

*Response:* ATSDR has developed a process for assigning priority to data needs identified in the agency's toxicological profiles for hazardous substances. Specifically, the process for prioritizing the data needs is based on a logical scientific approach as described in ATSDR's Decision Guide (54 FR 37618, September 11, 1989). The identified priority data needs (PDNs) are then subjected to public and peer review. Currently, ATSDR considers these PDNs to be the most critical research needs for these hazardous substances. However, the agency will continue to evaluate new data for these substances obtained through additional testings, e.g., industry groups' participation in other federal agencies' programs. Specifically, ATSDR is working closely with EPA on these activities where we have identified overlapping research priorities. Therefore, the status of these PDNs may change in the future. In this current **Federal Register** Notice announcing the final list of PDNs, ATSDR states that these PDNs remain on the agency's list but that they may potentially be filled by individual industry groups working under specific EPA programs (see Table 1).

In summary, as a result of the agency's evaluation of all the public comments received for the 10 hazardous substances, two priority data needs were changed. Specifically, *in vivo* endocrine disruptor studies via oral exposure and multigeneration reproduction study involving multiple matings and examining male and female fertility via oral exposure were initially identified as priority data needs for pentachlorophenol. During the public comment period, ATSDR received from the Pentachlorophenol Task Force a recently completed two-generation reproduction study that was subsequently published in a peer-reviewed journal. ATSDR accepted the data and no longer assigned priority to these research needs. No changes were made to the priority data needs for the other nine substances as a result of the public comments.

#### **Implementation of Substance-Specific Applied Research Program**

Regarding the implementation of the SSARP, 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 the Toxic Substances Control Act of 1976 (TSCA) and by registrants under the Federal

Insecticide, Fungicide, and Rodenticide Act of 1972 (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 through the direct use of CERCLA funds. CERCLA also requires that ATSDR consider recommendations of the Interagency Testing Committee (ITC), established under Section 4(e) of TSCA, on the types of research to be done. ATSDR actively participates on this committee; however, none of the proposed 10 substances are now on the ITC priority testing list.

The priority data needs identified in this Notice reflect the opinion of the agency, 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, ATSDR considers the recommendations of the Interagency Testing Committee established under section 4(e) of TSCA. Federally funded projects that collect information from 10 or more respondents and that are funded by cooperative agreements 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 conducting human health assessments involving these 10 substances by providing additional scientific information for the risk assessment process.

#### **Substance-Specific Priority Data Needs**

The final priority data needs are identified in Table 1. Unique identification numbers (37A through 46G) are assigned to the priority data needs for this list of 10 priority hazardous substances; the priority data needs for the first 50 substances were assigned identification numbers 1A through 36E (67 FR 4836). Parts of the proposed research are unique to CERCLA and may be most appropriately addressed by ATSDR programs as follows.

ATSDR's responsibility as a public health agency addressing environmental health issues is, when appropriate, to collect human data to validate substance-specific exposure and toxicity assumptions. 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.

In addition, the need to collect, evaluate, and interpret environmental data from contaminated media around hazardous waste sites remains a priority data need for all 10 priority hazardous substances ATSDR has identified for this third set.

However, some of this information has already been collected through individual state programs and the EPA's CERCLA activities; therefore, ATSDR will evaluate the extant information from these programs to better characterize the need for additional site-specific information.

ATSDR acknowledges that the conduct of human studies to determine possible links between exposure to hazardous substances and human health effects may be accomplished through mechanisms other than agency programs. We encourage private-sector organizations and other governmental programs to use ATSDR's priority data needs to plan their research activities, including identifying appropriate