LCCP

TO: Mike Hayes / Sid Pitts

FROM: T. G. Grumbles
DATE: November 24, 1987

Interoffice Communication

SUBJ: METHYL CHLORIDE INDUSTRY ASSOCIATION ACTIVITY (MCIA)

VISTA

Methyl Chloride is on the list of 100 chemicals for which the Agency for Toxic Substances and Disease Registry (ATSDR) has been mandated to prepare toxicological profiles. This activity is mandated by SARA, Title I. The toxicological profile will be used to identify data gaps. These "data gaps" will be filled by testing, which industry will pay for. Methyl Chloride is on the third priority list which means the profile is to be completed by the end of 1988.

In an effort to assure good science is used, MCIA will be working with EPA and their contractor to assure, among other things, unpublished industry data is made available to the Agency where appropriate.

I have attached a table of contents which outlines the type of data to be collected and reviewed. Please review this listing to determine, what "unpublished" data Vista may have to contribute to the MCIA effort. Specifically, I believe we may have information on monitoring, monitoring methods, and environmental release levels (i.e., fugitive emissions).

I need some indication of what we might have by February 2. After that time we can discuss how to prepare, or summarize, what we have.

T. G. Grumbles

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Attachment

cc Tom Huffman
Jim DeBernardi
Ron Poe

VVV 000014904

(2)

Federal Register

Thursday
October 15, 1987

Part III

Environmental Protection Agency

Department of Health and Human Services

Agency for Toxic Substances and Disease Registry

Availability of Toxicological Profiles; Notice

...TMENT OF HEALTH AND ...AN SERVICES

...ency For Toxic Substances and ...isease Registry

ENVIRONMENTAL PROTECTION AGENCY

[ATSDR-2; FRL-3269-7]

Availability of Toxicological Profiles

AGENCIES: Department of Health and Human Services (DHHS); Agency for *Toxic Substances and Disease Registry* (ATSDR); and Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Superfund Amendments and Reauthorization Act (SARA) (Pub. L. 99-499) amends the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*) by establishing certain requirements for the Agency for Toxic *Substances and Disease Registry* (ATSDR) of DHHS and EPA with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory requirements is a ...andate for the Administrator of ...SDR to prepare toxicological profiles for each substance previously included on the first priority list of 100 chemicals. The list identified the first 100 chemicals which both Agencies determined posed the most significant potential threat to human health. This list was published in the Federal Register on April 17th, 1987 (52 FR 12866) as required by SARA section 110.

This notice announces the expected availability dates of the first 25 draft toxicological profiles for review and comment.

Availability

The following draft toxicological profiles are expected to be publicly available by the date indicated:

Date/Profile	CAS number
October 17, 1987	
Benzo[a]anthracene	56-55-3
Benzo[a]pyrene	50-32-8
Beryllium	7440-41-7
Chloroform	67-66-3
Chromium	7440-47-3
Chrysene	218-01-9
Dibenz[a,h]anthracene	53-70-3
Heptachlor/Heptachlor epoxide	76-44-8/1024-57-3
Nickel	7440-02-0
N-Nitrosodiphenylamine	86-30-6
October 29, 1987	
...ldrin	309-00-2/60-57-1
Arsenic	7440-38-2
Benzo[b]fluoranthene	205-99-2
PCBs—Aroclor 1260, 1254, 1248, 1242, 1232, 1221, 1016	11096-82-5, 11097-69-1, 12672-29-6, 53469-21-9, 11141-16-5, 11104-28-2, 12674-11-2
2,3,7,8-Tetrachlorodibenzo-p-dioxin	1746-01-6
November 5, 1987	
Benzene	71-43-2
Bis(2-ethylhexyl)phthalate	117-81-7
Cadmium	7440-43-9
1,4-Dichlorobenzene	106-46-7
Methylene chloride	75-09-2
November 30, 1987	
Cyanide	57-12-5
Lead	7439-92-1
Tetrachloroethylene	127-18-4
Trichloroethylene	79-01-6
Vinyl chloride	75-01-4

A full 90-day public comment period will be provided for each profile, starting from the actual release date. The close of the comment period for each draft profile will be indicated on the front of each profile.

Requests for draft toxicological profiles should be sent to: Ms. Georgi Jones, Director, Office of External Affairs, Agency for Toxic Substances and Disease Registry, Chamblee 28 South, 1600 Clifton Rd., Atlanta, GA 30333.

Specify the profiles you wish to review. One copy of each profile requested will be forwarded, free of charge, as they become available. In the case of undue delays, requestors will be notified.

Five copies of all comments should be sent to Ms. Jones at the above address by the end of the comment period. All written comments and the draft profiles will be available for public inspection at the Agency for Toxic Substances and Disease Registry (ATSDR), Building 28 South, Room 1103, 4770 Buford Highway, NE., Chamblee, GA, from 8 am to 4:30 pm, Monday through Friday, except legal holidays. Written comments and other data submitted in response to this notice and the draft toxicological profiles should bear the docket control number ATSDR-2.

SUPPLEMENTARY INFORMATION:

I. Background

On October 17, 1986, the President signed the Superfund Amendments and Reauthorization Act of 1986 (Pub. L. 99-499), which extends and amends the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund, 42 U.S.C. 9601 *et seq.*).

Section 110 of SARA amends section 104(i) of CERCLA by establishing requirements for the preparation of: (1) Lists of hazardous substances in order of priority, (2) toxicological profiles of *those substances, and (3) a research* program to fill data gaps associated with the substances.

In compliance with section 104(i)(2)(A) of CERCLA, ATSDR and EPA published on April 17, 1987 (52 FR 12866) the first priority list of 100 hazardous substances. This priority list of 100 was further broken down into four groups of 25 chemicals. The first group of 25 was to be the subject of the second phase of the requirements, i.e., the development of the first set of toxicological profiles. Section 104(i)(3) of CERCLA spells out the content of these profiles and the timetable by which they must be developed. Profiles on at least substances on the first priority list were to be completed within one year of the enactment of SARA (by October 17, 1987). The remaining seventy-five are to be completed at a rate of at least twenty-five per year with the total 100 completed within four years after the enactment of the SARA amendments. Revision and republication is mandated as necessary but no less often than once every three years.

Each profile is required to include an examination, summary and interpretation of available toxicological information and epidemiologic evaluations. This information and data are to be used to ascertain the levels of significant human exposure for the substance and the associated health effects. The profiles must also include a determination of whether adequate information on the health effects of each substance is available or in the process of development. The Agencies' intention is that this information be used to identify the key toxicological testing needs that when filled will improve our ability to define significant human exposure levels.

The toxicological profiles are to be provided to the States and made available to the public. The profiles are to be prepared in accordance with the guidelines developed by ATSDR and EPA. These guidelines were published along with the priority list of 100 in the April 17, 1987 Federal Register Notice (52 FR 12870).

This current notice announces the projected availability dates of the first 25 draft toxicological profiles. The documents have undergone extensive internal review and have been subject to scientific and technical peer review by outside experts. We are now announcing their availability and encouraging public participation and comment on the further development of these profiles. Although the profiles will not be completed by the October 17, 1987 deadline, we believe that the extra time given to peer review and public

and comment is important to the lopment of quality profiles of ntific merit.

Although we are reasonably confident at the key studies for each of the 25 ostances were considered during the profile development process, this Federal Register notice solicits any significant studies, including unpublished data, which may aid in the revision of these draft profiles.

II. Levels of Significant Human Exposure

The setting of specific levels of significant human exposure has presented a unique set of problems. The significance of a specific level of a hazardous substance depends on the context in which that level is evaluated. For example, a low level that may be insignificant with respect to causing acute, immediately debilitating symptoms may be highly significant with respect to causing gradual, chronic effects over a longer term. Since these profiles are intended for use by a diverse group of people who have different sutiations in which to interpret the significance of specific levels, it was considered appropriate at this time to describe the range of exposures over which effects may occur (where date are available), and to allow the user to ake determinations as to which type of t is significant in any particular i nce. A format for graphically displaying the levels of significant human exposure has been developed and is used in the profiles to present the ranges over which effects may be observed.

We encourage public comment and recommendations on this specific issue.

III. Solicitation of Public Comment

We are soliciting public comment on all phases of the development of the toxicological profiles. A previous Federal Register notice, published on April 17, 1987 (52 FR 12866) solicited comment on the first priority list of hazardous substance. We are currently reviewing those comments and are evaluating the impact that those comments may have on the priority list and the methods used in its development.

As the first 25 toxicological profiles become available in draft form, we are eager to provide them to the States, industry, public health professionals, scientists and the general public. We welcome comment and feedback on the content of the profiles; the format and scope of the documents; the process used in the development of the levels of significant human exposure and the overall process used in the development of the profiles.

These are specific items that we would like to draw to the attention of the reader and would strongly encourage as candidates for close attention during the comment period.

A. Public Health Statement

The draft profiles include a public health statement which is intended to provide the lay public with a concise statement of the general health risks associated with the chemical of concern. The summary as originally planned should be able to stand alone. If removed from the rest of the document, it should still be capable of conveying to the public the substantive health concerns associated with the substance. We are also considering the development of more abbreviated versions of the public health statements and are evaluating a number of different formats. This notice specifically invites comments on the existing public health effects statements in the draft profiles and solicits recommendations for alternative approaches.

B. Data/Studies Used in the Development of the Profiles

In general, and for each chemical-specific profile, have the appropriate studies been used in the development of these documents? Our concern here is that we capture the critical, or "key", studies but not miss other data that may be important in the valid evaluation of the toxicological profile chemicals.

C. Format and Content of the Profiles

The draft profiles represent our best effort to provide the information required by section 104(i)(3) of CERCLA in the most useful format for the various identified users of the profiles, given the constraints of the tight timeframe. Every effort has been made to define sections clearly and to format the documents in such a way that they can be used as resource documents by many different audiences. We specifically request comment on the format and content of the initial set of profiles, including how the format might be modified for subsequent sets of profiles.

D. Levels of Significant Human Exposure

What is the most useful way of presenting this type of information? For this first generation of profiles we have selected a graphic presentation that reflects a "range" of values that covers both upper and lower bounds of effect levels. Is this more useful than a single number? Are there other ways of presenting this type of information that would be more useful to the eventual user?

E. Identification of Significant Data Gaps

The process used to develop the draft profiles has resulted in the identification of the full range of health effects data gaps associated with each chemical. However, depending on individual circumstances some subset of the identified data gaps may be essential in determining levels of significant exposure, while other data gaps may be less immediate. ATSDR, EPA, and the National Toxicology Program (NTP) have been exploring ways to identify the critical data elements that are needed to establish significant human exposure levels. This notice specifically requests comment and suggestions for approaching this phase of the toxicological profile process.

For The Agency For Toxic Substances and Disease Registry.

Dated: September 30, 1987.

James O. Mason,

Administrator, Agency for Toxic Substances and Disease Registry.

For The Environmental Protection Agency.

Dated: October 7, 1987.

Lee M. Thomas,

Administrator, Environmental Protection Agency.

[FR Doc. 87-23920 Filed 10-14-87; 8:45 am]
BILLING CODE 4160-70-M

Outline

I. Table of contents

II. Introduction
(To be written by ATSDR/EPA. It will state the purpose of the document, the audience for which it is intended, and limits on its use.)

III. Public health statement
(The non-technical summary for the general public.)
A. What is (CHEMICAL NAME)?
B. How might I be exposed to (CHEMICAL NAME)?
C. How does (CHEMICAL NAME) get into my body?
D. How can (CHEMICAL NAME) affect my health?
E. Is there a medical test to determine whether I have been exposed to (CHEMICAL NAME)?
F. What levels of exposure have resulted in harmful health effects?
G. What recommendations has the federal government made to protect human health?

IV. Health effects summary
(A more technical summary.)
A. Introduction
(To be written by ATSDR/EPA, discussing methodologies for developing the graphs.)
B. Levels of significant exposure
1. Key studies; graphs
2. Biological monitoring as a measure of exposure and effects
a. Exposure
b. Effects
3. Environmental levels as indicators of exposure and effects
a. Levels found in the environment
b. Human exposure potential
C. Adequacy of data base
1. Introduction
(Written by ATSDR/EPA, discussing the purpose of this section and the process for defining research programs to fill critical gaps in information.)
2. Adequacy of the data base for health effect endpoints
a. Introduction and graphic summary
* Introduce 3-D Data Adequacy Charts
* Explain N/A designations
* Define "some" vs. "adequate" data
b. Description of highlights of graphs
* Summarize key features of graphs for the substance
* Explain specific N/A designations
* For systemic toxicity highlight major organ system(s) affected or not adequately studied
c. Summary of relevant on-going research
3. Adequacy of the data base for other information needed

for risk assessment
a. Pharmacokinetics and mechanisms of action
* Mechanisms of action in human and animals
* Pharmacokinetics in humans and animals
* On-going research
b. Monitoring of human biological samples
* Human biomonitoring methods
* On-going research
c. Environmental considerations
* Bioavailability from environmental media
* Environmental transport and fate
* Interactions with other common co-contaminants
* On-going research

V. Chemical and physical information
A. Chemical identity
B. Physical and chemical properties

VI. Toxicological data
A. Toxicokinetics
1. Overview
2. Absorption
a. Inhalation
i. Human
ii. Animal
b. Oral
i. Human
ii. Animal
c. Dermal
i. Human
ii. Animal
3. Distribution
a. Inhalation
i. Human

etc.

4. Metabolism
a. Inhalation
i. Human

etc.

5. Excretion
a. Inhalation
i. Human

etc.

B. Toxicity
1. Lethality and decreased longevity
a. Overview
b. Inhalation
i. Human
ii. Animal

c. Oral
   i. Human
   ii. Animal
d. Dermal
   i. Human
   ii. Animal

2. Systemic/target organ toxicity
   a. Overview
   b. Endpoint 1
      i. Overview
      ii. Inhalation
         1) Human
         2) Animal
      iii. Oral
         1) Human
         2) Animal
      iv. Dermal
         1) Human
         2) Animal
      v. General discussion
   c. Endpoint 2
      i. Overview
      ii. Inhalation
         1) Human

         etc.

3. Developmental toxicity
   a. Overview
   b. Inhalation
      i. Human
      ii. Animal
   c. Oral
      i. Human

      etc.

   d. Dermal
      i. Human

      etc.

   e. General discussion

4. Reproductive toxicity

   etc.

5. Genotoxicity

   etc.

6. Carcinogenicity

   etc.

C. Interactions with other chemicals

VII. Manufacture, import, use, disposal
(A very short summary to lead into the next 2 sections.)
A. Overview
B. Production
C. Import
D. Use
E. Disposal

VIII. Environmental fate
A. Overview
B. Releases to the environment
C. Environmental fate

IX. Potential for human exposure
A. Overview
(This is the place to discuss how the volume of releases is modified by environmental fate processes to result in human exposure.)
B. Levels monitored or estimated in the environment
1. Air
2. Water
3. Soil
4. Other
C. Occupational exposures
D. Populations at high risk

X. Analytical methods
A. Environmental media
1. Air
2. Water
3. Soil
4. Food
B. Biomedical samples
1. Fluids/exudates
2. Tissues

XI. Regulatory and advisory status
A. International (World Health Organization)
B. National
1. Regulations
2. Advisory guidance
3. Data analysis
i. Reference doses (RfDs)
ii. Carcinogenic potency
1) q_1^*
2) Methods used by other agencies
C. State
1. Regulations
2. Advisory guidance

XII. References