UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DEC 21 '93

OSWER DIRECTIVE # 9285.7-16

OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

MEMORANDUM

SUBJECT: Use of IRIS Values in Superfund Risk Assessment

FROM: William H. Farland, Director
Office of Health and Environmental Assessment

Henry L. Longest II, Director
Office of Emergency and Remedial Response

TO: Directors, Waste Management Division
Region I, IV, V, VII, VIII
Director, Emergency and Remedial Response Division
Region II
Directors, Hazardous Waste Management Division
Regions III, VI, IX
Directors, Hazardous Waste Division
Region X

PURPOSE

This memorandum clarifies the policy stated at section 7.4.1 of the December 1988 Risk Assessment Guidance for Superfund (Volume I) Human Health Evaluation Manual (Part A)(RAGS) on the use of Integrated Risk Information System (IRIS) values in performing health risk assessments. Recent litigation has called attention to the need for all persons involved in the Superfund risk assessment and remedy selection processes to be fully aware of the role of IRIS values in those processes.

BACKGROUND

As indicated in RAGS, the Agency generally recommends IRIS as the principal source for toxicological data in preparing Superfund risk assessments. IRIS represents an Agency consensus as to appropriate values for a wide variety of chemicals commonly found at Superfund sites. The Agency believes IRIS is a valuable tool for expediting the assessment of risks posed by sites. IRIS values do not always undergo external peer review. However, IRIS values consistently undergo some type of peer review within the Agency and are often used in Agency rulemaking activities. Use of IRIS values avoids duplication and enhances consistency among Superfund risk assessments.

Recycled/Recyclable
Printed with Soy/Canola Ink on paper that contains at least 50% recycled fiber

At the same time, IRIS is not the only source of toxicological information, and in some cases more recent, credible and relevant data may come to the Agency's attention. In particular, toxicological information other than that in IRIS may be brought to the Agency by outside parties. Such information should be considered along with the data in IRIS in selecting toxicological values; ultimately, the Agency should evaluate risk based upon its best scientific judgment and consider all credible and relevant information available to it.

IMPLEMENTATION

As indicated in the preamble to the NCP, the Agency must respond substantively to any comments raised during the public comment period on the proposed plan that question the use of an IRIS value; see 55 FR 8711 (March 8, 1990).[1] In responding to such comments, Agency staff should keep in mind that the entry of a value in IRIS is not a rulemaking. Thus, the entry of a value on IRIS does not make the number legally binding (i.e., the value is not entitled to conclusive weight) for the purposes of Superfund risk assessments. When a toxicological value is questioned in a comment on the proposed plan, a written explanation for the value ultimately selected (whether it is the IRIS value or another number) must be included in the administrative record.[2]

The weight to be given information from sources other than IRIS will necessarily have to be determined on a case-by-case basis. When presented with alternative toxicological information that might be used in place of IRIS values, the Agency will consider all credible and relevant information before it. The evaluation of credible and relevant information should consider a variety of factors in evaluating the hazards associated with chemical exposure including: whether the study was designed using approved protocols and whether it was conducted observing good laboratory practices. In addition, the Agency wishes to avoid duplicating work that was done in developing the IRIS value. Thus, the work of the IRIS Workgroup may be a source of

---

[1]Such information may also be submitted by outside parties earlier in the process, such as during the workplan development phase of the baseline risk assessment. While EPA is not required to respond at that time, timely evaluation of such information can be more efficient than addressing issues only when they are raised during the public comment period.

[2]For assistance in evaluating such information, regional managers should contact the appropriate regional scientist and, secondarily, the technical contacts listed in IRIS. For further general information, contact the IRIS Risk Information Hotline at (513) 569-7254.

information that will aid in explaining the Agency's rationale that supports a toxicological value. Accordingly, while all credible and relevant information must be considered, departing from the IRIS value is generally discouraged where the information submitted consists of data previously evaluated in developing that value. In the event that the Agency determines that an IRIS value should be replaced with another value, the Toxics Integration Branch of the Office of Emergency and Remedial Response will work with both the Office of Research and Development and the Regions to promote the consistent use of toxicological values for the Superfund program in all Regions.

Finally, those using values from IRIS are reminded that toxicological values are subject to varying degrees of uncertainty, for a variety of reasons, and that the existence of such uncertainty should be taken into account in preparing site specific risk analyses. Further guidance in this regard can be found at section 7.6 of RAGS, and in the Deputy Administrator's February 26, 1992 memorandum entitled "Guidance on Risk Characterization for Risk Managers and Risk Assessors."