



Voluntary Research Program

Division of Toxicology

January 2004

The Agency for Toxic Substances and Disease Registry (ATSDR) developed the Voluntary Research Program (VRP) as a mechanism to fill research needs for priority hazardous substances identified under the provisions of the Substance-Specific Applied Research Program.

VRP has saved the agency approximately \$10 million in research costs because the industry groups conduct studies at no expense to the agency. At least 16 research needs are currently being addressed.

Program Objectives

- Fill critical research needs for toxic substances found at hazardous waste sites and in the environment.
- Encourage private sector organizations to volunteer to conduct studies to fill specific research needs at no expense to the agency.
- Enter only into voluntary research agreements that lead to high-quality scientific work with reliable data that can be shared with the public.

Program Activities

- Make ATSDR research needs available to the scientific community and the public and provide ATSDR procedures for conducting voluntary research.
- Develop memoranda of understanding (MOU) with industry groups that volunteer to conduct studies to fill ATSDR's research needs.
- Provide internal and external peer review for all study protocols and final reports.
- Accept data from voluntary studies on the bases of the reviewers' recommendations and the satisfactory response of the industry groups to all reviewers' comments.
- Use accepted data to update ATSDR's toxicological profiles and to improve the database which is used to conduct public health assessments.

- Make data available to the scientific community and the public.

Volunteer Organizations

To date, ATSDR has established MOUs with four private sector organizations to conduct studies to fill research needs the agency has identified for hazardous substances:

American Chemistry Council (ACC)

“Vinyl chloride combined inhalation two-generation reproduction and developmental toxicity study in CD rats.” Accepted by ATSDR: Nov. 22, 2000

Electric Power Research Institute, Inc. (EPRI)

“Verification of techniques for assessing the effects of neurotoxicants on neurodevelopment in children.” Estimated study completion date: Dec, 2003

General Electric Company (GE)

(1) “An assessment of the chronic toxicity and oncogenicity of Aroclors 1016, 1242, 1254, and 1260 administered in diet to rats.” Accepted by ATSDR: Oct. 2, 1997

(2) “Metabolite detection as a tool for the determination of naturally occurring aerobic PCB biodegradation.” Accepted by ATSDR: July 9, 1999

Halogenated Solvents Industry Alliance, Inc. (HSIA)

(1) “Addressing priority data needs for methylene chloride with physiologically based pharmacokinetic modeling.” Accepted by ATSDR: Feb. 28, 1997

(2a) “Methylene chloride: 28-day inhalation toxicity study in the rat to assess potential immunotoxicity.” Accepted by ATSDR: Nov. 14, 2000

(2b) “Estimating the immunotoxic potential of orally administered dichloromethane from immunotoxicity studies conducted by the inhalation route.” Accepted by ATSDR: Aug. 14, 2002

(3) “Trichloroethylene: Inhalation developmental toxicity study in CD rats.” Accepted by ATSDR: Sept. 28, 2001

(4) “Perchloroethylene: Study of effects on embryo-fetal development in CD rats by inhalation.” Estimated study completion date: 2004

Key Research Findings

- Lower chlorinated Aroclors (commercial polychlorinated biphenyl [PCB] mixtures) such as Aroclor 1016 and Aroclor 1242, which were previously thought to be less toxic, are capable of producing tumors in rats.
- Data from the PCB study were used by the U.S. Environmental Protection Agency (EPA) to revise its cancer slope factor for PCBs.
- Sediment samples collected from PCB-contaminated sites in the upper Hudson River were found to contain hydroxylated metabolites, which are strong indicators of naturally occurring aerobic PCB biodegradation.
- Adverse health effects on the central nervous system, liver, and the development of newborns may occur if people drink water containing large amounts of methylene chloride (approximately 600 – 6,000 mg of methylene chloride per liter of water).
- An acute oral minimal risk level (ATSDR health guidance value) of 0.2 mg/kg/day for methylene chloride was developed.
- Inhalation exposure to approximately 5,000 ppm of methylene chloride did not cause immunotoxicity in rats, based on IgM antibody response to sheep red blood cells and assessment of lymphoid organ weights, histopathology, and relevant hematological parameters. Also, physiologically based pharmacokinetic modeling, based on the above results, predicts that no adverse health effects are expected to occur to the human immune system from drinking water containing large amounts of methylene chloride over a short time period.

- Inhalation exposure to trichloroethylene (TCE) did not cause developmental toxicity in rats at TCE concentrations up to 600 ppm.
- Inhalation exposure to vinyl chloride did not cause reproductive or developmental toxicity in rats at vinyl chloride concentrations up to 1,100 ppm.

Program Impact

- Demonstrates the effectiveness of private-sector partnerships.
- Addresses at least 16 research needs.
- Saves ATSDR approximately \$10 million in research costs.

Future Directions

- Broaden efforts to include a wider range of potential private sector partners.
- Coordinate research programs with other federal organizations. For example, ATSDR and EPA officials responsible for carrying out the EPA Voluntary Children’s Chemical Evaluation Program are working with HSIA to fill key research needs for tetrachloroethylene and trichloroethylene.

For more information about the Voluntary Research Program, contact the Agency for Toxic Substances and Disease Registry, Division of Toxicology, 1600 Clifton Road NE, Mailstop F-29, Atlanta, GA 30333. Phone: 1-888-422-8737 (toll free). The ATSDR Web site is available at <http://www.atsdr.cdc.gov>.

Selected References

- Agency for Toxic Substances and Disease Registry. Revised procedures for conducting voluntary research. 1992. Fed Regist 57: 54160-54163.
- Mayes BA, McConnell EE, Neal BH, et al. 1998. Comparative carcinogenicity in Sprague-Dawley rats of the polychlorinated biphenyl mixtures aroclors 1016, 1242, 1254, and 1260. Toxicological Sciences 41: 62-76.
- Stevens Y-W, Cibulas W, De Rosa CT. 1998. Voluntary research program of the Agency for Toxic Substances and Disease Registry. Environ Law Pract 6: 28-31.
- Note: All final reports of voluntary research, conducted by industry groups and accepted by ATSDR, are available by contacting the Division of Toxicology, ATSDR.