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The U.S. Agency for Toxic Substances and Disease Registry (ATSDR): Statutory Authorities and Responsibilities

The U.S. Agency for Toxic Substances and Disease Registry (ATSDR) is a public health agency primarily responsible for summarizing toxicity information on chemicals most commonly present at contaminated sites. ATSDR also assesses whether exposures to chemicals present at specific sites, especially those sites that warrant federal attention, may pose risks to human health. ATSDR also supports other health studies involving chemical exposures and plays a response role in emergencies involving chemical releases. Although ATSDR's role is informational and not regulatory, the agency's findings and recommendations may inform decisions made by federal, state, and local regulatory agencies. As such, the process by which ATSDR evaluates information to make findings and recommendations in a timely manner has been of interest to Congress, regulatory authorities, and stakeholders.

Authorities for ATSDR are rooted in the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA; 42 U.S.C. §9601 et seq.), as amended, and Section 3019 of the Solid Waste Disposal Act (SWDA; 42 U.S.C. §6939a). CERCLA is the principal statute that governs the federal role for the identification, evaluation, and cleanup of contaminated sites. For information on other aspects of CERCLA, see CRS Report R41039, *Comprehensive Environmental Response, Compensation, and Liability Act: A Summary of Superfund Cleanup Authorities and Related Provisions of the Act*. SWDA Section 3019 focuses on the assessment of human health risks at landfills and surface impoundments.

ATSDR is an agency of the Public Health Service (PHS) in the U.S. Department of Health and Human Services (HHS). Pursuant to 42 U.S.C. §242c(a), the director of the Centers for Disease Control and Prevention (CDC), a presidentially appointed and Senate-confirmed position, serves as the ATSDR administrator. CDC performs many of the administrative functions for ATSDR. For FY2024, Congress appropriated \$81.6 million to ATSDR to carry out its authorities under CERCLA and SWDA Section 3019. In March 2025, HHS announced plans to reorganize the department, including the establishment of a new Administration for a Healthy America, which would subsume ATSDR.

Toxicological Profiles

CERCLA Section 104(i)(3) (42 U.S.C. §9604(i)(3)) directs ATSDR to prepare toxicological profiles for hazardous substances. "Hazardous substances" refers to a list of chemicals that the U.S. Environmental Protection Agency (EPA) has designated in regulation based on a process and criteria outlined by CERCLA. For a list of hazardous substances, see 40 C.F.R. §302.4. CERCLA Section

104(i)(18) (42 U.S.C. §9604(i)(18)) authorizes ATSDR to treat a pollutant or contaminant as a hazardous substance at the agency's discretion, so ATSDR may prepare a toxicological profile for a pollutant or contaminant.

A toxicological profile is a summary of peer-reviewed scientific studies and data on the toxicity of a specific chemical or category of chemicals. Information presented in toxicological profiles may be used to inform regulatory decisions by other federal or state agencies within their respective jurisdictions. ATSDR has developed guidance for (1) the nomination and selection of chemicals that warrant toxicological profiles and (2) the process to evaluate scientific and technical information to inform the development of toxicological profiles. The toxicological profile process includes the issuance of draft toxicological profiles and the opportunity for public comment.

ATSDR maintains over 180 toxicological profiles, which include various guidance values for exposure levels considered to present minimal risk. Other federal agencies, state and local governments, and organizations may use these guidance values to inform various actions. Since FY1989, Congress has limited ATSDR appropriations to the preparation of not more than 40 toxicological profiles annually. ATSDR may review existing toxicological profiles to determine if updates are warranted.

Public Health Assessments and Health Consultations

CERCLA Section 104(i)(6) (42 U.S.C. §9604(i)(6)) directs ATSDR to conduct a public health assessment (PHA) at each site—as designated by EPA—on the CERCLA National Priorities List (NPL). CERCLA also authorizes ATSDR to conduct PHAs at non-NPL sites in response to public petitions indicating that a chemical release is the probable source for exposure to a hazardous substance. ATSDR PHAs differ from site investigations and risk assessments that EPA and other entities may perform at an NPL site to inform cleanup actions under CERCLA. In general, PHAs evaluate the extent to which the presence of hazardous substances at a site may result in exposures that are harmful to individuals who may come in contact with such substances.

CERCLA Section 104(i)(4) (42 U.S.C. §9604(i)(4)) also authorizes ATSDR to conduct more limited health consultations in response to public petitions. Health consultations may focus on a specific contaminant or a specific pathway of exposure at a site. Resources for ATSDR to conduct PHAs and health consultations are subject to the availability of appropriations by Congress.

PHAs and health consultations generally do not involve the original study and testing of potentially exposed populations, but may incorporate data from such studies and tests if performed by other entities, such as state or local public health agencies. Like the development of toxicological profiles, the development of PHAs and health consultations involves the opportunity for public comment. ATSDR regulations for developing PHAs and health consultations are codified at 42 C.F.R. Part 90. More information is available in ATSDR's *Public Health Assessment Guidance Manual*.

ATSDR may conduct an exposure investigation if the agency determines that available health effects information is insufficient to conduct a PHA or health consultation. The objective of an exposure investigation is to determine whether individuals may have been exposed to hazardous substances, pollutants, or contaminants from a release involving chemicals. Exposure investigations typically involve evaluating data from environmental sampling or biomarker testing (e.g., lead concentrations in blood or urine).

Under CERCLA Section 107(a) (42 U.S.C. §9607(a)), costs of conducting PHAs, among other response actions, at NPL sites are recoverable from potentially responsible parties (i.e., those determined to be liable for paying response costs). Annual appropriations to ATSDR fund PHAs and health consultations at other sites (i.e., non-NPL sites). A site may be eligible for listing on the NPL if ATSDR issues a public health advisory and certain other criteria are satisfied pursuant to 40 C.F.R. §300.425(c)(3).

State Cooperative Agreements

ATSDR may enter into cooperative agreements with states for their respective health departments to carry out the preparation of PHAs, health consultations, and other activities for specific sites within their respective jurisdictions. These cooperative agreements generally provide federal funding to support these state-led activities.

Additional Health Studies

Based on the findings of a PHA, ATSDR may take further action to study health effects among a potentially exposed population at a site. Such actions include

- conducting an epidemiological study under CERCLA Section 104(i)(7) (42 U.S.C. §9604(i)(7)), or
- establishing a registry of exposed persons under CERCLA Section 104(i)(8) (42 U.S.C. §9604(i)(8)) if the agency finds a “potential significant risk to human health,” taking into account the “circumstances bearing on the usefulness of such a registry, including the seriousness or unique character of identified diseases or the likelihood of population migration from the affected area.”

If ATSDR were to find a “significant increased risk of adverse health effects in humans from exposure” at a site based on the results of a PHA, an epidemiological study, or a registry of potentially exposed persons, CERCLA Section 104(i)(9) (42 U.S.C. §9604(i)(9)) authorizes the agency to

conduct a health surveillance program that may involve periodic medical testing and referrals for medical treatment among the exposed population. Historically, ATSDR has rendered such findings in relatively few instances among all of the sites that it has examined across the United States. ATSDR epidemiological studies, exposure registries, and health surveillance programs therefore have been less common than ATSDR PHAs and health consultations. ATSDR authority is limited to information gathering and dissemination and does not extend to relocating individuals or closing a facility.

Directed Studies

Several laws and explanatory statements that accompany appropriations acts have directed ATSDR to conduct specific studies related to studies authorized under CERCLA. These directed studies generally focus on specific geographic areas or chemicals. For example, Section 316 of the National Defense Authorization Act for Fiscal Year 2018 (P.L. 115-91), as amended, authorizes CDC and ATSDR to conduct a joint study in consultation with the Department of Defense on the “human health implications” of potential exposure to per- and polyfluoroalkyl substances (PFAS) in different sources of water. This study is ongoing. Additional directives over the past few years have focused on continuing support for the Navajo Nation birth cohort study and Pediatric Environmental Health Specialty Units.

Role in Federal Response to Chemical Spills

The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) establishes the procedures for the federal response to oil and chemical spills. The NCP creates responsibilities for agencies to support federal response efforts by assessing threats to public health resulting from an incident. Within PHS, ATSDR takes the lead in providing support for chemical incidents, and CDC takes the lead in providing support for discharges of oil. Both ATSDR and CDC have 24-hour emergency response capabilities to provide scientific and technical assistance on human health threat assessment and analysis, and exposure prevention and mitigation, to federal, state, and local response agencies. For more detailed requirements, see 40 C.F.R. §300.175(b)(8)(i).

In addition, CERCLA Section 104(i)(1)(D) (42 U.S.C. §9604(i)(1)(D)) authorizes ATSDR to provide medical care and testing to individuals along with epidemiological studies and other assistance in the event of a public health emergency caused by, or believed to be caused by, exposure to toxic substances. ATSDR has assisted state and local partners in response to various emergencies. The resources of the agency to engage in these efforts are subject to appropriations by Congress. For more information on the federal framework for responding to oil and chemical spills, see CRS Report R43251, *Oil and Chemical Spills: Federal Emergency Response Framework*.

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