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Date: December 2, 2005.

**Robert E. Polson,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Toxic Substances and Disease Registry

[ATSDR-215]

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

**Editorial Note:** FR Doc. 05-23361 was originally published at page 71506 in the issue of Tuesday, November 29, 2005. The corrected document is republished below in its entirety, due to printing errors.

**AGENCY:** Agency for Toxic Substances and Disease Registry (ATSDR), U.S. 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 2002 (67 FR 4836). 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 (68 FR 63098, November 7, 2003), 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.

More recently, priority data needs for 10 additional hazardous substances frequently found at waste sites were determined and announced in the **Federal Register** (68 FR 22704). The ten 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-dichloroethene, ethylbenzene, pentachlorophenol, 1,1,2,2-tetrachloroethane, and total xylenes.

Currently, the priority data needs for acrolein and barium are being identified and will be reported in a future **Federal Register** notice.

To date, 270 priority data needs have been identified for the 60 hazardous substances, and 86 priority data needs have been filled (Table 1). ATSDR fills these research needs through U.S. Environmental Protection Agency (EPA) regulatory mechanisms (test rules), private-sector voluntarism, and the direct use of CERCLA funds. Additional priority 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. 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, National Institute of Environmental Health Sciences (NIEHS)/NTP, and the EPA, will review all proposed voluntary research studies.

**DATES:** ATSDR provides updates on the status of its Substance-Specific Applied Research Program approximately every three years or sooner, as needed. 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 Yee-Wan Stevens, M.S., Applied Toxicology Branch, Division of Toxicology and Environmental Medicine, ATSDR, 1600 Clifton Road, NE., Mailstop F-32, Atlanta, Georgia 30333, e-mail: [YStevens@cdc.gov](mailto:YStevens@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 ten 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:** Yee-Wan Stevens, M.S., Applied Toxicology Branch, Division of Toxicology and Environmental Medicine, ATSDR, 1600 Clifton Road, NE., Mailstop F-32, Atlanta, Georgia 30333, telephone: (770) 488-3325, fax: (770) 488-4178.

#### 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, in conjunction with NTP, 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, NIEHS/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 12 times since the initiation of the SSARP. It has guided referral of priority 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 priority 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.

#### 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.

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 (Exception: priority data needs referred to EPA [i.e., included in the EPA/ATSDR test rule] and/or ATSDR Voluntary Research Program remain as priority data needs until the studies have been completed, peer reviewed and accepted by ATSDR), OR

- If an updated ATSDR toxicological profile contains relevant new studies, or if other relevant, peer-reviewed, and publicly available new studies (not included in the toxicological profile) have been identified since the finalization of the priority data needs document; and based on such studies, it is generally agreed that a priority data need has been filled.

Furthermore, 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.

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 and/or ATSDR Voluntary Research Program, or it is associated with a pilot substance in EPA's Voluntary Children's Chemical Evaluation Program.

##### Specific Criteria

Examples of specific criteria for two categories of priority data needs are 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 (adults and/or children)—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., the Centers for Disease Control and Prevention's Third

National Report on Human Exposure to Environmental Chemicals, with data from a random sample of participants from the 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 for some of the chemicals listed in the National Report, the measurements are reported as below the limit of detection (LOD) for those chemicals. However, the LODs for all the chemicals monitored are available in the Report, and therefore, these data can be considered as estimates of background exposure levels.

In updating the SSARP, the status of the priority data needs may change 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 were not 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, in addressing issues relating to children's health, ATSDR considers it a priority to obtain data on exposure levels in children; therefore, when such information is available, it is used to fill this additional priority data need (e.g., cadmium, chlordane, chlorinated dibenzo-p-dioxins, DDT, lead, and pentachlorophenol, see Table 1).

In contrast, the Agency may consider a previously identified priority data need to no longer be a priority to fill at this time and thus be deleted from the list of priority data needs. However, it remains a data need for the Agency. For example, as a result of reevaluation of the database for di-n-butyl phthalate, two of its previously identified priority data needs, i.e., immunotoxicity and neurotoxicity studies via oral exposure are no longer considered to be priority data needs. This is due to the fact that the immune system does not appear to be a target for di-n-butyl phthalate toxicity and that additional neurotoxicity studies do not seem necessary because of the lack of effects seen in long-term neurotoxicity studies. In addition, under the Agency's Voluntary Research Program, the Halogenated Solvents Industry Alliance, Inc. (HSIA) proposed to fill a trichloroethylene priority data need (dose-response data for

intermediate-duration, oral exposure) by conducting PBPK modeling to obtain the data for oral exposure using existing inhalation data. However, ATSDR is concerned that, based on the existing data for this exposure duration, it is not clear if the most sensitive end point for oral exposure is the same as that for inhalation exposure. Therefore, the Agency believes it is prudent not to consider it a priority to conduct a PBPK study to obtain the oral data at this time pending evaluation of additional information. This is reflected in Table 1 from which this priority data need has been deleted.

#### 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.

##### A. TSCA/FIFRA

In developing and implementing the SSARP, ATSDR, NIEHS/NTP, and EPA have identified a subset of priority data needs for substances of mutual interest to the federal programs. These priority data needs are being addressed through a program of toxicological 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 considers 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 priority 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 13 ATSDR priority data needs (Table 2). The test rule is presently undergoing ATSDR and EPA final review and is anticipated to be available for public comment in Spring 2006.

At least seven metals included in the ATSDR's SSARP (arsenic, beryllium, chromium, manganese, mercury, nickel, and selenium, associated with 21 priority data needs) (Table 2) have been forwarded to EPA through TASARC for toxicity testing. The EPA is currently developing a risk assessment framework for metals. Once the framework has been adopted, the EPA will solicit testing proposals for these metals and

pursue appropriate testing mechanisms at a later date.

##### B. Private-Sector Voluntarism

As part of the Substance-Specific Applied Research Program (SSARP), ATSDR announced a set of proposed procedures for conducting voluntary research in the **Federal Register** (57 FR 4758) on February 7, 1992. Revisions based on public comments were published on November 16, 1992 (57 FR 54160). Private-sector organizations are encouraged to volunteer to conduct research to fill specific priority data needs at no expense to ATSDR. All study protocols and final reports are subjected to ATSDR's external peer review, and ATSDR accepts the study results based on the peer reviewers' recommendation and the industry groups' satisfactory response to the reviewers' comments.

To date, ATSDR has established memoranda of understanding with four industry groups. Through the voluntary research efforts of these organizations, at least 15 research needs (12 priority data needs and 3 data needs) for methylene chloride, tetrachloroethylene (perchloroethylene), trichloroethylene, polychlorinated biphenyl compounds [PCBs], and vinyl chloride have been or are being filled (Table 2).

Industry groups which conducted studies under the Voluntary Research Program include: *The American Chemistry Council (ACC)* [formerly the Chemical Manufacturers Association (CMA)] ATSDR accepted the ACC studies "Vinyl chloride: Combined inhalation two-generation reproduction and developmental toxicity study in CD rats."

##### *General Electric Company (GE)*

GE conducted studies on polychlorinated biphenyls including "An assessment of the chronic toxicity and oncogenicity of Aroclors 1016, 1242, 1254, and 1260 administered in diet to rats," "PCB congener analyses," and "Metabolite detection as a tool for determining naturally occurring aerobic PCB biodegradation." Although these studies do not specifically address ATSDR's priority data needs for PCBs, they do address other Agency research needs for these substances.

##### *Halogenated Solvents Industry Alliance, Inc. (HSIA)*

To date, ATSDR has entered into five MOUs with HSIA to conduct studies to fill priority data needs for methylene chloride, tetrachloroethylene and trichloroethylene. In addition, in 2002, HSIA signed a letter of agreement with ATSDR stating that HSIA volunteers to

conduct studies to fill ATSDR's remaining priority data needs for tetrachloroethylene (perchloroethylene) and trichloroethylene. These studies are being done in conjunction with the EPA/ATSDR test rule and EPA's Voluntary Children's Chemical Evaluation Program. In some cases, HSIA first conducted a study via inhalation which was followed by route extrapolation via PBPK modeling to obtain data for oral exposure. This is because, for specific chemicals, EPA requires inhalation data while ATSDR has determined that ingestion of contaminated environmental media is the primary exposure route at hazardous waste sites.

HSIA studies accepted by ATSDR include: Addressing priority data needs for methylene chloride with physiologically based pharmacokinetic modeling" which evaluates acute- and subchronic-duration toxicity and developmental toxicity via oral exposure.

"Methylene chloride: 28 day inhalation toxicity study in the rat to assess potential immunotoxicity."

"Immunotoxic potential of orally administered dichloromethane from immunotoxicity studies conducted by the inhalation route." (PBPK modeling)

"Trichloroethylene: Inhalation developmental toxicity study in CD rats." HSIA will conduct PBPK modeling to obtain data for oral exposure based on the inhalation data.

"Trichloroethylene (TCE): Immunotoxicity potential in CD rats following a 4-week vapor inhalation exposure." The final report of the study is undergoing ATSDR's external peer review. Pending ATSDR's acceptance of the inhalation study, HSIA will conduct PBPK modeling to obtain data for oral exposure based on the inhalation data.

"Perchloroethylene: Study of effects on embryo-fetal development in CD rats by inhalation administration." HSIA will conduct PBPK modeling to obtain data for oral exposure based on the inhalation data.

*Electric Power Research Institute, Inc. (EPRI)*

In addition to the substance-specific MOUs described above, ATSDR also signed an MOU with EPRI to conduct a study "Validation of test methods for assessing neurodevelopment in children." In this particular case, ATSDR and three other federal agencies (the Food and Drug Administration, EPA, and NIEHS) were also funding partners.

#### *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 at historically black colleges and universities. The MHPF mission is to research health problems that disproportionately affect poor and minority citizens. The purpose of the cooperative agreement was to address substance-specific data needs for priority hazardous substances identified by ATSDR. In addition, the agreement strengthened the environmental health research opportunities for scientists and students at MHPF member institutions and enhanced existing disciplinary capacities to conduct research in toxicology and environmental health. The MHPF published 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.

In the first five 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. Research initiated in the second 5-year project period included studies to address 10 additional priority data needs for chlordane, di-n-butyl phthalate, lead, manganese, the polycyclic aromatic hydrocarbons (PAHs), zinc, and eight other research needs. To date, 14 priority data needs have been filled through this cooperative agreement (Table 1).

During 2003, ATSDR announced a new five year cooperative agreement program with the MHPF. The purpose of the program is to apply findings from the previous ten year environmental health and Toxicology Research Program and to improve public health and environmental medicine in low-income and minority communities. The new program builds on earlier efforts and expands the Program's public environmental health impact on affected communities. Activities across the following four research and environmental public health focus areas were funded to initiate this new program: substance-specific toxicology research, environmental exposure

assessment, community-based environmental health education, and environmental health education for primary-care providers. No additional priority data needs are being addressed under this new program.

To date, Program research findings and other activities have resulted in the publication of more than 50 manuscripts in peer-reviewed journals. The institutions which have received awards and their respective studies 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 continues to collaborate with NTP to address priority data needs of mutual interest. Chemicals for which NTP has conducted studies (or is in the process of conducting studies) to fill ATSDR's priority data needs include carbon tetrachloride, 1,1-dichloroethene, di-n-butyl phthalate, disulfoton, and heptachlor (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 Fiscal Year 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 Human Health Effects Research Program have resulted in 70 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 which have received 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 59 of the 60 priority substances (Table 1). In some cases, ATSDR anticipates obtaining 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. Regarding the priority data need for exposure subregistries, the list of the 60 priority hazardous substances in the SSARP was forwarded to ATSDR's 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. Currently, ATSDR has established exposure subregistries for benzene, dioxin, 1,1,1-trichloroethane (not included in the SSARP), trichloroethylene, and tremolite asbestos.

#### 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 three years or sooner, as needed.

Dated: November 17, 2005.

**Kenneth Rose,**

*Acting Director, Office of Policy, Planning, and Evaluation, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.*

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Aldrin/Dieldrin .....	1A .....	Dose-response data in animals for intermediate-duration oral exposure.	.....	Filled .....	An MRL was derived in the 2000 updated ATSDR toxicological profile.
	1B .....	Bioavailability from soil.	.....	.....	This priority data need, previously addressed in a study in the Great Lakes Research Program, is no longer investigated in that study.
	1C .....	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....	.....	
	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.	.....	In addition to the data from the Great Lakes Research Program, 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.
	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 .....	

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Asbestos .....	3A .....	Epidemiologic studies of individuals occupationally exposed to asbestos levels lower than those experienced before the institution of current occupational standards governing the use of asbestos, but higher than current levels in the general population. These studies should be performed in conjunction with the immunotoxicity studies.			
	3B .....	Immunotoxicity studies of individuals occupationally exposed to asbestos.			
	3C .....	Development of human and rat lung retention models to aid in extrapolating between rat and human data.			
	3D .....	Improved analytical methods for screening samples and determining the chemical structure of asbestos fibers. Also, techniques are needed to normalize studies in which different analytical methods were employed.			
	3E .....	Exposure levels, fiber size distribution, and asbestos fiber type in areas with natural geologic deposits of friable asbestos and at hazardous waste sites. Also, techniques for estimating air levels of asbestos from soil concentrations and activity scenarios.			
	3F .....	Exposure levels in humans living near hazardous waste sites and in other populations, such as humans living in areas with naturally high levels of friable asbestos.			
	3G .....	Potential candidate for subregistry of exposed persons.	ATSDR ....	Filled .....	ATSDR established registry to follow the health of people who were exposed to asbestos in Libby, Montana. The name of the registry is the Tremolite Asbestos Registry (TAR).
Benzene .....	4A .....	Dose-response data in animals for acute- and intermediate-duration oral exposure. The subchronic study should include an extended reproductive organ histopathology.	EPA .....		Reproductive toxicity study is the only component of this PDN that is included in the EPA/ATSDR test rule.
	4B .....	Prenatal developmental toxicity study via oral exposure.	EPA .....		Previously planned study in the MHPF Research Program to address this priority data need was canceled.
	4C .....	Neurotoxicology battery of tests via oral exposure.	EPA.		
	4D .....	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.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Benzidine .....	4E .....	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....	Filled .....	Reference range concentrations are available (Ashley <i>et al.</i> 1992, 1994; Needham <i>et al.</i> 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.
	5A .....	Dose-response data for acute- and intermediate-duration exposure via the oral route (the study of intermediate-duration exposure should include evaluation of reproductive and endocrine organ histopathology, lymphoid tissues histopathology as well as examination of relevant blood components, and nervous system histopathology).	ATSDR.		
	5B .....	Exposure levels in humans living near hazardous waste sites.			
	5C .....	Exposure levels in children.			
Beryllium .....	5D .....	Potential candidate for subregistry of exposed persons.	EPA.		
	6A .....	Dose-response data in animals for acute- and intermediate-duration inhalation exposures. The subchronic study should include extended reproductive organ histopathology.	EPA.		
	6B .....	Prenatal developmental toxicity study via inhalation exposure.	EPA.		
	6C .....	Environmental fate in air; factors affecting bioavailability in air.	.....	Filled .....	Based on an evaluation of the data in ATSDR's 2000 updated toxicological profile.
	6D .....	Analytical methods to determine environmental speciation.	EPA.		
	6E .....	Immunotoxicology battery of tests following oral exposure.	.....	Filled .....	Reference range concentrations in urine are available (Paschal <i>et al.</i> 1998, CDC 2005). 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.
	6F .....	Exposure levels in humans (adults) living near hazardous waste sites and other populations, such as exposed workers.			
	6G .....	Exposure levels in children .....		Filled .....	Reference range concentrations in urine are available (CDC 2005).
Cadmium .....	6H .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	7A .....	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.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Carbon tetrachloride .....	7B .....	Exposure levels in humans (adults) living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes ..	Filled .....	In addition to the data from the Great Lakes Research Program, reference range concentrations in blood and urine are available (CDC 2005), and at least nine ATSDR studies that evaluated blood and urine cadmium levels and potential adverse health effects are available.
	7C .....	Exposure levels in children .....	.....	Filled .....	Reference range concentrations in blood and urine are available (CDC 2005).
	8A .....	Dose-response data in animals for chronic oral exposure. The study should include extended reproductive organ and nervous tissue histopathology.			
	8B .....	Immunotoxicology battery of tests via oral exposure.	NTP .....	Filled .....	NTP dose-finding study and one study in ATSDR's 1994 updated toxicological profile addressed the priority data need.
	8C .....	Half-life in soil .....	.....	Filled .....	One study in ATSDR's 1994 updated toxicological profile provided information on half-life in soil.
	8D .....	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 <i>et al.</i> 1992, 1994; Needham <i>et al.</i> 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.
Chlordane .....	8E .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	9A .....	Oral multigenerational studies to evaluate reproductive toxicity.	MHPF .....	Filled .....	Availability of studies in the MHPF Research Program.
	9B .....	Bioavailability studies following ingestion of contaminated media.			
	9C .....	Exposure levels in humans (adults) living near hazardous waste sites and other populations potentially exposed to chlordane.	.....	Filled .....	Reference range concentrations in serum are available (CDC 2005). 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.
	9D .....	Exposure levels in children .....	.....	Filled .....	Reference range concentrations in serum are available (CDC 2005).
Chlorinated dibenzo-p-dioxins (CDDs).	9E .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	10A .....	Studies via oral exposure designed to assess childhood susceptibility.			



TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Chloroethane .....	10B .....	Comparative toxicokinetic studies examining the relative absorption of CDDs across exposure routes and the relative contribution of each exposure route to total body burdens.	EPA.	Filled .....	Reference range concentrations in serum are available (CDC 2005). 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.
	10C .....	Exposure levels in humans (adults) living near hazardous waste sites.			
	10D .....	Exposure levels in children .....			
	11A .....	Dose-response data in animals for acute- and intermediate-duration oral exposures. The sub-chronic study should include an evaluation of immune and nervous system tissues, and extended reproductive organ histopathology.			
	11B .....	Dose-response data in animals for chronic inhalation exposures. The study should include an evaluation of nervous system tissues.			
Chloroform .....	11C .....	Potential candidate for subregistry of exposed persons.	ATSDR.	Filled .....	An MRL was derived in ATSDR's 1997 updated toxicological profile. 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.
	12A .....	Dose-response data in animals for intermediate-duration oral exposure.	.....		
	12B .....	Epidemiologic studies on the health effects of chloroform (Special emphasis end points include cancer, neurotoxicity, reproductive and developmental toxicity, hepatotoxicity, and renal toxicity).	.....		
	12C .....	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....		
Chromium .....	12D .....	Potential candidate for subregistry of exposed persons.	ATSDR.	Filled .....	Reference range concentrations in blood are available (Ashley <i>et al.</i> 1992, 1994; and Needham <i>et al.</i> 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.
	13A .....	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.		
	13B .....	Multigeneration reproductive toxicity study via oral exposure to chromium (III) and (VI).	EPA.		

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Cyanide .....	13C .....	Immunotoxicology battery of tests following oral exposure to chromium (III) and (VI).	EPA.		In addition to the data from the Great Lakes Research Program, reference range concentrations in urine are available (Paschal <i>et al.</i> 1998). Also, at least two ATSDR studies that evaluated urine chromium levels and potential adverse health effects are available.
	13D .....	Prenatal developmental toxicity study via oral exposure to chromium (III) and (VI).	EPA.		
	13E .....	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes ..	Filled .....	
	14A .....	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.		
	14B .....	Prenatal developmental toxicity study via oral exposure.	EPA.		
1,2-dibromo-3-chloropropane .....	14C .....	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.
	14D .....	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.			
	14E .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	15A .....	Dose-response data in animals for acute-duration exposure via the oral route (including reproductive organ histopathology).			
	15B .....	Dose-response data in animals for chronic-duration exposure via the oral route (including reproductive organ histopathology).			
	15C .....	Prenatal developmental toxicity study via oral exposure.			Previously planned study in the MHPF Research Program to address this priority data need was canceled.
	15D .....	Immunotoxicology testing battery via oral exposure.	.....	.....	
	15E .....	Neurotoxicology testing battery via oral exposure.	.....	.....	
	15F .....	Exposure levels in humans living near hazardous waste sites and other exposed populations, such as exposed workers.			
	15G .....	Potential candidate for subregistry of exposed persons.	ATSDR.		

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
1,2-Dibromoethane .....	16A .....	Dose-response data in animals for acute- and intermediate-duration exposure by the oral route (the study of intermediate-duration exposure should include evaluation of neuropathology and observation for overt signs of neurotoxicity).	ATSDR.		
	16B .....	Multigeneration reproductive toxicity studies via oral exposure.			
	16C .....	Developmental toxicity studies via oral exposure.			
	16D .....	Immunotoxicity battery studies via oral exposure.			
	16E .....	Exposure levels in humans living near hazardous waste sites and in other populations, such as workers exposed to 1, 2-dibromoethane.			
	16F .....	Exposure levels in children.			
1,2-Dichloroethane .....	16G .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	17A .....	Dose-response data in animals for acute-duration (14-day) exposure by the inhalation route, including a comparison of young and adult animals.			
	17B .....	Dose-response data in animals for acute-duration (14-day) exposure by the oral route, including a comparison of young and adult animals.			
	17C .....	Dose-response data in animals for intermediate-duration exposure by the inhalation route (the study should be performed in conjunction with the neurotoxicology battery of tests).			
	17D .....	Neurotoxicology battery of tests following inhalation exposure.			
	17E .....	Neurotoxicology battery of tests following oral exposure.			
	17F .....	Dose-response data in animals for chronic-duration exposure by the oral route.			
	17G .....	Prenatal developmental toxicity data for inhalation exposure (assessment of developmental cardiotoxicity and neurotoxicity).			
	17H .....	Prenatal developmental toxicity data for oral exposure (assessment of developmental cardiotoxicity and neurotoxicity).			
	17I .....	Additional analyses and studies for comparative toxicokinetics across species, ages, routes, and durations.			
	17J .....	Children's susceptibility.			
	17K .....	Exposure levels in humans living near hazardous waste sites.			
	17L .....	Exposure levels in children.			
1,1-Dichloroethene .....	17M .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	18A .....	Dose-response data in animals for acute-duration exposure by the inhalation route.			
			NTP .....	Filled .....	Availability of ongoing NTP study.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
DDT .....	18B .....	Dose-response data in animals for chronic-duration exposure by the inhalation route.	NTP .....	Filled .....	Availability of ongoing NTP study.
	18C .....	Dose-response data in animals for acute- and intermediate-duration exposure by the oral route.			
	18D .....	Carcinogenicity studies in two species following inhalation exposure.			
	18E .....	Reproductive toxicity studies assessing male and female end points following inhalation exposure.			
	18F .....	Prenatal developmental toxicity studies following oral exposure.			
	18G .....	Immunotoxicology battery of tests following oral exposure.			
	18H .....	Battery of neurobehavioral tests following inhalation exposure.			
	18I .....	Children's susceptibility.			
	18J .....	Exposure levels in humans living near hazardous waste sites.			
	18K .....	Exposure levels in children.			
	18L .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	19A .....	Dose-response data in animals for chronic-duration oral exposure.			
	19B .....	Comparative toxicokinetic study (across routes/species).			
	19C .....	Bioavailability and bioaccumulation from soil.			
	19D .....	Epidemiologic studies on the health effects of DDT, DDD, and DDE (Special emphasis end points include immunotoxicity, and reproductive and developmental toxicity).	G. Lakes ..	Filled .....	In addition to the data from the Great Lakes Research Program, multiple studies in ATSDR's 2000 updated toxicological profile are available.
	19E .....	Exposure levels in humans (adults) living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes ..	Filled .....	In addition to the data from the Great Lakes Research Program, reference range concentrations in serum are available (CDC 2005). 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.
	19F .....	Exposure levels in children .....	.....	Filled .....	Reference range concentrations in serum are available (CDC 2005).
	19G .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
Di (2-ethylhexyl) phthalate .....	20A .....	Epidemiologic studies on the health effects of DEHP (Special emphasis end points include cancer).			

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Di-n-butyl phthalate .....	20B .....	Dose-response data in animals for acute- and intermediate-duration oral exposures. The sub-chronic study should include an extended histopathologic evaluation of the immunologic and neurologic systems.	.....	.....	This research need remains as a priority data need because the previously developed MRL for acute-duration (1993 toxicological profile) was withdrawn. However, a new MRL for intermediate-duration was derived in ATSDR's 2002 updated Toxicological Profile. Therefore, this priority data need is considered partially filled because additional adequate acute-duration data for deriving an MRL are still lacking.
	20C .....	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 2002 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.
	20D .....	Comparative toxicokinetic studies (Studies designed to examine how primates metabolize and distribute DEHP as compared with rodents via oral exposure).	.....	Filled .....	The existing database provides adequate information to fill this priority data need based on ATSDR's reevaluation of the published data.
	20E .....	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	ATSDR.	.....	
	20F .....	Potential candidate for subregistry of exposed persons.			
	21A .....	Dose-response data in animals for acute-duration exposure via the oral route.	NTP .....	Filled .....	Availability of an NTP study.
	21B .....	Dose-response data in animals for chronic-duration exposure via the oral route.	MHPF .....	Filled .....	Availability of a study in the MHPF Research Program.
	21C .....	Carcinogenicity studies via oral exposure.			
	21D .....	In vivo genotoxicity studies .....			
	21E .....	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.			
	21F .....	Environmental fate of di-n-butyl phthalate in environmental media.	ATSDR.	.....	
	21G .....	Bioavailability in contaminated environmental media near hazardous waste sites.			
	21H .....	Potential candidate for subregistry of exposed persons.	NTP .....	Filled .....	Availability of ongoing NTP study.
	22A .....	Immunotoxicology testing battery following oral exposure.			
Disulfoton .....	22B .....	Exposure levels of disulfoton in tissues/fluids for populations living near hazardous waste sites and other populations, such as exposed workers.	ATSDR.	.....	
	22C .....	Disulfoton should be considered as a potential candidate for a subregistry of exposed persons.			

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Endosulfan ( $\alpha$ , $\beta$ , and sulfate) .....	23A .....	Acute-duration oral exposure studies.	ATSDR.		
	23B .....	Data on sensitive neurologic end point following oral exposure.			
	23C .....	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.			
	23D .....	Data on the bioavailability of endosulfan from soil.			
	23E .....	Potential candidate for subregistry of exposed persons.			
Endrin/endrin aldehyde .....	24A .....	Dose-response animal data for acute oral exposure to endrin.	ATSDR.		
	24B .....	Multigeneration reproductive toxicity studies via oral exposure to endrin.			
	24C .....	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.			
	24D .....	Exposure levels for endrin and its degradation products in humans living near hazardous waste sites.			
	24E .....	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.			
	24F .....	Potential candidate for subregistry of exposed persons.			
	24G .....	Exposure levels in humans living near hazardous waste sites.			
Ethylbenzene .....	25A .....	Dose-response data for acute-duration exposure by the inhalation route.	ATSDR.		
	25B .....	Dose-response data for chronic-duration exposure by the inhalation route.			
	25C .....	Dose-response data for acute- and intermediate-duration exposure by the oral route; the study of intermediate-duration exposure should include an evaluation of clinical signs of neurotoxicity and histopathology of reproductive organs, endocrine glands, and nervous system.			
	25D .....	Multigeneration toxicity study examining reproductive end points and indicators of endocrine disruption following inhalation exposure.			
	25E .....	Prenatal developmental study with continued assessment of offspring during postnatal development following oral exposure.			
	25F .....	Studies for comparative toxicokinetics.			
	25G .....	Exposure levels in humans living near hazardous waste sites.			
	25H .....	Exposure levels in children.			
	25I .....	Exposure levels in humans living near hazardous waste sites.			

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Heptachlor/heptachlor epoxide .....	25I .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	26A .....	Dose-response animal data for acute- and intermediate-duration oral exposures, including immunopathology.			
	26B .....	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 61:164–175.
	26C .....	Prenatal developmental toxicity studies via the oral route of exposure.	.....	Filled .....	Based on ATSDR's review of the literature, i.e., Smialowicz et al. (2001), Toxicological Sciences 61:164–175 and Moser et al. (2001) Toxicological Sciences 60 (2):315–326.
	26D .....	Exposure levels in humans (adults) living near hazardous waste sites and other populations, such as exposed workers.	.....	Filled .....	Reference range concentrations in serum are available (CDC 2005). 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.
	26E .....	Exposure levels in children .....	.....	Filled .....	Reference range concentrations in serum are available (CDC 2005).
	26F .....	Bioavailability from contaminated air, water, and soil and bioaccumulation potential.			
Hexachlorobutadiene .....	26G .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	27A .....	Dose-response data in animals for acute-duration exposure via the oral route.			
	27B .....	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.			
	27C .....	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.			
	27D .....	Bioavailability studies in soil and plants.			
Hexachlorocyclohexane ( $\alpha$ , $\beta$ and $\gamma$ ).	27E .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	28A .....	Dose-response data for chronic-duration oral exposure.	.....	Filled .....	An MRL was derived in ATSDR's 1999 updated toxicological profile.
	28B .....	Mechanistic studies on the neurotoxicity, hepatotoxicity, reproductive toxicity, and immunotoxicity of hexachlorocyclohexane.			

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
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Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Lead .....	28C .....	Exposure levels in humans (adults) living near hazardous waste sites and other populations, such as exposed workers.	.....	Filled .....	Reference range concentrations in serum are available (CDC 2005). 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.
	28D .....	Exposure levels in children .....	.....	Filled .....	Reference range concentrations in serum are available (CDC 2005).
	28E .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	29A .....	Mechanistic studies on the neurotoxic effects of lead.	MHPF .....	Filled .....	Multiple studies (at least 13 publications from the MHPF Research Program + numerous studies in ATSDR's 1999 updated toxicological profile) are available.
	29B .....	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.
	29C .....	Exposure levels in humans (adults) near hazardous waste sites and other populations, such as exposed workers.	MHPF .....	Filled .....	In addition to the data from Great Lakes Research Program and MHPF Research Program, reference range concentrations in blood and urine are available (CDC 2005; Paschal et al. 1998), and at least 19 ATSDR studies that evaluated blood lead levels and potential adverse health effects are available.
Manganese .....	29D .....	Exposure levels in children .....	.....	Filled .....	Reference range concentrations in blood and urine are available (CDC 2005).
	30A .....	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 .....	Filled .....	Availability of studies in the MHPF Research Program.
	30B .....	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 .....	Filled .....	Availability of studies in the MHPF Research Program.
	30C .....	Epidemiological studies on the health effects of manganese (Special emphasis end points include neurologic, reproductive, developmental, immunologic, and cancer).	.....	Filled .....	Based on an 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.



TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
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Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Mercury .....	30D .....	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	EPA.		
	30E .....	Relative bioavailability of different manganese compounds and bioavailability of manganese from soil.			
	31A .....	Multigeneration reproductive toxicity study via oral exposure.	MHPF .....	Filled .....	Availability of publications from the MHPF Research Program.
	31B .....	Dose-response data in animals from chronic-duration oral exposure.	.....	Filled .....	An MRL was derived in ATSDR's 1999 updated toxicological profile.
	31C .....	Immunotoxicology battery of tests via oral exposure.	EPA.		
	31D .....	Exposure levels in humans (adults) living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes ..	Filled .....	In addition to the data from the Great Lakes Research Program, background levels data are available in ATSDR's 1997 updated toxicological profile, and multiple ATSDR studies that evaluated blood, urine, hair mercury levels and potential adverse health effects are available. Also, reference range concentrations in blood and urine are available (CDC 2005).
Methoxychlor .....	31E .....	Exposure levels in children .....	.....	Filled .....	Reference range concentrations in blood and urine are available (CDC 2005).
	31F .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	32A .....	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.
	32B .....	Exposure levels of methoxychlor and primary metabolites in humans living near hazardous waste sites and those individuals with the potential to ingest it.			
	32C .....	Evaluate the fate, transport, and levels of the degradation products of methoxychlor in soil.			
Methylene chloride .....	32D .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	33A .....	Dose-response data in animals for acute- and intermediate-duration oral exposure. The sub-chronic study should include extended reproductive organ histopathology, neuropathology, and immunopathology.	EPA .....	Filled .....	ATSDR accepted HSIA's toxicity study for acute- and intermediate-duration exposure duration in February 1997. Also, ATSDR accepted HSIA's immunotoxicity study via inhalation in November 2000 and the oral data obtained via PBPK modeling conducted by HSIA based on the immunotoxicity data from the inhalation study. Neurotoxicity screening battery testing remains in the ATSDR/EPA test rule under development.
	33B .....	Prenatal developmental toxicity study via the oral route.	Vol Res ....	Filled .....	ATSDR accepted HSIA's study in February 1997.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
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Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Nickel .....	33C .....	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 <i>et al.</i> 1992, 1994; Needham <i>et al.</i> 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.
	33D .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	34A .....	Epidemiologic studies on the health effects of nickel (Special emphasis end points include reproductive toxicity).	.....	Filled .....	Based on at least two relevant studies 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.
	34B .....	Prenatal development toxicity study via the oral route.	EPA .....	Filled .....	In ATSDR's 1997 updated toxicological profile, a study confirming the results of two previous studies is available.
	34C .....	Dose-response data in animals for acute- and intermediate-duration oral exposures.	EPA.		
	34D .....	Neurotoxicology battery of tests via oral exposure.	EPA.		
	34E .....	Bioavailability of nickel from soil ..	EPA.		
Pentachlorophenol .....	34F .....	Exposure levels in humans (adults) living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes ..	Filled .....	Based on availability of the data from the Great Lakes Research Program and an evaluation of ATSDR's 1997 updated toxicological profile.
	34G .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	35A .....	Comparative toxicokinetic studies.			
	35B .....	Exposure levels in humans (adults) living near hazardous waste sites.	.....	Filled .....	Reference range concentrations in urine are available (CDC 2005). 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.
Polychlorinated biphenyls (PCBs)	35C .....	Exposure levels in children .....	.....	Filled .....	Reference range concentrations in urine are available (CDC 2005).
	35D .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	36A .....	Dose-response data in animals for acute- and intermediate-duration oral exposure.	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.
	36B .....	Biodegradation of PCBs in water; bioavailability of PCBs in air, water, and soil.			

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Polycyclic aromatic hydrocarbons (PAHs) (Includes 15 substances).	36C .....	Dose-response data in animals for acute- and intermediate-duration inhalation exposures. The subchronic study should include extended reproductive organ histopathology.			
	36D .....	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 .....	In addition to the data from the Great Lakes Research Program, multiple studies in ATSDR's 2000 updated toxicological profile are available.
	36E .....	Exposure levels in humans (adults) living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes ..	Filled .....	In addition to the data from the Great Lakes Research Program, background levels data are available (ATSDR's 1997 updated toxicological profile, Needham <i>et al.</i> 1996, and CDC 2005). Also, multiple ATSDR studies that evaluated blood and breast milk PCB levels and potential adverse health effects are available.
	36F .....	Exposure levels in children .....	.....	Filled .....	Reference range concentrations in serum are available (CDC 2005).
	36G .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	36H <sup>5</sup> ....	Chronic toxicity and oncogenicity via oral exposure.	Vol Res ....	Filled .....	ATSDR accepted the final report of the GE study in October 1997.
	36I <sup>5</sup> .....	Aerobic PCB biodegradation in sediment.	Vol Res ....	Filled .....	ATSDR accepted the final report of the GE study in July 1999.
	36J <sup>5</sup> ....	PCB congener analysis .....	Vol Res .... G. Lakes	Filled .....	ATSDR accepted the final report of the GE study in October 1997. Also, data from the Great Lakes Research Program are available.
	37A .....	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 toxicological profile. A publication from the MHPF Research Program addressing this priority data need is available.
	37B .....	Prenatal developmental toxicity study via inhalation or oral exposure.	MHPF .....	Filled .....	Data from the MHPF Research Program including a publication are available.
	37C .....	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 .....	In addition to publications from the MHPF Research Program, studies are available in ATSDR's 1995 updated toxicological profile.
	37D .....	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 .....	Data from the MHPF Research Program including one publication are available.
	37E .....	Epidemiologic studies on the health effects of PAHs (Special emphasis end points include cancer, dermal, hemolymphatic, and hepatic toxicity).	.....	Filled .....	Multiple 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.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Selenium .....	37F .....	Exposure levels in humans (adults) living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes ..	Filled .....	Based on data from the Great Lakes Research Program and an evaluation of the ATSDR 1995 updated toxicological profile. Also, reference range concentrations in urine are available (CDC 2005). The Agency continues to recognize the importance of collecting additional data on uniquely exposed populations at waste sites.
	37G .....	Exposure levels in children .....	.....	Filled .....	
	37H .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	38A .....	Dose-response data in animals for acute-duration oral exposure.	EPA.		Reference range concentrations in urine are available (CDC 2005).
	38B .....	Immunotoxicology battery of tests via oral exposure.	EPA.		
	38C .....	Epidemiologic studies on the health effects of selenium (Special emphasis end points include cancer, reproductive and developmental toxicity, hepatotoxicity, and adverse skin effects).	.....	Filled .....	
	38D .....	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	G. Lakes ..	Filled .....	
1,1,2,2-Tetrachloroethane .....	38E .....	Potential candidate for subregistry of exposed persons.	ATSDR.		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.
	39A .....	Prenatal developmental toxicity study by the oral route.			
	39B .....	Immunotoxicity battery following oral exposure.			
	39C .....	Mammalian in vivo genotoxicity assays.			
	39D .....	Exposure levels in humans living near hazardous waste sites.			
	39E .....	Exposure levels in children.			
	39F .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
Tetrachloroethylene .....	40A .....	Dose-response data in animals for acute-duration oral exposure, including neuropathology and demeanor, and immunopathology.	.....	Filled .....	An MRL was derived in the ATSDR 1997 updated toxicological profile.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Toluene .....	40B .....	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 will obtain the oral data from the inhalation study by conducting PBPK modeling.
	40C .....	Dose-response data in animals for intermediate-duration oral exposure, including neuropathology, and immunopathology.	EPA. .... Vol Res	.....	HSIA will obtain oral data for intermediate-duration toxicity and neurotoxicity by PBPK modeling based on existing inhalation data. Also, it will conduct an inhalation immunotoxicity study, followed by PBPK modeling to obtain oral data.
	40D .....	Prenatal developmental toxicity study via oral exposure.	Vol Res ....	.....	HSIA's developmental toxicity study via inhalation was accepted by ATSDR. However, ATSDR has identified ingestion of contaminated environmental media to be the primary exposure route for this chemical at waste sites. HSIA will obtain the oral data from the inhalation study by conducting PBPK modeling.
	40E .....	Developmental neurotoxicity study via oral exposure.	EPA Vol Res.	.....	Reference range concentrations in blood are available (Ashley <i>et al.</i> 1992, 1994; Needham <i>et al.</i> 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.
	40F .....	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.	.....	Filled .....	
	40G .....	Potential candidate for subregistry of exposed persons.	ATSDR.	.....	
	41A .....	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.	.....	Filled .....	Availability of MRLs for acute- and intermediate-exposure durations in ATSDR's 2000 updated toxicological profile.
	41B .....	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.
	41C .....	Neurotoxicology battery of tests via oral exposure.	EPA .... MHPF	.....	A publication for acute exposure but not longer term exposure is available in the MHPF Research Program. Also, this priority data need is included in the EPA/ATSDR test rule.
	41D .....	Mechanism of toluene-induced neurotoxicity.	.....	Filled .....	Multiple studies in ATSDR's 1994 and 2000 updated toxicological profiles are available.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Toxaphene .....	41E .....	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 <i>et al.</i> 1992, 1994; Needham <i>et al.</i> 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.
	41F .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	42A .....	Identify the long-term health consequences of exposure to environmental toxaphene via oral exposure.			
	42B .....	Conduct additional immunotoxicity studies for chronic-duration via oral route of exposure.			
	42C .....	Conduct additional neurotoxicity studies for chronic-duration via oral route of exposure.			
Trichloroethylene .....	42D .....	Exposure levels in humans living in areas near hazardous waste sites with toxaphene and in those individuals with the potential to ingest it.			
	42E .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	43A .....	Dose-response data in animals for acute-duration oral exposure.	.....	Filled .....	An MRL was derived in ATSDR's 1997 updated toxicological profile.
	43B .....	Neurotoxicology battery of tests via the oral route.	EPA MHPF ..... Vol Res	.....	A publication for acute exposure but not longer term exposure is available in the MHPF Research Program. Also, this priority data need is included in the EPA/ATSDR test rule and ATSDR's Voluntary Research Program.
	43C .....	Immunotoxicology battery of tests via oral route.	Vol Res ....	.....	HSIA has completed an inhalation immunotoxicity study which is undergoing ATSDR peer review. HSIA will obtain oral data via PBPK modeling based on the inhalation data.
	43D .....	Prenatal developmental toxicity study via oral exposure.	Vol Res ....	.....	ATSDR has accepted HSIA's final report for an inhalation developmental toxicity study. HSIA will use PBPK modeling to obtain data for oral exposure based on the results of its inhalation study.
	43E .....	Developmental neurotoxicity study via oral exposure.	EPA Vol Res		
	43F .....	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.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—  
Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
Vinyl chloride .....	43G .....	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 <i>et al.</i> 1992, 1994; Needham <i>et al.</i> 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.
	44A .....	Dose-response data in animals for acute-duration inhalation exposure.	.....	Filled .....	An MRL was derived in ATSDR's 1997 updated toxicological profile.
	44B .....	Multigeneration reproductive toxicity study via inhalation.	Vol Res ....	Filled .....	ATSDR accepted the final report of ACC's study in November 2000.
	44C .....	Dose-response data in animals for chronic-duration inhalation exposure.			
	44D .....	Mitigation of vinyl chloride-induced toxicity.			
	44E .....	Prenatal developmental toxicity study via inhalation.	Vol Res ....	Filled .....	ATSDR accepted the final report of ACC's study in November 2000.
Xylenes .....	44F .....	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers.			
	44G .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	45A .....	Dose-response data for chronic-duration exposure by the oral route. This study should be done in conjunction with the neurotoxicology battery of tests.			
	45B .....	Neurotoxicology battery of tests following oral exposure.			
	45C .....	Two-generation reproductive study following oral exposure.			
	45D .....	Developmental toxicity study that includes neurodevelopmental end points following oral exposure.			
Zinc .....	45E .....	Exposure levels in humans living near hazardous waste sites.			
	45F .....	Exposure levels in children.			
	45G .....	Potential candidate for subregistry of exposed persons.	ATSDR.		
	46A .....	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 .....	Availability of ongoing studies in the MHPF Research Program.
	46B .....	Multigeneration reproductive toxicity study via oral exposure.	MHPF .....	Filled .....	Availability of ongoing studies in the MHPF Research Program.
	46C .....	Carcinogenicity testing (2-year bioassay) via oral exposure.			
	46D .....	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.

TABLE 1.—ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS FOR 60 PRIORITY HAZARDOUS SUBSTANCES—Continued

Substances	PDN ID <sup>1</sup>	PDN description	Program <sup>2</sup>	Status change <sup>3</sup>	Comments <sup>4</sup>
	46E .....	Potential candidate for subregistry of exposed persons.	ATSDR.		

<sup>1</sup> Priority data need identification number.

<sup>2</sup> Programs addressing priority data needs. ATSDR = ATSDR's Division of Health Studies; EPA = U.S. Environmental Protection Agency; G. Lakes = Great Lakes Human Health Effects Research Program; MHPF = Minority Health Professions Foundation; NTP = National Toxicology Program; Vol Res = Voluntary research.

<sup>3</sup> PDN can be *filled* or remain unchanged based on reevaluation of the database using criteria developed by ATSDR.

<sup>4</sup> 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; MRL = Minimal Risk Level; CDC 2005 = The third National Report on Human Exposure to Environmental Chemicals, prepared by the National Center for Environmental Health, Centers for Disease Control and Prevention, Atlanta, GA; 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.

<sup>5</sup> Not a priority data need.

TABLE 2.—GROUPS WHICH ARE ADDRESSING/HAVE ADDRESSED ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS (PDNS)

Program	Firm, institution, agency, or consortium	Substance	PDN ID
Voluntarism .....	American Chemistry Council .....	Vinyl chloride .....	44B, 44E
		General Electric Company .....	36H*, 36I*, 36J*
		Halogenated Solvents Industry Alliance, Inc.	33A, 33B
		Methylene chloride .....	
Minority Health Professions Foundation.	Florida A & M University .....	Tetrachloroethylene .....	40B, 40C, 40D, 40E
		Trichloroethylene .....	43B, 43C, 43D, 43E
		Lead .....	29A
		Lead .....	29B, 29C
	The King/Drew Medical Center of the Charles R. Drew University of Medicine and Science.	PAHs .....	37A, 37B, 37C, 37D
		Lead .....	29C
		Di-n-butyl phthalate .....	21D
		Lead .....	29A
	Meharry Medical College .....	Toluene .....	41C
		Trichloroethylene .....	43B
		Chlordane .....	9A
		Mercury .....	31A
	Morehouse School of Medicine .....	Zinc .....	46A, 46B
		Manganese .....	30A, 30B
		Zinc .....	46A
		DDT/DDE .....	19D, 19E
Great Lakes Human Health Effects Research Program.	Tuskegee University .....	Lead .....	29C
		Mercury .....	31D
		PCBs .....	36D, 36E, 36J*
		Selenium .....	38D
	Xavier University .....	DDT/DDE .....	19E
		Lead .....	29C
		Mercury .....	31D
		PCBs .....	36D, 36E, 36J*
	Michigan State University .....	PCBs .....	36E
		DDT/DDE .....	19D, 19E
		Lead .....	29C
		Mercury .....	31D
	New York State Health Department ....	PCBs .....	36D, 36E, 36J*
		DDT/DDE .....	19D, 19E
		Lead .....	29C
		Mercury .....	31D
	State University of New York at Albany.	PCBs .....	36D, 36E, 36J*
		DDT/DDE .....	19D, 19E
		Lead .....	29C
		Mercury .....	31D
	State University of New York at Buffalo.	PCBs .....	36D, 36E, 36J*
		DDT/DDE .....	19D, 19E
		Lead .....	29C
		Mercury .....	31D
	State University of New York at Oswego.	PCBs .....	36D, 36E, 36J*
		DDT/DDE .....	19D, 19E
		Lead .....	29C
		Mercury .....	31D
	University of Illinois at Chicago .....	PCBs .....	36D, 36E, 36J*
		DDT/DDE .....	19D, 19E



TABLE 2.—GROUPS WHICH ARE ADDRESSING/HAVE ADDRESSED ATSDR'S SUBSTANCE-SPECIFIC PRIORITY DATA NEEDS (PDNs)—Continued

Program	Firm, institution, agency, or consortium	Substance	PDN ID
Environmental Protection Agency	University of Illinois at Urbana-Champaign.	Lead ..... Mercury ..... PCBs ..... DDT/DDE .....	29C 31D 36D, 36E, 36J* 19D, 19E
	University of Wisconsin-Milwaukee .....	Lead ..... Mercury ..... PCBs ..... DDT/DDE .....	29C 31D 36D, 36E, 36J* 19D, 19E
Environmental Protection Agency	Wisconsin Department of Health and Social Services—5 State Consortium.	Lead ..... Mercury ..... PCBs ..... Selenium ..... Arsenic .....	29C 31D 36A, 36D, 36E, 36J* 38D 2D
	EPA/ATSDR Test Rule .....	Cadmium ..... Chromium ..... DDT/DDE ..... Lead ..... Mercury ..... Nickel ..... PAHs ..... PCBs ..... Benzene .....	7B 13E 19D, 19E 29C 31D 34F 37F 36D, 36E, 36J* 4A, 4B, 4C
National Toxicology Program .....	Metals Testing Task Force (TASARC)	Chloroethane ..... Cyanide (hydrogen cyanide and sodium cyanide). Methylene chloride ..... Tetrachloroethylene ..... Toluene ..... Trichloroethylene ..... Arsenic ..... Beryllium ..... Chromium ..... Manganese ..... Mercury ..... Nickel ..... Selenium ..... Carbon tetrachloride .....	11A, 11B 14A, 14B 33A 40C, 40E 41C 43B, 43E 2A, 2B, 2C 6A, 6B, 6C, 6E 13A, 13B, 13C, 13D 30A, 30B, 30E 31C 34B, 34C, 34D, 34E 38A, 38B 8B
	National Institute of Environmental Health Sciences.	1,1-dichloroethene ..... Di-n-butyl phthalate ..... Disulfoton ..... Heptachlor .....	18A, 18B 21A 22A 26B

\* Not priority data needs.

**Editorial Note:** FR Doc. 05-23361 was originally published at page 71506 in the issue of Tuesday, November 29, 2005. The corrected document is republished in its entirety, due to printing errors.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

[60Day-06-0556]

#### Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic

summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-4766 or send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto:omb@cdc.gov).

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c)