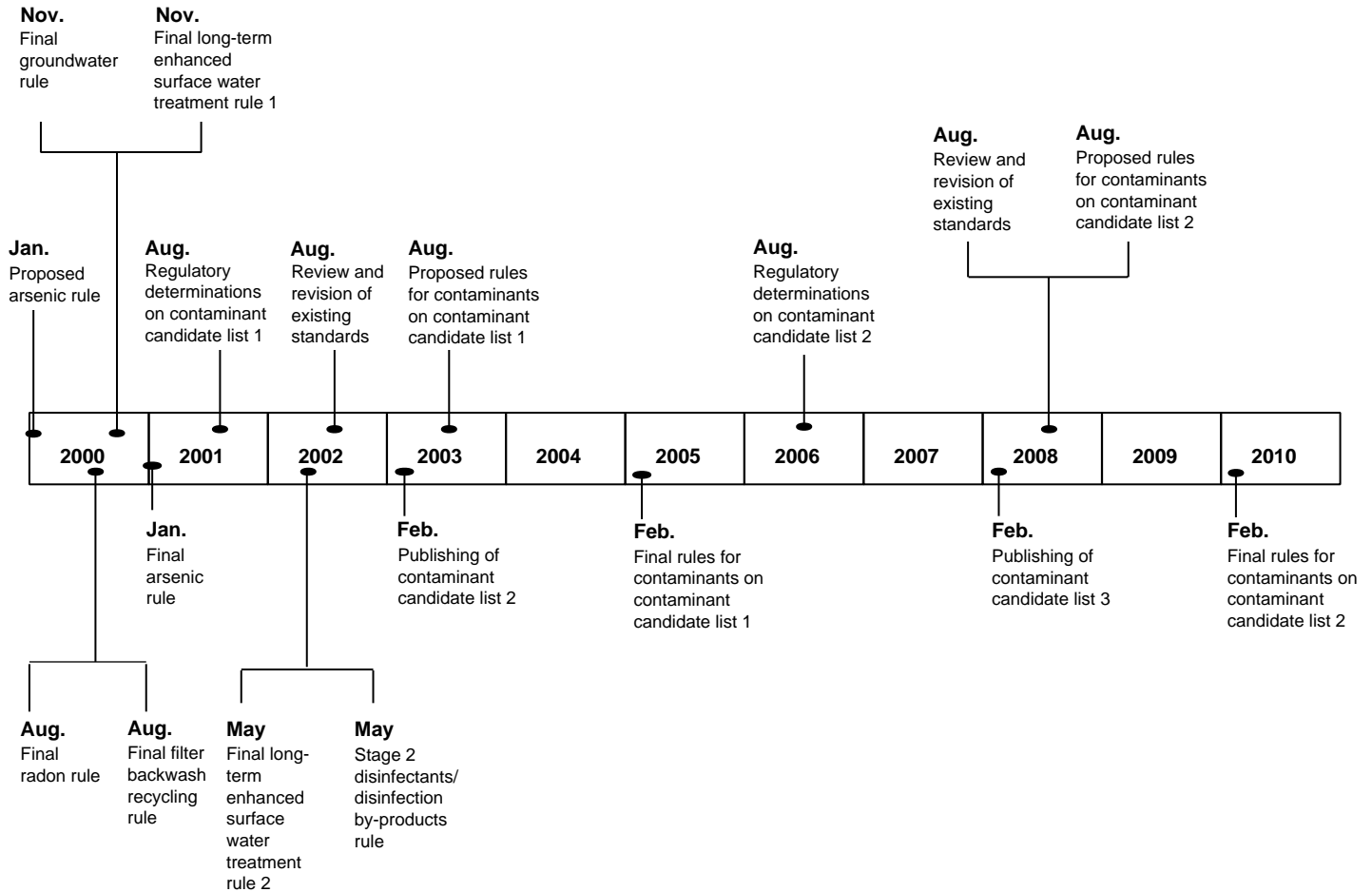
Mr. Chairman, this concludes our prepared statement. We would be pleased to answer any questions that you or Members of the Subcommittee may have.

Contact and Acknowledgments

For future contacts regarding this testimony, please contact Peter F. Guerrero at (202) 512-6111. Individuals making key contributions to this testimony included Ellen Crocker, Teresa Dee, and Les Mahagan.

Time Line for Upcoming Regulations and Regulatory Determinations

Time Line for Upcoming Regulations and Regulatory Determinations



Source: Based on information from EPA.

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