Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping

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Cumulative Risk Assessment-Planning and Scoping

Section I. Introduction

The practice of risk assessment within the Environmental Protection Agency (EPA) is evolving away from a focus on the potential of a single pollutant in one environmental medium for causing cancer toward integrated assessments involving suites of pollutants in several media that may cause a variety of adverse effects on humans, plants, animals, or even effects on ecological systems and their processes and functions.

In recent years, EPA's risk assessment emphasis has shifted increasingly to a more broadly based approach characterized by greater consideration of multiple endpoints, sources, pathways and routes of exposure; community-based decisionmaking; flexibility in achieving goals; case-specific responses; a focus on all of the environmental media; and significantly, holistic reduction of risk (Table 1). This more complex assessment involves cumulative risk assessment. It is defined in each case according to who or what is at risk of adverse effects—from identifiable sources and stressors—through several routes of exposure over varied time frames.

Table 1. Transition in EPA Risk Assessment Characteristics

Old	**New**
Single Endpoint	Multiple Endpoints
Single Source	Multiple Sources
Single Pathway	Multiple Pathways
Single Route of Exposure	Multiple Routes of Exposure
Central Decision-making	Community-based Decision-making
Command and Control	Flexibility in Achieving Goals
One-Size-Fits-All Response	Case-Specific Responses
Single Media-focused	Multi-media Focused
Single Stressor Risk Reduction	Holistic Reduction of Risk

This evolution has occurred at an uneven pace, propelled at times by the public and by Congressional concern about environmental risks and their cumulative effects; and, it has been restrained in some cases by statutory authority or limitations of technical knowledge, data and resources.

The scope of Agency risk assessments describes the currently identifiable context of the environmental risk that will (or can) be analyzed. It is defined according to *who* or *what* is at risk of *adverse effects* from identifiable *sources* and *stressors* through several *routes of exposure* over varied *time frames* (see Section V, Risk Assessment Terminology). A review of possible risk dimensions (shown in italics in the previous sentence) done at the beginning of the assessment can help to define its scope and how the risks will be integrated.

The term "cumulative risk assessment" covers a wide variety of risks. Currently, EPA assessments describe and where possible quantify the risks of adverse health and ecological effects from synthetic chemicals, radiation, and biological stressors. As part of planning an integrated risk assessment, risk assessors must define dimensions of the assessment, including the characteristics of the population at risk. These include individuals or sensitive subgroups which may be highly susceptible to risks from stressors or groups of stressors due to their age (for example, risks to infants and children), gender, disease history, size, or developmental stage. There are other risk issues, dimensions and concerns, however, that this guidance cannot address, at this time. This broader set of concerns, recognized as potentially important by many participants in the risk assessment process, relate to social, economic, behavioral or psychological stressors that may contribute to adverse health effects. These stressors may include—among other factors—existing health condition, anxiety, nutritional status, crime, and congestion. Currently, assessment of this broader perspective of risk is very difficult due to major deficiencies in: the data establishing plausible cause and effect relationships; capability to measure exposure to such risks, and understand their incidence and individual susceptibilities; availability of methods for assessing such risks; and techniques or approaches to manage them.

On the important topic of special subpopulations, EPA and others are giving more emphasis to the sensitivities of children and to gender-related differences in susceptibility and exposure to environmental stressors. New legislation requires that the Agency expand its historical approaches to determining human exposures and health impacts to improve our understanding of gender-related differences. It is the goal of the Agency to address gender- specific issues and use gender- and age-differentiated data, whenever it is appropriate and available, in Agency risk assessments and risk management decisions. Likewise, the Agency will pursue further research to provide this kind of information and address relevant data gaps once they are identified.

In this guidance, therefore, EPA will focus initially on risk assessments that integrate risks of adverse health and ecological effects from the narrower set of environmental stressors noted above. For the longer term, the Agency is focusing on research to improve integrated risk assessments as well as stakeholder and scientific community outreach efforts on the broader set of concerns. For example, pilot projects such as the Office of Prevention, Pesticides and Toxic Substances Baltimore Project and the Office of Policy Planning and Evaluation's Cumulative Exposure Project will likely lead to new ways to incorporate qualitative factors, also mentioned above, into our integrated risk assessment process.

Recommendations from the National Research Council's (NRC) "Understanding Risk: Informing Decisions in a Democratic Society" and a report from the Commission on Risk Assessment and Risk Management suggest that a variety of experts, including economists and social scientists, and stakeholders must be involved throughout the environmental risk assessment and risk management process. This guidance also recommends involving experts and stakeholders in the planning and scoping of risk assessments. The Agency is engaged in several activities that involve working with stakeholders. Experience from these activities will provide the solid basis for engaging interested and affected parties in risk assessment and risk management issues.

As it evolves, this guidance is designed to help risk managers and risk assessors plan and document the scope of risk assessments and to consider appropriate participants (that is, technical, advisory, or stakeholder) or information sources to enrich the risk assessment. Additionally, it augments the Agency's March 1995 Policy for Risk Characterization by providing a clear, transparent, reasonable, and consistent basis for any assessment. Regions and Program offices are strongly encouraged to undertake a formal problem formulation exercise for all risk assessments.

Section II. Key Characteristics of a Process for Integrating Environmental Risks

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Agency risk assessors and risk managers need to make judgments early in planning major risk assessments regarding the purpose, scope, and technical approach (that is, the conceptual model) by evaluating the full range of discernible human health and ecological dimensions of risk (that is, stressors, sources, effects, exposed populations, pathways of exposure, and time frames of risks). Agency managers need to place special emphasis on *cumulative risk* (that is, the potential risks presented by multiple stressors in aggregate). The specific elements of risk evaluated need to be determined as an explicit part of the Planning and Scoping (PS) stage of each risk assessment. During PS, risk assessors, such other technical experts as ecologists, toxicologists, economists and engineers, and risk managers work together as a team, inform by stakeholder input, to determine:

1. the overall purpose and general scope of the risk assessment;

2. the products needed by management for risk decision-making;

3. the approaches, including a review of the risk dimensions and technical elements that may be evaluated in the assessment (see sections III and IV);

4. the relationships among potential assessment end points and risk management options and;

5. an analysis plan and a conceptual model;

6. the resources (for example, data or models) required or available;

7. the identity of those involved and their roles (for example, technical, legal, or stakeholder advisors); and

8. the schedule to be followed (including provision for timely and adequate internal, and independent, external peer review).

Due to the current state of the practice and limited data, the aggregation of risks may often be based on a default assumption of additivity. The Agency will support research to improve our understanding of cumulative risks and to develop methods to account for the multiple elements of risks that affect humans, animals, plants and their environment. In addition, the Science Policy Council will support workshops for risk assessors and managers to discuss implementation opportunities and problems, and solutions.

To aid those involved in developing this planning and scoping process (including risk assessors, risk managers, ecologists, toxicologists, economists and other social scientists) an outline has been developed (see Section IV of this guidance) listing six dimensions of risk (that is, sources, stressors, pathways or routes, populations, endpoints and time frames) and specific elements that will be considered for evaluation in major risk assessments[1] . This outline of risk dimensions and elements is part of a systematic approach in which risk managers and technical experts develop a specific, yet broadly-based, conceptual plan for major risk assessments.

The conceptual model (mentioned above) is a description or diagram, of the relationship between the predicted responses of a population (or entity of concern) and its stressors laying out the environmental pathways and routes of exposure in the context of the assessment. The analytical plan needs to show how data sources and information will be used and integrated in the assessment and how measurement endpoints and uncertainties are related to the assessment endpoints. Decisions on the purpose, scope and conceptual plan must be summarized and attached to the final risk assessment. The conceptual plan must be available for peer review before major risk assessments are completed.

[1] Major assessments are defined here as those that require a Regulatory Impact Analysis or external peer review.

Section III. Implementation Tasks

Planning and scoping involves several steps that are described in this paper (see EPA (1996) for a more complete discussion of the steps). The planning and scoping process involves specific participants and processes. In the first step, a risk assessment dialogue among the risk manager, risk assessors, economists, and other technical experts should develop the broad dimensions and elements of the risk assessment, the management goals for the assessment, a tentative budget and schedule, and an approach for conducting the risk assessment. The overall approach for integrated risk assessment and management is shown in Figure 1. This figure shows that stakeholders (interested or affected parties) need to be involved in the process. The NRC in "Understanding Risk: Informing Decisions in a Democratic Society" and a draft report from the Commission on Risk Assessment and Risk Management recommend that stakeholders be involved throughout the process. The Agency is engaged in several activities that involve stakeholders in risk assessment and in the risk management decision process. Risk managers must decide on a case by case basis when and how stakeholders can be involved.

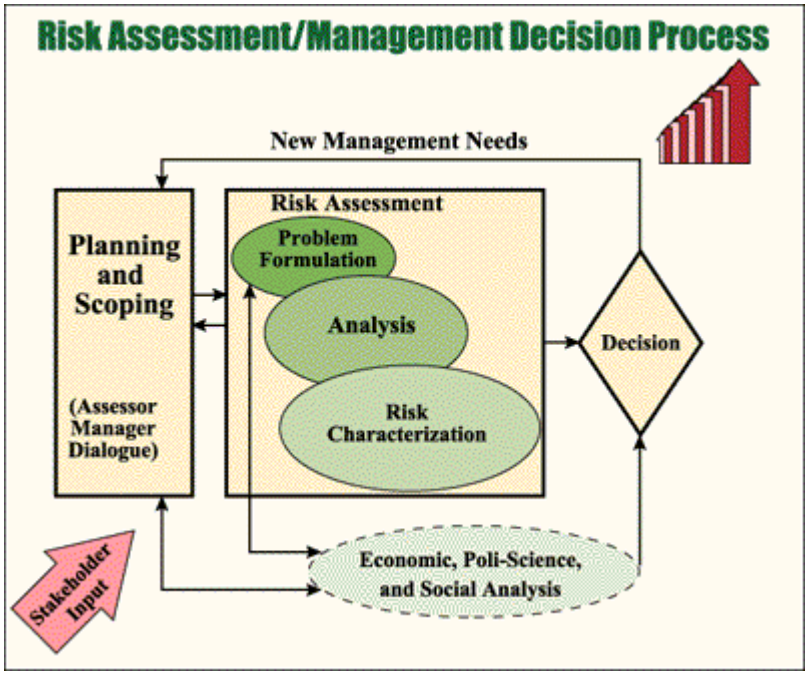

Figure 1 Stages in the integrated Risk Assessment Process

Risk Assessment Planning Dialogue

Task 1. Define the purpose for performing the risk assessment.

The risk manager must explain clearly why the assessment is being performed and what questions need to be addressed. The manager must also advise the assessors, economists, engineers, and other contributing experts on the planning team of any interested party, affected party, or policy interests to be considered in the context of the risk issue. These factors may influence the risk management options, management goals, key participants, data sources, selection of assessment endpoints, or the schedule for the developing the assessment. The manager and assessment planning team must discuss any regulatory basis for the risk assessment and what kind of information is required to satisfy such requirements.

Task 2. Define the scope of the risk assessment.

Initially, the risk assessor and manager (and the planning team) need to evaluate and select the kind of risk information, exposure scenarios and assessment issues that need to be covered. At this point, most EPA assessments focus on technical information related to the sources, effects, populations and the routes of exposure. Reasons to limit the technical scope of the assessment must be stated explicitly and must include details on limitations on resources, data, the impact of risk elements on the risk estimate, and methods available. In cases where an element of risk is likely to be important, but no valid data are available, the assessor must highlight this deficiency or use judgement or assumed values to approximate the missing data. Such judgements and approximations must be noted clearly and explained to the manager in the risk characterization.

Task 3. Develop a Cumulative Risk Outline

Use the example outline (section IV, or other appropriate and documented outline of risk dimensions and elements) to develop through brainstorming the specific elements that may be relevant to each dimension of the risk . In practice, *cumulative risk* as a term **must** be defined in each particular case in the context of the elements that will or will not (as well as can or cannot)

be included in the risk assessment. This is done through a planning and scoping process that considers the following dimensions:

A. Who, what or where is being affected or stressed?

B. What are the stressors?

C. What are the sources?

D. What are the environmental pathways and routes of exposure?

E. What are the relevant time frames?

F. What are the assessment endpoints?

For example, one could attempt to assess:

- **cumulative** acute and subchronic health **risk** to field workers' infants and toddlers in farm communities to organophosphate pesticide exposure (that is, through respiratory dermal, dietary and non-dietary ingestion) resulting from agricultural and residential uses in light of the nutritional status of field worker families; or
- **cumulative** ecological **risk** to the survival and reproduction of populations of blue crabs or striped bass in the Chesapeake Bay resulting from water and air emissions from both urban and agricultural sources.
- **cumulative risk** under the Food Quality Protection Act may be defined using terms such as aggregate exposure (that is, the exposure of consumers, manufacturers, applicators, and other workers to pesticide chemical residues with common mechanisms of toxicity through ingestion, skin or inhalation from occupational, dietary, and non-occupational sources) or cumulative effects (that is, the sum of all effects from pesticide chemical residues with the same mechanism of toxicity).

Participants and Process. The risk assessor and the risk manager need to review the outline initially to identify elements that may be included. Once the possibilities (that is, the elements of each dimension of the outline) have been identified through initial brainstorming, the risk assessor should indicate who could assist with technical information and how such information may affect the overall uncertainty of the assessment. The risk manager and assessor must determine what elements will and will not (or, can and cannot) be included in the risk assessment. Information gathered at this stage is preliminary and may be modified during the analysis phase.

Product. Ultimately, after iteration, this stage likely will produce a well-developed outline of cumulative risk possibilities (that is, a combining of the elements under each dimension) and document what is included and what is left out of the risk assessment, with an explanation of the reasons for the latter. The outline and rationale need to be available for risk characterization.

Task 4. **Problem Formulation** (the Technical Approach)

Problem formulation is an iterative process within which the risk assessor develops preliminary hypotheses about why adverse effects might occur or have occurred. It provides the foundation for the assessment. The *analytical plan* is used in defining the work required in the risk assessment and how the risks will be integrated.

Conceptual models are used to represent the predicted responses of populations to stressors to which they are exposed. The model is developed by the risk assessor and may include input from other experts (including stakeholders). The model needs to distinguish between what is known or

determined and what is assumed or based on default values. Also, it needs to include a discussion of uncertainties in the formulation of the assessment. In some cases, conceptual models will be submitted for peer review.

Players and Process. Although the development of a conceptual model is inherently a technical process, the selection of assessment endpoints should use input from the interested and affected parties either directly or by a summary of their opinions and concerns. Assessment endpoints should also be discussed with economists.

Product. The principle outputs from this stage are assessment endpoints that are related to the management objectives, the plan for analysis of the risk, and the conceptual model. These final products are summarized in the description of the risk assessment dialogue outcomes (the planning, scoping, and problem formulation tasks) required by this guidance. The conceptual model has features of both a scientific hypothesis and of a work plan. For a major assessment—for example, on dioxin, mercury, or pollutants with controversial methodological or scoping issues—this model needs to be peer reviewed.

Section IV. An Outline of Risk Dimensions and Elements

This outline is intended to help risk managers, risk assessors, economists, engineers and other experts discuss the technical dimensions and specific elements that might apply to a particular risk assessment. This outline can be used as a checklist to note how the risk assessment will be framed in terms of the sources, stressors, pathways, population, endpoints, and time frames. It can also be used to plan the risk assessment with the risk manager and explain the scope of the risk assessment to the interested and affected parties. The next step is the technical approach (also called Problem Formulation in the Agency's draft Ecological Risk Assessment Guidelines), a process in which the analysis plan and preliminary hypotheses about the relationship between stressors and effects on populations are developed in a conceptual model. This model needs to be peer reviewed.

For the purposes of this outline, six dimensions are used: sources, stressors, pathways, population, endpoints, and time frames. Each dimension is defined below by a question; and, some of the most likely answers are listed as elements for the risk assessment.

Dimension A. Population
("Who /What/Where is at Risk?")

1. Humans
    - a. Individual
    - b.General population distribution or estimation of central tendency and high end exposure
    - c. Population subgroups
        - (1) Highly exposed subgroup (for example, due to geographic area, age group, gender, racial or ethnic group, or economic status)
        - (2) Highly sensitive subgroups (for example, asthmatics or other pre-existing conditions, age, gender)
2. Ecological Entities
    - a. Groups of individuals
    - b. Populations
    - c. Multiple species

d. Habitats or ecosystems

3. Landscape or Geographic Concerns
    a. Groundwater aquifers
    b. Watersheds (that is, surface water bodies and their associated terrestrial ecosystems)
    c. Airsheds
    d. Regional ecosystems
    e. Recreational lands

Dimension B. Sources

(What are the Relevant Sources of Stressors?)

1. Single source
    a. point sources (for example, industrial or commercial discharge, superfund sites)
    b. non-point sources (for example, automobiles, agriculture, consumer use releases)
    c. natural sources (for example, flooding, hurricanes, earthquakes, forest fires)
2. Multi-sources (Combinations of those above)

Dimension C. Stressors

(What are the Stressors of Concern?)

1. Chemicals
    a. Single chemical
    b. Structurally related class of substances
        (1) Individual substances (that is, only one is present at a time)
        (2) Existing in a mixture
    c. Structurally unrelated substances with similar mechanism of impact and/or same target organ
        (1) Individual substances
        (2) Existing in a mixture
    d.Mixtures (that is, dissimilar structures or dissimilar mechanisms)
2. Radiation
3. Microbiological or biological (these range from morbidity to ecosystem disruption)
4. Nutritional (for example, diet, fitness, or metabolic state)
5. Economic (for example, access to health care)
6. Psychological (for example, knowledge of living near uncertain risks)
7. Habitat Alteration (for example, urbanization, hydrologic modification, timber harvest)
8. Land-use changes (for example, agriculture to residential, public to private recreational uses)
9. Global climate change
10. Natural Disasters (for example, floods, hurricanes, earthquakes, disease, pest invasions)

Dimension D. Pathways

(Environmental Pathways and Routes of Exposure. "What are the Relevant Exposures?")

1. Pathways (recognizing that one or more may be involved)
    a. Air
    b. Surface Water
    c. Groundwater
    d. Soil
    e. Solid Waste
    f. Food
    g. Non-food consumer products, pharmaceuticals
2. Routes of Human and single species exposures

a. Ingestion (both food and water)
b. Dermal (includes absorption and uptake by plants)
c. Inhalation (includes gaseous exchange)
d. Non-dietary ingestion (for example, "hand-to-mouth" behavior)

3. Routes of Exposure within communities and ecosystems
a. Direct Contact or ingestion (without accumulation)
b. Bioaccumulation
c. Biomagnification
d. Vector transfers (for example, parasites, mosquitoes)

Dimension E. Endpoints

(What are the assessment endpoints?)

1. Human Health Effects (for example as based on animal studies, morbidity and disease registries, laboratory and clinical studies, or epidemiological studies or data)
a. Carcinogenic
b. Neurotoxicologic
c. Reproductive dysfunction
d. Developmental
e. Cardio-vascular
f. Immunologic
g. Renal
h. Hepatic
i. Others

2. Ecological Effects
a. Population or Species
(1) Loss of fecundity
(2) Reduced rate of growth
(3) Acute or Chronic toxicity
(4) Change in biomass
b. Community
(1) Loss of species diversity
(2) Introduction of an exotic species
(3) Loss of keystone species
c. Ecosystem
(1) Loss of a function (for example, photosynthesis, mineral metabolism)
(2) Loss of habitat structure
(3) Loss of a functional group of organisms (for example, grazers, detritivores)
(4) Climate change (for example, sunlight, temperature change)
(5) Loss of landscape features (for example, migration corridors, home ranges)

Dimension F. Time frames
(What are the Relevant Time Frames: Frequency, Duration, Intensity and Overlap of Exposure Intervals for a Stressor or Mixtures of Stressors)?

1. Acute
2. Subchronic
3. Chronic or effects with a long latency period
4. Intermittent

Section V. Risk Assessment Terminology

This is a partial list of risk assessment terms that often associated with risk assessment practice. The list is not exhaustive, but it does include terminology used in this guidance and other terms that are closely related to the planning and scoping of risk assessments.

Agent-Suter et al. (1994) suggested it as an alternative for the term stressor. It is considered to be more neutral than stressor, and is used in EPA's Guidelines for Exposure Assessment.

Aggregate exposure - the sum of exposures to pesticide chemical residues with a common mechanism of toxicity from multiple sources and multiple routes of exposure (Food Quality Protection Act, 1996).

Analysis- The analytical phase of the risk assessment in which the potential for adverse effects are calculated based on the hazard identification, dose-response assessment, and the exposure assessment.

Assessment endpoint- functions or characteristics of a group or population of people or organisms (such as reproduction, growth, and lack of disease) that can be measured in relation to the intensity or concentration of a stressor.

Comparative Risk Assessment- A process that generally uses an expert judgement approach to evaluate the relative magnitude of effects (relative risk) and set priorities among a wide range of environmental problems (US EPA, 1993b). In some cases this may be done as a preliminary risk assessment.

Cumulative Risk Assessment- involves the consideration of the aggregate ecologic or human health risk to the target entity caused by the accumulation of risk from multiple stressors, [multiple pathways, sources] (US EPA, 1995).

Cumulative effects- 1) the sum of all environmental effects resulting from cumulative impacts (Liebowitz et al., 1992), and 2) the combination of effects from all pesticide chemical residues which have a common mechanism of toxicity (Food Quality Protection Act, 1996).

Cumulative impacts--the sum of all individual impacts occurring over time and space, including those of the foreseeable future (CEQ, 40 CFR Sect. 1508.7)

Conceptual model- a diagram or written description of the predicted key relationships between the stressor(s) and the assessment endpoint(s) for a risk assessment.

Disturbance-(See physical stressor) any event or series of events that disrupts ecosystem, community, or population structure and changes resources, substrate availability, or the physical environment.

Environmental Impact Assessment- an assessment required by the National Environmental Policy Act to evaluate fully potential environmental effects associated with proposed federal actions.

Exposure-the contact or co-occurrence of a stressor with a receptor.

Integrated Risk Assessment- a process that combines risks from multiple sources, stressors, and routes of exposure for humans, biota and ecological resources in one assessment with a defined point of focus (See also cumulative risk assessment).

Receptor-the entity which is exposed to the stressor.

Relative Risk Assessment- a process that involves estimating the risks associated with stressors or management actions that often uses qualitative risk techniques.

Source- an entity or action that releases to the environment or imposes on the environment chemical, biological, or physical stressor or stressors.

Stakeholder - a person, group of people, an organization (public or private), a business, or other party that has an interest in terms of knowledge or jurisdiction or is affected in terms of their health, property rights, or economy by an environmental risk (s).

Stressor- Any physical, chemical, or biological entity that can induce an adverse response.

Stress Regime- (1) a characterization of multiple exposures to stressors, (2) a synonym for exposure, or (3) a series of interactions of exposures and effects resulting in secondary effects. Because of its potential for confusion, the term is not used in guideline documents.

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