Inter-Agency Coordination on the Development of Health Assessments

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Abstract

The US Environmental Protection Agency's (US EPA) National Center for Environmental Assessment (NCEA) and the Agency for Toxic Substances and Disease Registry (ATSDR) recently established a memorandum of understanding (MOU). Under this MOU, the NCEA and ATSDR have agreed to increase their coordination on the development of health assessments for hazardous chemicals found in the environment. The ATSDR is mandated under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund), as amended by the Superfund Amendments and Reauthorization Act (SARA), to develop Toxicological Profiles for hazardous substances found at facilities on the CERCLA National Priorities List (NPL). The ATSDR is also required to update and republish profiles no less often than every three years. To date, 275 profiles have been published covering over 900 substances. The NCEA manages the IRIS, a US EPA database that contains the Agency's scientific consensus positions on human health effects that may result from exposure to chemical substances in the environment. The IRIS currently provides information on health effects associated with more than 500 chemical substances. Many of these health assessments are developed by the NCEA. The NCEA also prepares peer-reviewed provisional assessments for the Superfund program when an IRIS assessment is not available. The MOU encourages scientists from the two agencies to participate more actively in the development of each other's assessments. Additionally, the MOU provides opportunities for the two agencies to share resources. For example, the NCEA and ATSDR are collaborating on some literature search and retrieval efforts to prevent redundancy. Increased coordination in the development of health assessments will enable the US EPA and ATSDR to leverage federal resources and improve scientific concordance.

Introduction to the Two Programs

The ATSDR is an agency of the US Department of Health and Human Services that serves the public using the best science, taking responsive public health action, and providing trusted health information to prevent harmful exposures and diseases related to toxic substances. The NCEA serves as the US EPA's national resource center for human health and ecological risk assessment, conducting risk assessments, carrying out research to improve the state-of-the-science of risk assessments, and providing guidance and support to risk assessors. Within the Office of Research and Development, the NCEA strives to reduce environmental risks as part of US EPA's overall mission to protect human health and to safeguard air, water, and land upon which life depends. The ATSDR and NCEA share a responsibility for developing assessments for environmental chemicals and making these assessments available to the public. By Congressional mandate, the ATSDR produces Toxicological Profiles for hazardous substances found at NPL sites. The NCEA maintains the IRIS database of human health effects that may result from exposure to various substances found in the environment. The database contains IRIS Summaries and, for newer assessments, Toxicological Review support documents. The ATSDR's and EPA's programs serve somewhat different purposes:

- ATSDR develops a list of hazardous substances most commonly found at facilities on the Superfund Sites, prepares Toxicological Profiles (http://www.atsdr.cdc.gov/toxpro2.html) for each substance and ascertains significant human exposure levels. The Toxicological Profiles establish Minimum Risk Levels (MRLs) that are derived for acute (≤14 days), intermediate (15-364 days), and chronic (365 days and longer) exposure durations, for the oral and inhalation routes of exposure.
- EPA develops IRIS assessments (http://www.epa.gov/IRIS) of chemical substances for use in risk assessments, decision-making, and regulatory activities by various EPA programs and other users. IRIS contains descriptive and quantitative information in various categories. Oral reference doses and inhalation reference concentrations (RfDs and RfCs, respectively) for chronic noncarcinogenic health effects as well as hazard identification, oral slope factors, and oral and inhalation unit risks for carcinogenic effects are reported in IRIS Summaries and Toxicological Reviews.

Objectives of the Memorandum Of Understanding (MOU)

Because of the similarities between our agencies' missions and health assessment documents, we have recently established an MOU to:

- Facilitate interagency collaboration on the development of the Toxicological Profiles and IRIS assessments.
- Increase quality of the assessments by the sharing of scientific expertise.
- Improve efficiency by eliminating duplication of effort.
- Collaborate to leverage federal expenses.
- Share information that contributes to scientific concordance.

Similarities in Assessments

- Examination, summary, and interpretation of available toxicological information and epidemiologic evaluations of a hazardous substance.
- Are NOT intended to define clean up or action levels, but information may be used by risk managers.
- Subjected to thorough scientific review.

Differences in Assessments

- IRIS assessments evaluate both cancer and noncancer endpoints. The ATSDR reports, but does not independently evaluate cancer effects.
- Toxicological Profiles develop MRLs for different exposure durations. Currently IRIS assessments focus on chronic exposure durations, but a pilot to develop less than lifetime reference values is under way.
- Substances are chosen for assessment annually with different priorities and timing goals.

Workgroup

ATSDR and NCEA staff have begun to meet regularly to identify chemical-specific priorities of mutual interest and potential points of interaction that will provide opportunities to leverage resources and share information. The ATSDR and NCEA are currently collaborating on several assessments including: 1,4-dioxane, carbon tetrachloride, cyanide, dichlorobenzenes, and 1,1,1-trichloroethane. The implementation of the ATSDR-NCEA MOU is illustrated in the following example involving the assessment of 1,4-Dioxane:

- ATSDR prepared a draft Toxicological Profile for public comment in 2004.
- EPA began developing an IRIS Assessment in 2004.
- MOU Workgroup identified an opportunity for collaboration and facilitated the coordination of this effort.
- ATSDR provided results of their recent literature search for noncancer data to EPA to prevent a duplication of effort and to leverage federal resources.
- Chemical managers from both agencies have consulted and exchanged scientific ideas for the individual assessments.
- EPA chemical manager has reviewed and commented on the ATSDR draft assessments.
- ATSDR participated in early planning of the IRIS assessment and will review and comment on the draft assessment when completed.

Ongoing and Future activities

We are beginning collaboration on several additional assessments, including: acrolein, barium, and 1,1,2,2-tetrachloroethane. Future efforts may include the development of joint assessments, and other activities to leverage resources and pool scientific expertise.

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