

information which may be used to supplement these profiles. ATSDR remains committed to providing a public comment period for these documents as a means to best serve public health and our clients.

Dated: October 16, 2001.

Georgi Jones,

*Director, Office of Policy and External Affairs
Agency for Toxic Substances and Disease
Registry.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR-173]

Availability of Draft Toxicological Profiles

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), Section 104(i)(3) [42 U.S.C. 9604(i)(3)] directs the Administrator of ATSDR to prepare toxicological profiles of priority hazardous substances and to revise and publish each updated toxicological profile as necessary. This notice announces the availability of the 15th set of toxicological profiles, which consists of three new drafts and two updated drafts, prepared by ATSDR for review and comment.

DATES: In order to be considered, comments on these draft toxicological profiles must be received on or before February 22, 2002. Comments received after the close of the public comment period will be considered at the discretion of ATSDR based upon what is deemed to be in the best interest of the general public.

ADDRESSES: Requests for copies of the draft toxicological profiles should be sent to the attention of Ms. Franchetta Stephens, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E-29, 1600 Clifton Road, NE., Atlanta, Georgia 30333. Comments regarding the draft toxicological profiles should be sent to the attention of Dr. Ganga Choudhary,

Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E-29, 1600 Clifton Road, NE., Atlanta, Georgia 30333.

Requests for the draft toxicological profiles must be in writing, and must specifically identify the hazardous substance(s) profile(s) that you wish to receive. ATSDR reserves the right to provide only one copy of each profile requested, free of charge. In case of extended distribution delays, requestors will be notified.

Written comments and other data submitted in response to this notice and the draft toxicological profiles should bear the docket control number ATSDR-173. Send one copy of all comments and three copies of all supporting documents to Dr. Ganga Choudhary at the above stated address by the end of the comment period. Because all public comments regarding ATSDR toxicological profiles are available for public inspection, no confidential business or other confidential information should be submitted in response to this notice.

FOR FURTHER INFORMATION CONTACT: Ms. Franchetta Stephens, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E-29, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone 1-(888)422-8737 or (404)498-0720.

SUPPLEMENTARY INFORMATION: 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 responsibilities for the ATSDR and the Environmental Protection Agency (EPA) with regard to hazardous substances which are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these responsibilities is that the Administrator of ATSDR prepare toxicological profiles for substances included on the priority lists of hazardous substances. These lists identified 275 hazardous substances that ATSDR and EPA determined pose the most significant potential threat to human health. The availability of the revised priority list of 275 hazardous substances was announced in the **Federal Register** on October 21, 1999 (64 FR 56792). For prior versions of the list of substances see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166);

October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); April 29, 1996 (61 FR 18744) and November 17, 1997 (62 FR 61332). [CERCLA also requires ATSDR to assure the initiation of a research program to fill data needs associated with the substances.]

Section 104(i)(3) of CERCLA [42 U.S.C. 9604(i)(3)] outlines the content of these profiles. Each profile will include an examination, summary and interpretation of available toxicological information and epidemiologic evaluations. This information and these data are to be used to identify 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. When adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of research to determine these health effects.

Although key studies for each of the substances were considered during the profile development process, this **Federal Register** notice seeks to solicit any additional studies, particularly unpublished data and ongoing studies, which will be evaluated for possible addition to the profiles now or in the future.

The following draft toxicological profiles will be made available to the public on or about October 17, 2001.

Docu- ment	Hazardous substance	CAS No.
1	Atrazine	001912-24-9
2	Fluorides (Up- date).	016984-48-8
3	Malathion	000121-75-5
4	Pyrethrins and Pyrethroids.	Various.
5	Selenium (Up- date).	007782-49-2

All profiles issued as "Drafts for Public Comment" represent ATSDR's best efforts to provide important toxicological information on priority hazardous substances. We are seeking public comments and additional information which may be used to supplement these profiles. ATSDR remains committed to providing a public comment period for these documents as a means to best serve public health and our clients.

Dated: October 17, 2001.

Georgi Jones,

*Director, Office of Policy and External Affairs,
Agency for Toxic Substances and Disease
Registry.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR-175]

Availability of Final Toxicological Profiles

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of six updated final toxicological profiles of priority hazardous substances comprising the thirteenth set prepared by ATSDR.

FOR FURTHER INFORMATION CONTACT: Ms. Franchetta Stephens, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E-29, 1600 Clifton Road, NE., Atlanta, Georgia 30333, telephone 1-(888)422-8737 or (404)498-0720.

SUPPLEMENTARY INFORMATION: 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 ATSDR and the Environmental Protection Agency (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 included on the priority lists of hazardous substances. These lists identified 275 hazardous substances that ATSDR and EPA determined pose the most significant potential threat to human health. The availability of the revised list of the 275 priority substances was announced in the **Federal Register** on October 21, 1999 (64 FR 56792). For prior versions of the list of substances see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); April 29, 1996 (61 FR 18744); and November 17, 1997 (62 FR 61332).

Notice of the availability of drafts of these six updated toxicological profiles

for public review and comment was published in the **Federal Register** on October 15, 1999, (64 FR 55943), with notice of a 90-day public comment period for each profile, starting from the actual release date. Following the close of the comment period, chemical-specific comments were addressed, and where appropriate, changes were incorporated into each profile. The public comments and other data submitted in response to the **Federal Register** notices bear the docket control number ATSDR-152. This material is available for public inspection at the Division of Toxicology, Agency for Toxic Substances and Disease Registry, Building 4, Suite 2400, Executive Park Drive, Atlanta, Georgia, (not a mailing address) between 8:00 a.m. and 4:30 p.m., Monday through Friday, except legal holidays.

Availability

This notice announces the availability of six updated final toxicological profiles comprising the thirteenth set prepared by ATSDR. The following toxicological profiles are now available through the U.S. Department of Commerce, National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, Virginia 22161, telephone 1-800-553-6847. There is a charge for these profiles as determined by NTIS.

Toxicological profile	NTIS Order No.	CAS No.
Thirteenth Set:		
1. Asbestos	PB2001-109101	001332-21-4
Amosite Asbestos	012172-73-5
Chrysotile Asbestos	012001-29-5
2. Benzidine	PB2001-109102	000092-87-5
3. 1,2-Dichloroethane	PB2001-109103	000107-06-2
4. Di-n-butyl Phthalate	PB2001-109104	000084-74-2
5. Methyl Parathion	PB2001-109105	000298-00-0
6. Pentachlorophenol	PB2001-109106	000087-86-5

Dated: October 16, 2001.

Georgi Jones,

*Director, Office of Policy and External Affairs,
Agency for Toxic Substances and Disease
Registry.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N-0458]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry: Fast Track Drug Development Programs—Designation, Development, and Application Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the proposed collection of information concerning requests for fast track designation by sponsors of