DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR–178]

Update on the Status of the Superfund Substance-Specific Applied Research Program

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

ACTION: Notice.

SUMMARY: This Notice provides the status of ATSDR's Superfund-mandated Substance-Specific Applied Research Program (SSARP) which was last updated in a **Federal Register** notice in 1999 (64 FR 2760). Authorized by the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA, also known as the Superfund statute), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) 42 U.S.C. 9604 (i), this research program was initiated on October 17, 1991. At that time, a list of priority data needs for 38 priority hazardous substances frequently found at waste sites was announced in the **Federal Register** (56 FR 52178). The list was subsequently revised based on public comments and published in final form on November 16, 1992 (57 FR 54150).

The 38 substances, each of which is found on ATSDR's Priority List of Hazardous Substances (66 FR 54014, October 25, 2001), are aldrin/dieldrin, arsenic, benzene, beryllium, cadmium, carbon tetrachloride, chloroethane, chloroform, chromium, cyanide, p,p′-DDT,DDE,DDD, di(2-ethylhexyl) phthalate, lead, mercury, methylene chloride, nickel, polychlorinated biphenyl compounds (PCBs), polycyclic aromatic hydrocarbons (PAHs—includes 15 substances), selenium, tetrachloroethylene, toluene, trichloroethylene, vinyl chloride, and zinc.

On July 30, 1997, priority data needs for 12 additional hazardous substances frequently found at waste sites were determined and announced in the **Federal Register** (62 FR 40820). The 12 substances, each of which is included in ATSDR's Priority List of Hazardous Substances, are chlordane, 1,2-dibromo-3-chloropropane, di-n-butyl phthalate, disulfoton, endrin (includes endrin aldehyde), endosulfan (alpha-, beta-, and endosulfan sulfate), heptachlor (includes heptachlor epoxide), hexachlorobutadiene, hexachlorocyclohexane (alpha-, beta-, delta- and gamma-), manganese, methoxychlor, and toxaphene.

Recently, priority data needs for 10 additional hazardous substances frequently found at waste sites were determined and announced in the **Federal Register** (66 FR 42659). The 10 substances, each of which is included in ATSDR's Priority List of Hazardous Substances, are asbestos, benzidine, chlorinated dibenzo-p-dioxins, 1,2-dibromoethane, 1,2-dichloroethane, 1,1-dichloroethane, ethylbenzene, pentachlorophenol, 1,1,2,2-tetrachloroethane, and total xylenes. ATSDR invited the public to comment on the priority data needs for these substances during a period of 90 days. ATSDR is responding to the comments, and a final list of priority data needs will be published in the **Federal Register** in the near future.

To date, 190 priority data needs have been identified for the first 50 hazardous substances (Table 1). ATSDR fills these data needs through U.S. Environmental Protection Agency (EPA) regulatory mechanisms (test rules), private-sector voluntarism, and the direct use of CERCLA funds. Additional data needs are being addressed through collaboration with the National Toxicology Program (NTP), by ATSDR's Great Lakes Human Health Effects Research Program, and other agency programs. Currently, 101 priority data needs associated with the first 50 substances are being addressed via these mechanisms, and 62 priority data needs have been filled. Priority data needs documents describing ATSDR's rationale for prioritizing research needs for each substance are available. See **ADDRESSES** section of this Notice.

This Notice also serves as a continuous call for voluntary research proposals. Private-sector organizations may volunteer to conduct research to address specific priority data needs identified in this Notice by indicating their interest through submission of a letter of intent to ATSDR (see **ADDRESSES** section of this Notice). A Tri-Agency Superfund Applied Research Committee (TASARC) composed of scientists from ATSDR, NTP, and the EPA, will review all proposed voluntary research efforts.

DATES: ATSDR provides updates on the status of its Substance-Specific Applied Research Program approximately every 3 years. ATSDR considers the voluntary research effort to be important to the continuing implementation of the SSARP. Therefore, the agency strongly encourages private-sector organizations to volunteer at any time to conduct research to fill data needs until ATSDR announces that other research mechanisms are in place to address those specific data needs.

ADDRESSES: Private-sector organizations interested in volunteering to conduct research can write to Dr. William Cibulas, Chief, Research Implementation Branch, Division of Toxicology, ATSDR, 1600 Clifton Road, NE., Mailstop E–29, Atlanta, Georgia 30333, e-mail: wcibulas@cdc.gov. Information about pertinent ongoing or completed research that may fill priority data needs cited in this Notice should be similarly addressed.

Other Requirements: Projects that involve the collection of information from 10 or more individuals and funded by cooperative agreement will be subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act.

FOR FURTHER INFORMATION CONTACT: Dr. William Cibulas, Chief, Research Implementation Branch, Division of Toxicology, ATSDR, 1600 Clifton Road, NE., Mailstop E–29, Atlanta, Georgia 30333, telephone: (404) 498–0715, fax: (404) 498–0092. This notice will also be available on ATSDR's website at *http://www.atsdr.cdc.gov* or you may call the ATSDR Information Center at 1–888–422–8737.

SUPPLEMENTARY INFORMATION:

Background

CERCLA as amended by SARA (42 U.S.C. 9604(i)) requires that ATSDR (1) jointly with the EPA, develop and prioritize a list of hazardous substances found at National Priorities List (NPL) sites, (2) prepare toxicological profiles for these substances, and (3) assure the initiation of a research program to address identified data needs associated with the substances. Before starting such a program, ATSDR will consider recommendations of the Interagency Testing Committee on the type of research that should be done. This committee was established under Section 4(e) of the Toxic Substances Control Act of 1976 [15 U.S.C. 2604(e)](TSCA).

The major goals of the ATSDR SSARP are (1) to address the substance-specific information needs of the public and scientific community, and (2) to supply information necessary to improve the database used to conduct comprehensive public health assessments of populations living near hazardous waste sites. We anticipate that the information will help to establish linkages between levels of contaminants in the environment and levels in human tissue and organs

associated with adverse health effects. Once such links have been established, strategies to mitigate potentially harmful exposures can be developed. This program will also provide data that can be generalized to other substances or areas of science, including risk assessment of chemicals, thus creating a scientific information base for addressing a broader range of data needs.

ATSDR encourages the use of in vitro assessment methods and other innovative tools for filling priority data needs. For example, the agency believes that physiologically based pharmacokinetic (PBPK) modeling could serve as a valuable tool in predicting across route similarities (or differences) in toxicological responses to hazardous substances. Therefore, on a case-by-case basis, a priority data need can be filled using existing data and modeling. In addition, ATSDR is a member of NTP's Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) and supports development, validation, and acceptance of alternative toxicological test methods that reduce, refine, and replace the use of animals, as appropriate.

CERCLA section 104(i)(5)(D) states that it is the sense of Congress that the costs for conducting this research program ''be borne by the manufacturers and processors of the hazardous substance in question,'' as required in TSCA and the Federal Insecticide, Fungicide, and Rodenticide Act of 1972 (7 U.S.C. 136 *et seq.*) (FIFRA), or by cost recovery from responsible parties under CERCLA. To execute this statutory intent, ATSDR developed a plan whereby parts of the SSARP are being conducted via the regulatory mechanisms referenced (TSCA/FIFRA), private-sector voluntarism, and the direct use of CERCLA funds.

The TASARC, composed of scientists from ATSDR, NTP, and EPA, has been set up to:

(1) Advise ATSDR on the assignment of priorities for mechanisms to address data needs,

(2) Coordinate knowledge of research activities to avoid duplication of research in other programs and under other authorities,

(3) Advise ATSDR on issues of science related to substance-specific data needs, and

(4) Maintain a scheduled forum that provides an overall review of the ATSDR SSARP.

TASARC has met 10 times since the initiation of the SSARP. It has guided referral of data needs to EPA and the associated development of test rules through TSCA. In addition, it has endorsed the proposals of several private-sector organizations to conduct voluntary research. Furthermore, TASARC has become a forum for other federal agencies to bring forth their research agendas. For example, it has coordinated research efforts on hazardous pollutants with the Office of Air and Radiation, EPA. TASARC has developed testing guidelines for immunotoxicity; and has endorsed the use of decision-support methodologies such as physiologically based pharmacokinetic (PBPK) modeling and benchmark-dose modeling, where appropriate.

Additional data needs are being addressed through collaborative research efforts with NTP, by ATSDR's Great Lakes Human Health Effects Research Program, and other agency programs. To date, 101 priority data needs associated with the first 50 substances (Table 1) are being addressed via these mechanisms.

Criteria for Evaluating Status of Priority Data Needs

To update the activities covered under the SSARP, criteria for evaluating the status of the priority data needs were developed. Based on these criteria and the review of the current literature, a priority data need can be filled, or unchanged. In the event a priority data need is considered filled, it does not necessarily mean that the study has been completed and that ATSDR has accepted the data. It does, however, indicate that the agency no longer considers it a priority to initiate additional studies at this time.

The criteria for evaluating the status of the priority data needs are described below.

General Criteria

A priority data need is filled:

- If it has been referred to one of the implementation mechanisms and research has been initiated, or
- If an updated ATSDR toxicological profile or other recent review document contains relevant new (peer-reviewed and publicly available) studies since the finalization of the priority data needs document; and it is generally agreed that a priority data need no longer exists.

A priority data need remains unchanged:

- If no mechanism or information has been identified to address the priority data need, or
- If the priority data need is included in the ATSDR/EPA test rule under development, or is associated with a pilot substance in EPA's Voluntary Children's Chemical Evaluation Program.

Specific Criteria

Since the 1999 SSARP update in the **Federal Register**, ATSDR has developed specific criteria for two categories of data needs described below.

- *Epidemiologic studies*—A priority data need is filled if multiple new studies assessing key health end points are available in ATSDR's updated toxicological profile and/or ongoing studies have been identified, e.g., human health studies supported by ATSDR's Great Lakes Human Health Effects Research Program or the Minority Health Professions Foundation Research Program. In some cases, ATSDR indicates that it will continue to evaluate new data as they become available to determine whether additional studies are needed.
- *Exposure levels in humans*—A priority data need is filled if (a) there are current and adequate biomonitoring data for exposed populations associated with health effects (from published or ongoing studies), or (b) there are reference range data (e.g., National Health and Nutrition Examination Survey (NHANES)) or generally agreed upon background population levels. In the latter case, ATSDR acknowledges that reference concentration data can support exposure and health assessments at waste sites, but the agency also continues to recognize the importance of collecting additional data on uniquely exposed populations at waste sites.

It should be noted that the status of the priority data needs may change in future updates of the SSARP as new information becomes available. Further, during the literature review, new studies may be identified suggesting other effects of concern, such as those related to endocrine disruptors and children's health, which have not been included in the original list of priority data needs. In such cases, additional priority data needs may be added to the research agenda. For example, for both tetrachloroethylene and trichloroethylene, the priority data need for developmental neurotoxicity study is now listed separately from the priority data need for one-species developmental toxicity (see Table 1). Therefore, the total number of priority data needs changed accordingly, i.e., from a total of 188 reported in the **Federal Register** notice in 1999 (64 FR 2760) to 190 in the current update notice. Also, research needs previously considered filled might be reassigned as priority data needs, e.g., if a previously derived Minimal Risk Level (MRL), a

health guidance value, was withdrawn from the updated ATSDR toxicological profile. Finally, a priority data need previously associated with an implementation mechanism, may no longer be addressed via that mechanism (or any other mechanism) if the study being conducted to fill the specific priority data need is discontinued.

Based on the above criteria, 62 priority data needs have been filled.

Update of Activities in the SSARP

An update of the activities associated with the mechanisms for implementing the ATSDR Substance-Specific Applied Research Program (SSARP) is discussed below. Publications and reports of research completed under the various implementation mechanisms are available by writing to ATSDR (*see* **ADDRESSES** section of this Notice).

A. TSCA/FIFRA

In developing and implementing the SSARP, ATSDR, NTP, and EPA have identified a subset of priority data needs for substances of mutual interest to the federal programs. These data needs are being addressed through a program of toxicologic testing under TSCA according to established procedures and guidelines. On several occasions when ATSDR identified priority data needs for oral exposure, other agencies needed inhalation data. In response, ATSDR is considering proposals to conduct inhalation studies in conjunction with physiologically based pharmacokinetic (PBPK) studies in lieu of oral studies. ATSDR expects that inhalation data derived from these studies can be used with PBPK modeling to address its oral toxicity data needs. Currently, an EPA/ATSDR test rule, under development, includes eight ATSDR substances, i.e., benzene, chloroethane, cyanide (hydrogen cyanide and sodium cyanide), methylene chloride, tetrachloroethylene, toluene and trichloroethylene, and addresses 18 ATSDR priority data needs (Table 2). The test rule is presently undergoing ATSDR and EPA final review. We anticipate it will be available for public comment in the near future.

TASARC has established an interagency task force on metals and has conducted a survey to assess federal agencies' needs for testing metals. Currently, the task force has agreed to examine at least seven metals included in the ATSDR's SSARP (arsenic, beryllium, chromium, manganese, mercury, nickel, and selenium, associated with 22 priority data needs) (Table 2). The EPA will solicit testing proposals for these metals and pursue test rule development for these metals at a later date.

B. Private-Sector Voluntarism

On February 7, 1992, as part of the Substance-Specific Applied Research Program (SSARP), ATSDR announced a set of proposed procedures for conducting voluntary research (57 FR 4758). Revisions based on public comments were published on November 16, 1992 (57 FR 54160). Private-sector organizations were encouraged to volunteer to conduct research to fill specific priority data needs at no expense to ATSDR.

To date, ATSDR has established agreements with the American Chemistry Council (ACC) [formerly the Chemical Manufacturers Association (CMA)], the General Electric Company (GE), and the Halogenated Solvents Industry Alliance, Inc. (HSIA) to conduct substance-specific research (Table 2). Through the voluntary research efforts of these organizations, at least 16 research needs for polychlorinated biphenyl compounds [PCBs], methylene chloride, tetrachloroethylene, trichloroethylene, and vinyl chloride are being addressed (Table 2).

American Chemistry Council (ACC) Formerly the Chemical Manufacturers Association (CMA)

In 1996, ATSDR entered into a memorandum of understanding (MOU) with ACC covering two studies, ''Vinyl chloride: Combined inhalation two-generation reproduction and developmental toxicity study in CD rats.'' In November 2000, ATSDR accepted the final reports of the studies.

General Electric Company (GE)

In 1995, ATSDR entered into an MOU with SSARP covering two studies on PCBs: (1) ''An assessment of the chronic toxicity and oncogenicity of Aroclors 1016, 1242, 1254, and 1260 administered in diet to rats,'' including ''PCB congener analyses,'' and (2) ''Metabolite detection as a tool for determining naturally occurring aerobic PCB biodegradation.'' While the above studies do not address ATSDR's priority data needs for PCBs, they do address other agency research needs for these substances.

The agency accepted the final report for the chronic toxicity and oncogenicity of the four aroclors in October 1997,and the final report for the aerobic biodegradation study in July 1999.

Halogenated Solvents Industry Alliance (HSIA)

In 1995, ATSDR entered into an MOU with HSIA covering studies to address three priority data needs for methylene chloride. The studies, ''Addressing priority data needs for methylene chloride with physiologically based pharmacokinetic modeling,'' evaluated acute- and subchronic-duration toxicity and developmental toxicity via oral exposure. The data were obtained using physiologically based pharmacokinetic modeling. The final report for these studies was accepted by the agency in February 1997.

In September 1999, HSIA entered into a second MOU with ATSDR to conduct a study, ''Methylene chloride: 28 day inhalation toxicity study in the rat to assess potential immunotoxicity.'' The agency accepted the final report for the study in November 2000. HSIA is in the process of obtaining oral data from the inhalation study using PBPK modeling. This is because ATSDR has determined ingestion of contaminated environmental media to be the primary exposure route at hazardous waste sites. HSIA intends to conduct similar immunotoxicity studies for tetrachloroethylene and trichloroethylene.

In February 2000, ATSDR signed a third MOU with HSIA, which conducted a study, ''Trichloroethylene: Inhalation Developmental Toxicity Study in CD Rats.'' The agency accepted the final report of the study in September 2001. As in the case of the methylene chloride immunotoxicity study described above, HSIA intends to obtain developmental toxicity data for oral exposure using PBPK modeling. Also, HSIA plans to perform similar developmental toxicity studies for tetrachloroethylene. Finally, ATSDR and HSIA are continuing discussion to address additional priority data needs for trichloroethylene and tetrachloroethylene in conjunction with EPA's pilot studies for its Voluntary Children's Chemical Evaluation Program.

In addition to the substance-specific MOUs described above, in March 2001, ATSDR also signed an MOU with the Electric Power Research Institute, Inc. (EPRI) on ''Verification of Techniques for Assessing the Effects of Neurotoxicants on Neurodevelopment in Children.'' The objective of the study is to validate a battery of neurodevelopmental tests for use in assessing the effects of prenatal or postnatal exposure to developmental neurotoxicants. The study includes an evaluation of a broad spectrum of

functions; therefore, the validation of these tests will be useful for further assessing the developmental neurotoxicity of some of the ATSDR priority substances such as the PCBs, methylmercury, and lead. In addition to the private sector support (EPRI), ATSDR is coordinating a federal effort (via interagency agreements with EPA, Food and Drug Administration [FDA] and NIEHS) to support the study.

C. CERCLA-Funded Research (Minority Health Professions Foundation Research Program)

During FY 1992, ATSDR announced a $4 million cooperative agreement program with the Minority Health Professions Foundation (MHPF) to support substance-specific investigations. A not-for-profit Internal Revenue Code 501(c)(3) organization, the MHPF comprises 11 minority health professions schools. Its primary mission is to research health problems that disproportionately affect poor and minority citizens. The purpose of this cooperative agreement is to address substance-specific data needs for priority hazardous substances identified by ATSDR. In addition, this agreement strengthens the environmental health research opportunities for scientists and students at MHPF member institutions and enhances existing disciplinary capacities to conduct research in toxicology and environmental health.

In the first 5-year project period that concluded during FY 1997, nine priority data needs for 21 priority hazardous substances and 22 other research needs for these and other substances were addressed. The MHPF has developed a report, ''Environmental Health and Toxicology Research Program: Meeting Environmental Health Challenges Through Research, Education, and Service,'' that describes the research findings and other successes from the first 5 years of the program. New research initiated in the second 5-year project period includes studies to address 10 additional priority data needs for chlordane, 1,2-dibromo-3-chloropropane, di-n-butyl phthalate, lead, manganese, the polycyclic aromatic hydrocarbons (PAHs), zinc, and eight other research needs.

To date, the MHPF activities have resulted in the publication of 50 manuscripts in peer-reviewed journals. The institutions receiving awards and their current respective research projects that fill identified research needs are listed in Table 2.

D. National Toxicology Program (NTP)

Section 104(i)(5) of CERCLA directs the administrator of ATSDR (in consultation with the administrator of EPA and agencies and programs of the Public Health Service) to assess whether adequate information on the health effects of priority hazardous substances found at NPL sites is available. Where adequate information is not available, ATSDR, in cooperation with the National Toxicology Program (NTP), is required to assure the initiation of a program of research designed to determine these health effects (and techniques for developing methods to determine such health effects).

ATSDR has been collaborating with NTP to address priority data needs of mutual interest, including (1) di-n-butyl phthalate: dose-response data in animals for acute-duration exposure via oral exposure route, (2) carbon tetrachloride: immunotoxicology study via oral exposure, and (3) heptachlor: reproductive toxicity study via oral exposure (Table 2).

E. Great Lakes Human Health Effects Research Program

Some of the priority data needs identified in the SSARP have been independently identified as research needs through the ATSDR Great Lakes Human Health Effects Research Program, a separate research program.

In support of the Great Lakes Critical Programs Act of 1990, ATSDR announced in FY 1992 the availability of $2 million for a grant program to conduct research on the potential for short- and long-term adverse health effects from consumption of contaminated fish from the Great Lakes basin. Research undertaken through this program is intended to build on and amplify the results of past and ongoing fish consumption research in the Great Lakes basin. The ATSDR-supported research projects focus on known high-risk populations to define further the human health consequences of exposure to persistent toxic substances (PTSs) identified in the Great Lakes basin. These at-risk populations include sport anglers; African Americans, Asians and other non-English speaking populations; pregnant women; fetuses, nursing infants, and children of mothers who consume contaminated Great Lakes sport fish; the elderly, and the urban poor. To date, the research activities of the ATSDR Great Lakes research program have resulted in 55 publications in peer-reviewed journals.

Currently, 14 priority data needs for 24 priority hazardous substances (including 15 PAHs) identified in the SSARP are being addressed through this program. The institutions receiving awards and their respective studies are listed in Table 2.

F. Other ATSDR Programs

In its role as a public health agency addressing environmental health, ATSDR may collect human data to validate substance-specific exposure and toxicity findings. The need for additional information on levels of contaminants in humans has been identified, and remains as a priority data need for 49 of the first 50 priority substances (Table 1). ATSDR will obtain this information through exposure and health effects studies, and through establishing and using substance-specific subregistries of people within the agency's National Exposure Registry who have potentially been exposed to these substances.

The list of the 50 priority hazardous substances in the SSARP was forwarded to ATSDR's Exposure and Disease Registry Branch (EDRB), Division of Health Studies, for consideration as potential candidates for subregistries of exposed persons, based on criteria described in its 1994 document, ''National Exposure Registry: Policies and Procedures Manual (Revised),'' Agency for Toxic Substances and Disease Registry, Public Health Service, U.S. Department of Health and Human Services, Atlanta, Georgia, NTIS Publication No. PB95–154571. To date, of the first 50 priority substances in the SSARP, ATSDR has established subregistries for benzene, chromium, and trichloroethylene. Arsenic, cadmium, and lead are not considered to be in the pool of candidate substances for an exposure registry at this time, and, therefore, are not considered priority data needs. This decision will be reevaluated as more information on the chemicals and exposure sites become available. All other substances in the SSARP (Table 1) remain in the candidate pool and therefore continue to be classified as priority data needs. They will be considered for selection as primary contaminants during each selection process.

G. Conclusion

The results of the research conducted via the SSARP are expected to provide information necessary to improve the database used to conduct comprehensive public health assessments of populations living near hazardous waste sites. The information will enable the agency to establish linkages between levels of contaminants in the environment and levels in human tissue and organs associated with adverse health effects, ultimately helping to determine methods for interdicting exposure and mitigating toxicity. This program will also provide

data that can be generalized to other substances or areas of science, including risk assessment of chemicals, thus creating a scientific information base for addressing a broader range of data needs. The agency plans to provide an update on the status of this research program approximately every 3 years.

Dated: January 25, 2002.

Georgi Jones,

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

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
Aldrin/Dieldrin	1A	Dose-response data in animals for intermediate-duration oral exposure.	.....	Filled	An MRL was derived in the 2000 updated toxicological profile.
	1B	Bioavailability from soil.			
	1C	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....	.....	This priority data need, previously addressed in a study in the Great Lakes research program, is no longer investigated in that study.
	1D	Potential candidate for subregistry of exposed persons.	ATSDR.		
Arsenic	2A	Comparative toxicokinetic studies to determine if an appropriate animal species can be identified.	EPA.		
	2B	Half-lives in surface water, groundwater.	EPA.		
	2C	Bioavailability from soil	EPA.		
	2D	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes	Filled	Background level data are available in ATSDR's 1993 toxicological profile, and at least seven ATSDR studies that evaluated urine arsenic levels and potential adverse health effects are available. Also, additional studies are available in ATSDR's 2000 updated toxicological profile.
Benzene	3A	Dose-response data in animals for acute- and intermediate-duration oral exposure. The subchronic study should include an extended reproductive organ histopathology.	EPA.		
	3B	Two-species developmental toxicity study via oral exposure.	EPA	.....	Previously planned study in the MHPF research program to address this priority data need was canceled.
	3C	Neurotoxicology battery of tests via oral exposure.	EPA.		
	3D	Epidemiologic studies on the health effects of benzene (Special emphasis end points include immunotoxicity).	.....	Filled	Based on an evaluation of the data in ATSDR's 1997 updated toxicological profile. ATSDR will continue to evaluate new data as they become available to determine if additional studies are needed.
	3E	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....	Filled	Reference range concentrations are available (Ashley et al. 1992, 1994; Needham et al. 1995), and at least one ATSDR study that evaluated blood benzene levels and potential adverse health effects is available. ATSDR acknowledges that reference concentration data can support exposure and health assessments at waste sites, but the agency also continues to recognize the importance of collecting additional data on uniquely exposed populations at waste sites.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
Beryllium	4A	Dose-response data in animals for acute- and intermediate-duration inhalation exposures. The subchronic study should include extended reproductive organ histopathology.	EPA.		
	4B	Two-species developmental toxicity study via inhalation exposure.	EPA.		
	4C	Environmental fate in air; factors affecting bioavailability in air.	EPA.		
	4D	Analytical methods to determine environmental speciation.	.....	Filled	Based on an evaluation of the data in ATSDR's 2000 updated toxicological profile.
	4E	Immunotoxicology battery of tests following oral exposure.	EPA.		
	4F	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....	Filled	Reference range concentrations in urine are available (Paschal et al. 1998). ATSDR acknowledges that reference concentration data can support exposure and health assessments at waste sites, but the agency also continues to recognize the importance of collecting additional data on uniquely exposed populations at waste sites.
	4G	Potential candidate for subregistry of exposed persons.	ATSDR.		
Cadmium	5A	Analytical methods for biological tissues and fluids and environmental media.	.....	Filled	Based on an evaluation of the data in ATSDR's 1999 updated toxicological profile.
	5B	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes	Filled	Referent population urine cadmium levels are available (NHANES III), and at least nine ATSDR studies that evaluated blood and urine cadmium levels and potential adverse health effects are available.
Carbon tetrachloride	6A	Dose-response data in animals for chronic oral exposure. The study should include extended reproductive organ and nervous tissue histopathology.			
	6B	Immunotoxicology battery of tests via oral exposure.	NTP	Filled	NTP dose-finding study and one new study in ATSDR's 1994 updated toxicological profile addressed the priority data need.
	6C	Half-life in soil	.....	Filled	One new study in ATSDR's 1994 updated toxicological profile provided information on half-life in soil.
	6D	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....	Filled	Reference range concentrations in blood are available (Ashley et al. 1992, 1994; Needham et al. 1995). ATSDR acknowledges that reference concentration data can support exposure and health assessments at waste sites, but the agency also continues to recognize the importance of collecting additional data on uniquely exposed populations at waste sites.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
	6E	Potential candidate for subregistry of exposed persons.	ATSDR.		
Chlordane	7A	Oral multigenerational studies to evaluate reproductive toxicity.	MHPF ..... NTP.	Filled	Availability of ongoing study in the MHPF research program and anticipated initiation of an NTP study in 2002.
	7B	Bioavailability studies following ingestion of contaminated media.			
	7C	Exposure levels in humans living near hazardous waste sites and other populations potentially exposed to chlordane.			
	7D	Potential candidate for subregistry of exposed persons.	ATSDR.		
Chloroethane	8A	Dose-response data in animals for acute- and intermediate-duration oral exposures. The subchronic study should include an evaluation of immune and nervous system tissues, and extended reproductive organ histopathology.	EPA.		
	8B	Dose-response data in animals for chronic inhalation exposures. The study should include an evaluation of nervous system tissues.	EPA.		
	8C	Potential candidate for subregistry of exposed persons.	ATSDR.		
Chloroform	9A	Dose-response data in animals for intermediate-duration oral exposure.	.....	Filled	An MRL was derived in ATSDR's 1997 updated toxicological profile.
	9B	Epidemiologic studies on the health effects of chloroform (Special emphasis end points include cancer, neurotoxicity, reproductive and developmental toxicity, hepatotoxicity, and renal toxicity).	.....	Filled	Based on an evaluation of the data in ATSDR's 1997 updated toxicological profile. ATSDR will continue to evaluate new data as they become available to determine if additional studies are needed.
	9C	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....	Filled	Reference range concentrations in blood are available (Ashley et al. 1992, 1994; and Needham et al. 1995). ATSDR acknowledges that reference concentration data can support exposure and health assessments at waste sites, but the agency also continues to recognize the importance of collecting additional data on uniquely exposed populations at waste sites.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
	9D	Potential candidate for subregistry of exposed persons.	ATSDR.		
Chromium	10A	Dose-response data in animals for acute-duration exposure to chromium (VI) and (III) via oral exposure and for intermediate-duration exposure to chromium (VI) via oral exposure.	EPA.		
	10B	Multigeneration reproductive toxicity study via oral exposure to chromium (III) and (VI).	EPA.		
	10C	Immunotoxicology battery of tests following oral exposure to chromium (III) and (VI).	EPA.		
	10D	Two-species developmental toxicity study via oral exposure to chromium (III) and (VI).	EPA.		
	10E	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes	Filled	Reference range concentrations in urine are available (Paschal et al. 1998). Also, at least two ATSDR studies that evaluated urine chromium levels and potential adverse health effects are available. In addition, this PDN is being addressed in a study in the Great Lakes research program.
Cyanide	11A	Dose-response data in animals for acute- and intermediate-duration exposures via inhalation. The subchronic study should include extended reproductive organ histopathology and evaluation of neurobehavioral and neuropathological end points.	EPA.		
	11B	Two-species developmental toxicity study via oral exposure.	EPA.		
	11C	Evaluation of the environmental fate of cyanide in soil.	.....	Filled	A study addressing the priority data need was submitted by industry to EPA in response to EPA's solicitation for proposals for test rule making. Scientists from EPA and ATSDR reviewed the study and considered that this research need is no longer a priority.
	11D	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.			
	11E	Potential candidate for subregistry of exposed persons.	ATSDR.		
1,2-dibromo-3-chloropro pane	12A	Dose-response data in animals for acute- duration exposure via the oral route (including reproductive organ histopathology).			
	12B	Dose-response data in animals for chronic-duration exposure via the oral route (including reproductive organ histopathology).			
	12C	Two-species developmental toxicity study via oral exposure.			

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
	12D	Immunotoxicology testing battery via oral exposure.	.....	.....	Previously planned study in the MHPF research program to address this priority data need was canceled.
	12E	Neurotoxicology testing battery via oral exposure.	.....	.....	Previously planned study in the MHPF research program to address this priority data need was canceled.
	12F	Exposure levels in humans living near hazardous waste sites and other exposed populations, such as exposed workers.			
	12G	Potential candidate for subregistry of exposed persons.	ATSDR.		
DDT	13A	Dose-response data in animals for chronic-duration oral exposure.			
	13B	Comparative toxicokinetic study (across routes/species).			
	13C	Bioavailability and bioaccumulation from soil.			
	13D	Epidemiologic studies on the health of DDT, DDD, and DDE (Special emphasis end points include immunotoxicity, and reproductive and developmental toxicity.	G. Lakes	Filled	Multiple new studies in ATSDR's 2000 updated toxicological profile and five ongoing studies in the Great Lakes research program are available.
	13E	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes.		
	13F	Potential candidate for subregistry of exposed persons.	ATSDR.		
Di(2-ethyl-hexyl)phthalate	14A	Epidemiologic studies on the health effects of DEHP (Special emphasis end points include cancer).			
	14B	Dose-response data in animals for acute- and intermediate-duration oral exposures. The subchronic study should include an extended histopathologic evaluation of the immunologic and neurologic systems.	.....	.....	This research need is reassigned as a priority data need because of the data in ATSDR's 2000 updated toxicological profile. Specifically, the previously developed MRL for acute-duration (1993 toxicological profile) was withdrawn, and a provisional MRL for intermediate-duration was derived replacing the previously established one.
	14C	Multigeneration reproductive toxicity study via oral exposure.	.....	.....	This research need is reassigned as a priority data need based on an evaluation of the data in ATSDR's 2000 updated toxicological profile. Also, the NTP Center for the Evaluation of Risks to Human Reproduction Expert Panel Report (October 2000) has identified critical data needs for reproductive toxicity
	14D	Comparative toxicokinetic studies (Studies designed to examine how primates metabolize and distribute DEHP as compared with rodents via oral exposure).	.....	.....	The NTP Center for the Evaluation of Risks to Human Reproduction Expert Panel Report (October 2000) has also identified critical data needs for toxicokinetic information.
	14E	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.			
	14F	Potential candidate for subregistry of exposed persons.	ATSDR.		

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
Di-n-butyl phthalate	15A	Dose-response data in animals for acute-duration exposure via the oral route.	NTP	Filled	NTP completed a 14-day study.
	15B	Dose-response data in animals for chronic-duration exposure via the oral route.			
	15C	Carcinogenicity studies via oral exposure.			
	15D	*In vivo* genotoxicity studies	MHPF	Filled	Availability of ongoing studies in the MHPF research program.
	15E	Immunotoxicology studies via oral exposure.			Previously planned study in the MHPF research program to address this priority data need was canceled.
	15F	Neurotoxicity studies via oral exposure.			Previously planned study in the MHPF research program to address this priority data need was canceled.
	15G	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.			
	15H	Environmental fate of di-n-butyl phthalate in environmental media.			
	15I	Bioavailability in contaminated environmental media near hazardous waste sites.			
	15J	Potential candidate for subregistry of exposed persons.	ATSDR.		
Disulfoton	16A	Immunotoxicology testing battery following oral exposure.			
	16B	Exposure levels of disulfoton in tissues/fluids for populations living near hazardous waste sites and other populations, such as exposed workers.			
	16C	Disulfoton should be considered as a potential candidate for a subregistry of exposed persons.	ATSDR.		
Endosulfan (α,β, and sulfate)	17A	Acute-duration oral exposure.			
	17B	Data on sensitive neurologic end point following oral exposure.			
	17C	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.			
	17D	Data on the bioavailability of endosulfan from soil.			
	17E	Potential candidate for subregistry of exposed persons.	ATSDR.		
Endrin/endrin aldehyde	18A	Dose-response animal data for acute oral exposure to endrin.			
	18B	Multigeneration reproductive toxicity studies via oral exposure to endrin.	NTP.		
	18C	Accurately describe the toxicokinetics of endrin and its degradation products and identify the animal species to be used as the most appropriate model for human exposure.			
	18D	Exposure levels for endrin and its degradation products in humans living near hazardous waste sites.			

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
	18E	Accurately describe the environmental fate of endrin, including environmental breakdown products and rates, media half-lives, and chemical and physical properties of the breakdown products that help predict mobility and volatility.			
	18F	Potential candidate for subregistry of exposed persons.	ATSDR.		
Heptachlor/heptachlor epoxide	19A	Dose-response animal data for acute- and intermediate-duration oral exposures, including immunopathology.			
	19B	Multigeneration reproductive toxicity studies via the oral route of exposure.	NTP	Filled	Availability of publication ''The effects of perinatal/juvenile heptachlor exposure on adult immune and reproductive system function in rats'' by Smialowicz et al. (2001), Toxicological Sciences 61:164–75.
	19C	Two-species developmental toxicity studies via the oral route of exposure.			
	19D	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.			
	19E	Bioavailability from contaminated air, water, and soil and bioaccumulation potential.			
	19F	Potential candidate for subregistry of exposed persons.	ATSDR.		
Hexachloro-butadiene	20A	Dose-response data in animals for acute-duration exposure via the oral route.			
	20B	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.			
	20C	Environmental fate studies that determine the extent to which hexachlorobutadiene volatilizes from soil, and studies that determine the reactions and rates which drive degradation in soil.			
	20D	Bioavailability studies in soil and plants.			
	20E	Potential candidate for subregistry of exposed person.	ATSDR.		
Hexachloro-cyclohexane (α, β, δ, and γ).	21A	Dose-response data for chronic-duration oral exposure.	.....	Filled	An MRL was derived in ATSDR's 1999 updated toxicological profile.
	21B	Mechanistic studies on the neurotoxicity, hepatotoxicity, reproductive toxicity, and immunotoxicity of hexachlorocyclohexane.			
	21C	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....	Filled	Reference range concentrations in blood are available. ATSDR acknowledges that reference concentration data can support exposure and health assessments at waste sites, but the agency also continues to recognize the importance of collecting additional data on uniquely exposed populations at waste sites.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
	21D	Potential candidate for subregistry of exposed persons.	ATSDR.		
Lead	22A	Mechanistic studies on the neurotoxic effects of lead.	MHPF	Filled	Multiple new studies (13 publications from the MHPF research program + numerous new published studies in ATSDR's 1999 updated toxicological profile) are available.
	22B	Analytical methods for tissue levels.	MHPF	Filled	A publication from the MHPF research program and numerous studies in ATSDR's 1999 toxicological profile are available.
	22C	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	MHPF G. Lakes	Filled	Referent population blood and urine lead levels are available (NHANES III; Paschal et al. 1998), and at least 19 ATSDR studies that evaluated blood lead levels and potential adverse health effects are available.
Manganese	23A	Dose-response data for acute- and intermediate-duration oral exposures (the subchronic study should include reproductive histopathology and an evaluation of immunologic parameters including manganese effects on plaque-forming cells (SRBC), surface markers (D4:D8 ratio), and delayed hypersensitivity reactions).	MHPF EPA	Filled	Availability of ongoing studies in the MHPF research program.
	23B	Toxicokinetic studies on animals to investigate uptake and absorption, relative uptake of differing manganese compounds, metabolism of manganese, and interaction of manganese with other substances following oral exposure.	MHPF EPA	Filled	Avaialbiltiy of ongoing studies in the MHPF research program.
	23C	Epidemiological studies on the health effects of manganese (Special emphasis end points include neurologic, reproductive, developmental, immunologic, and cancer).		Filled	Based on evaluation of the data in ATSDR's 2000 updated toxicological profile. ATSDR will continue to evaluate new data as they become available to determine if additional studies are needed.
	23D	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.			
	23E	Relative bioavailability of different manganese compounds and bioavialability of manganese from soil.	EPA.		
Mercury	24A	Multigeneration reproductive toxicity study via oral exposure.	MHPF	Filled	Three publications from the MHPF research program are available.
	24B	Dose-response data in animals for chronic-duration oral exposure.	EPA	Filled	An MRL was derived in ATSDR's 1999 updated toxicological profile.
	24C	Immunotoxicology battery of tests via oral exposure.	EPA.		

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
	24D	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes	Filled	Background levels data are available in ATSDR's 1997 updated toxicological profile, and multiple studies that evaluated blood, urine, and hair mercury levels and potential adverse health effects are available (Five ATSDR studies + at least eight ongoing studies of the Great Lakes research program).
	24E	Potential candidate for subregistry of exposed persons.	ATSDR.		
Methoxychlor	25A	Evaluate neurologic effects after long-term, low-level oral exposure.	.....	Filled	Based on an evaluation of the data in ATSDR's 2000 updated toxicological profile.
	25B	Exposure levels of methoxychlor and primary metabolities in humans living near hazardous waste sites and in those individuals with the potential to ingest it.			
	25C	Evaluate the fate, transport, and levels of the degradation products of methoxychlor in soil.			
	25D	Potential candidate for subregistry of exposed persons.	ATSDR.		
Methylene chloride	26A	Dose-response data in animals for acute- and intermediate-duration oral exposure. The subchronic study should include extended reproductive organ histopathology, neuropathology, and immunopathology.	EPA ..... Vol Res.	Filled	ATSDR accepted HSIA's toxicity study for acute- and intermediate-exposure duration in February 1997. ATSDR accepted HSIAs immunotoxicity study via inhalation in November 2000. Currently, HSIA is conducting PBPK modeling to obtain data for oral exposure using the data from its inhalation study. Neurotoxicity screening battery testing remains in the ATSDR/EPA test rule under development.
	26B	Two-species developmental toxicity study via the oral route.	EPA ..... Vol Res.	Filled	ATSDR accepted HSIA's study in February 1997.
	26C	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....	Filled	Reference range concentrations in blood are available (Ashley et al. 1992, 1994; Needham et al. 1995). ATSDR acknowledges that reference concentration data can support exposure and health assessments at waste sites, but the agency also continues to recognize the importance of collecting additional data on uniquely exposed populations at waste sites.
	26D	Potential candidate for subregistry of exposed persons.	ATSDR.		
Nickel	27A	Epidemiologic studies on the health effects of nickel (Special emphasis end points include reproductive toxicity.	.....	Filled	At least two new relevant studies in ATSDR's 1997 updated toxicological profile are available. ATSDR will continue to evaluate new data as they become available to determine if additional studies are needed.
	27B	Two-species developmental toxicity study via the oral route.	EPA	Filed	In ATSDR's 1997 updated toxicological profile, a new study confirming the results of two previous studies is available

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
	27C	Dose-response data in animals for acute- and intermediate-duration oral exposures.	EPA.		
	27D	Neurotoxicology battery of tests via oral exposure.	EPA.		
	27E	Bioavailability of nickel from soil ...	EPA.		
	27F	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes	Filled	Based on availability of the study in the Great Lakes research program and an evaluation of ATSDR's 1997 updated toxicological profile.
	27G	Potential candidate for subregistry of exposed persons.	ATSDR.		
PAHs (Includes 15 substances)	28A	Dose-response data in animals for intermediate-duration oral exposures. The subchronic study should include extended reproductive organ histopathology and immunopathology.	MHPF	Filled	MRLs for four PAHs were derived in ATSDR's 1995 updated toxological profile. A publication from the MHPF research program addressing this priority data need is available.
	28B	Two-species developmental toxicity study via inhalation or oral exposure.	MHPF	Filled	Ongoing studies in the MHPF research program and one publication from the program are available.
	28C	Mechanistic studies on PAHs, on how mixtures of PAHs can influence the ultimate activation of PAHs, and on how PAHs affect rapidly proliferating tissues.	MHPF	Filled	At least 12 new studies in ATSDR's 1995 updated toxicological profile and two publications from the MHPF research program are available.
	28D	Dose-response data in animals for acute- and intermediate-duration inhalation exposures. the subchronic study should include extended reproductive organ histopathology and immunopathology.	MHPF	Filled	Ongoing studies in the MHPF research program and one publication from the program are available.
	28E	Epidemiologic studies on the health effects of PAHs (Special emphasis end points include cancer, dermal, hemolymphatic, and hepatic toxicity.	.....	Filled	At least three new studies in ATSDR's 1995 updated toxicological profile are available. ATSDR will continue to evaluate new data as they become available to determine if additional studies are needed.
	28F	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes	Filled	Based on ongoing study in the Great Lakes research program and an evaluation of the ATSDR 1995 updated toxicological profile. Also, the agency continues to recognize the importance of collecting additional data on uniquely exposed populations at waste sites.
	28G	Potential candidate for subregistry of exposed persons.	ATSDR.		
PCBs	29A	Dose-response data in animals for acute- and intermediate-duration oral exposures.	G. Lakes	.....	Although an MRL for intermediate-exposure duration was derived in ATSDR's 2000 updated toxicological profile, an MRL for acute-exposure duration is still lacking.
	29B	Biodegradation of PCBs in water; bioavailability of PCBs in air, water, and soil.			
	29C	Dose-response data in animals for acute- and intermediate-duration inhalation exposures. The subchronic study should include extended reproductive organ histopathology.			

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
	29D	Epidemiologic studies on the health effects of PCBs (Special emphasis end points include immunotoxicity, gastrointestinal toxicity, liver toxicity, kidney toxicity, thyroid toxicity, and reproductive/developmental toxicity).	G. Lakes	Filled	Multiple new published studies in ATSDR's 2000 updated toxicological profile and at least nine ongoing studies in the Great Lakes research program are available.
	29E	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes	Filled	Background levels data are available (ATSDR's 1997 updated toxicological profile, and Needham et al. 1996). Also, multiple studies that evaluated blood and breast milk PCB levels and potential adverse health effects are available (at least six ATSDR studies + at least eight ongoing studies in the Great Lakes research program).
	29F	Potential candidate for subregistry of exposed persons.	ATSDR.		
	29G [5]	Chronic toxicity and oncogenicity via oral exposure.	Vol Res ..	Filled	ATSDR accepted the final report of the GE in October 1997.
	29H [5]	Aerobic PCB biodegradation in sediment.	Vol Res ..	Filled	ATSDR accepted the final report of the GE study in July 1999.
	29I [5]	PCB congener analysis	Vol Res .. G. Lakes	Filled	ATSDR accepted the final report of the GE study in October 1997. Also, ongoing studies in the Great Lakes research program are available.
Selenium	30A	Dose-response data in animals for acute-duration oral exposure.	EPA.		
	30B	Immunotoxicology battery of tests via oral exposure.	EPA.		
	30C	Epidemiologic studies on the health effects of selenium (Special emphasis end points include cancer, reproductive and developmental toxicity, hepatotoxicity, and adverse skin effects).	.....	Filled	Based on an evaluation of ATSDR's 2001 updated toxicological profile. ATSDR will continue to evaluate new data as they become available to determine if additional studies are needed.
	30D	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes	Filled	Referent population serum selenium levels are known (NHANES III). Two ongoing studies in the Great Lakes research program are available. ATSDR acknowledges that reference concentration data can support exposure and health assessments at waste sites, but the agency also continues to recognize the importance of collecting additional data on uniquely exposed populations at waste sites.
	30E	Potential candidate for subregistry of exposed persons.	ATSDR.		
Tetrach loroethy lene	31A	Dose-response data in animals for acute-duration oral exposure, including neuropathology and demeanor, and immunopathology.	.....	Filled	An MRL was derived in the 1997 updated toxicological profile.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
	31B	Multigeneration reproductive toxicity study via oral exposure.	Vol Res ..	.....	HSIA's inhalation study was accepted by ATSDR and included in ATSDR's 1997 updated toxicological profile. However, ATSDR has identified ingestion of contaminated environmental media to be the primary exposure route for this chemical at waste sites. HSIA plans to obtain the oral data from the inhalation study by conducting PBPK modeling.
	31C	Dose-response data in animals for intermediate-duration oral exposure, including neuropathology, and immunopathology.	EPA ..... Vol Res.	.....	HSIA intends to obtain oral data for neurotoxicity by PBPK modeling, and to conduct an immunotoxicity study.
	31D	One-species developmental toxicity study via oral exposure.	EPA ..... Vol Res.		
	31E	Developmental neurotoxicity study via oral exposure.	EPA ..... Vol Res.		
	31F	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....	Filled	Reference range concentrations in blood are available (Ashley et al. 1992, 1994; Needham et al. 1995). ATSDR acknowledges that reference concentration data can support exposure and health assessments at waste sites, but the agency also continues to recognize the importance of collecting additional data on uniquely exposed populations at waste sites.
	31G	Potential candidate for subregistry of exposed persons.	ATSDR.		
Toluene	32A	Dose-response data in animals for acute- and intermediate-duration oral exposures. The subchronic study should include an extended histopathologic evaluation of the immune system.	EPA	Filled	Availability of MRLs for acute- and intermediate-exposure durations in ATSDR's 2000 updated toxicological profile. Immunotoxicity study remains in the ATSDR/EPA test rule under development.
	32B	Comparative toxicokinetic studies (Characterization of absorption, distribution, and excretion via oral exposure).	.....	Filled	Based on evaluation of the data in ATSDR's 2000 updated toxicological profile.
	32C	Neurotoxicology battery of tests via oral exposure.	EPA ..... MHPF.		
	32D	Mechanism of toluene-induced neurotoxicity.	.....	Filled	At least 15 studies in ATSDR's 1994 updated toxicological profile and additional new data in ATSDR's 2000 updated toxicological profile are available.
	32E	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed worker.	.....	Filled	Reference range concentrations in blood are available (Ashley et al. 1992, 1994; Needham et al. 1995), and additional data in ATSDR's 2000 updated toxicological profile are available. ATSDR acknowledges that reference concentration data can support exposure and health assessments at waste sites, but the agency also continues to recognize the importance of collecting additional data on uniquely exposed populations at waste sites.
	32F	Potential candidate for subregistry of exposed persons.	ATSDR.		

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
Toxaphene	33A	Identify the long-term health consequences of exposure to environmental toxaphene via oral exposure..			
	33B	Conduct additional immunotoxicity studies for chronic-duration via oral route of exposure.			
	33C	Conduct additional neurotoxicity studies for chronic-duration via oral route of exposure.			
	33D	Exposure levels in humans living in areas near hazardous waste sites with toxaphene and in those individuals with the potential to ingest it.			
	33E	Potential candidate for subregistry of exposed persons..	ATSDR.		
Trichloroethylene	34A	Dose-response data in animals for acute-duration oral exposure.	.....	Filled	An MRL was derived in ATSDR's 1997 updated toxicological profile.
	34B	Dose-response data in animals for intermediate-duration oral exposure.	EPA ..... Vol Res.		
	34C	Neurotoxicology battery of tests via the oral route.	EPA ..... MHPF ..... Vol Res.		
	34D	Immunotoxicology battery of tests via the oral route.	EPA ..... Vol Res.		
	34E	One-species developmental toxicity study via oral exposure.	Vol Res ..	.....	ATSDR accepted HSIA's final report for an inhalation developmental toxicity study in September 2001. HSIA is currently using PBPK modeling to obtain data for oral exposure using the data from its inhalation study.
	34F	Developmental neurotoxicity study via oral exposure.	EPA ..... Vol Res.		
	34G	Epidemiologic studies on the health effects of trichloroethylene (Special emphasis end points include cancer, hepatotoxicity, renal toxicity, developmental toxicity, and neurotoxicity).	.....	Filled	Based on evaluation of the data in ATSDR's 1997 updated toxicological profile. ATSDR will continue to evaluate new data as they become available to determine if additional studies are needed.
	34H	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....	Filled	Reference range concentrations in blood are available (Ashley et al. 1992, 1994; Needham et al. 1995). ATSDR acknowledges that reference concentration data can support exposure and health assessments at waste sites, but the agency also continues to recognize the importance of collecting additional data on uniquely exposed populations at waste sites.
Vinyl chloride	35A	Dose-response data in animals for acute-duration inhalation exposure.	.....	Filled	An MRL was derived in ATSDR's 1997 updated toxicological profile.
	35B	Multigeneration reproductive toxicity study via inhalation.	Vol Res ..	Filled	ATSDR accepted the final report of ACC's study in November 2000.
	35C	Dose-response data in animals for chronic-duration inhalation exposure.			
	35D	Mitigation of vinyl chloride-induced toxicity.			

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 50 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID [1]	PDN description	Program [2]	Status change [3]	Comments [4]
	35E	Two-species developmental toxicity study via inhalation..	Vol Res ..	Filled	ATSDR accepted the final report of ACC's study in November 2000.
	35F	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.			
	35G	Potential candidate for subregistry of exposed persons.	ATSDR.		
Zinc	36A	Dose-response data in animals for acute- and intermediate-duration oral exposures. The subchronic study should include an extended histopathologic evaluation of the immunologic and neurologic systems.	MHPF	Filled	Ongoing studies in the MHPF research program are available.
	36B	Multigeneration reproductive toxicity study via oral exposure.	MHPF.		
	36C	Carcinogenicity testing (2-year bioassay) via oral exposure.			
	36D	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....	.....	This priority data need, previously anticipated to be addressed under the voluntary research program, is not being investigated under any of the ATSDR research programs.
	36E	Potential candidate for subregistry of exposed persons.	ATSDR.		

[1] Priority data need identification number.

[2] Programs addressing data needs. ATSDR=ATSDR's Division of Health Studies; EPA=Environmental Protection Agency; G. Lakes=Great Lakes Human Health Effects Research Program; MHPF=Minority Health Professions Foundation schools; NTP=National Toxicology Program; Vol Res=Voluntary research.

[3] PDN can be filled or remain unchanged based on reevaluation of the database using criteria developed by ATSDR.

[4] ACC=American Chemistry Council; Ashley et al. 1992=Ashley DL, Bonin MA, Cardinali FL, et al. Anal Chem (1992) 64:1021–29; Ashley et al. 1994=Ashley DL, Bonin MA, Cardinali FL et al., Clin Chem (1994) 40/7:1401–4; ATSDR studies=Studies conducted by ATSDR's Division of Health Studies; GE=General Electric Company ; HSIA=Halogenated Solvents Industry Alliance, Inc.; MHPF=Minority Health Professions Foundation schools; MRL=Minimal Risk Level; Needham et al. 1995=Needham LL, Hill RH Jr, Ashley DL, Pirkle JL, and Sampson EJ. Environ Health Perspect 103 (Suppl 3):89–94; Needham et al. 1996=Needham LL, Patterson DG Jr, Burse VW, Paschal DC, Turner WE, and Hill VW Jr. Toxicol Ind Health 12:507–513; NHANES III=The Third National Health and Nutrition Examination Survey, conducted by the National Center for Health Statistics, Centers for Disease Control and Prevention, Atlanta, GA; NTP=National Toxicology Program; Paschal et al. 1998=Paschal DC, Ting BC, Morrow JC, et al. Environ Res, Section A 76: 53–59; PBPK modeling=physiologically based pharmacokinetic modeling; Toxicological profile=ATSDR's toxicological profiles for the agency's priority hazardous substances.

[5] Not a priority data need.

TABLE 2.—GROUPS ADDRESSING ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS (PDNS)

ATSDR program	Firm, institution, agency, or consortium	Substance	PDN ID
Voluntarism	American Chemistry Council	Vinyl Chloride	35B, 35E
	General Electric Company	PCBs	29G,* 29H,* 29I*
	Halogenated Solvents Industry Alliance, Inc.	Methylene chloride	26A, 26B
		Tetrachloroethylene	31B, 31C, 31D, 31E
		Trichloroethylene	34B, 34C, 34D, 34E, 34F
Minority Health Professions Foundation Schools.	Florida A & M University	Lead	22A
	The King/Drew Medical Center of the Charles R. Drew University of Medicine and Science.	Lead	22B, 22C
	Meharry Medical College	PAHS	28A, 28B, 28C, 28D
	Morehouse School of Medicine	Lead	22C
	Texas Southern University	Di-n-butyl phthalate	15D
		Lead	22A
		Toluene	32C
		Trichloroethylene	34C

TABLE 2.—GROUPS ADDRESSING ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS (PDNS)—Continued

ATSDR program	Firm, institution, agency, or consortium	Substance	PDN ID
	Tuskegee University	Chlordane	7A
		Mercury	24A
		Zinc	36A, 36B
	Xavier University	Manganese	23A, 23B
		Zinc	36A
Great Lakes Human Health Effects Research Program.	Michigan State University	DDT/DDE	13D, 13E
		Lead	22C
		Mercury	24D
		PCBs	29D, 29E, 29I
		Selenium	30D
	New York State Health Department.	DDT/DDE	13E
		Lead	22C
		Mercury	24D
		PCBs	29D, 29E, 29I
	State University of New York at Buffalo.	DDT/DDE	13D, 13E
		Lead	22C
		Mercury	24D
		PCBs	29D, 29E, 291
	State University of New York at Oswego.	DDT/DDE	13D, 13E
		Lead	22C
		Mercury	24D
		PCBs	29D, 29E, 29I
	University of Illinois at Chicago	DDT/DDE	13D, 13E
		Lead	22C
		Mercury	24D
		PCBs	29D, 29E, 291
	University of Illinois at Urbana-Champaign.	DDT/DDE	13D, 13E
		Lead	22C
		Mercury	24D
		PCBs	29D, 29E, 29I
	University of Wisconsin—Milwaukee.	DDT/DDE	13D, 13E
		Lead	22C
		Mercury	24D
		PCBs	29A, 29D, 29E, 29I
		Selenium	30D
	Wisconsin Department of Health and Social Services—5 State Consortium.	Arsenic	2D
		Cadmium	5B
		Chromium	10E
		DDT/DDE	13D, 13E
		Lead	22C
		Mercury	24D
		Nickel	27F
		PAHs	28F
		PCBs	29D, 29E, 29I
Environmental Protection Agency TSCA/FIFRA.	ATSDR Test Rule	Benzene	3A, 3B, 3C
		Chloroethane	8A, 8B
		Cyanide (hydrogen cyanide and sodium cyanide).	11A, 11B
		Methylene chloride	26A, 26B
		Tetrachloroethylene	31C, 31D, 31E
		Toluene	32A, 32C
		Trichloroethylene	34B, 34C, 34D, 34F
	Metals Testing Task Force (TASARC).	Arsenic	2A, 2B, 2C
		Beryllium	4A, 4B, 4C, 4E
		Chromium	10A, 10B, 10C, 10D
		Manganese	23A, 23B, 23E
		Mercury	24B, 24C
		Nickel	27B, 27C, 27D, 27E
		Selenium	30A, 30B
National Toxicology Program	National Institute of Environmental Health Sciences.	Carbon Tetrachloride	6B
		Chlordane	7A
		Di-n-butyl phthalate	15A
		Endrin	18B
		Heptachlor	19B

*Not priority data needs.

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