

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

CTL017991

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES**
**Agency for Toxic Substances and
Disease 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 mandate for the Administrator of ATSDR 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	
Benz(a)anthracene	56-55-3
Benz(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	
Aldrin/dieldrin	309-00-2/60-57-1
Arsenic	7440-38-2
Benzobifluoranthene	205-99-2

Date/Profile	CAS number
PCBs—Aroclor 1260, 1254, 1248, 1242, 1232, 1221, 1016	
	11096-82-5, 11097-60-1, 12672-29-6, 53469- 21-9, 11141-16-5, 11104-28-2, 12674- 11-2 1746-01-6
2,3,7,8-Tetrachlorodibenzo-p- dioxin	
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

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review and comment is important to the development of quality profiles of scientific merit.

Although we are reasonably confident that the key studies for each of the 25 substances 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 situations 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 data are available), and to allow the user to make determinations as to which type of effect is significant in any particular instance. 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.

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