

Dated: May 10, 2000.

**Oscar Morales,**

*Director, Collection Strategies Division.*

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6700-5]

### Integrated Risk Information System (IRIS): Announcement of 2000 Program—Addendum; Request for Information

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice; addendum to announcement of IRIS 2000 program and request for scientific information on health effects that may result from chronic exposure to chemical substances.

**SUMMARY:** The Integrated Risk Information System (IRIS) is an Environmental Protection Agency (EPA) data base that contains EPA scientific consensus positions on human health effects that may result from chronic exposure to chemical substances in the environment. On January 12, 2000, EPA announced the 2000 IRIS agenda and solicited scientific information from the public for consideration in assessing health effects from specific chemical substances. This notice adds the chemical substances hexachlorobenzene and hexahydro-1,3,5-trinitro-triazine ("RDX") to the IRIS agenda, and solicits scientific data and evaluations for consideration in EPA's assessments.

**DATES:** Please submit information in response to this notice by July 17, 2000.

**ADDRESSES:** Please send relevant scientific information to the IRIS Submission Desk in accordance with the instructions provided under "Submission of Information" in this notice.

**FOR FURTHER INFORMATION CONTACT:** For information on the IRIS program, contact Amy Mills, National Center for Environmental Assessment (mail code 8601D), U.S. Environmental Protection Agency, Washington, DC 20460, or call (202) 564-3204, or send electronic mail inquiries to mills.amy@epa.gov. For general questions about access to IRIS, or the content of IRIS, please call the Risk Information Hotline at (513) 569-7254.

#### SUPPLEMENTARY INFORMATION:

#### Background

IRIS is an EPA data base containing Agency consensus scientific positions

on potential adverse human health effects that may result from chronic (or lifetime) exposure to chemical substances found in the environment. IRIS currently provides health effects information on over 500 specific chemical substances.

IRIS contains chemical-specific summaries of qualitative and quantitative health information in support of the first two steps of the risk assessment process, i.e., hazard identification and dose-response evaluation. IRIS information includes the reference dose for noncancer health effects resulting from oral exposure, the reference concentration for noncancer health effects resulting from inhalation exposure, and the carcinogen assessment for both oral and inhalation exposure. Combined with specific situational exposure assessment information, the summary health hazard information in IRIS may be used as a source in evaluating potential public health risks from environmental contaminants.

#### The IRIS Program

EPA's process for developing IRIS consists of: (1) An annual **Federal Register** announcement of EPA's IRIS agenda and call for scientific information from the public on the selected chemical substances, (2) a search of the current literature, (3) development of health assessments and draft IRIS summaries, (4) peer review within EPA, (5) peer review outside EPA, (6) EPA consensus review and management approval, (7) preparation of final IRIS summaries and supporting documents, and (8) entry of summaries and supporting documents into the IRIS data base.

#### Purpose of This Notice

EPA is adding the chemical substances hexachlorobenzene (CAS No. 118-74-1) and hexahydro-1,3,5-trinitro-triazine or "RDX," (CAS No. 121-82-4) to its assessment agenda for fiscal year 2000. EPA is hereby requesting scientific information from the public for consideration in these two assessments.

As described in the January 12, 2000, **Federal Register** document (63 FR 1863) announcing the IRIS agenda for fiscal year 2000, EPA is testing ways to cooperate with external parties, including other government agencies, in the development of supporting documentation for IRIS. The Agency is initiating these two assessments to build upon a common interest with other federal agencies. EPA's Superfund program has identified a strong need to update the existing IRIS entry for

hexachlorobenzene. This substance is frequently found at Superfund sites and is critical to a number of human health risk assessments. Concurrently, the Agency for Toxic Substances and Disease Registry (ATSDR) has identified hexachlorobenzene as a priority substance for developing a revised Toxicological Profile. EPA and ATSDR will therefore coordinate their efforts in developing the IRIS Toxicological Review and the revised ATSDR Toxicological Profile for Hexachlorobenzene. Similarly, the U.S. Army has identified a strong need to update the existing IRIS entry for RDX, which frequently occurs at federal facilities operated by the U.S. Army and is critical to a number of human health risk assessments. EPA and the U.S. Army will coordinate their efforts in developing a Toxicological Review for RDX. New scientific information is available to evaluate and reassess the potential health effects of both substances.

These joint efforts with other federal agencies is a pilot effort to utilize federal resources more effectively and provide more consistent information to the public. Completion of the hexachlorobenzene and RDX assessments and addition to the IRIS data base is expected by fiscal year 2002.

#### Submission of Information

As in previous **Federal Register** documents announcing the annual IRIS agenda, EPA is soliciting public information on hexachlorobenzene and RDX. While EPA conducts a thorough literature search for each chemical substance, there may be other articles or unpublished studies we are not aware of. We would greatly appreciate receiving scientific information from the public during the information gathering. Interested persons should provide scientific comments, analyses, studies, and other pertinent scientific information. The most useful documents for EPA are unpublished studies or other primary technical sources that we may not otherwise obtain through open literature searches. Also note that if you have submitted certain information previously, there is no need to resubmit that information. Information from the public is being solicited for 60 days via this notice.

#### Procedures for Submission

As described in the January 12, 2000, **Federal Register** document, submissions will be handled in a three-step process:

1. Submission Inventory: First, you should simply provide a list within 60

days of this notice briefly identifying all the information (reports, papers, articles, etc.) you wish to submit. The list should specify by name and CASRN (Chemical Abstract Service Registry Number) the chemical substance(s) to which the information pertains, state the type of assessment that is being addressed (e.g., carcinogenicity), and describe briefly the information to be submitted for consideration. Where possible, documents should be listed in scientific citation format, that is, author(s), title, journal, and date. Your cover letter should: state that the correspondence is an IRIS submission, describe in general terms the purpose of the submission, and include names, addresses, and telephone numbers of persons to contact for additional information. Mail two copies of the submission to the IRIS Submission Desk, c/o Courtney R. Johnson, National Center for Environmental Assessment (8601D), U.S. Environmental Protection Agency, Washington, DC 20460.

Alternatively, you may submit the submission inventory and cover letter electronically to IRIS.desk@epa.gov. Electronic information must be submitted in WordPerfect or as an ASCII file. Information will also be accepted on 3.5" disks. All information in electronic form must be identified as an IRIS submission.

2. EPA Replies to Submission Inventory: In the second step, EPA will compare the submission inventory to existing files and identify the information that should be submitted. This step will help prevent an influx of duplicative information. You will receive notification requesting full submission of the selected material.

3. Full Submission of Selected Material: In the third step, you should send in the information indicated by EPA within 30 days of EPA's reply. Prompt response to EPA will ensure that your material can be considered in the assessment in a timely fashion. Submittals should include a cover letter addressing all of the points in item 1 above. In addition, when you submit results of new health effects studies concerning existing substances on IRIS, you should include a specific explanation of how and why the study results could change the information in IRIS.

Please send two copies, at least one of which should be unbound, to the IRIS Submission Desk, as described in Step 1. The IRIS Submission Desk will acknowledge receipt of your information.

Confidential Business Information (CBI) should not be submitted to the IRIS Submission Desk. CBI must be

submitted to the appropriate EPA office via established procedures for submission of CBI (see 40 CFR, part 2, subpart B). If you believe that a CBI submission contains information with implications for IRIS, please note that in the cover letter accompanying the submission to the appropriate office.

You may also request to augment your submission with a scientific briefing to EPA staff. Such requests should be made directly to Amy Mills, IRIS Program Manager (see **FOR FURTHER INFORMATION CONTACT**).

Dated: May 4, 2000.

**William H. Farland,**

*Director, National Center for Environmental Assessment.*

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## **ENVIRONMENTAL PROTECTION AGENCY**

**[OPP-00660; FRL-6559-6]**

### **FIFRA Scientific Advisory Panel; Notice of Public Meeting**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** There will be a 2-day meeting of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and Food Quality Protection Act (FQPA) Scientific Advisory Panel (SAP) to review the following set of scientific issues being considered by the Agency pertaining to Consultation: National Drinking Water Survey Design for Assessing Chronic Exposure and Mammalian Toxicity Assessment Guidelines for Protein Plant-Pesticides. The meeting is open to the public. Seating at the meeting will be on a first-come basis. Individuals requiring special accommodations at this meeting, including wheelchair access, should contact Larry Dorsey or Paul Lewis at the address listed under **FOR FURTHER INFORMATION CONTACT** at least 5 business days prior to the meeting so that appropriate arrangements can be made.

**DATES:** The meeting will be held on Tuesday, June 6 and Wednesday, June 7, 2000, from 8:30 a.m. to 4:30 p.m.

**ADDRESSES:** The meeting will be held at Sheraton Crystal City Hotel, 1800 Jefferson Davis Highway, Arlington, VA. The telephone number for the Sheraton hotel is: (703) 486-1111.

Requests to participate may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit III. of the

**SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your request must identify docket control number OPP-00660 in the subject line on the first page of your response.

#### **FOR FURTHER INFORMATION CONTACT:**

Larry Dorsey or Paul Lewis, Designated Federal Officials, FIFRA SAP (7101C), Office of Science Coordination and Policy, Environmental Protection Agency, Ariel Rios Bldg., 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-5369; fax number: (703) 605-0656; e-mail address: dorsey.larry or lewis.paul@epa.gov.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Does this Action Apply to Me?**

This action is directed to the public in general. This action may, however, be of interest to those persons who are or may be required to conduct testing of chemical substances under the Food Quality Protection Act (FQPA) or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**. This 2-day meeting concerns several scientific issues undergoing consideration within the EPA Office of Pesticide Programs (OPP). The topics to be discussed are the following:

Session 1—Under the FQPA, drinking water is considered in aggregate exposure assessments for pesticide tolerance reassessments. Since targeted monitoring data are needed for refined exposure assessments, OPP has proposed a design framework for assessing annual average pesticide concentrations in surface waters used as drinking water. Details of survey design issues and options will be presented on OPP's proposed design framework and on an independently proposed design framework.

Session 2—For this session, the Agency is soliciting guidance from the Panel on the assessment of the potential mammalian toxicity of proteins expressed as plant-pesticides. Questions will be presented on the use of amino acid homology with known toxins, *in-vitro* digestibility, dietary exposure, mechanisms of toxicity and other topics regarding the assessment of introduced proteins for potential mammalian toxicity.