



CHEMICAL MANUFACTURERS ASSOCIATION

May 2, 1996

Dear Vinyl Chloride Health Committee Members:

The following items are enclosed for your review and discussion on the May 9, 1996 conference call:

- 1) agenda for the May 9, 1996 conference call;
- 2) Federal Register notice of Tuesday, April 4, 1996 regarding the EPA's Integrated Risk Information System (IRIS). The IRIS process already has begun for Vinyl Chloride (a new entry) with a request for identification of all technical information related to cancer and non-cancer assessments. Over the next six to eight months, EPA will compare submitted inventories with existing files and collect only that information which it has not previously compiled. By initially requesting only data inventories, EPA plans to avoid an influx of duplicative information. After EPA is satisfied that a comprehensive search has been conducted, it will develop draft health assessments for review by internal (within EPA) and external (outside EPA) peer review committees. Internal consensus review and management approval will determine the final entry into the IRIS database;
- 3) CMA letter to Joan Dollarhyde of EPA's IRIS Submission Desk explaining the Committee's intent to submit information on Vinyl Chloride for entry into the IRIS database and work with the Agency on its IRIS pilot project;
- 4) Proposal to Impact the Reevaluation of Vinyl Chloride (VCI) carcinogenicity. Please review this proposal carefully so that we can decide during the conference call whether we wish to retain ChemRisk's services. The cost estimates provided by ChemRisk are significantly higher than what the Committee has budgeted. Please identify any areas in the proposal that may be done by Health Committee members to reduce costs, if the Committee decides to retain ChemRisk's services; and,
- 5) *Predicting Cancer Risk from Vinyl Chloride Exposure with a Physiologically Based Pharmacokinetic Model*, Reitz, et. al.

I am waiting for the protocol for the Brain Cancer Case-Control study from Carlo Tamburro, and the molecular research protocol from Jim Swenberg. I will fax the protocols to you when they arrive. The information on agenda items 6, 7, and 8, was sent to you earlier. I will provide an update on these items during the conference call. Please call me at 703/741-5637 if you have any questions.

Sincerely,

Hasmukh C. Shah, Ph.D.
Manager, Vinyl Chloride Panel

BFG 00067

Enclosure



approval within EPA, (6) preparation of final IRIS summaries and supporting documents, and (7) entry of summaries into the IRIS data base.

The appropriate level of external peer review will be determined for each chemical substance. Depending upon the complexity of the scientific information and other factors, the form of the peer review will either be via mail, forums of experts, or formal federal advisory committees.

The Pilot will also test some improvements in IRIS entries to more fully characterize health information associated with each chemical. For example, the IRIS summaries will provide greater elaboration of uncertainties in the data, and our confidence in the assessment.

Pilot Substances

The eleven Pilot chemical substances were chosen on the basis of the Agency's need for new or updated hazard or dose-response information, and in an effort to represent a range of technical complexity so the new process is realistically tested. Qualitative and quantitative information will be developed for non-cancer and cancer effects of all Pilot substances. In some cases, the assessment will be developed for the first time; in others, the assessment will be reviewed in light of new information and updated in IRIS if appropriate.

The following substances will be reviewed under the Pilot Program:

Name/CAS.No.

- Arsenic—7440-38-2
- Bentazon—25057-89-0
- Beryllium—7440-41-7
- Chlordane—57-74-9
- Chromium (III)—16065-83-1
- Chromium (VI)—18540-29-9
- Total chromium—7440-47-3
- Cumene—98-82-8
- Methyl methacrylate—80-62-6
- Methylene diphenyl isocyanate—101-68-8
- Naphthalene—91-20-3
- Tributyltin oxide—56-35-9
- Vinyl chloride—75-01-4

Note that EPA may initiate other chemical substance reviews during the Pilot period; the Pilot does not preclude additional work on IRIS.

Submission of Information

The Pilot Program is designed to provide early opportunity for public involvement. While the Agency conducts a thorough literature search for each chemical substance, there may be other articles or unpublished studies we are not aware of. The Agency would greatly appreciate receiving scientific

information from the public during the information gathering stage of the Pilot. 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, such as in response to the 1993 FR Notice, then there is no need to resubmit that information. Information from the public is being solicited for 30 days via this Notice.

As described in the 1993 FR Notice, submissions will be handled in a three-step process:

1. First, interested parties should simply provide a list (submission inventory), briefly identifying all the information they wish to submit to the IRIS Information Submission Desk. The list should specify by name and CAS (Chemical Abstract Registry) number the Pilot chemical substance to which the information pertains, state the assessment that is being addressed (e.g., carcinogenicity), and describe briefly the information being submitted for consideration. Where possible, documents should be listed in scientific citation format, that is, author(s), title, journal, and date. A 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 on the submission.

2. 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. The submitter will receive notification requesting full submission of the selected material.

3. In the third step, the submitter should promptly send in the information requested by EPA. Submittals should include a cover letter addressing all of the points in item 1 above. In addition, persons submitting results of new health effects studies should include a specific explanation of how and why the study results could change the information in IRIS.

Submitters sending paper copies are requested to send three copies, at least one of which should be unbound. As mentioned previously (see ADDRESSES), the Agency also welcomes electronic submission of information in response to this Notice. EPA will transfer all correspondence received electronically

into printed, paper form as it is received and will place the paper copies along with all information submitted directly in writing to the IRIS Submission Desk. Receipt of information will be acknowledged in the manner in which it is received, that is, in writing or electronically.

Other aspects of the information submittal process are unchanged and are detailed in the 1993 FR Notice. Most importantly, Confidential Business Information (CBI) should not be submitted to the IRIS Submission Desk. CBI must be submitted to the appropriate office via approved Agency procedures for submission of CBI as codified in the Code of Federal Regulations (40 CFR, Part 2, Subpart B). If a submitter believes that a CBI submission contains information with implications for IRIS, it should be noted in the cover letter accompanying the submission to the appropriate office.

Dated: March 27, 1996.

Robert J. Huggett,

Assistant Administrator for Research and Development.

[FR Doc. 96-8007 Filed 4-1-96; 8:45 am]

BILLING CODE 6560-60-P

[FRL-5451-5

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), this notice announces the Office of Management and Budget's (OMB) responses to Agency PRA clearance requests. 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 OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer (202) 260-2740. Please refer to the EPA ICR No.

SUPPLEMENTARY INFORMATION:

OMB Responses to Agency PRA Clearance Requests

OMB Approvals

EPA ICR No. 1560.04; National Water Quality Inventory Reports—Clean Water Act Sections 305(b), 303(d), 314(a), and 106(e); was approved 02/21/96. OMB No. 2040-0071 expires 02/28/99.

EPA ICR No. 1598.02; Reporting and Recordkeeping Requirements under

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.

Respondent/Affected Entities: 40.

Estimated Number of Respondents: 40.

Frequency of Response: Variable.

Estimated Total Annual Hour Burden: 11,420 hours.

Estimated Total Annualized Cost Burden: \$347,739.

Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods of minimizing respondent burden, including through the use of automated collection techniques to the following addresses. Please refer to EPA ICR No. 0664 and OMB Control No. 2060-0006 in any correspondence.

Ms. Sandy Farmer, U.S. Environmental Protection Agency, OPPE 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 10503.

Dated: March 29, 1996.

Joseph Retzer,

Director, Regulatory Information Division.

[FR Doc. 96-7874 Filed 4-1-96; 8:45 am]

BILLING CODE 5540-60-M

[FRL-5452-2]

Integrated Risk Information System (IRIS); Announcement of Pilot Program; Request for Information

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice: Announcement of IRIS Pilot Program and request for technical information on Pilot chemical substances.

SUMMARY: The Integrated Risk Information System (IRIS) is a data base of the United States Environmental Protection Agency (EPA) that contains EPA scientific consensus positions on potential human health effects from environmental contaminants. On February 25, 1993 (58 FR 11490) EPA requested public comment to improve IRIS and make it more useful. In that notice, EPA also described efforts in the Agency to identify issues in the development and presentation of information in the data base. Many of the issues concern the way consensus

health information is developed prior to entry into the data base. As a consequence of analyzing the IRIS program and considering suggestions received about IRIS over the past several years, EPA has initiated a Pilot Program to improve the consensus health information process and strengthen peer review. The Pilot will produce new or updated health assessments and IRIS entries for eleven priority environmental chemical substances utilizing this new process. The purpose of this Notice is to advise the public that the Pilot is underway, and to request technical information from the public on the eleven Pilot substances.

DATES: Please submit information in response to this Notice by May 2, 1996.

ADDRESSES: Please mail information (three copies, at least one of which should be unbound) to the IRIS Submission Desk, NCEA (MS-190), U.S. Environmental Protection Agency, 26 Martin Luther King Drive, Cincinnati, OH 45268. Information may instead be submitted electronically by sending electronic mail (e-mail) to:

IRIS.comments@epamail.epa.gov. Electronic information must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Information will also be accepted on disks in WordPerfect 5.1 format or ASCII file format. All information in electronic form must be identified as IRIS Submission.

FOR FURTHER INFORMATION: For information on the Pilot, contact Amy Mills, National Center for Environmental Assessment (mail code 8623), U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. The public information phone line for the Pilot is (202) 260-8930, or email inquiries may be addressed to mills.amy@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Background

The Integrated Risk Information System (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 environmental contaminants. 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 non-cancer health effects resulting from oral exposure, the reference concentration for non-cancer 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.

As the data base has expanded and its use has increased over the last decade, issues have surfaced with regard to entering new information in a timely manner, while soliciting information from a broad spectrum of outside scientists and the public. In 1993, an EPA team evaluated the status of IRIS and proposed options for improvement. This effort was announced in a Notice in the Federal Register of February 25, 1993 (58 FR 11490). The Notice addressed the use of IRIS, and avenues for public involvement and external scientific peer review of IRIS summaries and supporting documents. Public involvement means opportunities for affected or interested parties to have some level of input into IRIS health hazard information, such as providing relevant health data. Public involvement can involve a broader spectrum of participants than external peer review, which refers to a critical scientific appraisal by experts outside of EPA.

The Agency and the public have continued to express support for maintaining IRIS and strengthening the process for developing consensus health information, public involvement, and peer review. This support has given rise to the new Pilot Program.

The Pilot Program

As a consequence of analyzing the IRIS program and considering suggestions received about IRIS over the past several years, the Agency has decided to test some improvements through a Pilot Program. The Pilot will primarily address the scientific consensus and review process that precedes IRIS data base entries. EPA will develop (or update, for existing entries) all non-cancer and cancer information for the eleven Pilot substances. The Pilot process will consist of, (1) A call for technical information on the eleven substances from the public via this FR Notice, (2) a search of the current literature, (3) development of health assessments and draft IRIS summaries, (3) internal peer review (i.e., within EPA), (4) external peer review (outside EPA), (5) consensus review and management



CHEMICAL MANUFACTURERS ASSOCIATION

May 2, 1996

Ms. Joan Dollarhyde
Integrated Risk Information System (IRIS) Submission Desk
NCEA (MS-190)
U.S. Environmental Protection Agency (EPA)
26 Martin Luther King Drive
Cincinnati, OH 45268

Dear Ms. Dollarhyde:

In accordance with the Federal Register notice of Tuesday, April 4, 1996, this is to inform you of our intent to submit information about Vinyl Chloride (CAS. NO. 75-01-4) for the IRIS Pilot Project. The purpose of our submission is to identify cancer and non-cancer risk assessment materials which may not be readily accessible to EPA's internal and external peer review groups. Specifically, we intend to submit information on the following:

- Reitz, R.H., et al, "Predicting Cancer Risk from Vinyl Chloride Exposure with a Physiologically Based Pharmacokinetic Model." *Toxicology and Applied Pharmacology* 137, 253-267 (1996)
- Clewell, H.J., et al, "Considering Pharmacokinetic and Mechanistic Information in Cancer Risk Assessments for Environmental Contaminants: Examples with Vinyl Chloride and Trichloroethylene." In Press.

In addition, through a Memorandum of Understanding with the Agency for Toxic Substances and Disease Registry, CMA is conducting a combined inhalation two-generation reproductive and developmental toxicity study of Vinyl Chloride in rats. The results of this study also will be made available to EPA for the IRIS Pilot Project.

CMA's interest in the IRIS Pilot Project represents the concern of its Vinyl Chloride Health Committee which is composed of representatives from all U.S. manufacturers of Vinyl Chloride. The Committee also will be gathering information on Vinyl Chloride in the near future which may not be easily accessible to EPA.

We believe that the organization of this material is of key importance to a comprehensive characterization of Vinyl Chloride risk assessment. We look forward to working with EPA on this issue. Any questions about this material should be referred to me at 703/741-5639.

Sincerely,

Robert A. Venezia, Dr.P.H.
Manager, CHEMSTAR

BFG 00070



