



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

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OFFICE OF
SOLID WASTE AND EMERGENCY
RESPONSE

MEMORANDUM

SUBJECT: Administrative Reforms for Lead Risk Assessment

FROM: *Stephen D. Luftig*
Stephen D. Luftig, Director
Office of Emergency and Remedial Response

TO: Director, Office of Site Remediation and Restoration
Region I
Director, Emergency and Remedial Response Division
Region II
Director, Hazardous Waste Management Division
Regions III, IX
Director, Waste Management Division
Region IV
Director, Superfund Division
Regions V, VI, VII
Assistant Regional Administrator, Office of Ecosystems
Protection and Remediation
Region VIII
Director, Environmental Cleanup Office
Region X

This memorandum outlines specific steps to implement the principles outlined in the Administrator's October 2, 1995 Administrative Reforms related to lead.

Lead is one of the most frequently encountered chemicals at Superfund sites. Lead cleanups are also reported to be some of the most costly cleanups. In the spirit of continuous improvement, we believe that this is a time to seek out information on the consistent implementation of the OSWER Lead Directive. These efforts to collect and analyze lead-related information will require your support.

Technical Review Workgroup for Lead and Review of Draft Lead Issues Plan

Background

In order to support site-specific lead risk assessments and assist in the development of national lead policy for Superfund, the Technical Review Workgroup (TRW) for lead was established more than five years ago and is a resource that is available to advise Regions on questions relating to site-specific risk

assessments. The TRW has recently expanded its membership and completed a transition in leadership. We welcome the new co-chairs, Pat Van Leeuwen (312-886-4904) of Region 5 and Paul White (202-260-2589) of the Office of Research and Development, who have recently taken on the challenge of leadership for the TRW. We believe that this transition is a good time to improve communications among Regions and Headquarters to better conform with the objectives of the Administrative Reform for lead.

I am attaching a draft issues plan for lead. In the spirit of continuous improvement, the draft lead issues' plan proposes several activities to provide for improved communications among Regions and with Headquarters. One of the most significant of these actions would be the formation of a policy group for lead that should include senior managers from all Regions and Headquarters. It is our intent to use the Policy Group to work for clarity and consistency across the country in managing lead sites.

Action

Please comment by May 31 to Larry Zaragoza on the draft lead issues plan and on priorities for work identified in the plan.

Review of Site-Specific Lead Risk Assessments for Children in Residential Areas

Background

Since the publication of the January 1994 Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK: version .99d), few lead risk assessments have been brought to the attention of the TRW for their review during the planning stages. We have seen some assessments later in the process, and the review by the TRW has resulted in improvements in the application of the IEUBK model. Earlier reviews are a much more efficient use of resources. In the spirit of continuous improvement, it is in our long-term interests to review our IEUBK risk assessments for consistency with guidance and, if appropriate, modify our guidance to promote continually improving science.

Action: In order to promote consistency and address these concerns, each Region should:

- 1) **Send all completed lead risk assessments which used the IEUBK model to the TRW. A review will focus on consistency with guidance.**
- 2) **Identify all IEUBK risk assessments that are either in planning or underway.**
- 3) **Identify any application of the IEUBK that is expected to be challenged or will set a precedent in IEUBK application.**

Thus, the TRW can be informed of the issues and provided an opportunity to comment on the approach undertaken.

- 4) Send any draft Regional Guidance relating to lead to Headquarters for review before release.

Materials requested above should be sent to Larry Zaragoza (703-603-8867), the Headquarters member of the TRW.

Support for Adult Lead Risk Assessments

I am pleased to report that a number of adult lead risk assessments are being referred to the TRW, which is developing guidance on this issue. It is our belief that these reviews will promote consistency and help ensure that information is shared across Regions. To request consultation, contact Mark Maddaloni (212-637-4315) of EPA's Region 2, the head of the adult lead subcommittee.

Feedback on the Process

Questions on policy or the overall approach outlined in this memo should be directed to Larry G. Reed (703-603-8960), Deputy Director, OERR. Questions specific to the application of risk assessment in Superfund should be directed to David Bennett (703-603-8759), Senior Process Manager for Risk.

cc: E. Laws

Attachment

DRAFT LEAD ISSUES PLAN

Introduction

On October 2, Administrator Browner announced a series of Administrative Reforms to improve the operations of the Superfund Program. Administrative Reform 2 is "Risk Assessments Grounded in Reality". Lead was a visible pollutant before this Administrative Reform. The effect of the latest round of Administrative Reforms will be to focus efforts to develop and implement actions that improve the consistency and understanding of Superfund Risk Assessments. The output for this administrative reform involves continued utilization of the Lead Work Group (usually known as the Technical Review Workgroup [TRW]). The TRW has been responsible for supporting the refinement of the model (Integrated Exposure Uptake Biokinetic Model--IEUBK), which is used to assess the impact of environmental lead levels on child blood levels. This document provides a plan for addressing the issues associated with effective implementation of more effective use of the TRW and establishing clear communication links in the reorganized OERR.

Lead is a key pollutant for the Superfund program for two reasons. First, the information on the adverse health effects associated with lead exposure is more extensive than for other environmental contaminants. As a result of our improved understanding of lead relative to other chemicals, EPA has developed the IEUBK to assess the relative contributions of lead exposure to blood lead levels in children. This approach allows for the relative contributions of all environmental sources of lead to be assessed (e.g., paint, soil lead, house dust). Second, as the most prevalent chemical found at Superfund sites, the costs of lead cleanups are expected to be high. The combination of complex environmental assessment issues and high cleanup costs makes lead one of the more controversial chemicals for Superfund sites.

This plan is intended to promote consistent assessment of lead at Superfund sites, identify primary responsibilities for different activities, and establish a communication network between headquarters and EPA Regional Offices on lead issues. It is designed to support the continued work of the Lead TRW and establishes a network for the communication of lead related policy issues. Policy issues, such as development of a short sheet that outlines how the IEUBK should be used to assess lead impacts at non-emergency removal sites, would be addressed by this group. The policy related issues will be closely coordinated with the Lead Technical Workgroup. Both groups will be served by a group of individuals within headquarters that will support the communication of policy issues for the policy group and generally support certain logistics for the Lead TRW.

OERR has recently undergone a reorganization and there has been a change in staff associated with the reorganization. In order to minimize any impact of reorganization and personnel changes, this plan proposes new points of contact and working relationships. This plan should help to ease disruptions that would otherwise occur as a result of Headquarters, and possibly, Regional reorganization efforts. This draft plan is currently being circulated as a draft

to obtain a common understanding of the objectives to be obtained and ideas of both Regional and Headquarters members of the TRW. At this point, this draft document has been circulated to members of the TRW and others. We are seeking additional comment before revising this draft. This document should serve as a vehicle to develop some agreement on the issues of key importance. Such a compilation of responsibilities, activities, and priorities has not been prepared for lead in the past. As a first effort, this plan we intend to use this plan to improve communications and the efficiency of program activities on lead.

Lead Technical Review Workgroup (TRW)

The Lead TRW provides sites specific assistance in the application of the IEUBK, undertakes tasks to improve the IEUBK, and issues associated with the assessment of lead risks at Superfund sites. The TRW is composed of lead health specialists from EPA Headquarters and Regional Offices. In addition to providing advice on a number of sites that are being evaluated with the IEUBK, the TRW produced the guidance manual for the application of the IEUBK, as well as the model refinements to better prepare the model for site specific application at Superfund sites. A primary function of the TRW is to promote good science. A listing of specific projects that are scheduled for the workgroup is provided in Appendix A.

The current membership of the TRW is included as part of Table 1. This composition of the TRW has served the program well. It provides representation from EPA Regional Offices, ORD and OPPTS.

In addition to sharing information on program directions on lead assessment efforts, the other program office representatives have helped to build better working relationships with the Superfund Program. This structure helps to promote more efficient communication on lead program activities across the Agency as well as sharing scientific and technical information that might not otherwise be shared as efficiently.

Policy Group

One of the suggestions made at this year's OERR Strategic Planning Retreat was that we should have a policy group to discuss lead related issues and to promote consistency in the lead policy issues. The approach that this group would take would be similar to the approach taken by the Large Area Lead Mining Sites group, which has had periodic meeting to discuss key lead policy issues. The support of this group would also provide a resource for access on lead assessment approaches that should promote consistency. Finally, because the Policy Group would be briefed on various lead activities, the support of the Policy Group for continued dedication of staff to support the Technical Review Workgroup and other activities would be sought.

The membership of this group will be composed of Regional Managers. The group may be chaired by the OERR Director/Deputy Director and support will be provided by OERR and Regional staff.

Headquarters Coordination Group

The Headquarters coordination group would be responsible for the coordination of information generated by the Technical Review Workgroup and the Policy Group. In addition, this group would track and share information that is generated by the other groups that perform lead related work that are identified in this plan. This will help to ensure that information provided by the Regions will be available to all Regions to better understand the effectiveness of National lead policies. Moreover, this group will also seek to ensure that Headquarters requests for information on lead will be coordinated and not duplicated. In order to achieve this objective, a network of lead contacts will be established that will include at least one staff from each Regional Center and Regional Contacts for lead issues (again, at least one from each region).

Work with Regional Coordinators

Given the challenges in Superfund Reauthorization, interests from Congress, and others, we often find it necessary to seek information on lead. In order to avoid duplicate requests, information on lead sites will normally be centralized and coordinated according to the responsibilities outlined in Table 1. This will help to promote a more efficient use of headquarters staff and reduce repeated requests from EPA Regions for site specific information. Finally, this will provide a known source where information on lead sites has been centralized.

Requests for Information on Lead to Support Reauthorization

Given that much of the information outlined in this plan will address how the Superfund program assesses lead and requires ready access to the information outlined in this plan, information in this area will be coordinated through the headquarters lead contacts, as identified in Table 1. This work would also include continuing support for the Three City Lead Study and outreach with the Community Involvement and Outreach Center (e.g., Kim Fletcher).

Information Management Issues

In order to improve information that is maintained with known quality (sources of information and accuracy and precision are characterized), lead related information management issues will be coordinated through this group. Types of information that will be sought shall include: sites where the IEUBK has been used (and the version of the IEUBK), cleanup levels, cost of cleanup, satisfaction of the community with the outcome and other information that is deemed important to assessing progress with lead related assessments and associated cleanups. This work will be coordinated with Jim Konz, who is preparing the electronic reporting requirements for risk information, and others. Larry Zaragoza will provide the lead for this activity.

Management Support

Lead issues are clearly a high visibility activity for OERR, and management support will be key to success. David Bennett, the Process Manager for Risk will be a resource to help secure resources for lead related issues (e.g., contractor support). In order to ensure communications in critical areas, regular communications will take place with the Process Manager for Risk on key activities in any lead area and the OERR Director. There will also be quarterly meetings that will address all areas of lead work. Larry Zaragoza will serve as the overall coordinator for lead related activities and he will be responsible for communicating with the different levels of management on the items outlined above.

Coordination with Other Federal Agencies

ATSDR

ATSDR coordination will be facilitated through the Mid-Level Managers' Workgroup and the Senior-Level Managers' Workgroup. This group will work directly with the Headquarters Coordination Group.

Centers for Disease Control (CDC)

The CDC is responsible for a variety of public health issues including national lead survey work. They also have established standards for sampling blood lead and conducting epidemiological studies that are relevant to the interpretation of health data for Superfund sites. Their review and comment is sought when appropriate.

Other Federal Agencies

Other Federal Agencies (e.g., Department of Energy, Department of Defense, Housing and Urban Development) also have interests in lead risk assessment and the implementation of policies. Promoting consistency requires outreach and exchange of information.

Representation on the Title X Workgroup for OPPTS

Larry Zaragoza will continue OERR representation in the Title X Workgroup efforts, which includes an economic analysis that will support the upcoming OPPTS rulemaking under Title X. Given Congressional interest in Superfund and its relationship to other programs, this effort is important to both OPPTS and OERR.

Table 1. Contacts for Lead Activities

Activity	Participants
Technical Review Workgroup	Region II (Mark Maddaloni) Region III (Roy Smith) Region V (Pat Van Leeuwen, Co-chair) Region VIII (Susan Griffin and Chris Weis) Headquarters: ORD (Harlal Choudhury/Cinn; Rob Elias and Allan Marcus/RTP; and Paul White/DC, Co-Chair) OPPTS (Karen Hogan) OSWER/OERR (Larry Zaragoza/Barbara Davis)
Policy Group	Steve Luftig Staff Support: Larry Zaragoza
Headquarters Coordination Group	Chair, Larry Zaragoza Lisa Askari
Other Federal Agency Coordination	Steve Luftig/Larry Reed/Elaine Davies/David Bennett

Appendix A: Listing of Lead Projects of the Technical Review Workgroup

LEAD TECHNICAL REVIEW WORKGROUP Ongoing Lead Projects

Title	Activity	Chair(s)	Members
Site-Specific Support	Support reviews of site specific lead risk assessments.	Pat Van Leeuwen, Mark Maddaloni	Entire workgroup
Validation Work	1) Compare measured blood lead levels in children with IEUBK model results. 2) Check computer code for consistency with documentation and correct computations.	Karen Hogan	Paul White, Allan Marcus, Barbara Davis
Independent Verification	Oversee independent review of the computer code for the IEUBK.	Karen Hogan, Larry Zaragoza	Rob Elias, Susan Griffin
Validation Workshop	Schedule and hold a workshop on lead model validation in the fall of 1996	Harlal Choudhury, Larry Zaragoza	Barbara Davis, Karen Hogan, Paul White, Allan Marcus, Roy Smith, Rob Elias
Structure Paper	Publish a paper that describes the structure of the IEUBK model.	Paul White	Pat Van Leeuwen, Barbara Davis, Mark Maddaloni
Adult Lead Number	Develop guidance for assessment of adult lead risks using a subgroup.	Mark Maddaloni	Pat Van Leeuwen, Paul White, Allan Marcus, Rob Elias, Roy Smith, Susan Griffin, Harlal Choudhury, Barbara Davis
Sampling Guidance	Management of a subgroup and contractor effort that develops sampling guidance for lead sites.	Susan Griffin	Chris Weis, Karen Hogan, Mark Maddaloni, Paul White, Roy Smith, Rob Elias, Harlal Choudhury, Barbara Davis, Pat Van Leeuwen
Research Planning	Develop a research plan for lead.	Chris Weis, Rob Elias	Karen Hogan, Mark Maddaloni, Bruce Means, Paul White, Allan Marcus, Harlal Choudhury, Barbara Davis
Title X	Track and coordinate TRW issues with Title X (urban lead concerns with OPPTS/HUD)	Karen Hogan	Paul White, Larry Zaragoza

NEW ISSUES (Issues may require a short sheet, technical memorandum, or coordination efforts):

1. **Criteria for Removal Action**
Given the differences in the approaches that have been used to conduct removals, what health-based criteria should be used in risk assessments that employ the IEUBK to support time critical and non-time critical removals.
2. **Blood Lead Studies**
How should blood lead studies be used in assessing lead exposures at sites (e.g., comparison of IEUBK model results with results of blood lead studies, adjusting input values in IEUBK Model, etc.) What is acceptable data from a blood lead study; criteria.
3. **Uncertainty in Lead Risk Assessments**
How should uncertainty in results of either the IEUBK or the Adult model be characterized. Should the output be a single number, a matrix, what?
4. **The individual GSD**
Should site-specific GSDs be used instead of Model defaults (the Manual gives cautions). What methods should be used to develop the GSD?
5. **Soil to Dust Coefficient**
When are the IEUBK model defaults inappropriate; what data is needed to justify a change in the default value; what methodology(ies) should be used to develop soil to dust concentration ratios?
6. **PB STAT**
Can the PB STAT computer program be used to provide useful comparison data? Should it be there or not?
7. **IEUBK Model, v. 0.99e**
Region 8 has sponsored development of version 0.99e, which includes a batch mode for operation. The workgroup should address the question of the distribution/use of this version, especially given that other enhancements have been recommended as a result of the Independent Validation and Verification Effort.
8. **Other Enhancements to 0.99d**
A number of other enhancements to the IEUBK Model are expected to be desired by users; these are not yet under development (e.g., improving code, development of a Windows version).
9. **Sampling Manual Short Sheets**
RPMs are asking for sampling protocols, e.g., dust sampling. Given the differences that alternative methods can produce and the desire to have consistency with other Federal

agency activities, how do we become consistent? Is consistency important here?
Will it help/restrict our validation exercises?

10. **Trespasser Scenarios**

Review of the trespasser exposure scenario. How/when should the trespasser scenario be used in lead risk assessments? What are the appropriate exposure duration and exposure frequency.

11. **Home Gardening Scenario**

Evaluation of home garden exposure assumptions. Values recommended in the Manual may need adjustment. Some commercial programs have values for transfer of lead in soil/water to vegetables, meat, milk!!

12. **Attributable Risk**

Attributable risk--different interpretations and estimations. Are we consistent in our definitions and use of attributable risk?

13. **Bioavailability Data**

Review of bioavailability data. Should we provide recommendations for changes in the IEUBK Model based on species and/or matrix effects. Are there limitations? What data is needed? When are defaults appropriate?

14. **Leaded Paint**

Should there be some guidance on use of lead paint data in CERCLA risk assessments? Does it differ for interior paint/exterior paint? OSWER Directive warrants clarification, especially given the experience working with the 1994 OSWER Lead Directive.