Principles of Chemical Risk Assessment: The ATSDR Perspective

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Hazardous wastes released into the general environment are of concern to the public and to public health authorities. In response to this concern, the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (commonly called Superfund), was enacted in 1980 to provide a framework for environmental, public health, and legal actions concerning uncontrolled releases of hazardous substances. The Agency for Toxic Substances and Disease Registry (ATSDR) was created by Superfund to address the public health issues of hazardous wastes in the community environment.

Two key Agency programs, Public Health Assessments and Toxicological Profiles, are designed to assess the risk to human health of exposures to hazardous substances that migrate from waste sites or through emergency releases (e.g., chemical spills). The Agency's public health assessment is a structured process that permits ATSDR to identify which waste sites or other point sources require traditional public health actions (e.g., human exposure studies, health studies, registries, health surveillance, health advisories). The ATSDR qualitative public health assessment complements the U.S. Environmental Protection Agency's quantitative risk assessment. For Superfund purposes, both assessments are site-specific. ATSDR's toxicological profiles are prepared for priority hazardous substances found most frequently at Superfund sites. Each profile presents the current toxicologic and human health effects information about the substance being profiled. Each profile also contains Minimal Risk Levels (MRLs), a type of risk assessment value. This paper covers ATSDR's experience in conducting public health assessments and developing MRLs, and it relates this experience to recommendations on how to improve chemical risk assessments.

Introduction

Chemical risk assessments are the source of great activity in government and private sector organizations. Risk assessments on individual chemicals and broad environmental problems have become a staple in regulatory agencies, at both the federal and state levels. Some nonregulatory agencies also conduct risk assessments. The risk assessment approaches and experiences of a nonregulatory, federal, public health agency are the subject of this paper.

The Agency for Toxic Substances and Disease Registry (ATSDR) is one of the eight agencies that constitute the U.S. Public Health Service. Congress created ATSDR in 1980 as part of the Comprehensive Environmental Response, Compensation, and Liability Act (known as Superfund). The Agency was mandated by Superfund to work with the U.S. Environmental Protection Agency (EPA), the states, and the private sector to elucidate the public health consequences of hazardous waste, principally the releases from waste sites covered under Superfund.[1]

What and how we experience things molds our thinking on what represents reality. ATSDR's reality is to work in an emotionally charged area of public health. We often experience high emotions in communities around hazardous waste sites, including some near federal facilities. Our Agency participates in many meetings with community groups who are suspicious of government agencies and generally unimpressed with numbers from numerical risk assessments.

Because of this experience with the public, ATSDR's reality regarding risk assessment can best be described as a somewhat "schizophrenic" existence. We recognize the importance to regulatory agencies of a systematic assessment of risk, and because resources are limited but problems are not, we acknowledge the importance of having a tool that can be used to compare risks. However, we are concerned that the current approach to quantitative risk assessment has not performed very well in many instances — hence our schizophrenia.

This paper outlines the Agency's approach to hazard evaluation of waste sites, proceeding from the complex problem of assessing public hazards posed by individual waste sites to the situation of risk assessment for a single toxicant. ATSDR's public health assessment will be described first.

Public Health Assessments

To set the stage for defining a public health assessment, consider the American public's concern in 1980 that toxic waste in the environment was compromising human health. Moreover, opinion polls in 1991 indicate that this concern continues at the same high level. The public remains fearful

of the health consequences of hazardous waste and toxic substances. Many communities would like — indeed would insist on — a full-scale epidemiologic study of their health. To put this in perspective, EPA now lists 33,000 uncontrolled toxic waste sites in the United States.[2] Using their Hazard Ranking System, EPA ranks each site in terms of its environmental contamination and its ecologic and health significance. The result is called the National Priorities List (NPL) of hazardous waste sites. This list is important because placement on it brings monies from the Superfund trust fund to remediate the site.

The message is that there are very large numbers of uncontrolled — and also controlled — waste sites and facilities in the U.S. that can potentially compromise public health. Given the widespread angst about such sites, a belief is built into the public's mind that EVERY site should be the subject of an intensive, in-depth, health investigation. If the list of most important hazardous waste sites were to number only 2000 and if a community epidemiologic study would cost $2 million or more in today's market, then the cost for such an epidemiological undertaking would be $4 billion. Cost, as well as scientific considerations, lead one to conclude that long-term health studies cannot be conducted at every waste site.

How then does a government public health agency decide which sites (and here we must think in terms of communities of young, elderly, healthy, ill, wealthy, poor, educated, and illiterate human beings) really do require some kind of health action in response to confirmed environmental contamination? ATSDR's instrument for triage in this difficult situation is the public health assessment, or more simply, health assessment.

Definition

ATSDR's public health assessment is "the *evaluation of data and information* [emphasis added] 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* [emphasis added]."[3] In the context of an ATSDR public health assessment, "evaluation of data and information" means employing professional judgments, according to specified guidelines, to characterize the nature and extent of the hazard to human health presented by releases from individual hazardous waste sites. As a federal health agency, we believe that consequential health decisions ought to be predicated on a foundation that permits, indeed encourages, the exercise of professional judgment. The second point of emphasis pertains to the prevention of adverse human health effects. ATSDR uses the public health assessment to identify conditions of exposure to hazardous substances that, when reduced in severity, will prevent morbidity or mortality.

Public Health Assessment Compared with Risk Assessment

ATSDR is often asked how its public health assessment of a waste site differs from an EPA risk assessment for the same site. The implication sometimes is that the two instruments are duplicative and, hence, wasteful. In fact, these two kinds of assessments are complementary, as will be described later; each serves a useful purpose to the agency that utilizes it. But as a hypothetical argument, assume that the risk assessment and the public health assessment are, in fact, fully duplicative. Would the duplication be a waste of resources? To answer this question, consider what happens when a family member is diagnosed as having a fatal disease, resulting in a recommendation for radical clinical intervention. Many people in such situations seek a second medical opinion, sometimes more, because the implications to personal health of being wrong are sometimes too important to rest in the hands of a single medical specialist.

Are hazardous waste sites also worthy of "second opinions"? Given that the average cost of remediating a nonfederal waste site is a multimillion dollar effort, and knowing that public health questions are a serious concern to affected communities, a plausible case can be made for the importance of two opinions, independently derived.

Aside from the foregoing hypothetical argument, an ATSDR public health assessment has several significant distinctions from an EPA risk assessment of the same waste site. These differences are rooted in the respective agencies' needs, policies, and statutory responsibilities. The principal differences are shown in Table I. Both kinds of assessments serve practical purposes and are generally complementary.

Conduct of Public Health Assessments

How do ATSDR and the state health departments conduct public health assessments?[3] The public health assessment is conducted by a multidisciplinary staff using three key databases:

- Environmental contamination data (normally obtained from EPA, sometimes supplemented by data from state agencies, characterize levels of contaminants in environmental media related to the site).
- Health outcome data (normally obtained, when available, from state and local health agencies, e.g., community-specific cancer rates or adverse reproductive outcomes).
- Community health concerns (expressions from the community around the site about their health concerns).

The ATSDR health assessors conduct site visits to obtain a significant amount of these three types of data. Using a weight-of-evidence approach, the health assessors factor the following considerations into their overall assessment of the

TABLE I. Characteristics of ATSDR Health Assessments and EPA Risk Assessments

ATSDR Public Health Assessment	EPA Risk Assessment
• Qualitative, site-specific; uses environmental contamination, health outcomes, and community health concerns data.	• Quantitative, compound-oriented, site-specific; uses environmental contamination data.
• Medical and public health perspectives are weighted to assess health hazards.	• Statistical and/or biologic models are used to calculate numerical estimates of health risks.
• Used to evaluate human health impacts and to identify public health interventions.	• Used to facilitate remediations or other risk management actions.
• May lead to pilot health effects studies, surveillance, epidemiologic studies, or exposure registry.	• May lead to selection of particular remediation measures at a site.
• Is advisory.	• Bears regulatory weight of authority.

public health significance of the site:

- Environmental contamination data are evaluated as follows:
  1. Using existing toxicological information bases, the principal contaminants are identified. Contaminant levels are compared with published environmental media guides derived by ATSDR or with EPA regulatory standards to assess if human exposure to these levels may constitute a public health hazard.
  2. Current and possible future exposure pathways of public health concern are identified. For some sites, models that predict migration of contaminant plumes are used to identify communities at risk of exposure and, on occasion, to attempt to reconstruct the extent of historical exposures.
  3. Special populations at risk of exposure, e.g., children, are identified and, where possible, the extent of their exposure to contaminants of concern is assessed.
- Health outcome data are obtained when they are available and can be focused on a county, community, census tract, or defined area around the site. This approach produces a broad picture of the health status of a community that may have experienced toxic releases. The data *do not* represent an epidemiologic evaluation of the community at risk. That type of refinement occurs through follow-up studies whenever the public health assessment identifies the need. In addition, health outcome data are an important tool the Agency uses to address concerns about excess disease occurrence in communities living near a waste site.
- Community health concerns are obtained by establishing contact with citizens' groups, local health-care providers, and community leaders. These types of data serve two purposes. First, by reaching out to the community, a contact is made that begins a health communication and education effort that must attend every public health assessment. Second, some health data or other pertinent site-specific information may be unrecognized by health authorities, but known to the citizens.

From the public health assessment will come a ranking of the site in terms of its overall significance to public health. ATSDR currently uses five categories of importance (with Agency Actions for each category): A: Urgent Public Health Hazard (health advisory); B: Public Health Hazard (health follow-up); C: Indeterminate Public Health Hazard (possible health follow-up, identify gaps); D: No Apparent Public Health Hazard (environmental health education, monitoring and revisit); and E: No Public Health Hazard (no actions by ATSDR).[3] The specific actions for each site are determined by an intra-agency panel, implemented by designated divisions, and monitored by the intra-agency panel. Besides guiding ATSDR as to which sites require follow-up health actions, the site classifications are one factor considered by EPA to set priorities of sites for remediation.

Based on the site-specific recommendations made, each health assessment identifies what health actions are to be undertaken. The actions range from health studies carried out by ATSDR, often in cooperation with state health departments, to actions related to preventing exposure by EPA's restricting access to contaminated areas, if access had not already been restricted.

Legal Requirements

Superfund directs ATSDR to conduct a public health assessment of every site that is proposed for, or placed on, EPA's NPL within 1 year of its proposal or placement. Of the 1292 sites currently on the NPL, about 10% are federal sites or facilities. More specifically, 97 sites on the current NPL are Department of Defense (DoD) sites; another 17 are Department of Energy (DoE) facilities; and 1 site is currently split between DoD and DoE. There are five other NPL sites under federal responsibility (the Department of Transportation and the Department of Interior, two each; and the Small

Business Administration, one). Through interagency agreements, ATSDR has begun receiving the financial resources necessary to undertake Public Health Assessments of DoD and DoE sites and facilities. Because considerable environmental contamination may have occurred around some federal sites, the public health assessments will be difficult and their conduct protracted.

In addition to mandating public health assessments of NPL sites, Superfund permits individuals to petition ATSDR to conduct these assessments for sites of concern to them. This brings government resources to address the concerns of individual citizens. ATSDR has received approximately 150 petitions since 1987 and has accepted about 70% for the conduct of public health assessments. (Petitions are rejected when evidence is lacking of any actual or potential releases of hazardous substances.) Approximately 55% of petitions have come from individual citizens; the remainder have been submitted from members of Congress, attorneys, local elected officials, and state/local health departments. ATSDR anticipates the number of petitions will increase as awareness of the petitioning mechanism grows.

Also, under Section 3019 of the Resource Conservation and Recovery Act (RCRA) amendments of 1984, ATSDR can conduct a public health assessment of a RCRA facility if requested by EPA, a state, or an individual. However, statutory language requires that the request for a public health assessment be accompanied by funds. ATSDR has conducted very few public health assessments of RCRA facilities, approximately one dozen to date. This number is too low to permit any generalizations.

Findings from Public Health Assessments

The ATSDR public health assessment database contains information that is useful in assessing the overall extent of adverse health effects associated with releases of hazardous substances. The database contains information about substances released from individual sites and facilities, citizens' health concerns, and some health data from state and local health departments. ATSDR is currently consolidating its databases into a single, comprehensive database called HAZDAT to probe associations between releases of hazardous substances and health outcomes. The Agency anticipates that HAZDAT will be available to the public in 1992.

Drawing on various Agency reports and documents, it is possible to summarize some of the principal findings to date from the large number of public health assessments conducted.[4,5] More detailed analyses will be available when the HAZDAT information base is fully operational.

Public Health Assessments and Consultations

- The majority of NPL sites on the list through 1988 are either industrial sites (31%) or landfills (30%).
- Several volatile organic chemicals (e.g., trichloroethylene, benzene, tetrachloroethylene) and metals (e.g., lead, chromium, arsenic) are the substances most often identified at the sites as potential contaminants of concern to health.
- Overall, ATSDR estimates that 4.1 million people live within 1-mile radii of the 725 sites for which population data were available, resulting in an average of about 5700 persons within 1 mile of each site. (This figure should be understood in terms of its limitations. For some sites, not all persons within a 1-mile radius are at risk of exposure, depending on migration patterns of substances released. In addition, for some sites, the population at risk of exposure extends beyond a 1-mile radius where there is documented groundwater contamination.) EPA estimates that approximately 41 million people live within 4 miles of a Superfund site.[6]
- Using data available in 1988, ATSDR reported that conditions and exposure potentials at 109 of the 951 sites then on the NPL were considered to constitute ongoing or probable public health concerns, a health follow-up rate of about 11.5%.[4] During 1990, ATSDR implemented a more intensive health action analysis. Of the 261 sites reviewed in fiscal year 1991, 38% were identified as requiring some kind of health action.
- Because of their recreational activities and their propensity for hand-to-mouth activities, children less than 6 years of age are at increased risk of exposure to contaminants in dirt and dusts, compared with older children and adults. Boys are more likely than girls to come into contact with soil-laden contamination.
- Where off-site migration of hazardous substances occurred, groundwater was often contaminated. For example, using data available to ATSDR in 1988, groundwater was contaminated at 71% of sites with documented evidence of migration of metals and at 88% of sites with such evidence for volatile organic chemicals. Evidence of lead migration into groundwater was detected at about 17% of all NPL sites, based on health assessment data from 951 NPL sites.
- Working with state agencies, ATSDR has found that the overall assessment of potential health consequences from historical exposures to hazardous substances is a matter of considerable public health importance. For example, the Agency is working with one state health department to advise young women whose prior exposure to lead could result in endogenous releases of lead during pregnancy.
- ATSDR's health consultations confirm that acute, adverse health effects are commonly reported fol-

lowing emergency releases of hazardous substances. Eye irritation, dermatologic effects, respiratory problems, and a variety of neurologic complaints constitute the bulk of these acute health problems.

- Preliminary findings from a surveillance system of emergency events indicate that two-thirds of hazardous substance releases occur from stationary facilities; one-third occur from moving equipment.
- ATSDR's public health assessment experience indicates that large numbers of minorities live near hazardous waste sites. A report from a public interest group suggests that minorities are more than three times as likely as white Americans to live near hazardous waste sites.[7] The Agency is currently developing demographic data about who lives around Superfund sites.

Health Investigations and Registries

ATSDR's public health assessments are linked to investigations of the effects of hazardous substances on the etiology of chronic disease and acute, adverse health effects. ATSDR has identified seven Superfund Priority Health Conditions that will be the focus of health investigations by the Agency, university researchers, and state health investigators. The seven conditions were identified through a comprehensive analysis of the literature on toxicologic and human health effects associated with known Superfund hazardous substances (Table II).

In 1987, in cooperation with state agencies, ATSDR undertook a series of human exposure assessments, surveillance projects, and epidemiologic health investigations of persons who may be at increased risk of exposure to hazardous substances released from waste sites. To date, the Agency has conducted 37 pilot health studies (principally exposure assessments), 18 epidemiology investigations, and 20 surveillance projects. The aggregate findings from this work are currently being evaluated.

In general, average biological exposure levels have been low compared with occupational exposures to the same substances. However, the Agency has found that each exposure assessment must consider the distribution of all exposures within the community investigated, not relying simply on the mean or median value.[8] Where individuals exceed health-based exposure standards or guidelines, ATSDR works with state and local authorities to reduce the exposure for those individuals.

TABLE II. ATSDR's Superfund Priority Health Conditions in Alphabetical Order

Birth defects and reproductive disorders
Cancers (select)
Immune function disorders
Kidney dysfunction
Liver dysfunction
Lung and respiratory diseases
Neurotoxic disorders

TABLE III. Top-Ten Superfund Hazardous Substances*

1. Lead	6. Cadmium
2. Arsenic	7. Polychlorinated biphenyls
3. Mercury	8. Chloroform
4. Vinyl chloride	9. Benzo(b)fluoranthene
5. Benzene	10. Trichloroethylene

*Note: These are the top 10 substances from the list of 275 prioritized substances.[9]

ATSDR's national exposure registry program promises new, important information on the health effects of long-term exposure to low concentrations of hazardous substances. The exposure registry is a listing, along with health status information, of persons who have had exposure to a hazardous substance of primary interest, at exposure levels of concern. Such registries can be evaluated over time to assess health trends. Currently, the Agency has established national subregistries of persons exposed to dioxin (4 NPL sites) and trichloroethylene (13 NPL sites), has initiated a subregistry of persons exposed to benzene, and has plans for a chromium subregistry. The Agency considers the national exposure registry of great importance for determining the health effects of long-term exposure to hazardous substances.

Risk Assessments of Individual Chemicals

ATSDR public health assessments for individual hazardous waste sites usually involve the presence of mixtures of hazardous substances. In addition, ATSDR develops risk assessment estimates for individual chemicals. These risk estimates are for substances prioritized jointly by ATSDR and EPA. Substances are ranked by frequency at NPL sites, inherent toxicity, and likelihood for human exposure. Currently, 275 substances have been ranked.[9] (The top ten substances are listed in Table III.)

For each substance, Superfund requires that ATSDR develop a toxicological profile and make it available to the public. Each profile must describe what is known about a substance's toxicity and human health effects. In addition, determinations as to the levels of exposure that present a significant risk to human health, e.g., Significant Human Exposure Levels (SHELs), must be provided in each profile. ATSDR is currently addressing the development and dissemination of SHELs by determining Minimal Risk Levels.

Minimal Risk Levels

The ATSDR Minimal Risk Level (MRL) is defined as "an estimate of the daily human exposure to a dose of a chemical that is likely to be without an appreciable risk of adverse, noncancerous effects over a specified duration of exposure."[10] Inhalation MRLs are exposure concentrations

expressed in parts per million for gases and volatile substances or milligrams per cubic meter for particles. Oral MRLs are expressed as daily human doses of mg/kg/day. ATSDR does not derive MRLs for dermal exposure, owing to lack of methodology to develop them. The purpose of these estimates is to provide health professionals with a concept of levels at which adverse health effects are not expected to occur in humans. They are not meant to support regulatory action, but the MRL should serve as an advisory that physicians and public health officials can consider when making recommendations to protect populations living in the vicinity of hazardous waste sites or chemical emissions. ATSDR considers such values as an adjunct to the overall context in which decisions regarding health issues are made, rather than a "pivot point" for such decisions.

Because chemicals may elicit more than one toxic effect, ATSDR attempts to determine the critical effect in the target organ, i.e., the first adverse effect or its known precursor that occurs as the dose increases. The critical effect for a given exposure duration and route is determined only after assessing the scope of the database and the quality of all studies identifying effects by the route of exposure being considered. If the most sensitive target system cannot be identified, the critical effect cannot be determined. It follows that a MRL cannot be derived from this database.

When the critical effect for the route and duration has been identified, MRLs are derived from the no-observed-adverse-effect level (NOAEL). In lieu of a NOAEL, an uncertainty factor (UF) of 10 is employed for use of a lowest-observed-adverse-effect level (LOAEL). Additional UFs of 10 may be employed for animal-to-human and human-to-human extrapolations. MRLs can, therefore, have uncertainty factors ranging from 10 (data derived from humans) to 1000 (derived from animal LOAELs). MRLs are derived using the following formula.

$$\text{MRL} = \frac{\text{NOAEL}}{\text{UF}}$$

The determination of ATSDR's MRLs relies heavily on the same methodology used to derive the EPA Reference Risk Dose (RfD). Moreover, personnel from both agencies serve on work groups that develop each of these numbers.

However, there are some key differences between MRLs and RfDs. ATSDR develops MRLs for acute, intermediate, and chronic exposure durations and for both oral and inhalation routes of exposure. EPA develops its verified RfDs for chronic oral and Reference Concentrations (RfCs) for inhalation exposures. It is current ATSDR policy not to extrapolate data across routes and durations of exposure; rather, pharmacokinetic data are used to bridge these kinds of extrapolations, if such data are available.

MRLs are not applicable to nonthreshold effects such as genotoxicity and cancer. The Agency accepts the categories of carcinogens as published by the Department of Health and Human Services, the International Agency for Research on Cancer, and the EPA. It is Agency policy to prevent or mitigate any human exposure to an identified carcinogen.

The Agency has prepared Toxicological Profiles for 130 substances. A potential exists for the derivation of 780 MRLs for the three duration and two exposure categories. To date, 187 MRLs have been developed and are found in individual Agency toxicological profiles. As can be inferred, the Agency's scientists found database inadequacies that prohibited the development of many MRLs. These inadequacies circumscribe the health assessor's opportunity to fully evaluate the potential health effects posed by hazardous substances at a site or release.

Superfund directs ATSDR to initiate a program of research to fill data needs for priority hazardous substances. ATSDR initiated the program in 1991 through an announcement of the data needs for 38 priority substances.[11] As an example, ATSDR identified key data needs for arsenic to be 1) comparative toxicokinetics, 2) determination of half-lives in surface water and groundwater, and 3) bioavailability from soil. The findings from this program of research should be quite useful in improving the scientific database used in chemical risk assessment.

ATSDR's experience in developing MRLs has led to some observations about the process. One key observation is the problem of data quality. What constitutes acceptable data? How does a governmental agency assess the adequacy of experimental investigations, assurance of data quality, and confidence in interpretation of findings by investigators whose work may be crucial for determining an MRL? Any risk assessor faces this question in a variety of ways. Currently, no agreed-upon standards are available, and the subject of data quality is currently being discussed by the World Health Organization's International Program on Chemical Safety and various national agencies.

Recommendations for Improving Chemical Risk Assessments

Based on its experiences conducting public health assessments of Superfund sites and deriving MRLs for substances in its toxicological profiles, together with the involvement of its technical staff in developing risk assessment policies and procedures at federal and state levels, ATSDR recommends the following to improve risk assessments of individual chemicals.

- Risk assessments should state clearly the key assumptions, uncertainties, and limitations inherent in conducting each risk assessment. This information should be routinely provided to the risk manager and to other users of the risk assessment. Consideration might be given to presenting risk as a range rather than as a single point estimate.
- The science undergirding risk assessment must be

improved through a program of directed research. In particular, priority should be given to research on human exposure assessment, pharmacokinetics, extrapolations between species and between routes of exposure, and basic mechanisms of toxicity. It is important that the methods required for utilizations of these kinds of data in the context of risk analysis should be a component of this directed research.

- Weight-of-evidence and weight-of-judgment should be included in conducting risk assessments. Also, consideration should be given to "negative-outcome" studies as well as those with positive outcomes.
- Models that have not been validated with experimental data should be viewed skeptically. This suggests the increased use of biologically based risk assessments.
- Agencies should consider adopting independent, scientific, peer review of risk assessments and providing draft versions to the public for review and reaction. ATSDR practices both of these actions when developing its toxicological profiles and other reports. These actions enhance the scientific quality of risk assessments, in ATSDR's experience.
- In the absence of adequate scientific information, a risk assessment should not be done. All risk assessments acquire a certain degree of permanency, and those that are poorly developed are difficult to retract or revise and lead to diminished credibility of the risk assessor. Rather than developing a risk assessment predicated on an insecure foundation, it is better to identify and conduct the key research needed to perform a specific risk assessment.

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