Health effects study	NTIS document Number
Sympton and Disease Prevalence With Biomarkers Health Study, Cornhusker Army Ammunition Plant, Hall County, Nebraska, ATSDR/HS–96–72.	PB96–187760
Disease and Sympton Prevalence Survey, Tucson International Airport Site, Tucson, Arizona, ATSDR/HS–96–71	PB96–199484
Evaluation of Developmental Disabilities in Relation to Environmental Exposures in Groton, Massachusetts, ATSDR/HS–97–75.	PB97–137715
Adult Environmental Neurobehavioral Test Battery, ATSDR/HS–95–58	PB96–109012
Standardized Assessment of Birth Defects and Reproductive Disorders in Environmental Health Field Studies, ATSDR/HS–96–73.	PB96–199609
Pediatric Environmental Neurobehavioral Test Battery, ATSDR/HS–96–74	PB96–207352
National Exposure Registry, Trichloroethylene (TCE) Subregistry, TCE Baseline, CD–ROM Series: TCE, Volume: Baseline, No. 1.	PB95–501987

In accordance with 42 CFR 90.11, copies of these final publications have been distributed, as appropriate, to the Environmental Protection Agency; the applicable State and local government agencies; the affected local communities; and parties potentially responsible for their release, if their identity is readily available to ATSDR.

Additional final reports will be announced semiannually in the **Federal Register** as they become available.

Dated: July 24, 1997.

Georgi Jones,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR–124]

Announcement of Final Priority Data Needs for 12 Priority Hazardous Substances and Call for Voluntary Research Proposals

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

ACTION: Announcement of final priority data needs and ongoing call for Voluntary Research Proposals.

SUMMARY: This notice announces the final priority data needs for 12 priority hazardous substances (see attached Table 1) as part of the continuing development and implementation of the ATSDR Substance-Specific Applied Research Program (SSARP). The notice also serves as a continuous call for voluntary research proposals. The SSARP is authorized by the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Superfund) or CERCLA, 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 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).

Twelve substances constitute the second list of hazardous substances for which priority data needs are identified by ATSDR. In developing this list, ATSDR solicited input from the Environmental Protection Agency (EPA) and the National Institute of Environmental Health Sciences (NIEHS). The 12 substances, which are included in the ATSDR Priority List of Hazardous Substances established by ATSDR and EPA (59 FR 9486, February 28, 1994), 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
*Toxaphene.

The priority data needs for these 12 substances were initially announced by ATSDR in the **Federal Register** on April 1, 1996 (61 FR 14430). The public was invited to comment on the priority data needs during a 90-day period. ATSDR received comments from industry groups concerning substance-specific priority data needs. The agency responded to these comments and has finalized the ''Priority Data Needs'' documents for these 12 hazardous substances. Both the agency's responses and the revised ''Priority Data Needs'' documents are available for public inspection at ATSDR (see **ADDRESSES** section).

These priority data needs will be addressed by the mechanisms described in the **Implementation of Substance-Specific Applied Research Program** section of this **Federal Register** 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 in this notice by indicating their interest through submission of a research proposal to ATSDR (see **ADDRESSES** section). A Tri-Agency Superfund Applied Research Committee (TASARC) comprised of scientists from ATSDR, the National Toxicology Program (NTP), and EPA will review all proposals. The ''Priority Data Needs'' documents are available by writing to ATSDR (see **ADDRESSES** section).

DATES: ATSDR considers the voluntary research effort to be of significant importance to the continuing development of the Substance-Specific Applied Research Program, and believes this effort should be an open and continuous one. Therefore, private-sector organizations are encouraged to volunteer to conduct research to address identified data needs, beginning with the publication of this notice and until that time when ATSDR announces that research has been initiated for a specific data need.

ADDRESSES: Private-sector organizations interested in volunteering to conduct research to address identified data needs should announce their intention by writing to Dr. William Cibulas, Research Implementation Branch, Division of Toxicology, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mailstop E–29, Atlanta, Georgia 30333. Requests for the final ''Priority Data Needs'' documents and ATSDR's response to public comments should be addressed similarly.

These documents are available for public inspection at the Agency for Toxic Substances and Disease Registry, Building 4, Suite 2400, Executive Park Drive, Atlanta, Georgia (not a mailing address), from 8 a.m. until 4:30 p.m., Monday through Friday, except for legal holidays.

FOR FURTHER INFORMATION CONTACT:

Dr. William Cibulas, Chief, Research Implementation Branch, Division of Toxicology, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE., Mailstop E–29, Atlanta, Georgia 30333, telephone 404–639–6306.

SUPPLEMENTARY INFORMATION:

Background

The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (Superfund) or CERCLA (42 U.S.C. 9604 (i)), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA) (42 U.S.C. 9604(i)), requires that ATSDR: (1) Develop jointly with EPA a list of hazardous substances found at National Priorities List (NPL) sites (in order of priority), (2) prepare toxicological profiles of these substances, and (3) assure the initiation of a research program to address identified priority data needs associated with the substances.

The Substance-Specified Applied Research Program (SSARP) was initiated on October 17, 1991. At that time, a list of priority data needs for 38 priority hazardous substances 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).

Twelve substances constitute the second list of hazardous substances for which priority data needs are identified by ATSDR. The priority data needs for these 12 substances were initially announced by ATSDR in the **Federal Register** on April 1, 1996 (61 FR 14430). The exposure and toxicity priority data needs in this notice have been identified from information gaps via a ''Decision Guide'' that was published in the **Federal Register** on September 11, 1989 (54 FR 37618). The priority data needs represent essential information to improve the database to conduct public health assessments. Research to address these data needs will help determine the types or levels of exposure that may present significant risks of adverse health effects in people exposed to the subject substances.

The priority data needs identified in this notice reflect the opinion of ATSDR, in consultation with other Federal programs, of the research needed pursuant to ATSDR's authority under CERCLA. They do not represent the priority data needs for any other program.

Consistent with Section 104(i)(12) of CERCLA as amended (42 U.S.C. 9604(i)(12)), nothing in this research program shall be construed to delay or otherwise affect or impair the authority of the President, the Administrator of ATSDR, or the Administrator of EPA, to exercise any authority regarding any other provision of law, including the Toxic Substances Control Act of 1976 (TSCA) and the Federal Insecticide, Fungicide, and Rodenticide Act of 1972 (FIFRA), or the response and abatement authorities of CERCLA.

In developing this research program, ATSDR has worked with other Federal programs to determine common substance-specific data needs, as well as mechanisms to implement research that may include authorities under TSCA and FIFRA, private-sector voluntarism, or the direct use of CERCLA funds.

When deciding the type of research that should be done, ARSDR considers the recommendations of the Interagency Testing Committee (ITC) established under Section 4(e) of TSCA. Federally funded projects that collection information from 10 or more respondents and are funded by cooperative agreement are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. If the proposed project involves research on human subjects, the applicants must comply with Department of Health and Human Services' regulations (45 CFR Part 46) regarding the protection of human subjects. Assurance must be provided that the project will be subject to initial and continuing review by the appropriate institutional review committees. Overall, data generated from this research program will lend support to others involved in human health assessments involving these 12 substances (and related ones) by providing additional scientific information for the risk assessment process.

Implementation of Substance-Specified Applied Research Program

In Section 104(i)(5)(D), CERCLA 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 substances under TSCA and by registrants under 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 regulatory mechanisms (TSCA/FIFRA), private-sector voluntarism, and the direct use of CERCLA funds.

CERCLA also requires that ATSDR consider recommendations of the ITC on the types of research to be done. ATSDR actively participates on this committee; however, none of the proposed 12 substances are now on the ITC priority testing list.

The mechanisms for implementing the SSARP are discussed below. The status of the SSARP in addressing priority data needs of the first set of 38 priority hazardous substances via these mechanisms was described in a **Federal Register** notice on April 1, 1996 (61 FR 14420).

A. TSCA/FIFRA

In developing and implementing the SSARP, ATSDR and EPA established procedures to identify priority data needs of mutual interest to Federal programs. Generally, this begins before or during the finalization of the priority data needs. These data needs will be addressed through a program of toxicologic testing under TSCA or FIFRA. This part of the research will be conducted according to established TSCA/FIFRA procedures and guidelines. Generally, this testing will fulfill more than one Federal program's need.

Currently, in collaboration with EPA, the ATSDR test rule for seven organic chemicals (benzene, trichloroethylyene, tetrachloroethylene, cyanide, toluene, methylene chloride, and chloroethane) is being developed. In addition, the Metals Testing Task Force, consisting of scientists from ATSDR, EPA, and NIEHS, met last February and established a draft list of priority metals (including all of ATSDR's priority metals) for testing. A draft survey for soliciting testing needs of other government agencies was also developed. A second meeting of the Task Force to help set priorities for testing needs is scheduled for early fall.

B. Private-Sector Voluntarism

As part of the SSARP, on February 7, 1992, ATSDR announced a set of proposed procedures for conducting voluntary research (56 FR 4758). Revisions based on public comments were published on November 16, 1992 (57 FR 54160). ATSDR strongly encourages private-sector organizations to propose research to address data needs at any time until ATSDR announces that research has already been initiated for a specific data need

(e.g., via EPA test rule development). 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 research proposal.

The research proposal should be a brief statement (1–2 pages) that identifies the priority data need(s) to be addressed and the methods to be used. The TASARC will review these proposals. Based on the review committee's recommendations, ATSDR will determine which specific voluntary research projects will be pursued (and how) with the volunteer organizations. ATSDR will only enter into those voluntary research projects that lead to high quality, peer-reviewed scientific work. Additional details regarding the process for voluntary research are in the **Federal Register** notices cited in this section.

Recently, the first research study conducted under ATSDR's voluntary research program was completed. The study, conducted by the Halogenated Solvents Industry Alliance, Inc. (HSIA), addressed three priority data needs for methylene chloride using physiologicially-based parhmacokinetic (PBPK) modeling. HSIA has also proposed to conduct an immunotoxicity assessment for methylene chloride via inhalation exposure, and to obtain the oral immunotoxicity data via PBPK modeling. HSIA and ATSDR are continuing to discuss voluntary research efforts for trichloroethylene and tetrachloroethylene.

Presently, ATSDR has three memorandums of understanding with private-sector organizations: HSIA, to conduct studies on methylene chloride; the Chemical Manufacturers Association, to conduct research on vinyl chloride; and the General Electric Company (GE), to conduct studies on polychlorinated biphenyl compounds. The final report of GE's study on an assessment of the chronic toxicity and oncogenicity of Aroclor–1016, Aroclor–1242, Aroclor–1254, and Aroclor–1260 administered in diet to rats was recently reviewed by ATSDR's peer reviewers. ATSDR will accept the report pending GE's satisfactory response to the review's comments.

C. CERCLA

Those priority data needs that are not addressed by TSCA/FIFRA or initial voluntarism will be considered for funding by ATSDR through its CERCLA budget. A large part of this research program is envisioned to be unique to CERCLA, for example, research on substances not regulated by other programs or research needs specific to public health assessments. Current examples of the direct use of CERCLA funds include interagency agreements with other Federal agencies and cooperative agreements and grants with academic institutions.

Mechanisms to address these priority data may include a second call for voluntarism. Again, scientific peer review of study protocols and results would occur for all research conducted under this auspice.

Substance-Specific Priority Data Needs

The final priority data needs are identified in Table 1. Unique identification numbers (25A through 36H) are assigned to the priority data needs for this list of 12 priority hazardous substances; the initial list of 38 substances has identification numbers 1A through 24C (59 FR 11434, March 10, 1994).

As previously stated, ATSDR believes that part of this research will be most appropriately conducted using CERCLA data and resources. Toward this end, ATSDR has identified particular data needs that may be implemented by ATSDR programs. These priority data needs fall into both the exposure and toxicity data needs categories.

A major exposure priority data need for all 12 substances will be to collect, evaluate, and interpret data from contaminated environmental media around hazardous waste sites. However, a substantial amount of this information has already been collected through individual State programs and EPA's CERCLA activities. ATSDR scientists will, therefore, evaluate the extant information from these programs to better characterize the need for additional site-specific information.

ATSDR's role as a public health agency addressing environmental health is, when appropriate, to collect human data to validate substance-specific exposure and toxicity findings. ATSDR will obtain this information by conducting exposure and health effects studies, and by establishing and using substance-specific subregistries of people enrolled in the agency's National Exposure Registry who are potentially exposed to these substances. When a subregistry or a human exposure study is identified as a priority data need, the responsible ATSDR program will determine its feasibility, which depends on identifying appropriate populations and funding. These priority data needs may be reclassified following considerations of feasibility. Any reclassification will be published in the **Federal Register**.

ATSDR acknowledges that the conduct of human studies to determine possible links between exposure to hazardous substances and human health effects may be accomplished other than by ATSDR's or under other ATSDR-sponsored projects. We encourage private-sector organizations and other governmental programs to use ATSDR's priority data needs to plan their research activities, including identifying appropriate populations and conducting studies to answer specific human health questions.

The results of the research conducted via this ATSDR Substance-Specific Applied Research Program will be used for public health assessment purposes and to reassess ATSDR's substance-specific priority data needs. ATSDR intends to reevaluate the priority data needs for hazardous substances every three years.

Dated: July 24, 1997.

Georgi Jones,

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

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Table 1
Substance-Specific Priority Data Needs (PDNs) for 12 Priority Hazardous Substances

Substance		PDN ID	Priority Data Need
Hexachlorobutadiene	Exposure	25A	Evaluate existing data on concentrations of hexachlorobutadiene in contaminated environmental media at hazardous waste sites
		25B	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers
		25C	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
		25D	Bioavailability studies in soil and plants
		25E	Potential candidate for subregistry of exposed persons
	Toxicity	25F	Dose-response data in animals for acute-duration exposure via the oral route
Chlordane	Exposure	26A	Evaluate existing data on concentrations of chlordane in contaminated environmental media at hazardous waste sites
		26B	Exposure levels in humans living near hazardous waste sites and other populations potentially exposed to chlordane
		26C	Bioavailability studies following ingestion of contaminated media
		26D	Potential candidate for subregistry of exposed persons
	Toxicity	26E	Oral multigenerational studies to evaluate reproductive toxicity

Hexachlorocyclohexane α Hexachlorocyclohexane β Hexachlorocyclohexane δ Hexachlorocyclohexane γ	Exposure	27A	Evaluate existing data on concentrations of HCH in contaminated environmental media at hazardous waste sites
		27B	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers
		27C	Potential candidate for subregistry of exposed persons
	Toxicity	27D	Dose-response data for chronic-duration oral exposure
		27E	Mechanistic studies on the neurotoxicity, hepatotoxicity, reproductive toxicity, and immunotoxicity of hexachlorocyclohexane
Heptachlor Heptachlor epoxide	Exposure	28A	Evaluate existing data on concentrations of heptachlor/heptachlor epoxide in contaminated environmental media at hazardous waste sites
		28B	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers
		28C	Bioavailability from contaminated air, water, and soil and bioaccumulation potential
		28D	Potential candidate for subregistry of exposed persons
	Toxicity	28E	Dose-response animal data for acute- and intermediate-duration oral exposures, including immunopathology
		28F	Multigenerational reproductive toxicity studies via the oral route of exposure
		28G	Two-species developmental toxicity studies via the oral route of exposure

Di-n-butyl phthalate	Exposure	29A	Evaluate existing data on the concentration of di-n-butyl phthalate in contaminated environmental media at hazardous waste sites
		29B	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers
		29C	Environmental fate of di-n-butyl phthalate in environmental media
		29D	Bioavailability in contaminated environmental media near hazardous waste sites
		29E	Potential candidate for subregistry of exposed persons
	Toxicity	29F	Dose-response data in animals for acute-duration exposure via the oral route
		29G	Dose-response data in animals for chronic-duration exposure via the oral route
		29H	Carcinogenicity studies via oral exposure
		29I	In vivo genotoxicity studies
		29J	Immunotoxicology studies via oral exposure
		29K	Neurotoxicity studies via oral exposure
Toxaphene	Exposure	30A	Exposure levels in humans living in areas near hazardous waste sites with toxaphene and in those individuals with the potential to ingest it
		30B	Evaluate existing data on concentrations of toxaphene in contaminated environmental media, particularly at hazardous waste sites
		30C	Potential candidate for subregistry of exposed persons
	Toxicity	30D	Identify the long-term health consequences of exposure to environmental toxaphene via oral exposure
		30E	Conduct additional chronic animal immunotoxicity studies via the oral route of exposure
		30F	Conduct additional chronic animal neurotoxicity studies via the oral route of exposure

Endosulfan Endosulfan α Endosulfan β Endosulfan sulfate	Exposure	31A	Evaluate existing data on concentrations of endosulfan in the environment, particularly at hazardous waste sites
		31B	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers
		31C	Data on the bioavailability of endosulfan from soil
		31D	Potential candidate for subregistry of exposed persons
	Toxicity	31E	Acute-duration oral exposure studies
		31F	Sensitive end point neurologic data on the effects of oral endosulfan exposure
Disulfoton	Exposure	32A	Evaluate existing data on concentrations of disulfoton in contaminated environmental media at hazardous waste sites
		32B	Exposure levels of disulfoton in tissues/fluids for populations living near hazardous waste sites and other populations, such as exposed workers
		32C	Potential candidate for a subregistry of exposed persons
	Toxicity	32D	Immunotoxicology testing battery following oral exposure

Endrin Endrin aldehyde	Exposure	33A	Evaluate existing data on concentration of endrin and its degradation products in contaminated environmental media at hazardous waste sites
		33B	Exposure levels for endrin and its degradation products in humans living near hazardous waste sites
		33C	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
		33D	Potential candidate for subregistry of exposed persons
	Toxicity	33E	Dose-response animal data for acute oral exposure to endrin
		33F	Multigenerational reproductive toxicity studies via oral exposure to endrin
		33G	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
Manganese	Exposure	34A	Evaluate existing data on concentrations of manganese in contaminated environmental media at hazardous waste sites
		34B	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers
		34C	Potential candidate for subregistry of exposed persons
		34D	Relative bioavailability of different manganese compounds and bioavailability of manganese from soil
	Toxicity	34E	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)
		34F	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
		34G	Epidemiological studies on the health effects of manganese (special emphasis end points include neurologic, reproductive, developmental, immunologic, and cancer)

Methoxychlor	Exposure	35A	Evaluate existing data on concentrations of methoxychlor in contaminated media, particularly at hazardous waste sites
		35B	Exposure levels of methoxychlor and primary metabolites in humans living near hazardous waste sites and in those individuals with the potential to ingest it
		35C	Evaluate the fate, transport, and levels of the degradation products of methoxychlor in soil
		35D	Potential candidate for subregistry of exposed persons
	Toxicity	35E	Evaluate neurologic effects after long-term, low-level oral exposure
1,2-dibromo-3-chloropropane	Exposure	36A	Evaluate existing data on concentrations of 1,2-dibromo-3-chloropropane in contaminated environmental media at hazardous waste sites
		36B	Exposure levels in humans living near hazardous waste sites and other populations, such as exposed workers
		36C	Potential candidate for subregistry of exposed persons
	Toxicity	36D	Dose-response data in animals for acute-duration exposure via the oral route (including reproductive organ histopathology)
		36E	Dose-response data in animals for chronic-duration exposure via the oral route (including reproductive organ histopathology)
		36F	Two-species developmental toxicity study via oral exposure
		36G	Immunotoxicology testing battery via oral exposure
		36H	Neurotoxicology testing battery via oral exposure

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