

## **THE ROLE OF THE AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY UNDER THE SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT OF 1986**

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### **Summary**

The Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6901 *et seq.*, as amended, and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. § 9601 *et seq.*, both parallel and potentially conflict with each other in several important respects. These similarities and differences can affect the hazardous waste enforcement program of the United States. This article discusses how EPA and the Justice Department must account for the overlaps and differences among RCRA and CERCLA in enforcing these acts, in order to give clear and consistent signals to the regulated community and thereby achieve an efficient and effective enforcement program.

To place the discussion in context, the article briefly describes the history of each statute, focusing on the initially quite different purposes and contrasting approaches of the two laws. Next, the Hazardous and Solid Waste Amendments of 1984 and the Superfund Amendments and Reauthorization Act of 1986 are discussed, particularly with regard to the ways in which several key changes are causing the missions of the two statutes to converge.

The body of the discussion sets forth several explicit statutory overlaps between RCRA and CERCLA that can affect the negotiation and litigation of federal hazardous waste cases. The relationship between cleanup standards and requirements under RCRA and applicable or relevant and appropriate cleanup standards under CERCLA is one example of such an overlap. In addition, the article addresses several basic policy determinations that may affect enforcement, such as the RCRA/CERCLA listing policy and the procedural and substantive requirements, not yet established, for corrective action under RCRA.

Finally, the article points out the need for increased coordination and cooperation not only between the federal government and the states, but between the program officials and their EPA and DOJ counsel. The existing, but limited, delegations of RCRA authority to the states will require the federal government and the states to work together with some degree of harmony; the increasing importance of scientific and technical issues under RCRA and CERCLA will lead federal enforcers both to influence and to seek program guidance at all stages of federal activity.

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## Introduction

In 1980, U.S. Congress passed the Comprehensive Environmental Response, Compensation, and Liability Act ("CERCLA" or "Superfund"), 42 U.S.C. 9601 *et seq.*, and the Federal government set about the task of cleaning up the nation's hazardous waste sites. In addition to the more familiar aspects of the Superfund program, CERCLA called for the creation of a new agency, the Agency for Toxic Substances and Disease Registry ("ATSDR"). ATSDR was assigned to work in cooperation with EPA and various Federal health agencies to collect information on the health effects of exposure to toxic substances.

ATSDR's responsibilities were expanded by the Superfund Amendments and Reauthorization Act of 1986 ("SARA"), P.L. 99-499. SARA gives ATSDR the task of assessing the health risks posed by particular hazardous substances and waste sites.

This article can serve as the beginning of a process to educate the interested public concerning the responsibilities and the potentially very important role to be played by ATSDR. ATSDR's implementation of the new SARA programs will surely be the subject of debate and litigation, and the health effects data developed by ATSDR and will be perceived to be of relevance to post-cleanup tort litigation. But more importantly, the ATSDR effort, with proper public support and input, should result in better informed deliberations over hazardous waste issues. It may also establish that an effective and prompt effort to clean up contaminated sites can prevent contamination from creating actual health problems. In all events, the ATSDR role will be a key element in the administrative records being developed under SARA.

### 1. The evolution of ATSDR

Prior to the enactment of SARA, CERCLA sections 104(a)(1) and (b) gave the President broad discretion to conduct health studies and investigations in connection with hazardous waste sites. The President delegated this authority to EPA and various other agencies. In addition, CERCLA section 104(i) (now § 104(i)(1)) provided for the establishment of ATSDR and gave the new agency general authority to perform toxicological studies, compile toxicological information and evaluate the health effects of hazardous waste sites. After an initial delay, ATSDR was established as an independent agency within the Public Health Service, and it began to perform these functions on a limited basis.

In the course of Superfund reauthorization, the Administration proposed amendments designed among other things to clarify that the main purpose of CERCLA's health authorities was to support EPA response actions through health assessments and technical assistance relating to the health effects of exposure to hazardous substances. H.R. 1342, 99th Cong., 1st Sess., 131 Cong.

Rec. H944 (daily ed. Feb. 28, 1985); S. 494, 99th Cong., 1st Sess., 131 Cong. Rec. S1823 (daily ed. Feb. 22, 1985). In addition, the Administration sought to codify ATSDR's ability to develop and compile information on the health effects of hazardous substances and to make public health recommendations. *Id.* The congressional response was SARA. SARA expands ATSDR's responsibilities beyond the scope of prior law and the Administration proposal by establishing a detailed schedule of mandatory duties and earmarking funds to support the agency's newly mandated activities. In most cases, ATSDR or the President already had the authority to undertake the activities set out in SARA; the key effect of the amendment is to specify the scope of ATSDR's activities and mandate performance according to a rigorous schedule.

## 2. ATSDR's responsibilities under SARA

ATSDR's principal responsibilities under SARA fall into two categories: the collection and evaluation of information on the health effects of individual hazardous substances, and the assessment of the health risks posed by individual hazardous waste sites.<sup>2</sup> ATSDR's responsibilities with respect to substances are organized around the preparation of "toxicological profiles" of the hazardous substances commonly found at Superfund sites that pose the greatest potential health risk. These profiles are to (i) summarize the toxicological information available on the substances; (ii) determine whether adequate information is available to determine what levels of exposure present a significant risk to human health; and (iii) identify, where appropriate, what toxicological testing is needed to determine what exposure levels may present a significant health risk. SARA establishes priority factors and a schedule for ATSDR, together with EPA, to compile lists of the substances to be profiled and to prepare and update the profiles. § 104(i)(2)-(3). If ATSDR determines that adequate information on the health effects of an identified substance is not available, it must take steps to assure the development of such information. § 104(i)(5). ATSDR is further charged with promulgating regulations for the recovery of the costs of any required research from the manufacturers and processors of the hazardous substances in question. § 104(i)(5)(D). These regulations are to be modeled after the provisions for recovery of testing costs found in the Toxic Substances Control Act and the Federal Insecticide, Fungicide, and Rodenticide Act, and the provisions for the recovery of cleanup costs found in CERCLA.

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<sup>2</sup>The main SARA section dealing with ATSDR is SARA § 110, which amends CERCLA § 104(i) by adding new paragraphs (i)(2) through (i)(18). In addition, SARA §§ 107(b), 111(h), and 111(d)(1) contain provisions relating to funding for ATSDR activities, and § 118(f) directs ATSDR to undertake a study of lead poisoning in children.

For convenience, all citations herein are to CERCLA as amended by SARA unless otherwise noted.

ATSDR's second and potentially even more controversial task is the collection and evaluation of information on the potential risk to human health posed by individual hazardous waste sites. SARA requires ATSDR to perform such a "health assessment" for each hazardous waste site on the National Priorities List. § 104(i)(6)(A),(F). As with toxicological profiles, the statute includes priority factors and a detailed schedule for the completion of the health assessments. § 104(i)(6)(C),(A) ATSDR must provide EPA and the affected states with the results of the health assessment, and must use the health assessment to assist in determining whether additional studies or health-protection measures are required. § 104(i)(6)(G) Additional studies may include pilot or full scale epidemiological studies, § 104(i)(7), registries of persons exposed to the hazardous substance, § 104(i)(8), and periodic medical testing and treatment referrals for the exposed population, § 104(i)(9). All studies other than health assessments must undergo "peer review" by panels of disinterested scientific experts. § 104(i)(13)

In addition to the mandatory health assessments of sites on the National Priorities List, ATSDR may also perform health assessments of other sites where individuals have been exposed to hazardous substances. § 104(i)(6)(B) Individuals and licensed physicians may petition ATSDR to perform health assessments of particular sites, and if ATSDR does not initiate an assessment, it must explain in writing why a health assessment is not appropriate. *Id.* Most importantly, if a health assessment or other ATSDR study indicates that exposure to hazardous substances from the site presents a "significant risk to human health"<sup>3a</sup> the President is required to "take such steps as may be necessary to reduce such exposure and eliminate or substantially mitigate the significant risk to human health".<sup>3b</sup> § 104(i)(11) These steps may include, but are not limited to, relocating the affected persons or providing them with alternative water supplies. *Id.* Finally, SARA requires the President to provide adequate personnel – at least 100 full-time employees – for ATSDR, and authorizes funding for ATSDR at a level of at least \$50 million per year. § 104(i)(16), §

<sup>3a</sup>The precise formulation of the finding that is necessary to trigger various duties under the statute varies from section to section. Compare section 104(i)(11) (mitigation requirements arise when a health assessment "contains a finding that the exposure concerned presents a *significant risk to human health*") with section 104(i)(9) (requirement that ATSDR conduct a health surveillance program arises when "the Administrator ... [determines] that there is a *significant increased risk of adverse health effects in humans*"); section 104(i)(8) (requirement for the Administrator to consider establishment of a registry of exposed persons is triggered when "the results of a health assessment indicate a *potential significant risk to human health*"); section 104(i)(6)(H) (requirement that the Administrator refer the site to EPA for possible inclusion on the National Priority List is triggered "if the health assessment indicates that the release ... *may pose a serious threat to human health or the environment*"). (Emphasis added.)

<sup>3b</sup>The President has delegated this mitigation authority to EPA, ATSDR, and various other Executive departments and agencies. § 2(k), Executive Order 12580 (Jan. 23, 1987).

*111(m)* Funding for ATSDR and its various programs is to come from the Superfund. § 111(c)(4)

The costs of health assessments and other health effects studies may be recovered from responsible parties as response costs. § 107(a)(4)(D).

### **3. Implementing the ATSDR programs – emerging issues and the potential for litigation**

As ATSDR implements its new responsibilities under SARA, numerous questions about the design and execution of ATSDR's programs will emerge. Resolution of these questions will involve specific program decisions, the promulgation of regulations and guidelines, and, inevitably, lawsuits by industry and environmental groups and affected individuals.

Originally, CERCLA did not provide for citizens' suits. SARA added a new section 310 to CERCLA which expressly provides for suits by "any person" against any person (including a government agency) alleged to be in violation of "any standard, regulation, condition, requirement, or order" effective under the act. § 310(a)(1). Furthermore, section 310 expressly provides for suits

against the President or any other officer of the United States (including the Administrator of the Environmental Protection Agency and the Administrator of the ATSDR) where there is alleged a failure of the President or of such other officer to perform any act or duty under this Act ... which is not discretionary with the President or such other officer.

§ 310(a)(2) (emphasis added).

#### *3.1 Deadline suits*

The first type of suit that ATSDR is likely to face is litigation over missed deadlines. The process which SARA sets out for the preparation of the toxicological profiles and health assessments includes numerous statutorily mandated deadlines. One such deadline – which ATSDR successfully met – was for ATSDR and EPA to publish by April 17, 1987, an initial list of 100 hazardous substances commonly found at Superfund sites. § 104(i)(2)(A). *Vide* 52 Fed. Reg. 12866. ATSDR and EPA are required to revise this list by adding at least 100 more substances by October 17, 1988, and at least 25 more substances in each subsequent year. § 104(i)(2)(B). ATSDR is further required to prepare a toxicological profile for each substance on the list, at a rate of at least 25 substances per year. § 104(i)(3). The first 25 profiles were due October 17, 1987; profiles of all 100 substances on the April 17, 1987 initial list must be completed by October 1990. *Id.*

In addition, by December 10, 1988, ATSDR must complete health assessments for all sites on or proposed for inclusion on the National Priorities List as of October 17, 1986 – a total of 888 sites. § 104(i)(6)(A). Health assessments for sites proposed for the National Priorities List after October 17, 1986 must be completed within one year of the data they are proposed. *Id.* A number of 64 of such sites were proposed in January, 1987, and EPA was expected to

propose more sites last fall. Thus, ATSDR will have to complete over 950 health assessments in the next 18 months if it is to meet the SARA deadlines.

These deadlines reflect the strong congressional desire for quick action in dealing with hazardous waste problems. ATSDR has not yet indicated whether it expects to meet the deadlines, but as a practical matter they may be impossible to meet. Failure to meet them will raise the potential for citizen's suits against the Administrator of ATSDR for failure to perform a nondiscretionary duty. Moreover, since health assessments and toxicological profiles may have significant impact in both CERCLA and private toxic tort litigation, parties to such litigation may be sufficiently motivated to sue ATSDR over missed deadlines. The government in its defense of these cases will be very concerned about ensuring that the recent proliferation of exacting deadlines in environmental legislation, coupled with citizens suit provisions, not transfer to the courts undue prescriptive authority over the source of regulatory programs.

### *3.2 Challenges to regulations and the health assessment program*

SARA requires EPA to promulgate regulations governing recovery of the costs of testing hazardous substances for which it determines there is inadequate toxicological data. § 104(i)(5). In addition, ATSDR may elect to promulgate regulations governing how it will carry out its health assessment responsibilities.<sup>4</sup> These regulations may in turn generate legal challenges by industry and environmental groups interested in attempting to shape the parameters of the ATSDR programs.

Because of its complexity and potentially significant impact on the Superfund cleanup process, the health assessment program is a particularly fertile source of questions which could lead to litigation. For instance: ATSDR will have to develop a process for selecting and prioritizing sites for health assessments. (Site prioritization will be especially important if ATSDR falls significantly behind schedule in performing the health assessments.) It will also need to delineate the sources and types of information it will consider in its health assessments, and it will need to determine the extent to which EPA, potentially responsible parties and other affected parties will be allowed to participate in the preparation of health assessments.

In addition, ATSDR will need to establish criteria for responding to citizen petitions for health assessments. Specific issues include whether petitioners must meet some threshold level of information on exposures in order to obtain consideration, and what factors ATSDR will consider in deciding whether to grant such petitions.

Moreover, because SARA embodies a complex scheme of interrelationships

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<sup>4</sup>SARA also requires ATSDR and EPA to promulgate guidelines for the development of the toxicological profiles required by the statute. These were published in the Federal Register on April 17, 1987, at 52 Fed. Reg. 12870.

between EPA and ATSDR, the ATSDR health assessment program must be designed to mesh with EPA's Superfund responsibilities while still preserving the independence of the two agencies. In this regard, ATSDR will need to determine how to coordinate the scheduling of health assessments with the timetables in EPA's response actions. ATSDR and EPA will have to work together to determine what significance health assessments will have in EPA remedial action decisions and settlements.<sup>5</sup> EPA has placed great priority on developing a unitary administrative process for Superfund sites and the work of ATSDR will be appropriately integrated into that process.

ATSDR will undoubtedly attempt to resolve many of these questions through regulations or guidelines, but given the complexity and importance of the issues, many of these questions may ultimately result in litigation.

### *3.3 Challenges to individual health assessment decisions*

In addition to the programmatic issues discussed above, ATSDR can also expect to be sued over individual health assessments and decisions not to perform health assessments. Such lawsuits are likely because the health assessment has the potential substantially to impact virtually every phase of the CERCLA response process, from the initial investigation through remedial action and cost recovery. The health assessment will, of course, be an important factor in EPA's evaluation of the site. In addition, the health assessment may prove useful and influential for many of the other parties connected with the site. For instance, a health assessment finding significant health effects is likely to have a powerful effect on community and state comment on the remedial investigation and feasibility study and the proposed remedial decision. In addition, the availability of mitigation under § 104(i)(11) is contingent upon a finding of significant risk to human health in the health assessment. Similarly, an assessment finding no significant health effects is likely to influence the positions taken by potentially responsible parties in settlement negotiations or challenges to remedial action decisions. And courts are likely to give serious consideration to the health assessment when they review EPA remediation decisions in cost-recovery actions.

Health assessments are also likely to be perceived as useful and authoritative evidence in private toxic tort suits. As a result, individuals living near the site will have a considerable incentive to challenge a health assessment which concludes that a site does not present a significant risk to human health, or an ATSDR decision not to grant a petition for a discretionary health assessment. Likewise, the defendants in such cases may have a significant incentive to challenge a health assessment finding that a site creates a significant risk to

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<sup>5</sup>Before the passage of SARA, EPA looked to ATSDR for information on health effects to support EPA removal actions. SARA codifies that practice with respect to removals, but does not expressly define whether ATSDR should also be involved in EPA remedial actions or settlements.

human health<sup>6</sup> One hopes that interested parties will make their views known and help to develop data during the administrative process itself.

Further increasing the likelihood for litigation is the fact that the ATSDR health assessment may in some cases present a very different picture of conditions at the site than the EPA risk assessment. Such differences should not be surprising given the different orientations and mandates of the two agencies. ATSDR is a public health agency. Its job is to collect and analyze toxicological and epidemiological data, and to evaluate the actual current public health effects of given exposures. In contrast, EPA risk assessments predict potential risks on the basis of projected future exposure scenarios and use these projections to determine what level of cleanup is needed to protect both human health and the environment. As a result, instances will undoubtedly arise where the EPA risk assessment is superficially or genuinely inconsistent with the ATSDR health assessment. The parties connected with the site can be expected to seize on such inconsistencies to bolster their own positions.

### *3.4 Challenges to mitigation measures*

Another type of litigation likely to arise out of the health assessment process is challenges to the adequacy of mitigation measures taken pursuant to section 104(i)(11).<sup>7</sup> The section establishes what appears to be a nondiscretionary duty (“the President shall take such steps as may be necessary”<sup>8</sup>....), while providing only a broad definition of what that duty entails (.... “to reduce such

<sup>6</sup>These incentives will be partially offset by the heavy burden that a challenger would have to meet to prevail, and the limited relief such a suit would bring. The appropriate standard of judicial review of a health assessment, like most other agency actions, is the “arbitrary and capricious” standard of the Administrative Procedure Act, 5 U.S.C. § 706. Thus, the ATSDR’s health assessments are entitled to a high degree of deference by a reviewing court, and can be rejected only if they are completely without rational basis. Furthermore, even if a court were to find a health assessment defective, the proper remedy would be a remand to ATSDR for further consideration. Even a successful challenge, then, would not necessarily result in a substantive change in the health assessment.

<sup>7</sup>Section 104(i)(11) provides:

If a health assessment or other study carried out under this subsection contains a finding that the exposure concerned presents a significant risk to human health, the President shall take such steps as may be necessary to reduce such exposure and eliminate or substantially mitigate the significant risk to human health. Such steps may include the use of any authority under this Act, including, but not limited to:

- (A) provision of alternative water supplies, and
- (B) permanent or temporary relocation of individuals.

In any case in which information is insufficient, in the judgement of the Administrator of ATSDR or the President to determine a significant human exposure level with respect to a hazardous substance, the President may take such steps as may be necessary to reduce the exposure of any person to such hazardous substance to such level as the President deems necessary to protect human health.

<sup>8</sup>See footnote 3.



exposure and eliminate or substantially mitigate the significant risk to human health”). Given the slippery nature of the key operative terms, and the importance persons affected by waste sites are likely to place on mitigation measures, legal challenges to the adequacy of any proposed mitigation measures would appear likely. To help define the proper scope of the statute and thereby reduce the amount of litigation, EPA or ATSDR may elect to promulgate regulations that more clearly delineate these mitigation requirements. In that case, challenges to the regulations instead of individual mitigation proposals could be expected.

#### **4. Conclusion**

CERCLA created ATSDR and assigned it to gather information about the health effects of toxic substances and hazardous waste sites for use in the Superfund cleanup process. SARA establishes an expanded agenda for ATSDR. ATSDR now faces the difficult task of meeting this ambitious agenda. The larger role given to ATSDR by the Congress can provide a critical opportunity to enhance the education of all interested persons that the presence of contamination requiring cleanup under SARA does not necessarily establish current adverse health effects. All persons have an interest in the development of reliable health effects data without unnecessary litigation and in solving contamination problems before they become health problems.

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