

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:

I. General Information

A. Does this document apply to me?

This document describes the major elements of EPA's Endocrine Disruptor Screening Program, and does not require any action by any potentially affected entity. EPA will provide operational details regarding the Endocrine Disruptor Screening Program and its regulatory implementation in a later **Federal Register** document. EPA will provide an opportunity for public comment on the Screening Program in this later document. You may be interested in the program set forth in this document if you produce, manufacture or import pesticide chemicals, substances that may have an effect cumulative to an effect of a pesticide, or substances found in sources of drinking water. To determine whether you or your business may have an interest in this document you should carefully examine section 408(p) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996 (Pub. L. 104-170), 21 U.S.C. 346a(p) and amendments to the Safe Drinking Water Act (Pub. L. 104-182), 42 U.S.C. 300j-17. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed in the "FOR FURTHER INFORMATION CONTACT" section at the beginning of this document.

B. How can I get additional information or copies of this document.

1. *Electronically.* You may obtain electronic copies of this document from the EPA internet Home Page at <http://www.epa.gov/>. On the Home Page select "Laws and Regulations" and then look up the entry for this document under the "**Federal Register** - Environmental Documents." You can also go directly to the "**Federal Register**" listings at <http://www.epa.gov/homepage/fedrgstr/>.

2. *In person or by phone.* If you have any questions or need additional information about this action, contact the technical person identified in the "FOR FURTHER INFORMATION CONTACT" section at the beginning of this document. A public version of this record, including printed, paper versions which does not include any information claimed as CBI, is available for inspection at the address in the "ADDRESSES" section at the beginning of this document. The Document Control Office telephone number is 202-260-7093.

II. Background

Section 408(p) of the Federal Food, Drug, and Cosmetic Act, as amended by

the Food Quality Protection Act of 1996 (Pub. L. 104-170), 21 U.S.C. 46a(p), requires EPA, not later than August 3, 1998, to:

* * * develop a screening program using, appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect as the Administrator may designate.

When carrying out the Screening Program, EPA "shall provide for the testing of all pesticide chemicals" and "may provide for the testing of any other substance that may have an effect that is cumulative to an effect of a pesticide chemical if the Administrator determines that a substantial population may be exposed to such a substance." 21 U.S.C. 346a(p)(3).

In addition, Congress amended the Safe Drinking Water Act and gave EPA authority to provide for the testing, under the FQPA Screening Program, "of any other substance that may be found in sources of drinking water if the Administrator determines that a substantial population may be exposed to such substance." 42 U.S.C. 300j-17.

This document sets forth the Screening Program that EPA has developed to comply with requirements of section 408(p) of the FFDCA as amended by FQPA. In a later **Federal Register** document, EPA will provide additional information about the Screening Program and its implementation and an opportunity for the public to comment on it. After public comment and before implementation, EPA will submit the Screening Program to a joint panel of the Federal Insecticide, Fungicide, and Rodenticide Act Scientific Advisory Panel and the EPA Science Advisory Board for review.

III. Endocrine Disruptor Screening Program

EPA has considered recommendations of the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) in developing its Screening Program. The full text of the EDSTAC Draft Final Report is available on EPA's worldwide web site at: www.epa.gov/opptintr/opptendo. Paper copies can be obtained upon request from the TSCA Hotline at the address listed in "FOR FURTHER INFORMATION CONTACT" at the beginning of this document.

Initially, the Endocrine Disruptor Screening Program will focus on estrogenic, androgenic, and thyroid hormone effects. These three hormone systems are presently the most studied of the approximately 50 known

vertebrate hormones. *In vitro* and *in vivo* test systems to examine estrogen, androgen, and thyroid effects exist, and are currently the most amenable for regulatory use. Further, inclusion of estrogen, androgen, and thyroid effects will cover aspects of reproduction, development, and growth.

EPA recognizes that there is a great deal of ongoing research related to other hormones and test systems. As more scientific information becomes available, EPA will consider expanding the scope of the Endocrine Disruptor Screening Program to other hormones. For now, however, the estrogen, androgen, and thyroid hormone effects and test systems represent a scientifically reasonable focus for the Agency's Endocrine Disruptor Screening Program.

EPA's Endocrine Disruptor Screening Program uses a tiered approach for determining whether a substance may have an effect in humans that is similar to an effect produced by naturally occurring estrogen, androgen, or thyroid hormones. The core elements of the tiered approach include initial sorting, priority setting, Tier 1 analysis, and Tier 2 analysis.

A. Initial Sorting

Chemicals under consideration for estrogen, androgen, and thyroid screening will undergo initial sorting based on existing, scientifically relevant information. EPA will use the existing information to place a chemical into one of the following four categories.

1. *Category 1—Hold.* Chemicals with sufficient, scientifically relevant information to determine that they are not likely to interact with the estrogen, androgen, and thyroid hormone systems. If EPA is able to determine, based on scientifically relevant information, that a specific chemical is not likely to interact with the estrogen, androgen, or thyroid hormone systems, it will place that chemical in a hold category. Chemicals in this hold category will have the lowest priority for further analysis and may not undergo further analysis unless new and compelling information suggests that the chemical may interact with the endocrine system. Although EPA will place chemicals in the hold category during the initial sorting phase of the Screening Program, it may add chemicals to this category if, during a later phase of the Screening Program (priority setting, Tier 1 analysis, or Tier 2 analysis), the Agency determines that a particular chemical is not likely to interact with the endocrine system.

2. *Category 2—Priority Setting/Tier 1 Analysis.* Chemicals for which there is

insufficient, scientifically relevant information to determine whether or not they are likely to interact with the estrogen, androgen, and thyroid systems. If EPA is not able to determine, based on scientifically relevant information, whether or not a chemical is likely to interact with the estrogen, androgen, and thyroid hormone systems, it will place that chemical into a "priority setting" category. Category 2 chemicals are those for which there is insufficient scientifically relevant information to be placed on hold (Category 1), or assigned to Tier 2 analysis (Category 3) or hazard assessment (Category 4). EPA anticipates that it will likely place the majority of chemicals into this category. Category 2 chemicals will be subjected to formal priority setting, Tier 1 analysis, and as appropriate, Tier 2 analysis.

3. Category 3—Tier 2 Analysis.

Chemicals with sufficient, scientifically relevant information comparable to that provided by the Tier 1 analysis. Recognizing the need for flexibility, EPA has included Tier 1 analysis bypass possibilities. For example, if sufficient, scientifically relevant information exists regarding a specific chemical, EPA may move that chemical directly into Tier 2 analysis. In addition, EPA may allow a chemical to bypass Tier 1 analysis if the chemical's producer or registrant chooses to conduct Tier analysis without performing Tier 1.

4. Category 4—Hazard Assessment.

Chemicals with sufficient, scientifically relevant information to bypass Tier 1 and Tier 2 analysis. For certain chemicals, there already may be sufficient, scientifically relevant information regarding their interaction with the estrogen, androgen, thyroid hormone systems—information comparable to that derived from Tier 1 and Tier 2 analysis—to move them directly into hazard assessment for endocrine disruption. These chemicals, thus, will bypass Tier 1 and Tier 2 analysis. It is anticipated that this will be a relatively small number (less than 100) of chemicals.

B. Priority Setting

During priority setting, EPA will determine in what order the chemicals placed in Category 2 during "initial sorting" will enter Tier 1 analysis. EPA will set priorities using existing exposure and effects data and statutory criteria. The exposure and effects data will consist of empirical data where available and may also employ models to estimate exposure or effects characteristics. EPA recognizes that existing endocrine specific effects data

are incomplete or lacking for most chemicals. To address this inadequacy, EPA, in partnership with others, will conduct selected *in vitro* assays in a high-speed, automated fashion. This step is called "high throughput pre-screening" (HTPS). EPA will use the data that it generates from HTPS for priority setting. HTPS data alone is insufficient to ascertain whether or not a chemical may be an endocrine disruptor. Priority setting will result in a phased approach to screening with the highest priority chemicals evaluated first, followed by medium priority chemicals, and then low priority chemicals. EPA has adopted a priority setting approach because the available resources and laboratory capacity necessary for the Endocrine Disruptor Screening Program will not allow simultaneous entry of hundreds to thousands of chemicals into the process.

C. Tier 1 Analysis

Tier 1 analysis is designed to identify those chemicals that are not likely to interact with the estrogen, androgen, and thyroid hormone systems. During Tier 1 analysis, the Agency hopes to eliminate those chemicals that are unlikely to interact with the estrogen, androgen, and thyroid hormone systems. EPA does not believe that Tier 1 analysis will be adequate to determine whether a chemical may have an endocrine effect. Completion of Tier 1 analysis will result in either a decision to move the chemical into Tier 2 analysis, or an initial decision that no further analysis is needed, in which case EPA will place the chemical on hold (Category 1).

Under EPA's Screening Program, Tier 1 analysis involves both *in vitro* and *in vivo* test systems. The Tier 1 assays were designed and selected as a battery. EPA believes that data from the entire battery are necessary to make the necessary decisions about the chemicals. The individual assays and the battery were selected on the basis of scientific relevance and state of scientific development. All of the assays will be validated prior to the Screening Program's implementation. Validation will be addressed by EPA in the future **Federal Register** document. EPA will also include several alternative assays in its validation activities. The Tier 1 *in vivo* and *in vitro* assays are listed below.

1. *In Vitro* assays include an estrogen receptor binding or reporter gene assay, an androgen receptor binding or reporter gene assay, and a steroidogenesis assay with minced testis.

2. *In Vivo* assays include a rodent 3-day uterotrophic assay, a rodent 20-day

pubertal female assay with enhanced thyroid endpoints, a rodent 5 to 7-day Hershberger assay, a frog metamorphosis assay, and a fish gonadal recrudescence assay.

D. Tier 2 Analysis

Tier 2 analysis is designed to determine whether a chemical may have an effect in humans similar to that of naturally occurring hormones and to identify, characterize, and quantify those effects for estrogen, androgen, and thyroid hormones. Like the Tier 1 battery, the Tier 2 analysis scheme is designed as a battery. A negative outcome in Tier 2 analysis will supersede a positive outcome in Tier 1 analysis. Furthermore, each Tier 2 assay includes endpoints that will permit a decision regarding whether or not a tested chemical may be an endocrine disruptor for estrogen, androgen, or thyroid effects. Conducting all five assays in the Tier 2 battery will provide the type of information necessary for endocrine disruptor hazard assessment. A decision to require less testing may be made by EPA based on scientifically relevant information showing that exposure is limited or that effects can be adequately characterized in a one generation assay.

1. *Tier 2 assays.* Tier 2 assays include a two-generation mammalian reproductive toxicity study or a less comprehensive alternative mammalian reproductive toxicity assay, an avian reproduction toxicity assay, a fish life cycle toxicity assay, an opossum shrimp (Mysidacea) or other invertebrate life cycle toxicity assay, and an amphibian development and reproduction assay.

2. *Assay selection.* EPA will provide guidance on the selection of Tier 2 assays, focusing upon:

a. The determination of which of the five taxonomic groups should be included in the Tier 2 analysis of a specific chemical.

b. The circumstances under which it may be appropriate to perform an alternative assay, with a particular focus on the selection of alternative mammalian assays.

c. The selection of endpoints.

d. The special case of chemicals that bypass Tier 1 analysis and go directly to Tier 2 analysis.

e. The potential need for supplemental information to complete Tier 2 analysis.

E. Evaluation of Results

A weight-of-evidence approach will be used to evaluate Tier 1 and Tier 2 analysis results. The weight-of-evidence approach will include:

1. The balance of positive and negative responses observed in both the *in vitro* and *in vivo* assays.

2. The nature and range of the biological effects observed.

3. The shape of the dose-response curves when available.

4. The severity and magnitude of the effects induced.

5. The presence or absence of responses in multiple taxa.

The evaluation of Tier 1 data, and other scientifically relevant information (e.g., HTS or literature data), will result in a decision that either the chemical needs no further analysis and can be moved to the hold category or a decision that the chemical needs to undergo Tier 2 analysis to determine whether it may have an effect in humans that is similar to the effect produced by a naturally occurring hormone. Similarly, an evaluation of Tier 2 data will result in a decision either to move the chemical into the hold category or to move it into hazard assessment.

IV. Development of EPA Policies

EPA currently is developing policies to implement the Endocrine Disruptor Screening Program. EPA will set forth these policies in another **Federal Register** document later this year. This document will provide interpretive and operational details, and address such issues as standardization and validation of the assays, statutory and regulatory mechanisms for requiring the development of data, data reporting requirements, data compensation, confidential business information, and the process for granting waivers from screening requirements.

List of Subjects

Environmental protection.

Dated: July 31, 1998

Approved by:

J. Charles Fox,

Assistant Administrator for Water.

Lynn R. Goldman,

Assistant Administrator for Prevention, Pesticides, and Toxic Substances.

[FR Doc. 98-21522 Filed 8-10-98; 8:45 am]

BILLING CODE 6560-50-F

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collections Approved by Office of Management and Budget

August 4, 1998.

The Federal Communications Commission (FCC) has received Office

of Management and Budget (OMB) approval for the following public information collection pursuant to the Paperwork Reduction Act of 1995, Pub. L. 104-13. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid control number. For further information contact Shannon Belliman, Federal Communications Commission, (202) 418-0408.

Federal Communications Commission.

OMB Control No.: 3060-0454.

Expiration Date: July 7, 2001.

Title: CC Docket No. 90-337, Regulation of International Accounting Rates.

Form No.: N/A.

Respondents: Business or other for-profit entities.

Number of Respondents: 12.

Estimated Time Per Response: 1 hour.

Frequency of Response: On occasion.

Estimated Annual Reporting and Recordkeeping Cost Burden: \$5,850.

Total Annual Burden: 780 hours.

Needs and Uses: The FCC requests this collection of information as a method to monitor the international accounting rates to insure that the public interest is being served and also to enforce Commission policies. By requiring a U.S. carrier to make an equivalency showing and to file other documents for end users interconnected international private lines, the FCC will be able to preclude one-way bypass and safeguard its international settlements policy. The data collected is required by Section 43.51(d) of the FCC's rules. Obligation to respond: required. Public reporting burden for the collection of information is as noted above. Send comments regarding the burden estimate or any other aspect of the collections of information, including suggestions for reducing the burden to Performance evaluation and Records Management, Washington, D.C. 20554.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 98-21440 Filed 8-10-98; 8:45 am]

BILLING CODE 6712-01-F

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 2289]

Petitions for Reconsideration and Clarification of Action in Rulemaking Proceeding

August 4, 1998.

Petitions for reconsideration and clarification have been filed in the

Commission's rulemaking proceedings listed in this Public Notice and published pursuant to 47 CFR Section 1.429(e). The full text of these documents are available for viewing and copying in Room 239, 1919 M Street, NW., Washington, DC or may be purchased from the Commission's copy contractor, ITS, Inc., (202) 857-3800. Oppositions to these petitions must be filed August 26, 1998. See Section 1.4(b)(1) of the Commission's rule (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: Implementation of the Telecommunications Act of 1996: (CC Docket No. 96-115).

Telecommunications Carriers' Use of Customer Proprietary Network Information and Other Customer Information.

Implementation of the Non-Accounting Safeguards of Sections 271 and 272 of the Communications Act of 1934, as amended (CC Docket No. 96-149).

Number of Petitions Filed: 3.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 98-21438 Filed 8-10-98; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 26, 1998.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63102-2034:

1. *Hattie L. Preston, as trustee of the Hattie L. Preston Revocable Trust,* Henderson, Kentucky; to retain voting