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Implementation of CERCLA Health Authorities
By the Agency for Toxic Substances and Disease Registry

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ABSTRACT

The Superfund Amendments and Reauthorization Act of 1986 (SARA)(a) greatly expanded the health authorities of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund).(b) The federal agency most affected by the health orientation emphasis of SARA is the Agency for Toxic Substances and Disease Registry (ATSDR) of the U.S. Public Health Service (PHS). One of ATSDR's main responsibilities is to complete health assessments for all sites on, or proposed for, the Environmental Protection Agency's (EPA) National Priorities List (NPL). This paper will review ATSDR's efforts to address this new statutory mandate, especially for federal facilities, and will focus on different conceptual frameworks for implementing the health assessment program.

BACKGROUND

The formation of ATSDR was authorized under the original CERCLA law in 1980. Like its sister agency, the Centers for Disease Control (CDC), ATSDR is part of U.S. Public Health Service (PHS), which is a component of the Department of Health and Human Services. ATSDR's 1989 fiscal year budget was \$44.5 million, and it employed 175 individuals.

With the passage of the SARA in 1986, Congress demonstrated an increased

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interest in the relationship between hazardous waste sites and human health effects. Among other things, the newly amended section 104(i) of CERCLA(c) mandated ATSDR to conduct health assessments at every site on, or proposed for inclusion on, the NPL; establish priority lists of hazardous substances found at Superfund sites; produce toxicological profiles for each of the substances on this list; and undertake various research and health studies related to hazardous substances.

SARA laid out a very specific framework for the conduct of health assessments at Superfund sites. Prior to 1986, ATSDR generally conducted health assessments only in response to requests from EPA. Under the amended CERCLA, this responsibility to conduct health assessments at all NPL sites became mandatory. ATSDR was required to conduct a health assessment by December 10, 1988, for the 887 sites on or proposed for the NPL at time of passage of SARA in October 1986. In addition, ATSDR is required to complete a health assessment within one year for every new site proposed for inclusion on the NPL. For instance, in January 1987 EPA proposed to add 64 new sites to the NPL; ATSDR was required to complete health assessments for these sites by January 1988.

ATSDR defines a health assessment as "the evaluation of data and information on the release of hazardous substances into the environment in order to: assess any current or future impact on public health, develop health advisories or other recommendations, and identify studies or actions needed to evaluate and mitigate or prevent human health effects."(d) Section 104(i)(6)(G) of CERCLA(e) specifies that the two principal purposes of the health assessments are to assist in determining 1) whether action should be

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taken to reduce human exposure to hazardous substances and 2) whether additional information on human exposure and associated health risks at a site is needed and should be acquired by conducting health effects studies for the site.

ATSDR has attempted to standardize, to the extent possible, the format and conclusions of all health assessments.^(f) Generally, the health assessment will contain information describing the site location, on- and off-site contamination, physical hazards, the populations at risk near the site, and land use. The health assessment will also describe the environmental pathways, human exposure pathways, and the public health implications of this information. Finally, the health assessment is supposed to include conclusions and recommendations about the public health implications of the site, including future data-gathering needs.

CERCLA identifies the additional health effects studies to include pilot studies, epidemiological studies, health surveillance programs, and registries. The conduct of these additional health effects studies is discretionary for ATSDR. ATSDR can also issue health advisories for specific sites when it feels that these sites pose an acute risk to public health.

ATSDR encountered a number of difficulties in implementing the SARA requirements. Even in the best of times, ATSDR would have faced an imposing task to meet the health assessment mandates set forth in SARA. At the time of SARA's passage, however, ATSDR was ill-prepared to meet this challenge. In fiscal year 1986, ATSDR had an annual budget of approximately \$30 million and had approximately 75 employees (FTEs, or fulltime equivalents), a large number of whom were spread out on detail to other PHS agencies.

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In addition, ATSDR suffered a severe identity crisis in how it was perceived by other federal agencies, Congress, and the public, a condition which currently persists, although to a lesser degree. Common misconceptions were that ATSDR was simply a component of CDC or EPA.

ATSDR is greatly dependent upon EPA, which serves as trustee for the Superfund, for endorsement of its funding requests. ATSDR must have its annual appropriations initially approved by EPA. This requires ATSDR to justify its funding requests, and thereby its policy objectives, to an agency which itself is competing for limited Superfund dollars. Accordingly, faced with limited staff and budgets and with these factors largely controlled by other agencies with competing demands, ATSDR has been understandably hindered in its efforts to meet its statutory mandates.

CONCEPTUAL MODELS FOR HEALTH ASSESSMENTS

There are two different, though not mutually exclusive, models which ATSDR could have adopted to guide its implementation of its health assessment responsibilities. These conceptual models differ primarily in terms of the timing of the health assessment and potential impact on the EPA remediation process.

The first model emphasizes early identification of potential public health problems and intervention to address possible problems at a site. Under this model, resources would be directed to fulfill the CERCLA mandate to complete health assessments at all newly proposed NPL sites within one year.

The advantages of this model are that public health issues are addressed very early in the Superfund process, potential public health problems are identified so as to reduce possible mortality and morbidity associated with a

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site, and public health data needs and concerns are identified so as to influence EPA data gathering and other activities at the site. This early intervention model also enables decision-makers to prioritize a large number of sites, allowing resources to be dedicated for further health studies to the sites which pose the most serious health risks. The principal disadvantage of this model is that quite frequently there is very little site characterization information available at the time of this initial assessment, thereby limiting ATSDR's ability to make definitive judgments about the risks posed by a site.

The second possible conceptual model for health assessments concentrates health assessment activity later in the Superfund process, generally during or after the remedial investigation/feasibility study (RI/FS) stage. Under this model, minimum effort would be directed to addressing the one-year statutory requirement for newly proposed sites, with the maximum amount of resources dedicated to a comprehensive review of RI/FS data when they become available. The advantages of this model are that it allows ATSDR to make its review and recommendations on more complete information and that it could help EPA select remedial alternatives and prioritize remedial actions across sites. The disadvantages are that it minimizes ATSDR's ability to influence EPA's data gathering at sites, reduces the possibility of meaningful early public health interventions, and is more resource-intensive because of its commitment to conduct full health assessments based on RI/FS data at all NPL sites, regardless of the magnitude of health risks posed by each site.

As noted above, these models are not mutually exclusive. It is possible to incorporate elements of one model into the other model. However, the two

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models do demonstrate fundamentally different conceptions about the role and implementation of the health assessment responsibilities of ATSDR. Given sufficient resources, it would be possible for ATSDR to devote adequate attention to both the early health assessments and those conducted during or following the RI/FS. However, limited resources force ATSDR to focus its efforts in one area or the other. As a general rule, ATSDR has leaned heavily in favor of the second model with an emphasis on conducting assessments based on RI/FS data for all sites.

IMPLEMENTATION OF SITE-SPECIFIC HEALTH RESPONSIBILITIES BY ATSDR

The requirement that ATSDR conduct health assessments for all sites within one year of the date they are proposed to be added to the NPL posed a dilemma for ATSDR officials. Prior to SARA, ATSDR conducted health assessments at the request of EPA during or following the RI/FS stage of the Superfund process, the point at which the most complete site characterization information is available. However, RI/FSs rarely, if ever, are initiated within one year of the time a site is proposed for addition to the NPL. Normally, a site's nomination to the NPL is based on little more than EPA's preliminary assessment/site investigation, which frequently does not include detailed information on environmental pathways and potential human exposures.

Accordingly, soon after the passage of SARA, ATSDR was required to make an implicit decision concerning which conceptual model to follow in implementing its health assessment responsibilities. ATSDR was confronted with a problem. It could wait to conduct its health assessments until the most complete environmental characterization data were available following the RI/FS, but, in doing so, essentially ignore part of its statutory mandate

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to conduct assessments for sites within one year of their proposal to the NPL. Alternatively, ATSDR could comply with this statutory requirement by making its best public health judgement based on what it felt was less than complete information.

During 1986 and 1987, ATSDR generally viewed the two alternatives, representing the two different conceptual models, as mutually exclusive. At that time, ATSDR chose to defer the conduct of the majority of its health assessments until RI/FS data were available.

However, this approach changed as ATSDR faced its first statutory deadline for health assessments on January 20, 1988. One year prior, EPA issued its Update 6 list proposing to add 64 new sites to the NPL. Under the amended CERCLA, ATSDR had one-year to complete health assessments for these sites. Under its philosophy to defer the conduct of health assessments until the RI/FS stage, ATSDR had made the implicit decision to miss this deadline, and by implication, the one-year requirement for all newly proposed sites.

In December 1987 and early January 1988, ATSDR's approach to the timing of health assessments shifted. ATSDR decided to meet all health assessment-related statutory deadlines, including not only the one-year requirement for newly proposed sites, but also the December 10, 1988, deadline for existing NPL sites.

Accordingly, ATSDR created the concept of the "preliminary" health assessment to identify those health assessments completed prior to the availability of the RI/FS data. Under this approach, ATSDR claimed to meet both its January 20, 1988, (for the 64 Update 6 sites) and December 10, 1988, (for the remaining 887 sites) deadlines by preparing draft "preliminary" and

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"full" health assessments. Of the 951 sites requiring assessments, 504 involved "preliminary" assessments, while 282 were "full" assessments. Another 165 assessments were conducted before October 1986.(g) Many of these were in draft form at the deadlines. While CERCLA requires that the health assessments be "completed" by the specified dates, ATSDR maintains that these drafts satisfy the statutory requirements. As of June 1989, many of these draft health assessments remain unfinalized.

While ATSDR did institute the practice of issuing the "preliminary" health assessments, its programmatic emphasis and resources continued to be largely dedicated to preparing the "full" assessments. Although there are indications this position may change, ATSDR currently remains committed to conducting a "full" health assessment for every site, even if the "preliminary" health assessment indicated little cause for public health concern.(h)

ATSDR has since failed to meet a deadline of June 24, 1989, for EPA's Update 7 sites to the NPL. ATSDR estimated it would address only 135 of the 229 sites on the Update 7 list.(i)

HEALTH ASSESSMENT FINDINGS

A central question which Congress hoped to address through SARA was to what extent do hazardous waste sites pose a risk to public health. At this time, based upon ATSDR's work, it is difficult to answer this question in anything other than general terms. ATSDR has estimated that about 80% of all NPL sites indicate a pathway of potential human exposure to hazardous substances and that 10% of all NPL sites present a pathway of potential exposure of sufficient concern to warrant further health study.(j) While ATSDR has characterized risks posed by individual sites, it has not compiled and analyzed this

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information on a national basis. There is also no information available about the number of health advisories issued by ATSDR, although it has recommended emergency action at several sites. In addition, ATSDR has not prepared any guidelines or criteria for the issuance of health advisories for specific sites.

IMPACT OF HEALTH ASSESSMENTS ON FEDERAL FACILITIES AND SITE REMEDIATION

With the passage of SARA, many observers felt that ATSDR health studies, especially health assessments, would have a dramatic impact on EPA site remediation decisions, toxic tort litigation, and community and government awareness of public health risks associated with hazardous waste sites. It was felt that these health assessments, and other ATSDR activities, would provide credible information to help guide EPA and others in data gathering and reviewing remedial options as well as provide citizens with valuable information for becoming more involved in the Superfund process. This was especially true for federal facilities, which, as a general rule, are more complex than other Superfund sites and are believed to present greater public health risks. To a large extent, ATSDR has not yet fulfilled these expectations.

The magnitude of the statutory mandate, staff and other resource limitations, competing program responsibilities, and its conceptual approach to conducting health assessments have limited ATSDR's ability to effectively address many of the more complex federal facilities. For instance, the document which ATSDR considers to constitute the health assessment for the Rocky Flats DOE site in Colorado is simply an evaluation of a proposed test burn of an incinerator at the facility.^(k) This document does not appear to satisfy the statutory requirement of addressing the public health risks posed by the entire site or the need for further health studies. In addition, in finalizing

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a health assessment for the Rocky Mountain Arsenal site, an Army facility outside Denver, Colorado, ATSDR chose not to respond to detailed comments from the Army, the U.S. Department of Justice, and the state of Colorado.⁽¹⁾ ATSDR also failed to meet the statutory deadline for preparing health assessments for the Hanford DOE site in Washington. It is not certain how ATSDR will address the 52 federal facilities that EPA nominated for the NPL in July 1989. Given ATSDR's current approach for conducting health assessments, it is likely health assessments will have minimal impact on federal facilities.

It is fair to say that for a number of NPL sites, ATSDR's health assessments have contributed to a better understanding of the potential public health risks associated with these sites. However, ATSDR's continued emphasis on "full" health assessments after the RI/FS stage rather than "preliminary" health assessments earlier in the process has clearly impacted its ability to address the complex federal facilities in accordance with the CERCLA requirements. This emphasis has clear resource implications. In an era of resource limitations, it is necessary for ATSDR to explicitly evaluate and implement a health assessment model which addresses the CERCLA mandate most effectively by identifying public health problems at a point where meaningful intervention can occur and so health concerns are adequately addressed as part of EPA's site characterizations and remediation.

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ENDNOTES

(a) Pub. L. 99-499.

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- (b) 42 U.S.C. 9601 et seq.
- (c) 42 U.S.C. 9604(i).
- (d) Health Assessments and Health Effects Studies of Hazardous Substances Releases and Facilities, 53 Fed. Reg. 32259 (1988) (to be codified at 42 C.F.R. 90).
- (e) 42 U.S.C. 9604(i)(6)(G)
- (f) Agency for Toxic Substances and Disease Registry. Health Assessment Format, Guidelines and Methodology. ATSDR, Atlanta, Ga.
- (g) Memorandum from Barry L. Johnson, Associate Administrator, ATSDR, to Walter R. Dowdle, Acting ATSDR Administrator, May 19, 1989.
- (h) Statement by James O. Mason, Administrator, ATSDR, Before the Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, U.S. House of Representatives, June 20, 1988.
- (i) Letter from Walter R. Dowdle, Acting Administrator, ATSDR to Rep. Richard A. Gephardt, June 16, 1989.
- (j) Id.
- (k) Memorandum from Steven D. Von Allmen to the Record, October 18, 1988 (Establishment of Preliminary Health Assessment Equivalency for the Rocky Flats NPL Site, Golden, Colorado).
- (l) Agency for Toxic Substances and Disease Registry, 1988. Preliminary Health Assessment for Rocky Mountain Arsenal. ATSDR, Atlanta, Ga.