Drinking Water and Human Health: The Role of the U.S. Department of Health and Human Services

Subcommittee on Drinking Water and Health
Environmental Health Policy Committee

July 1997

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

Table of Contents

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Preface

Throughout this century, the Public Health Service (PHS) has taken a leading role in providing safe drinking water for Americans. The PHS advanced the scientific knowledge needed to implement and promote appropriate technologies by sponsoring the development of breakpoint chlorination, linking the levels of coliform bacteria in water with waterborne disease rates, and demonstrating the diarrheal and parasitic burden experienced by rural households without access to safe water or sanitary facilities. Following passage of the Safe Drinking Water Act (SDWA) in 1974, the U.S. Environmental Protection Agency (EPA) assumed primary responsibility in the Federal effort to protect the public's drinking water supply. With EPA establishing and enforcing drinking water standards and funding water projects, the drinking water-related responsibilities of the U.S. Department of Health and Human Services (HHS), the parent agency of the PHS, became fragmented.

In recognition of these departmental responsibilities, the Environmental Health Policy Committee (see Appendix 1), chaired by the Assistant Secretary for Health, Dr. Philip Lee, created a subcommittee to evaluate the HHS role in ensuring safe drinking water. The new Subcommittee on Drinking Water and Health (see Appendix 2) was chaired by Dr. Richard Jackson, Director, National Center for Environmental Health, Centers for Disease Control and Prevention (NCEH, CDC), and included representatives from HHS and other Federal departments. This report is a summary of the consensus of discussions at the subcommittee's six meetings between March 1995 and January 1996.

The plan of action that concludes this report was crafted by the subcommittee's agency representatives. This report and the discussions from which it came will enable HHS to play an effective and engaged role in the evolution of safe drinking water protection in the coming years.

Executive Summary

Several agencies within the Federal Government form a regulatory and technical network for ensuring the safety of Americans' drinking water. The mandates and responsibilities of the different agencies are quite varied, span Government departments, and are based in different parts of the country, occasionally resulting in a fragmented approach to drinking water policy and research. HHS agencies have undertaken a variety of independent responsibilities (e.g., regulating bottled water, upgrading water supplies of Native Americans, and conducting research) in support of, or in complement to the EPA, which is the principal Federal regulator of drinking water safety as dictated by the Safe Drinking Water Act. To improve coordination and communication within HHS and between HHS and other Federal agencies, the HHS Environmental Health Policy Committee (see Appendix 1) formed a Subcommittee on Drinking Water and Health (see Appendix 2). This report summarizes the present and potential future roles for HHS in the issues involving drinking water, as envisioned by the subcommittee members after 1 year of bimonthly meetings.

The subcommittee has identified several areas of research and public service that require increased Federal attention. Among research issues requiring further attention are the following: (1) quantifying the association between various contaminants and adverse health effects, (2) developing methodologies and arrangements to use existing data better, (3) developing laboratory and field techniques for measuring hazards, (4) expanding the Federal capacity to deal with waterborne outbreaks, (5) exploring social justice issues surrounding drinking water, and (6) investigating health consequences among people not protected by Federal drinking water quality laws. Areas where expanded service is needed include the following: (1) improving advocacy on behalf of certain populations that receive substandard service, (2) expanding the breadth of Federal responses to outbreaks and disease surveillance, and (3) developing techniques for educating the public and the water industry.

Given the present public concern about drinking water and the finite resources of the Federal Government, expanded research and service efforts can best be achieved in the short run through greater coordination and efficiency. To promote coordination and efficiency, the subcommittee proposes the following measures:

- Member agencies should develop cross-notification schemes and standard operating procedures for responding to acute water-related crises.

- Agencies should improve their dissemination and sharing of data with other agencies, as well as the use of the water-quality data, health data, and risk assessment information presently collected by the Government.

- A World Wide Web page should be established on the Internet to post information on major Federal activities related to drinking water and health.

- The subcommittee should continue to meet on a semiannual basis to maintain ongoing dialogue and facilitate coordi-nation of drinking water and health issues.

The subcommittee hopes that this document, and the ongoing dialogue from which it came, will help Federal public health workers to serve the public better.

Present Activities and Responsibilities

The agencies cited below are engaged in numerous activities related to drinking water. These activities vary from year to year and may be initiated upon specific outbreaks or disasters. The summaries below describe general categories of activities or major initiatives and are not comprehensive. The purpose of the summaries is to encapsulate the scope and nature of each agency's efforts.

HHS AGENCIES

Agency for Toxic Substances and Disease Registry

The ATSDR was created under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) to assess possible human health effects associated with EPA-designated hazardous waste sites. As part of the agency's site evaluation and health assessment activities, ATSDR regularly addresses issues involving drinking water contamination from hazardous chemicals. ATSDR's role under CERCLA is to identify unsafe sources of drinking water and related health effects caused by chemical contamination of drinking water at Superfund sites and to assist EPA and State and local governments in ensuring a safe water supply for the affected population.

Centers for Disease Control and Prevention

The CDC is a public health research and technical support institution. State governments solicit assistance from CDC on virtually all issues involving the public's health. Many of CDC's activities related to drinking water arise from instances of disease outbreaks or poisonings for which it may provide epidemiological, communication, and laboratory assistance. CDC also conducts several ongoing services regarding drinking water. For example, CDC tabulates the occurrence and characteristics of waterborne outbreaks in

the United States. In cooperation with EPA, CDC publishes a biannual summary that helps to delineate larger issues, such as the emergence of new pathogens, and to identify systematic patterns of infrastructure shortcomings, such as those associated with unchlorinated groundwater systems. The CDC Dental Health Program provides technical support for the promotion of water fluoridation. Laboratories at CDC monitor body burdens of a variety of substances, identify and characterize waterborne pathogens, and develop new techniques for isolating various hazardous agents in water and in humans.

Food and Drug Administration

The FDA is primarily a regulatory agency. Within its mandate fall several aspects of drinking water safety. In particular, water used in food processing, bottled water, and drinking water provided on interstate conveyances are all within FDA's regulatory authority. The EPA Primary Drinking Water Standards are employed as the minimum criteria for bottled water quality. FDA provides guidance and recommendations regarding retail food service practices and equipment. A more complete listing of FDA's activities related to water is included as Appendix 3.

Health Resources and Services Administration

The HRSA Bureau of Primary Health Care addresses drinking water-related issues as a consequence of its advocacy activities on the part of disadvantaged subgroups of the population that often lack access to adequate amounts of safe water. The agency's legislative mandate includes the detection and alleviation of unhealthy conditions associated with water and other environmental factors related to health. At present, the Division of Community and Migrant Health is actively advocating compliance with the Safe Drinking Water Act and Clean Water Act standards on those farms hosting migrant and seasonal farm workers. In addition, with the National Cancer Institute, the agency is conducting a retrospective analysis of cancer occurrences among migrant and seasonal farm workers.

Indian Health Service

The IHS is charged with assisting Indian Nations with the protection and promotion of health among their people. In this regard, identifying water-related deficiencies and designing, constructing, and upgrading water supplies are a significant part of their activities. Technical and educational assistance also is provided to ensure proper operation, maintenance, and monitoring of water systems. As a public health organization, the IHS lends health education and epidemiologic support to Indian populations and responds to public health emergencies. As a multi-Nation entity, the IHS maintains national data on Indian-owned systems and serves as an advocate for the Native American community on legislation that may influence water quality for this population.

NATIONAL INSTITUTES OF HEALTH

National Cancer Institute

The NCI is a research institution whose mission is to study the causes of cancer and to determine effective prevention measures and cancer treatment modalities. The research program at NCI is conducted to understand basic relationships between water contaminants and the occurrence of cancer in humans. Current epidemiologic research efforts are focused on several factors that influence drinking water quality, including chemical byproducts of disinfection, nitrate, arsenic, and fluoride. Among the types of cancer under scrutiny are leukemia, lymphoma, and cancers of the stomach, esophagus, brain, bladder, kidney, pancreas, colon, and rectum.

National Institute of Environmental Health Sciences

For both ground and surface water resources, the human health issues of interest to the NIEHS are primarily those involving chronic human exposures to chemicals that result from agricultural and industrial activities and improper waste disposal. The NIEHS grant program includes (1) studies of the effects of chlorinated organics, their pathology, and toxicity in mammalian organ systems; (2) epidemiology of health risk factors related to

water resources; and (3) the analysis and development of remediation technologies for groundwater contamination (done under the NIEHS Superfund Research Program). In addition, the NIEHS National Toxicology Program has conducted several studies on compounds (i.e., disinfection byproducts) that result from drinking water disinfection by halogenation. These disinfection byproducts are a series of compounds that result from the chlorination, bromination, and ozonation of drinking water. With concern about the rates of colorectal cancer in the United States, these compounds were approved for nomination to the bioassay program. These results will be used by the EPA Office of Water in its risk assessments.

National Library of Medicine

The NLM Division of Specialized Information Services, Toxicology and Environmental Health Information Program (TEHIP), maintains both bibliographic and factual files on chemical and biological contaminants. One important factual file includes information about chemical contaminants found in drinking water supplies. Through an interagency agreement with EPA, Federal and State drinking water guidelines and standards for chemical pollutants are included in this data file. Access to the file, as well as EPA's Integrated Risk Information System, the Toxic Chemical Release Inventory Files, and other specialized files in areas such as carcinogenesis, mutagenesis, and teratogenesis, is available through NLM's TOXNET system. TOXNET is a system of networked computers used for database file building, updates, and online searching for most of the databases in the TEHIP.

OTHER FEDERAL AGENCIES

Department of Defense

The DOD obtains water for its installations from both municipal water supplies and systems owned and operated by the military. All of these systems adhere to EPA SDWA standards, and water-quality data are supplied to State governments as part of ongoing monitoring activities. The DOD

provides guidance for operating and monitoring water systems located on U.S. Military installations, both in the United States and in foreign countries. In addition, the Armed Forces have explicit regulations governing water quality for DOD personnel deployed at sea or in the field, away from municipal water supplies. Water-related disease outbreaks at military installations are addressed by military preventive medicine units and are reported to State authorities where appropriate.

Environmental Protection Agency

The EPA is the primary Federal agency charged with ensuring the safety of the public's drinking water under the SDWA. The EPA evaluates potential drinking water contaminants and sets both enforceable (primary) drinking water standards, as well as nonenforceable secondary drinking water standards (i.e., for color, taste, and odor). Although States, cities, local governments, and private utilities are responsible for the day-to-day monitoring of water treatment plants, the EPA sets basic monitoring requirements and works with the State programs to ensure compliance with the SDWA. EPA activities and guidance cover virtually all aspects of drinking water safety, from watershed protection programs, to plant operation procedures, to household tap water sampling methods for lead and copper. Educational efforts under EPA's mandate include developing messages for the public, training utility company and laboratory staff, and developing problem overviews and assessments for Congress. The EPA research program addresses the health effects of drinking water contaminants; exposure, risk assessment, and analytical methods; and technologies for drinking water treatment. Through its own affiliations with institutions, universities, and other organizations, the EPA is responsible for much of the research related to drinking water conducted in the United States. A synopsis of EPA's Drinking Water Research Program is included as Appendix 4.

Department of Agriculture

The USDA has a wide variety of programs that influence drinking water quality. Through these activities, USDA attempts to reduce initial groundwater and runoff contamination by providing guidelines and education regarding pesticide and fertilizer use, encouraging soil conservation efforts, and conducting community watershed education programs. The National Farmstead Assessment Program helps educate rural residents in water pollution risks and prevention strategies. The USDA works to provide safe water for small communities through the Rural Development Agency. The Water Quality Information Center produces bibliographies of water quality issues.

U.S. Geological Survey, Department of the Interior

The USGS has collected information on water quality and quantity across the United States since the early 1900's. Information on the quantity of water used for a variety of purposes, including drinking, is released at 5-year intervals. The status and trends of quality of both surface and groundwater supplies are measured as part of the USGS National Water Quality Assessment (NWQA) program. Data on geological and geophysical features of land are used to understand better how and why water quality changes over space and time. The EROS Data Center provides satellite imagery of remotely sensed environmental data. Regional patterns of water quality, such as the recent findings on the frequency of atrazine in ground water and streams of the Midwest and the occurrence of pesticides and other organic compounds in public supplies across Washington State, are examples of USGS findings about water used as public or domestic supplies. The USGS Water Quality Laboratory performs analysis under tight quality assurance/ quality control for a wide variety of organic and inorganic compounds, providing results at low detection levels that are easily interpretable across political boundaries on the basis of consistent methodologies nationwide.

Present Activities and Responsibilities

Collective Activities of Federal Agencies

The general categories of tasks undertaken by various Federal agencies are summarized in Table 1. This table uses the symbol ✓ to denote activities conducted with the intent of serving all U.S. citizens and ✗ for those activities that are undertaken only for some subset of the population.

Table 1 lists a variety of current Federal activities related to drinking water and health and the specific Federal agencies involved. Hazardous components of water come either from nonpoint sources (agricultural, man-altered and natural runoff, and atmospheric deposition), from point sources, or through the treatment and distribution process. The EPA regulates most point source pollution through the Clean Water Act and has some influence over atmospheric deposition of harmful contaminants through the Clean Air Act. The agricultural contributions to surface and groundwater contamination are significant in many areas and, with the exception of herbicide and pesticide regulation, are largely unregulated by the Federal Government. The USDA has several programs to minimize nutrient flow to surface waters, to control sediment loading of surface waters, and to encourage prudent use of agricultural chemicals. Most of these programs depend on the voluntary cooperation of farmers and on the ability, using USDA's limited resources, to get information to farmers. Specific agricultural compounds are registered, and can be deregistered or banned, by the EPA.

Nonpoint-source pollution from urban and suburban environs can be significant, as the USGS has documented through its National Water Quality Assessment. Although the EPA and many States have extensive programs to diminish pollution transported through storm water and sediment runoff, most of these programs depend on voluntary cooperation of participants or on the enforcement of local regulations.

Thus, whereas collective Federal efforts to ensure water safety are extensive, the Federal Government does not have the ability to control all pollution at the source.

Table 1. Activities of Subcommittee Agencies Associated With Drinking Water

	HHS Agencies						Non-HHS			
Type of Activity	ATSDR	CDC	FDA	HRSA	IHS	NIH	DOD	EPA	USDA	USGS
Source Water Monitoring/Investigation	✗						✗	✓		✓
Source Water Protection	✗							✓	✓	
Raw Water Monitoring/Investigation	✗						✗	✓		
Treatment Plant Support/Education/Investigation					✗			✓		
Treatment Plant Design/Construction/Upgrading					✗			✓		
Monitoring Treated Water Quality							✗	✓		
Distribution System Support/Education/Investigation								✓		
Population Consumption/Use Patterns		✓				✓		✓	✓	✓
Household Water Quality						✓		✓	✗	
Monitoring Health Outcomes	✗	✓		✗			✗	✗		
Health Risk Assessments	✗			✗				✓		
Monitoring/Assessing Economic Outcomes								✓		
Monitoring/Assessing Social Equity Issues		✗		✗				✓		

✓-denotes activities conducted to serve all U.S. citizens; ✗-denotes an activity for some subset of the U.S. population.

Table 1. Activities of Subcommittee Agencies Associated With Drinking Water (continued)

Type of Activity	HHS Agencies						Non-HHS			
	ATSDR	CDC	FDA	HRSA	IHS	NIH	DOD	EPA	USDA	USGS
Monitoring/Assessing Social Equity Issues		✗		✗				✓		
Developing Water Quality Testing Techniques (Laboratory Methods, Field Methods, QA/QC, Equipment)		✓						✓		✓
Health Effects Investigation Acute/Outbreaks	✗	✓			✗		✗	✓		
—Chronic/Cancer/Long Term	✗	✓				✓	✗	✗		
Standard Setting —Regulating								✓		
—Data and Analysis Pertaining to								✓		
Guideline Development								✓		
Public Education				✗	✗	✓		✓	✓	
Enforcement/Compliance					✗			✓		
Developing and Maintaining Informational Resources						✓		✓		✓
Monitoring/Guidance for Food Product-Related Water			✓							

✓-denotes activities conducted to serve all U.S. citizens; ✗-denotes an activity for some subset of the U.S. population.

Information and Research Needs

Historically, a primary role for the PHS has been to conduct applied research, which has guided public policy and contributed to social progress. Coordination between agencies and the setting of priorities are essential steps toward minimizing in a cost-effective manner the waterborne hazards experienced by the public. Priority areas for investigation include the following concerns:

- The EPA is required by the SDWA to publish maximum contaminant level goals (MCLG's) and promulgate MCL's for contaminants in drinking water that may cause adverse effects to human health and that are known or anticipated to occur in public water systems. As part of this process, the EPA reviews available data to quantify the human risks from specific contaminants. The data to complete the risk assessment come from toxicity studies of laboratory animals or from epidemiologic studies. To ensure that the best available scientific data are used when characterizing risks for specific drinking water contaminants, it is important to establish a procedure for sharing toxicologic and epidemiologic data generated across Federal organizations. In addition, it is important to coordinate research efforts and to prevent unnecessary duplication of efforts and to utilize effectively the limited resources available.

- At present, extensive monitoring of water quality occurs in natural systems and in the waterworks of utilities. The 1991 *Inventory of Environmental Exposure-Related Data Systems in the Federal Government* listed no less than 25 data systems related to water quality; none have as a goal the recording of human exposures to contaminants in drinking water. Likewise, several registries (reportable diseases, adverse reproductive outcomes, cancer) measure adverse health outcomes that may be associated with contaminants in water. Yet, only in focused studies is the water exposure of individuals characterized for seeking associations between water quality and health outcomes. In the absence of such studies, data gaps usually are filled by using default values.

Collecting environmental data and health outcome data should be done in concert to permit the evaluation of associations between water constituents and chronic or rare disease outcomes. Where such coordination is not possible, additional information should be acquired to characterize human exposure to waterborne contaminants.

- The development of laboratory and field techniques for identifying drinking water contaminants and monitoring their effects upon human health remains crucial for the Federal Government. As new threats are discovered, methods for measuring chemical and biological disease-causing agents in water are essential for estimating adverse health outcomes associated with water contamination and for preventing future exposures. Methodologies for identifying chemical contaminants in drinking water and their metabolites in human samples are often crucial for documenting past exposures and for determining the extent of an exposure within a population. HHS scientists have made significant contributions to the development of laboratory techniques for identifying such contaminants as *Escherichia coli* O157:H7, rotavirus, benzene, heavy metals and metabolites of atrazine, metalachlor, alachlor, and chlorpyrifos in samples from humans. However, the need for methodologies for detecting water pollutants is likely to increase, given public concern about drinking water quality and new evaluations regarding the association between specific chemical exposures and chronic diseases and adverse reproductive outcomes.

- 13.8 million households obtain their drinking water from single or multihouse water systems that are not regulated under the SDWA. These wells and small systems are not routinely inspected or tested. A recent survey of more than 5,000 household wells in the Midwest found that 12 percent contained *Escherichia coli* and 10 percent had nitrate concentrations of greater than 20 mg/L, indicating that problems with these unregulated systems are common. The extent of the health problems that are a result of poor construction, maintenance, or source protection is unknown. Modest amounts of research could quantify the hazards associated with various unsanitary conditions and provide insight into preventive measures. There is a need for guidelines

regarding the monitoring, maintenance, and evaluation of all systems that are not regulated (e.g., wells, multihouse systems, and home-treatment units).

- Some of the most frequently overlooked elements of a safe community water system relate to the knowledge, skills, and abilities of the water system operators. While considerable engineering, process, and management training now is conducted by the water industry, the PHS should play a role in developing minimum educational standards for operators of water systems that are based on the public health consequences of actions related to potable water treatment and delivery. These educational efforts should be expanded to include the public where appropriate.

- HRSA estimates that several million people in the United States, primarily rural and migrant workers, lack running water. The IHS estimates that 20,400 American Indian and Alaska Native homes lack piped potable water. The extent of this problem and its associated health consequences, both urban and rural, should be investigated and monitored.

Areas for Expanded Service

Although the general quality of water and the oversight of the water industry is of a relatively high level in most States, no system of Federal environmental oversight is perfect or complete; certain areas of Government oversight or support are weaker than others. Listed below are service gaps as perceived by members of the subcommittee:

- Certain subpopulations (e.g., migrants, people in substandard housing, and people living in certain geographical areas, such as the U.S.-Mexico border) lack access to adequate quantities of safe water. HRSA is mandated to defend their interests; however, its budget is not sufficient to monitor these problems or to promote enforcement of existing laws.

- Outbreak investigations are the main source of public health information about waterborne pathogens and their transmission. These investigations are also an important vehicle for developing insight into the limitations of the sanitary barriers erected to protect the public water supply. CDC and State health departments often have had to respond to waterborne outbreaks through epidemiologic investigations that include limited environmental and engineering analyses. For some outbreaks, EPA has been able to provide scientists and engineers, who have significantly broadened the scope and capacity of the Federal Government's investigations and the thoroughness of the responses. The knowledge gained by an interdisciplinary investigation of outbreaks that combines the expertise of CDC, EPA, and other agencies will enable the Federal Government to formulate integrated and coordinated strategies for source water protection, educational campaigns, and disease surveillance. Multidisciplinary teams should be developed for rapid response during acute exposure or outbreak-type events. Resources and operating procedures need to be established for this purpose.

- The CDC-EPA waterborne disease outbreak surveillance system depends on States to report outbreaks and may be incomplete. Its purpose is to characterize waterborne outbreaks epidemiologically (e.g., to investigate the agents, the reasons for the outbreak, and the adequacy of various

treatment methods) and to strengthen the public health community's ability to respond to these outbreaks. Out-break summaries are produced biannually after information is obtained and verified, and enough reports have been collected to justify summarizing. New methods for identifying outbreaks should be explored in order to increase the sensitivity and timeliness of the surveillance system.

- The HHS, EPA, and other Federal agencies can do a better job of informing the public of the potential health risks from specific drinking water problems and the health benefits of various programs and measures taken by public health agencies. This educational effort should address specific ongoing issues of public concern (as is now occurring with *Cryptosporidium*) and should include the preparing of educational messages (such as "boil water" notices) for various types of public health crises.

- Training and education programs and professional guidelines should be examined and strengthened as needed to emphasize human health protection. Enhanced programs might address, for example, issues, such as distribution system flushing and inspection or watershed protection campaigns. Educational messages (e.g., communicating the value of bottled water for specific subpopulations in specific instances) should be developed and tested before they are needed.

Action Plan

To maximize coordination between agencies and to address the information and service needs described in previous sections, the subcommittee proposes the following actions:

1. **Federal agencies should continue the process of developing cross-notification mechanisms to help mobilize interdisciplinary teams when outbreaks or other emergencies occur**. While the CDC and EPA have developed a written understanding, this process should be formalized, and additional agencies should become engaged in the process of responding to water-related health crises. Responsible parties are the Office of Research and Development, EPA, and the National Center for Infectious Diseases (NCID), CDC.

2. **Those agencies involved in human health protection or drinking water research should communicate ways to utilize and link existing data sets better**. Although data sets involving health events or water quality have been collected by, or as a result of the mandate of, Federal agencies, these data sets often are difficult for several agencies to use simultaneously. The utilization of these data across disciplines and agencies should be improved and collection procedures coordinated to enable the linking of water-quality and health-outcome data. Responsibility: NCEH, CDC.

3. **A World Wide Web page or electronic bulletin board should be established.** The site could include summaries of completed research, ongoing and planned research activities, planned meetings and events, recently published documents regarding drinking water and human health, and links to key resources, such as the *Federal Register*. Although most agencies have a web site, this project would assist in coordinating Federal activities in this area and in helping the public understand the breadth of Federal vigilance about drinking water. Responsibility: NLM, NIH.

4. **The CDC will complete a survey of the States regarding the monitoring and service of those water supplies not covered under the SDWA**. The subcommittee will use the results of the survey in its continuing evaluation of this issue. Further steps regarding information and guidance for those Americans not receiving public water will be based on information garnered through this survey and further activities. Responsibility: NCEH, CDC.

5. **Through the Subcommittee on Drinking Water and Health, each agency should provide other agencies with a list of contact people by subject area of technical expertise.** Responsibility: NCEH, CDC.

6. **The subcommittee should continue to meet semiannually**. The subcommittee has improved interagency communication about drinking water and health. Many concrete components of improved interagency cooperation, such as sharing technical expertise, coordinating research agendas, and conducting interagency cross-reviews of ongoing programs and proposals, can best be cultivated through an ongoing process. Richard Jackson will continue to initiate meetings of the Subcommittee on Drinking Water and Health every 6 months until the subcommittee chooses to change the frequency. Responsibility: NCEH, CDC.

Appendix 1. Environmental Health Policy Committee

Jo Ivey Boufford, Chair
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Mark Olesen
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Tara O' Toole
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Robert Reginato
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Rosemary Sokas
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Kaye Wachsmuth
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Appendix 2. Subcommittee on Drinking Water and Health

LIST OF SUBCOMMITTEE MEMBERS AND OTHER ATTENDEES AND REPRESENTATIVES

Subcommittee Members

Richard Jackson, Chair
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Appendix 3. FDA's Activities Related to Water

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), food means articles used for food or drink by man or other animals and components of such articles. By this definition, water is considered a food and is subject to the provisions of the FD&C Act. The FDA's regulatory activities to ensure the safety of the U.S. food supply as it relates to water follow.

1. **Water Used in Food Processing**. When water enters a food manufacturing establishment, the FDA has jurisdiction for regulation of that water when it is to be used in the processing of food. The FDA's current good manufacturing practice (CGMP) regulations for manufacturing, packing, or holding human foods require use of safe and sanitary water for food processing. Use of safe and sanitary water for seafood processing at manufacturing plants, at docks, and on ships is of particular importance to ensure the safety of seafood products. All substances added to water after entering a food processing establishment are subject to FDA's food additive regulations under the FD&C Act.

2. **Bottled Drinking Water**. The FDA's quality standard regulations for bottled water establish maximum allowable levels for contaminants (physical, chemical, radiological, and microbiological) in bottled water products, including mineral water. The FDA's CGMP regulations for processing and bottling of bottled drinking water require safe and sanitary conditions during the manufacture, packing, and holding of bottled water products; approval of source waters for bottling; and monitoring for contaminants to ensure that water is safe and to ensure compliance with the bottled water quality standard.

   The FDA has established an identity standard for bottled water that includes definitions for various types of bottled water (e.g., artesian water, ground water, mineral water, purified water, sparkling bottled water, spring water, sterile water, well water). The identity standard for

bottled water also requires any declared bottled water ingredient (e.g., mineral, well, artesian, spring, or purified) in a multicomponent food to meet FDA's definitions for those types of water and the bottle water quality standard regulations.

3. **Retail Foods**. The FDA's Model Code provides guidance and recommendations to State and local officials regarding safe handling of foods (including the use of water) at the retail level, such as food service establishments (e.g., restaurants), institutions (e.g., nursing homes), and grocery stores.

4. **Harvest Water for Seafood**. The FDA, in cooperation with the Interstate Shellfish Sanitation Conference, establishes public health controls for incorporation into the National Shellfish Sanitation Program (NSSP) Manuals of Operation. These manuals provide guidance to States and industry concerning the sanitary control of the molluscan shellfish industry.

   Included in these guidelines are specific requirements for the classification of shellfish growing waters to ensure that shellfish are harvested only from unpolluted areas where they will not pose a health hazard to consumers who often eat them raw or partially cooked. In accordance with NSSP requirements, waters which demonstrate unacceptable bacteriological quality, and may therefore be contaminated with pathogenic microorganisms, are closed to the harvesting of shellfish.

   The FDA provides guidance to the States for closing of waters under State jurisdiction for finfish harvesting when finfish are found to contain levels of chemical contaminants that exceed FDA action levels. In addition, the FDA works closely with the National Marine Fisheries Service (NMFS), which oversees Federal waters, to determine the safety of those waters for finfish harvesting.

   The FDA monitors chemical spills and dump sites. For example, samples have been taken from the Boston Harbor area for radionuclide

examination after nuclear waste dump sites were found in the area. The area is closed by the NMFS to commercial fishing as a result of cooperative efforts between that agency and FDA.

5. **Interstate Conveyance Sanitation**. Under the Public Health Service Act, the FDA regulates potable water, including water for ice, and water for other uses on conveyances (planes, trains, and ships) that are in interstate traffic.

   The FDA approves watering points for potable water for drinking and culinary purposes on conveyances to ensure that the potable water supply meets EPA's Primary Drinking Water Regulations.

   The FDA regulates water for other uses (e.g., wash water, swimming pool water) and equipment and facilities (e.g., potable water systems, drinking fountains and coolers, water storage containers, toilets and lavatories) on conveyances to ensure safe and sanitary use of water.

Appendix 4. EPA Office of Research and Development Drinking Water Research Program

GOALS

- Develop scientifically sound approaches to assessing and characterizing drinking water risks.
- Provide common-sense, cost-effective approaches for preventing and managing drinking water risks.

OBJECTIVES

- Characterize health effects caused by exposure to drinking water contaminants.
- Develop and apply analytical and exposure measurement methods to assess human exposures to drinking water contaminants.
- Develop more realistic assessments of drinking water risks.
- Evaluate the effectiveness of options for reducing drinking water risks.

RESULTS

- Support the development of drinking water standards.
- Support the identification of "Best Available Technology" for drinking water treatment.

- Provide technical assistance to States and localities.

APPROACH

- Conduct research in house in Office of Research and Development labs.
- Sponsor research at universities and other institutions through competitively awarded grants and cooperative agreements.
- Coordinate research efforts with other Federal agencies and research organizations.

RESEARCH PROGRAM COMPONENTS

1. **Health Effects Research**

Current research areas

- Toxicology—evaluation of cancer, reproductive, and other effects of priority contaminants.
- Studies to improve understanding of biological basis for effects.
- Human studies—epidemiology, where feasible, on different types of disinfected waters to evaluate chemical and microbial risks.

Accomplishments

- Key toxicity data for setting trihalomethane and haloacid standards.
- Critical data on arsenic metabolism and toxicity.
- Dose-response information on *Cryptosporidium.*

Future directions

- Health impacts of alternative disinfectants.

- More emphasis on noncancer effects, e.g., reproductive data to improve biological basis for assessing risk.

2. **Exposure Assessment Research**

Current research areas

- Develop standardized and cost-effective methods for chemical contaminants, with emphasis on byproducts of alternative disinfectants.

- Develop more reliable methods for detection of protozoa, e.g., *Cryptosporidium*, and viruses.

- Improve characterization of byproduct formation under different disinfection scenarios.

Accomplishments

- Developed and validated methods for measuring drinking water pollutants; disinfection byproducts; bacteria, parasites, and viruses; and pesticides and metals.

- Developed screening methods for compliance monitoring.

- Developed quality assurance training, workshops, and certification of laboratories throughout the United States.

Future directions

- Identification of byproducts from alternative disinfectants, e.g., ozone.

- Assessments of actual exposures to contaminants.

3. **Risk Assessment Research**

Current research areas

- Comparative risk analysis: chemicals and microbes.

- Risk assessment methods.

- Single chemical.

- Multiple chemicals/complex exposures.

- Cancer risk assessments for specific dibromopropanes.

- Analysis of epidemiology studies.

Accomplishments

- Improved methods for noncancer effects, e.g., benchmark dose, risk above the reference dose for aldicarb, arsenic, and boron.

- Improved methods for cancer risk assessment, e.g, threshold models for carcinogens (dichloroacetic acids), and combined data assessments (PCB's, dibromo-chloromethane).

Future directions

- Better methods for use of human data.
- Microbial risk assessment.
- Comparative risk assessment.

4. **Risk Management Research**

Current research areas

- Membrane technology evaluation—potential for removal of microorganisms, chemicals, and particulates.
- Use of ozone for disinfection and resulting byproducts.
- *Cryptosporidium* removal techniques.
- Cost and modeling studies—used by water utilities to design cost-effective treatment systems.
- Control of copper in drinking water systems.

Accomplishments

- Dispatched experts to help local authorities control outbreaks of waterborne diseases in Milwaukee, New York, and Peru.
- Research leading to largest granular activated carbon treatment plant in world (Cincinnati).
- Evaluation of "package plants" for small community drinking water systems.
- Evaluation of filtration for controlling and removing microbial pathogens.
- Software for predicting water quality in distribution systems.

Future directions

- Integrated treatment studies on pathogens and disinfection byproducts.
- Small system technologies.
- Source water protection strategies.

Glossary of Abbreviations

ORGANIZATIONS

ASTHO—Association of State and Territorial Health Officers

ATSDR—Agency for Toxic Substances and Disease Registry

CDC—Centers for Disease Control and Prevention
- NCEH—National Center for Environmental Health
- NCID—National Center for Infectious Diseases
- NCPS—National Center for Prevention Services
- NIOSH—National Institute for Occupational Safety and Health

DOD—U.S. Department of Defense

EPA—U.S. Environmental Protection Agency
- OGWDW—Office of Ground Water and Drinking Water
- OW—Office of Water
- OST—Office of Science and Technology

FDA—Food and Drug Administration

HHS—U.S. Department of Health and Human Services

HRSA—Health Resources and Services Administration

IHS—Indian Health Service

NIH—National Institutes of Health
- NCI—National Cancer Institute
- NIEHS—National Institute of Environmental Health Sciences
- NLM—National Library of Medicine

PHS—Public Health Service

USDA—U.S. Department of Agriculture

USGS—U.S. Geological Survey

OTHER TERMS

CERCLA—Comprehensive Environmental Response, Compensation, and Liability Act

EHPC—HHS Environmental Health Policy Committee

HSDB—Hazardous Substances Data Bank

MCL—maximum contaminant level

MCLG—maximum contaminant level goals

NAWQA—National Water Quality Assessment

QA/QC—quality assurance/quality control

SDWA—Safe Drinking Water Act

TEHIP—Toxicology and Environmental Health Information Program