



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

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SEP 20 1985

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

MEMORANDUM

SUBJECT: Endangerment Assessment Guidance

FROM: J. Winston Porter
Assistant Administrator

TO: Addressees

PURPOSE

This memorandum clarifies the requirement that an endangerment assessment be developed to support all administrative and judicial enforcement actions under Section 106 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and Section 7003 of the Resource Conservation and Recovery Act (RCRA). Before taking enforcement action under these provisions to abate the hazards or potential hazards at a site, the Environmental Protection Agency (EPA) must be able to properly document and justify its assertion that an imminent and substantial endangerment to public health or welfare or the environment may exist. The endangerment assessment provides this documentation and justification. The endangerment assessment is not necessary to support cost recovery for Section 104 remedial actions.

This memorandum also provides guidance on the content, timing, level of detail, format, and resources required for the preparation of endangerment assessments.

WHAT IS AN ENDANGERMENT ASSESSMENT

An endangerment assessment is a determination of the magnitude and probability of actual or potential harm to public health or welfare or the environment by the threatened or actual release of a hazardous substance (for a CERCLA action) or a hazardous waste (for a RCRA action).

An endangerment assessment evaluates the collective demographic, geographic, physical, chemical, and biological factors which describe the extent of the impacts of a potential or actual release of a hazardous substance and/or hazardous waste.

In general, the endangerment assessment should identify and characterize:

- (a) Hazardous substances and/or hazardous wastes present in all relevant environmental media (e.g., air, water, soil, sediment, biota);
- (b) Environmental fate and transport mechanisms within specified environmental media, such as physical, chemical and biological degradation processes and hydrogeological evaluations and assessments;
- (c) Intrinsic toxicological properties or human health standards and criteria of specified hazardous substances or hazardous wastes;
- (d) Exposure pathways and extent of expected or potential exposure;
- (e) Populations at risk; and,
- (f) Extent of expected harm and the likelihood of such harm occurring (i.e., risk characterization).

WHY PERFORM AN ENDANGERMENT ASSESSMENT

Under Section 106(a) of CERCLA, if the President determines that there may be an imminent and substantial endangerment to public health or welfare or the environment from an actual or threatened release of a hazardous substance, the President may secure such relief as may be necessary to abate such danger or threat. Such relief may be in the form of a judicial action or an administrative order to compel responsible parties to respond to hazardous conditions.

Before an order can be issued under §106 of CERCLA, EPA must be able to document and justify its assertion that an imminent and substantial endangerment to public health or welfare or the environment may exist. The endangerment assessment provides this documentation and justification. It is the basis for the findings of fact in administrative orders, consent decrees, and complaints.

In situations dealing with hazardous wastes or solid wastes under RCRA, rather than hazardous substances under CERCLA, Section 7003 of RCRA may be used as the authority under which EPA may issue orders or file civil actions ^{1/}. Section 7003 of RCRA requires a similar finding of imminent and substantial endangerment and, therefore, EPA must also document and justify such an assertion with an endangerment assessment before taking enforcement action.

^{1/} "Final Revised Guidance Memorandum on the Use and Issuance of Administrative Orders Under Section 7003 of the Resource Conservation and Recovery Act", September 26, 1984 signed by Courtney Price and Lee Thomas.

It is important to note that "imminent" does not mean immediate harm. Rather, it means an impending risk of harm. Sufficient justification for a determination of an imminent endangerment may exist if harm is threatened; no actual injury need have occurred or be occurring. Similarly, "endangerment" means something less than actual harm.

WHEN TO PERFORM AN ENDANGERMENT ASSESSMENT

At remedial sites subsequently targeted for CERCLA §106 or RCRA §7003 enforcement action, all of the elements of an endangerment assessment will be provided by completing the contamination assessment, public health evaluation, and environmental assessment during the RI/FS process. As such, these assessments are equivalent to the endangerment assessment for enforcement sites. The information from the contamination assessment, public health evaluation, and environmental assessment will be considered sufficient to issue an order although additional work may be needed prior to litigation (See Attachment 1 and the RI/FS guidance documents referenced on Page 6 of this guidance).

Where an RI/FS has not been initiated or completed, an endangerment assessment must be prepared to justify an administrative order or judicial action under CERCLA §106 or RCRA §7003. For example, orders issued to govern responsible party conduct of an RI/FS or to compel responsible party performance of immediate response actions will require an endangerment assessment prior to issuance. In both cases, the endangerment assessments will demonstrate that there may be an imminent and substantial endangerment which justifies either further investigative action to determine the appropriate remedy for a site or an immediate response action.

In isolated cases, EPA has negotiated with potentially responsible parties for the site remedy before it has developed the RI/FS. In these few cases, an endangerment assessment must be developed independently of the RI/FS and completed prior to issuance of the order or decree for remedial action.

An endangerment assessment is required for all future RCRA §7003 actions, as well as older RCRA §7003 cases to which CERCLA §106 authority has been or will be added. An endangerment assessment is not required for older RCRA §7003 cases already filed by the Department of Justice without an endangerment assessment. The litigation team, however, may determine on a case-by-case basis that the preparation of an endangerment assessment or its equivalent would substantially strengthen the government's case.

Endangerment assessments must be prepared for all RCRA §7003 or CERCLA §106 orders issued to another Federal agency for cleanup of a Federally-owned facility. Normally, EPA will seek response action at a Federal facility through a site-specific compliance agreement with the appropriate Federal agency or other responsible parties. If, however, a compliance agreement is not complied with by Federal owners or responsible parties, EPA may issue an order.

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WHAT LEVEL OF DETAIL

The determination that an imminent and substantial endangerment to public health or welfare or the environment may exist is a legal prerequisite that must be met before an order can be issued. It is EPA policy that endangerment assessments should be undertaken only to the extent "necessary and sufficient" to fulfill the requirements of legal enforcement proceedings. At any site, there is the potential for conducting studies beyond the level of detail needed for enforcement actions. The level of detail of the endangerment assessment should be limited to the amount of information needed to sufficiently demonstrate an actual or potential imminent and substantial endangerment. The level of detail to sufficiently demonstrate endangerment will vary from case to case based on the following factors:

- the type of enforcement action (e.g., AO for removal vs litigation);
- the type of response action (e.g., removal vs remedial); and
- the stage of response action (e.g., RI/FS workplan vs RI/FS completed).

The level of detail required to support a particular enforcement action will ultimately be determined on a case-by-case basis by Regional program personnel in consultation with Regional Counsel. As a general guide, the matrix on page 5 defines these levels of detail based on the factors listed above. The matrix should help the Regions to both (1) determine what constitutes an adequate endangerment assessment for a particular enforcement action, and (2) plan their intramural and extramural resources accordingly.

When endangerment assessments are developed to support administrative orders for private party RI/FS or immediate removal actions, information already available about the site will generally be sufficient. Where sites are targeted for enforcement action after completion of an RI/FS, the endangerment assessments developed as part of the RI/FS will be more detailed and generally more quantitative as they will be based on information obtained from the remedial investigation. Such endangerment assessments will be used to support any subsequent CERCLA §106 orders or judicial actions seeking design and construction of site remedies.

The information gathered in an RI/FS is generally similar to the type of information needed for an endangerment assessment. However, RI/FS and endangerment assessments are developed for different purposes. RI/FS are used to determine appropriate response actions under CERCLA §104, while endangerment assessments are used for enforcement actions under CERCLA §106 or RCRA §7003. For sites with CERCLA §106 or RCRA §7003 enforcement potential, Regions should review the RI/FS workplan to determine whether information developed as part of the RI/FS will be sufficient for an endangerment assessment. In certain complex cases, additional information may be needed and a separate endangerment assessment workplan may be required.

<u>Complexity</u>	<u>Type of Action</u>	<u>Data Base</u>	<u>Type of Assessment</u>	<u>Remarks</u>
Level I	AO for removal action, AO for private party RI/FS, preliminary scoping	May be limited, probably consisting of information from the Preliminary Site Assessment, Site Inspection Report, and Hazard Ranking System evaluation, if completed. No health studies available; no demographic studies available. Preliminary sampling data will probably be available on pollutants present. Data on extent of release or concentrations of materials at the point of exposure may be available.	Qualitative assessment of exposure routes, population at risk, and probability of harm occurring. Critical pollutants and their toxicological properties can be readily identified and quantity of pollutants estimated. Reasonable and prudent to conclude that an exposure may exist because the release.	For removal actions where the normal site ranking process has not been completed or undertaken, information for the assessment may be available from record searches, State sponsored investigations, written reports from inspections by government authorities, and notification in accordance with CERCLA §103.
Level II	Issuance of AO or consent decree for private party cleanup	Remedial Investigation complete or other quantitative data available on nature/extent of release. Data may be available on magnitude and demographics of population at risk. Possibly some preliminary health effects studies. Sources and specific materials associated with release are identified.	Semi-quantitative appraisal considering specific exposure routes and critical pollutants. The assessment should be able to identify any data gaps and recommend additional studies, if necessary.	This assessment must be able to support legal action in the event that it is challenged by a recalcitrant PRP. Should be conclusive enough that PRPs will be encouraged to make a firm commitment to complete remedial action, but not necessarily detailed and complete if based on RI/FS.
Level III	Litigation (site-by-site basis)	RI and FS complete. All required geological, hydrogeological, and health studies complete.	Detailed, quantitative review to identify potential health effects, critical exposure levels, and necessary follow-up health studies. Critical pollutants and routes identified, and existing exposures defined or estimated. This will constitute an appraisal to the best of expertise and knowledge and an estimate of the uncertainty.	May require endangerment assessment work in addition to information generated during RI/FS.

Note: The matrix is flexible and may shift on a case-by-case basis as required to support a particular enforcement action.

The endangerment assessment should evaluate the adequacy, accuracy, precision, comprehensiveness, reliability, and overall quality of identified information and data.

Emergency actions do not require the same depth of assessment as planned or remedial activities. By definition, an immediate and significant risk of harm to human life or health or the environment will be present in an emergency, making the assessment of endangerment easier to prepare. Further, EPA is justifying only the need for immediate action, not the long-term remedial solution. Thus, the endangerment assessment may be much briefer, although the Regions should attempt to use as much available information as feasible. The Action Memorandum supporting the emergency action will normally be considered adequate to serve as an endangerment assessment in support of an enforcement action under §106 of CERCLA for an immediate response.

Attachment 2 is an abstract of a detailed paper on "Endangerment Assessments for Superfund Enforcement Actions", prepared by Technical Support Branch, CERCLA Enforcement Division, the Office of Waste Programs Enforcement (OWPE). This paper, previously distributed to the Regions, will provide technical assistance in preparing qualitative and quantitative assessments. OWPE is also preparing a handbook on preparation of endangerment assessments.

Methodologies used for performance of such aspects of the endangerment assessment as exposure and risk assessment should be consistent with the concepts and methods currently in use by the EPA Office of Research and Development (ORD).

Attachment 3 shows how the various toxicity, exposure, and risk evaluations are used to define the overall problems and hazards (endangerment) at a site. Although the use of these evaluations is possible at every site, the need for a detailed analysis, as outlined, is likely to be appropriate at only a limited number of sites to sufficiently demonstrate an actual or potential imminent and substantial endangerment.

The Office of Emergency and Remedial Response (OERR) has developed guidance manuals covering the performance of remedial investigations and feasibility studies. The chapters listed below from these documents and the OWPE handbook will provide guidance in preparing endangerment assessments:

Guidance on Remedial Investigations Under CERCLA (OERR, May 1985)

Chapter 7 - Site Characterization

Chapter 9 - Remedial Investigation Report Format

Guidance on Feasibility Studies Under CERCLA (OERR, April 1985)

Chapter 5 - Evaluate Protection of Public Health Requirements

Handbook on Preparation of Endangerment Assessments (OWPE -
Technical Support Branch, Summer 1985)

Attachment 4 is a list of references that can be used in preparation of the endangerment assessment.

FORMAT

The endangerment assessment generally should follow a standard framework as provided in Attachment 5 and use qualitative and/or quantitative terms as appropriate.

The Action Memorandum will normally be considered adequate to serve as the endangerment assessment document in support of an order under §106 for an emergency action.

The endangerment assessment document may be the order itself (where the order contains all of the elements of an endangerment assessment) or a separate document. In deciding whether to develop a separate document or to include the elements of the endangerment assessment in the order, Regions should consider the following factors:

1. Are the responsible parties more likely to consent to an order if the endangerment assessment is part of the body of the order, or a separate document?

2. Is the order likely to be issued unilaterally or on consent? A separate document will, of course, be more important in adversarial settings.

We strongly urge that the endangerment assessment in support of an administrative order for private party cleanup be a separate document. Where all of the elements of an endangerment assessment are in the RI/FS documents, a separate document may consist simply of a brief statement cross-referencing the appropriate elements of the RI/FS.

WHO SHOULD PERFORM AN ENDANGERMENT ASSESSMENT

The Regions have the responsibility to assure that endangerment assessments are performed. The Regions can draw on technical expertise available in their Regional offices, OWPE - Technical Support Branch, ORD, the Agency for Toxic Substances and Disease Registry (see MOU between ATSDR and EPA), and/or contractor personnel available through the Technical Enforcement Support (TES) or REM/FIT and TAT contracts.

Endangerment assessments used to justify administrative orders or judicial actions issued or filed before development of the RI/FS should normally be drafted by Regional personnel with the assistance of the TES contractor. The Regions and TES contractor also have the lead in preparation of endangerment assessments for older cases where an RI/FS has not been completed.

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If responsible parties elect to perform the RI/FS, they will, in effect, perform an endangerment assessment because they will develop many or all of the elements of an endangerment assessment as part of the RI/FS. Regions should review the RI/FS workplan to determine whether information developed as part of the RI/FS will be sufficient to show that an imminent and substantial endangerment may exist. Because subsequent enforcement actions will rely on the endangerment assessment developed as part of the RI/FS, close Regional oversight should be given to this responsible party work.

The authority for determinations of imminent and substantial endangerment relating to emergency response actions costing up to one million dollars has been delegated to the Regions, subject to the directives issued by the Office of Solid Waste and Emergency Response. (See Delegation 14-1-A, Selection and Performance of Removal Actions Costing Up to \$1,000,000 and the Memorandum "Waiver of Advance Concurrence Requirements for Certain Consent Administrative Orders, Gene A. Lucero, January 3, 1985).

When exercising the authority to determine that an imminent and substantial endangerment exists for the purposes of taking enforcement action, the Region must consult with OWPE as outlined in the November 30, 1984 Regional Assignment Memo (also see the Memorandum "Superfund Delegations of Authority - ACTION MEMORANDUM", Howard Messner, April 4, 1984). In contacting OWPE, Regional staff should be prepared to discuss the details of the endangerment assessment for each determination. In certain cases involving complex health and environmental endangerment issues, OWPE may request a copy of the draft endangerment assessment for review. OWPE will complete a review of this document within 14 days of receipt, to ensure consistent, timely response.

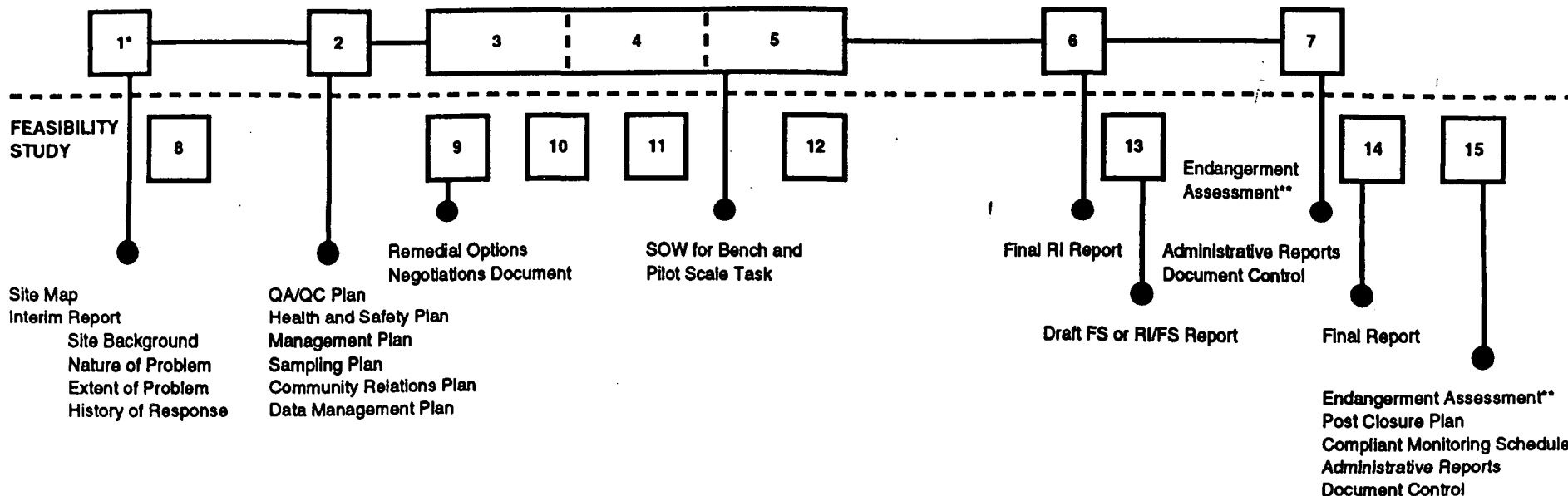
USE OF THIS GUIDANCE

The policy and procedures set forth here, and internal office procedures adopted in conjunction with this document, are intended for the guidance of staff personnel, attorneys, and other employees of the U.S. Environmental Protection Agency. They do not constitute rulemaking by the Agency, and may not be relied upon to create a right or benefit, substantive or procedural, enforceable at law or in equity, by any person. The Agency may take any action at variance with the policies or procedures contained in this memorandum or which are not in compliance with internal office procedures that may be adopted pursuant to those materials.

If you have any questions or concerns regarding this guidance, please have your staff contact Chuck Morgan (FTS-475-6690), Chief of the Environmental Health Sciences Section of OWPE or Linda Southerland (FTS-382-2035) of the Guidance and Oversight Branch.

Attachment 1 RI/FS Process

REMEDIAL INVESTIGATION



Remedial Investigation

Model Statement of Work for Remedial Investigations		Guidance Document for Remedial Investigations Under CERCLA	
Task #1	Description of Current Situation	CH 1	Introduction
		CH 2	Scoping
Task #2	Plans to Management	CH 3	Sampling Plan Development
		CH 4	Data Management Procedures
Task #3	Site Investigation	CH 5	Health and Safety Planning for Remedial Investigations
Task #4	Site Investigation Analysis	CH 6	Institutional Issues
Task #5	Laboratory & Bench Scale Studies	CH 7	Site Characterization
Task #6	Reports	CH 8	Pilot and Bench Studies
Task #7	Community Relations Support	CH 9	Remedial Investigation Report format

Feasibility Study

Model Statement of Work for Feasibility Studies		Guidance Document for Feasibility Studies Under CERCLA	
Task #8	Description of Proposed Response	CH 1	Executive Summary
Task #9	Preliminary Remedial Technologies	CH 2	Develop a Range of Remedial Alternatives
Task #10	Development of Alternatives	CH 3	Conduct a Detailed Technical Evaluation
Task #11	Initial Screening of Alternatives	CH 4	Evaluate Institutional Requirements
Task #12	Evaluation of Alternatives	CH 5	Evaluate Protection of Public Health Requirements
		CH 6	Evaluate Environmental Impacts
Task #13	Preliminary Report	CH 7	Cost Analysis
Task #14	Final Report	CH 8	Summarize Alternatives
Task #15	Additional Requirements	CH 9	Feasibility Study Report Format

*Numbers in the boxes point to tasks considered in the Model Statement of Work for RI/FS under CERCLA Guidance issued February, 1985. See Appendix A.

**Endangerment assessments may be prepared at any point in the RI/FS process of enforcement of laws.

Attachment 2

ENDANGERMENT ASSESSMENTS FOR SUPERFUND ENFORCEMENT ACTIONS¹

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ABSTRACT

The Comprehensive Environmental Response, Compensation and Liability Act of 1980 (CERCLA) gave the Environmental Protection Agency (EPA) new responsibilities and powers to take actions in response to releases of hazardous substances into the environment which may present an imminent and substantial endangerment to the environment, or the public health or welfare.

In an action to abate an endangerment, an assessment is made of the hazards or potential hazards at a site according to methods outlined in the National Contingency Plan. Information needed to perform an endangerment assessment includes the site history and management practices, identification and quantification of hazardous substances at a site, and their likely transport and fate. Estimates of actual or potential human and environmental exposures are compared to toxicological data to describe the kind and degree of endangerment.

This paper discusses the many factors that should be considered in an endangerment assessment and stresses the need for strict quality assurance and sound scientific judgment.

¹ The information presented in the paper is based on the technical enforcement case development experiences of the authors.

² Contact to whom comments should be addressed:
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Attachment 3

Data Collection/Problem Characterization

Data Collection/Problem Characterization

I. Site Characterization

- A. physical description of the site
- B. geographical location
- C. demographic surroundings
- D. type of facility (landfill, incinerator, impoundment)
- E. management practices

II. Contaminants Found at the Site

- A. identity/type
- B. quantity
- C. form
- D. manner of disposal
- E. ambient levels

III. Factors Affecting Migration

- A. topography
- B. soil parameters
- C. geological parameters
- D. hydrological characteristics
- E. climate

IV. Environmental Fate of Contaminants

- A. physical and chemical degradation characteristics
- B. movement between environmental media
- C. hydrogeological/geochemical characteristics
- D. evidence migration

V. Hazard Identification (site/population specific)

- A. Toxicological evaluation, e.g.
 - organ toxicity, carcinogenic
 - mutagenic, teratogenic
 - neurotoxic, etc.

B. Impact Evaluation (actual)

1. Environmental impacts

- a. determination of need
- b. literature searches
- c. lab tests
- d. food chain studies
- e) environmental effect observation
 - stressed vegetation
 - wildlife or aquatic life morbidity/mortality
 - domestic animal morbidity/mortality
- f) natural resource damages

2. Public Health Impacts (actual)

a) health assessment/advisory (short-term)

- 1. determination of need?
- 2. literature searches
- 3. lab tests, pilot biological testing
- 4. testing of food chain contamination
- 5. health assessment document
- 6. health advisories

b) human health studies (long-term)

- epidemiological studies
- clinical studies
- registries

c) human health standards and criteria

Data Interpretation

I. Dose-Response Assessment (predictive)

- A. quantitative component of cancer mathematical modeling- probability
- B. ADI calculations for non-carcinogens

II. Exposure Assessment

- A. locate potential populations at risk of exposure
- B. determine routes and pathways of exposure for each in various environmental media, and environmental transport and fate data
- C. calculate maximum short-term dose and average dose expected over a lifetime

III. Risk Characterization (predictive)

- A. combining exposure, hazard and dose-response assessments for a specific site
- B. estimation of the magnitude of the public health problem at a particular site including Medical Panel concerns.

Risk Management

process of evaluating and selecting options; environmental, economic, social and political consequences may be considered

BIBLIOGRAPHY

Proposed Guidelines for Carcinogen Risk Assessment, EPA, 49 FR 84-30724 November 23, 1984.

Proposed Guidelines for Exposure Assessment, EPA, 49 FR 84-30723 November 23, 1984.

Proposed Guidelines for Mutagenicity Risk Assessment, EPA, 49 FR 84-30722 November 23, 1984.

Proposed Guidelines for the Health Assessment of Suspect Developmental Toxicants, EPA, 49 FR 84-30721 November 23, 1984.

Proposed Guidelines for the Health Risk Assessment of Chemical Mixtures, EPA, 50 FR 85-589 January 9, 1985.

Remedial Investigations Guidance Document, February 1985.

Interim Procedures and Guidelines for Health Risk and Economic Impact Assessments for Suspected Carcinogens, EPA, 41 FR 24102 May 25, 1976.

Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks, Report by the Work Group on Risk Assessment of the Interagency Regulatory Liaison Group, 44 FR 39858 July 6, 1979.

Guidelines and Methodology Used in the Preparation of Health Assessment Chapters of the Consent Decree Water Criteria Documents, Appendix C of Water Quality Criteria Documents: EPA, 45 FR 79347 November 28, 1980.

Appendix E: Response to Comments on the Human Health Effects Methodology for Deriving Ambient Water Quality Criteria, 45 FR 79368.

Endangerment Assessments for Superfund Enforcement Actions, HMCRI Compendium of Papers, November, 1984.

Risk Assessment and Management: Framework for Decision Making U.S. EPA, December 1984.

* Further references are forthcoming in the Feasibility Study Guidance Document, the Superfund Exposure Assessment Manual, the Superfund Public Health Evaluation Process: Procedures Manual, the Superfund Risk Evaluation Manual, and the Office of Research and Development Handbook for Performing Exposure Assessments.

Attachment 5

1. Physical Description of the Site and Site History

- a. geographic location
- b. management practices/site use/site modifications
- c. chronological survey
- d. facility description/containment systems
- e. substances brought on site (identity, quantity, form manner of disposal)

2. Site Contamination/Off-Site Contamination

- a. identity of substances detected
- b. concentration of substances detected
- c. analytical methodology and QA/QC
- d. survey of environmental monitoring studies (detailed discussion of environmental media and contamination levels)

3. Environmental Fate and Transport

- a. physical-chemical properties of specified chemicals/ substances (e.g., soil/sediment adsorption coefficients, vapor pressures, solubility, etc.)
- b. photodegradation rates, decomposition rates, hydrolysis rates, chemical transformations, etc.
- c. local topography
- d. description of the hydrological setting and flow system
- e. soil analyses
- f. climatic factors, other factors affecting fate and transport
- g. prediction of fate and transport (where necessary using modeling methods)

4. Toxicological Properties (hazard identification)

- a. metabolism
- b. acute toxicity
- c. subchronic toxicity
- d. chronic toxicity
- e. carcinogenicity
- f. mutagenicity
- g. teratogenicity/reproductive effects
- h. other health effects as relevant including neurotoxicity, immuno-depressant activity, allergic reactions, etc.
- i. epidemiological evidence (chemical specific or site specific)
- j. aquatic/non-human terrestrial species toxicity/ environmental quality impairment
- k. human health standards and criteria

5. Exposure Assessment

- a. demographic profile of populations at risk including subpopulation at special risk
- b. background chemical exposures
- c. life style and occupation histories
- d. population macro-and micro-environments
- e. exposure routes
- f. magnitude, source, and probability of exposure to specified substances

6. Risk Evaluation and Impact Evaluation

- a. carcinogenic risk assessment
- b. probability of non-carcinogenic human health effects
- c. non-human species risk assessment
- d. environmental impacts/ecosystem alterations

7. Conclusions

8. Documentation (Appendices)