provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: Distributors of gasoline containing ethanol.

Estimated Number of Respondents: 8,792 gasoline distributors, only 4,396 of which have a measurable annual hourly burden.

Frequency of Response: 307 business transactions per year per respondent with paperwork required on the occasion of the transactions; approximately 2,706,000 total annual responses.

Estimated Total Annual Hour Burden: 1,319 hours.

Estimated Total Annualized Cost Burden: 0.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the following addresses. Please refer to EPA ICR No. 1367.05 and OMB Control No. 2060–0178 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, Office of Policy, Regulatory Information Division (2137), 401 M Street, SW, Washington, DC 20460;

and

Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for EPA, 725 17th Street, NW, Washington, DC 20503.

Dated: August 5, 1998.

Stephen T. Vineski,

Regulatory Information Division.

[FR Doc. 98–21524 Filed 8–10–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6140–8]

Waterborne Disease Studies and National Estimate of Waterborne Disease Occurrence

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data availability and request for comments.

SUMMARY: The Safe Drinking Water Act (SDWA) Amendments of 1996, section 1458(d), provides that within two years of enactment the Environmental Protection Agency (EPA) and the Centers for Disease Control and Prevention (CDC) will conduct pilot waterborne disease occurrence studies for at least five major U.S. communities or public water systems. Section 1458(d) also provides that, within five years of enactment, EPA and CDC will prepare a report on the findings of these pilot studies and develop a national estimate of waterborne disease occurrence (''the national estimate'').

The purpose of this **Federal Register** document is to inform the public about how EPA and CDC are addressing this provision. The document includes descriptions of planned and ongoing epidemiological studies and discusses public involvement in developing an approach for estimating the national level of waterborne disease occurrence. Comments are requested on issues related to the epidemiological studies and to developing the national estimate.

DATES: Comments should be postmarked or delivered by hand on or before November 9, 1998.

ADDRESSES: Send written comments to Susan Shaw, (MC–4607); U.S. Environmental Protection Agency; 401 M Street, SW, Washington, DC 20460, or by email to shaw.susan@epamail.epa.gov. Comments may also be hand-delivered to Kimberly Miller, U.S. Environmental Protection Agency; 401 M Street, SW, Room 3809, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: For further general information and for copies of the reports from the 1997 Atlanta and the Washington, D.C. workshops discussed herein, contact the Safe Drinking Water Hotline, Telephone (800) 426–4791. The Safe Drinking Water Hotline is open Monday through Friday, excluding Federal holidays, from 9 a.m. to 5:30 p.m. Eastern Time. For technical inquiries, contact Susan Shaw, Office of Ground Water and Drinking Water (MC4607), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; telephone (202) 260–8049; email: shaw.susan@epamail.epa.gov. To receive additional information about the spring 1999 public meeting, contact Kimberly Miller, Office of Ground Water and Drinking Water (MC4607), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460; telephone (202) 260–0718; email: miller.kimberly@epamail.epa.gov.

Abbreviations Used In This Document

CDC: Centers for Disease Control and Prevention
EPA: US Environmental Protection Agency
SDWA: Safe Drinking Water Act, as amended in 1986 and 1996

Table of Contents

1. Introduction and Statutory Authority

The Safe Drinking Water Act (SDWA) Amendments of 1996, section 1458(d), provides that within two years of enactment the Environmental Protection Agency (EPA) and the Centers for Disease Control and Prevention (CDC) will conduct pilot waterborne disease occurrence studies for at least five major U.S. communities or public water systems. Section 1458(d) also provides that, within five years of enactment, EPA and CDC will prepare a report on the findings of these pilot studies and develop a national estimate of waterborne disease occurrence.

The purpose of this **Federal Register** document is to inform the public about how EPA and CDC are addressing the provision to conduct studies on waterborne disease occurrence and to develop a national estimate of waterborne disease occurrence due to drinking water (the ''national estimate''). The document is organized as follows:

Background: Discussion of the difficulties inherent in quantifying infectious disease due to drinking water.

EPA and CDC actions and strategy to develop the national estimate: Describes

actions taken by EPA and CDC to conduct waterborne disease occurrence studies, and to develop the national estimate of waterborne disease occurrence; discusses overall strategy for complying with Section 1458(d), including public involvement.

Waterborne disease studies: Describes ongoing and planned studies funded by EPA that are expected to contribute directly to developing the national estimate of waterborne disease occurrence.

Conclusions: CDC and EPA actions to date, and next steps, including public participation and request for comments

2. Background

Although outbreaks of infectious disease attributable to drinking water are not common in the United States, they remain a concern and the extent to which they occur unrecognized by the health authorities has been the focus of much debate in recent years. One critical question of interest to those who are concerned about the microbial quality of drinking water and the associated health effects is: What is the magnitude of infectious disease in the United States that can be attributed to drinking water and, in particular, what are the levels of disease due to drinking water from public water systems that meet state and federal drinking water standards. There is no obvious and easy answer to this question. It is generally recognized that cases of waterborne disease are not likely to be recognized as such, and that therefore there is little direct information on which to base an estimate of waterborne disease occurrence and its associated costs to society. Illnesses caused by contaminated water are generally not specific to water, e.g diseases such as gastroenteritis could be caused by contaminated food or person-to-person transmission; moreover most cases will not result in illness deemed sufficiently serious by the ill person to require consulting a health care provider. Even if the disease is serious, it is highly unlikely to be traced back to drinking contaminated water unless the health care provider notices a sudden increase in the number of cases beyond what is normally expected, i.e. more cases than normal background levels within the population. In this case it is possible that the health authorities may be alerted and may consider that the increase in cases warrants an investigation which could lead to determining the vehicle of the disease agent, and thus to tracing the disease back to contaminated drinking water. This is only likely to happen in the case of an outbreak where a large fraction of the population has been infected. In order to detect any background levels of infectious disease due to drinking water, it is necessary to conduct targeted epidemiological investigations.

The issue of waterborne disease detection and how to detect disease within a population that can be attributed to drinking water is discussed in the reports from the two EPA/CDC workshops described below. The reports are available from EPA through the Safe Drinking Water Hotline. This notice describes how EPA and CDC are proceeding to develop an estimate of the level of waterborne disease in the United States based on data from targeted epidemiological studies.

3. EPA and CDC Actions and Strategy to Develop the National Estimate

EPA and CDC are working in close partnership to meet the requirements of the mandate to conduct studies on waterborne disease and to develop a national estimate of waterborne disease occurrence. Based on the legislative history, EPA and CDC interpret the term ''waterborne disease'' to refer to waterborne disease due to disease-causing microbes (pathogens) in drinking water, rather than to disease caused by chemical contamination. To the extent possible, EPA and CDC intend to consider which populations are at greatest risk, the economic impact of waterborne disease, which infectious agents are causing waterborne disease and their relative contribution to the overall incidence of waterborne disease due to drinking water, and the characteristics of water systems that are more likely to lead to waterborne disease.

In developing an approach to address the SDWA mandate, EPA and CDC invited the participation of outside experts and the public in two jointly-sponsored workshops. An initial workshop of public health experts from universities and from state and federal government took place in Atlanta in March 1997. A follow-up public workshop with wider representation of experts and other interested persons was held in the Washington, DC area in October 1997. Through this process of cooperative deliberation, EPA and CDC sought to review existing knowledge on waterborne disease and associated factors, and to evaluate different study designs to provide data necessary for calculating the national estimate of waterborne disease occurrence. Detailed summary reports of both meetings, including a list of participants, are available from EPA.

At the Atlanta workshop, attendees suggested that two components were needed to calculate a national estimate of waterborne disease: the incidence of gastrointestinal illness and the fraction of gastrointestinal illness attributable to drinking water. Cross-sectional surveys of the population were suggested as a straightforward means of determining the incidence of gastrointestinal illness. The workshop then focused on reviewing different study designs for establishing the fraction of gastroenteritis in a population that is attributable to drinking water. The participants identified the strengths and weaknesses of various designs and suggested that each be further evaluated for possible systematic biases, methods available for controlling bias, number of participants needed for a statistically stable estimate of increased risk, and the feasibility of measuring the specific pathogens associated with observed waterborne disease. Most participants felt that a population-based study, e.g. a household intervention study, would provide the strongest epidemiological evidence of waterborne disease and was the best design to determine the attributable fraction. However, participants also felt that other study designs were useful for estimating the attributable fraction and that more convincing evidence of waterborne disease risk and its magnitude would be provided by implementing several different study designs, rather than relying on multiple studies of the same design.

At the Washington workshop, specific ongoing and proposed studies and study designs were reviewed with respect to how they could contribute to the national estimate, and participants proposed alternate designs and combinations of designs. CDC presented an analysis of why it had decided to proceed with a pilot household intervention study. The participants again felt that it would be advantageous to conduct a variety of different study designs. This position is reflected in the request for proposals that was recently issued by CDC for three additional studies to provide data towards the national estimate in which the choice of study design is open to the researcher. In addition, EPA's in-house research program is conducting waterborne disease studies using other study designs.

EPA and CDC plan to host another public workshop in the spring of 1999 to review ongoing and planned studies and the need for specific additional information, and to discuss ideas on feasible approaches to developing the national estimate, taking cost and the development schedule into consideration. EPA and CDC welcome

comments on issues related to this proposed workshop, and encourage people who are interested in participating or who would like to receive notice of future meetings to notify EPA.

Since the initial workshop in March 1997, a total of $3.0 million from EPA's fiscal year 1997 and 1998 appropriations has been transferred to CDC to allow funding for seven studies on waterborne disease occurrence: A pilot household intervention study, two full-scale household intervention studies, a cross-sectional gastroenteritis and water consumption survey, and three epidemiological studies of unspecified design. CDC is managing the above projects; however, EPA and CDC work together in the review and selection of the study proposals. In addition to the above CDC/EPA collaborative studies, EPA, through its National Health and Environmental Effects Research Laboratory is funding research to characterize microbial enteric disease in a series of ''community intervention'' studies. These studies are described in more detail below.

In combination, these studies will provide a considerable amount of new data to support the development of a national estimate of waterborne disease occurrence by August 2001. However, EPA and CDC share a concern that given the two to two-and-a-half year duration for completion of some of the studies (the two household intervention studies), some of the data may not have undergone a full review by mid-2001. If this turns out to be the case, the national estimate will be revised if necessary by August 2002.

4. Studies for Developing the National Estimate of Waterborne Disease Occurrence

This section provides a brief summary of EPA and CDC's planned and ongoing studies that will contribute to developing the national estimate, including the study objectives, design, and population. Information from other studies by other organizations on waterborne disease, and relevant aspects of water quality and water treatment, will also be considered in the development of the national estimate.

A. Cross-Sectional Gastroenteritis and Water Consumption Survey

This study is being conducted as part of the CDC's FoodNet Survey, and is based on a randomized telephone survey to detect the incidence of foodborne disease, including gastroenteritis, at seven sites within the United States, including specific populations in California, Oregon, Minnesota, Georgia, New York, Maryland, and Connecticut. Approximately 9000 interviews are conducted annually. The questionnaire has recently been expanded to include questions on type and quantity of water consumption. The survey will provide data on which to base an estimate of the national incidence of gastroenteritis and national drinking water consumption patterns. The national incidence of gastroenteritis and the fraction of gastroenteritis that can be attributed to drinking water in a community (data from some of the studies described below) will provide useful information towards calculating an estimate of the national incidence of gastroenteritis due to drinking water. Other useful information from the survey includes data on measures of disease impact such as time lost from work or school, use of outpatient medical care, and hospitalization for gastrointestinal illness. However, the survey is unlikely to provide any information regarding causative pathogens or the relationship of water quality indicators with gastrointestinal illness.

B. Triple-Blinded Household Intervention Pilot Study

This is an experimental study in which persons in different households are randomly assigned to drink regular tap water or specially treated water that is expected to be pathogen free. The difference in tap water quality is achieved by installing identical looking devices at the water taps of homes of both groups; however, one group receives a device that further filters and disinfects the regular tap water, whereas the other group receives sham devices that do not provide additional treatment. If the group with the sham device has a higher incidence of gastroenteritis than the otherwise similar group with the real treatment device (the ''intervention''), then the difference will be assumed to be attributable to contamination in the regular tap water. The ''triple blinding'' refers to the design feature of ''blinding'' the researchers, statisticians and participants until the end of the study as to which households have regular tap water and which the specially treated tap water. Of particular interest for this type of study is whether persons in the households can detect (i.e. are blinded to) whether they are drinking regular tap water or the specially treated water, since knowing what group they are in might bias their response regarding whether or not they experience gastrointestinal illness.

CDC and EPA considered it necessary to perform a pilot study to test whether blinding is possible and to develop guidance regarding the logistics of future household intervention studies. The triple-blinded household intervention study design is favored because its random assignment of treatment reduces the effects of confounding, and the blinding of all participants avoids biases that affect most other study designs. The Atlanta workshop participants generally agreed that this study design, a so-called population-based intervention study, would provide the strongest epidemiological evidence of waterborne disease risk and the best estimate of the attributable risk due to drinking water. However, of all the studies evaluated, it is the most expensive to conduct. For this reason, EPA and CDC presently envision performing this type of study in only two large public water systems: a surface water site and a ground water site.

The pilot study was awarded to the California Emerging Infections Program. The site selected for the study is the Contra Costa Water District in California. Specific data that will be collected in this pilot study include amount of water consumption; symptoms of gastrointestinal illness; results of stool, sera and saliva tests; and impact of illness. The study is expected to be completed at the beginning of 1999.

C. Household Intervention—Two Requests for Proposals

In October 1998, CDC expects to issue a request for proposals for conducting two household intervention studies: One in a municipality receiving drinking water from a conventionally treated surface water source, and a second in a municipality with ground water source. In addition to determining the fraction of gastrointestinal illness due to drinking water, the project includes the collection of water quality and water treatment plant data in order to evaluate the relationship between water quality and disease incidence.

Initial funding available for the epidemiological aspects of the two projects amounts to $1.8 million. Additional funds will be available to fully fund the projects and to collect water quality data. The projects are expected to be awarded in the spring of 1999.

D. Three CDC Requests for Proposals

CDC issued a request for proposals for three additional studies to estimate the incidence of waterborne disease due to microbial contamination of drinking

water and/or to identify and describe the relationship between measures of water quality and health outcomes or evidence of infection due to gastrointestinal pathogens. The choice of study design is open to the researcher. Combined funding available for these projects amounts to $450, 000, and is anticipated to be awarded in the fall of 1998.

E. Community Intervention Studies

EPA is conducting a series of community intervention studies that are designed to characterize microbial gastroenteritis associated with drinking water that originates from selected surface water and groundwater sources. By studying communities that are planning to make improvements to their water treatment systems (e.g., adding filtration units or changing disinfectants), a ''natural experiment'' can be conducted which evaluates the enteric disease that may be present both before and after the implementation of the new system. The specific objectives of the first community study, which was conducted between June 1996 and December 1997, were to: (1) Determine rates of gastroenteritis; (2) determine the relative source contribution of factors implicated in gastroenteritis; (3) identify the microbial cause of gastroenteritis; and (4) assess surveillance methods of gastroenteritis. The data collected during the study are currently being analyzed. A community for the next community intervention study has been identified and data collection is slated to begin in the fall of 1998. EPA is also considering communities that use either ground water or surface water supplies as possible sites for future studies. EPA would welcome suggestions from the public on additional community studies.

F. Other Studies To Assist in National Estimate Development

In its development of the national estimate of waterborne disease occurrence and interpretation of the data from the epidemiological studies, EPA and CDC expect to use data from other relevant studies and databases. Information to be considered includes completed or ongoing epidemiological studies not specifically associated with the EPA/CDC effort, data on pathogen occurrence currently being collected by many utilities, studies on the effectiveness of water treatment, the dose-response relationship of certain pathogens, and studies on factors that affect the susceptibility of persons to infectious disease and disease severity.

5. Conclusions

EPA and CDC have committed to conducting waterborne infectious disease occurrence studies in at least five major U.S. communities or public water systems. One such study—a community intervention study—is nearing completion and a second community intervention study is scheduled to begin this fall. A pilot study for the two household intervention studies is underway and the two full-scale household intervention studies are expected to be awarded by April 1999. Three additional epidemiological studies of non-specified design are expected to be awarded in the fall of 1998.

In 1997, at two public workshops, EPA and CDC proposed one possible approach to developing the national estimate. However, EPA and CDC intend to continue the dialogue on this and other approaches to developing the national estimate at a public meeting scheduled for late next spring. EPA will announce the meeting in the **Federal Register**; however, to facilitate planning the meeting, EPA suggests that people who are interested in attending the meeting, or in receiving additional information about the meeting, notify EPA now (see section **FOR FURTHER INFORMATION** above) . EPA and CDC welcome comments on the issues discussed in this notice, as well as the reader's opinion on the extent to which, and how, the national estimate should address the social and economic impact of waterborne disease, the contribution of specific pathogens to the prevalence of waterborne disease, and the characteristics of public water systems and water quality indicators that are associated with a higher risk of waterborne disease. (For information on whom to address comments, see section **ADDRESSES** above.)

Dated: August 3, 1998.

J. Charles Fox,

Acting Assistant Administrator for Water.

[FR Doc. 98–21343 Filed 8–10–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–42206; FRL–6021–3]

Endocrine Disruptor Screening Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: As mandated by the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, EPA is setting forth its screening program for determining which pesticide chemicals and other substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects. In developing the screening program, EPA considered recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee, a panel chartered pursuant to the Federal Advisory Committee Act. EPA refers to this program as the ''Endocrine Disruptor Screening Program'' or the ''Screening Program.'' This document describes the major elements of EPA's Endocrine Disruptor Screening Program. EPA will provide operational details regarding the Screening Program, its regulatory implementation, and provide an opportunity for public comment in a later **Federal Register** document. After public comment and before implementation, EPA will submit the Screening Program for review to a joint panel of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel and the EPA Science Advisory Board.

ADDRESSES: The official record for this document, including a public version, has been established for this document under docket control number OPPTS–42206. The public version of this record is available for inspection from noon to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located at the TSCA Nonconfidential Information Center, Rm. NE–B607, 401 M St., SW., Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: *For general information or copies of the EDSTAC report:* Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St. SW., Washington DC, 20460; telephone 202–554–1404; TDD 202–554–0551; e-mail: TSCA-Hotline@epa.gov.

For technical information: Anthony Maciorowski, Ph.D., Senior Technical Advisor, Office of Prevention, Pesticides and Toxic Substances; telephone: 202–260–3048; e-mail: maciorowski.anthony@epa.gov or Gary Timm, Senior Technical Advisor, Chemical Control Division, Office of Pollution Prevention and Toxics; telephone: 202–260–1859; e-mail: timm.gary@epa.gov).

SUPPLEMENTARY INFORMATION: