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Review

Cumulative risk assessment lessons learned: A review of case studies and issue papers

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HIGHLIGHTS

- Authors identify six lessons learned from ten US EPA cumulative risk assessments.
- Due to a population focus cumulative risk assessments need engaged stakeholders.
- Tiering can focus the scope of cumulative risk assessments and prioritize stressors.
- An iterative approach for cumulative assessments reduces complications of multiple stressors.
- Quantifying risks in vulnerable populations is important, but data gaps remain.

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ABSTRACT

Cumulative risk assessments (CRAs) examine potential risks posed by exposure to multiple and sometimes disparate environmental stressors. CRAs are more resource intensive than single chemical assessments, and pose additional challenges and sources of uncertainty. CRAs may examine the impact of several factors on risk, including exposure magnitude and timing, chemical mixture composition, as well as physical, biological, or psychosocial stressors. CRAs are meant to increase the relevance of risk assessments, providing decision makers with information based on real world exposure scenarios that improve the characterization of actual risks and hazards. The U.S. Environmental Protection Agency has evaluated a number of CRAs, performed by or commissioned for the Agency, to seek insight into CRA concepts, methods, and lessons learned. In this article, ten case studies and five issue papers on key CRA topics are examined and a set of lessons learned are identified for CRA implementation. The lessons address the iterative nature of CRAs, importance of considering vulnerability, need for stakeholder engagement, value of a tiered approach, new methods to assess multiroute exposures to chemical mixtures, and the impact of geographical scale on approach and purpose.

Abbreviations: BMD_{10}, benchmark dose estimate for 10%; CAG, Common Assessment Group; CEP, Community Environmental Partnership; CRA, cumulative risk assessment; CRPF, cumulative relative potency factor; DBP, disinfection by-product; EPA, Environmental Protection Agency; ERA, ecological risk assessment; FQPA, Food Quality Protection Act; HAP, hazardous air pollutant; HI, hazard index; HQ, hazard quotient; ICED, index chemical equivalent dose; MOA, mode of action; NATA, National-Scale Air Toxics Assessment; OP, organophosphorus pesticides; OPP, Office of Pesticide Programs; RAIMI, Regional Air Impact Modeling Initiative; ReVA, Regional Vulnerability Assessment; RPF, relative potency factor.

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Contents

1. Background and purpose

Evaluations of environmental hazards and human health risks are expanding from single chemical or simple chemical mixture approaches to more comprehensive approaches that examine risks posed by exposures to multiple stressors, including chemical, physical, biological, and psychosocial stressors. Traditional environmental risk assessment approaches focus on chemical or microbial hazards, independently of other hazards or stressors. Attempting to analyze "real world" exposures and improve the accuracy of the characterization of risks, cumulative risk assessments (CRAs) examine human health and environmental risks from the perspective that populations are exposed simultaneously to multiple stressors via multiple exposure routes and pathways (Callahan and Sexton, 2007).

The U.S. Environmental Protection Agency (EPA) has long recognized the potential importance of expanding the focus of risk assessment activities beyond single chemicals (Browner, 1995). In 2003, the EPA published the *Framework for Cumulative Risk Assessment* (herein called the *Framework*) (US EPA, 2003b). The *Framework* defines cumulative risk as "the combined risks from aggregate exposures to multiple agents or stressors" and emphasizes considering population vulnerabilities. After its publication, the EPA initiated two efforts to amass information for developing CRA Guidelines. First, the EPA collected Agency assessments that addressed one or more aspects of CRA and examined the utility of the methods used in these CRA "case studies". Second, the EPA commissioned five issue papers that investigated key CRA topics deemed critical to understand and improve the accuracy of risks predicted by CRA methods.

2. Scope of the paper

This article describes six key "lessons learned" from the CRA case studies (Table 1) and issue papers (Table 2). While evaluating these individually to determine their contributions to critical aspects of CRA, we note that several of these lessons apply generally to risk assessment practices. The case studies highlight approaches that EPA program and regional offices and research programs developed to address risks posed by exposures to multiple stressors. They reflect varied geographic scales, including CRAs conducted at both national and community levels, and varied scope, with three evaluating ecological endpoints, six evaluating human health endpoints, and one evaluating both human health and ecological endpoints separately (rather than in an integrated manner).

The five issue papers (Table 2) investigated specific topics that include: articulating the challenges to conducting CRAs, evaluating combined health effects from multiple stressors, incorporating vulnerability into CRA, assessing environmental mixtures, and using biomarkers to inform CRA (Callahan and Sexton, 2007; DeFur et al., 2007; Menzie et al., 2007; Ryan et al., 2007; Sexton and Hattis, 2007).

3. Lessons learned from the case studies and issue papers

3.1. Lesson 1: iterative nature of CRA

EPA's *Framework* recognized that iteration would be essential in the conduct of CRAs. The three phases of a CRA -planning, scoping, and problem formulation; analysis; and risk characterization-would not always be conducted unidirectionally (US EPA, 2003b). As different types of stressors and population vulnerabilities are identified and associated risks are characterized, the need for additional data on interactions among stressors of interest, other stressors that could be related (e.g., cause same health effect), or population vulnerabilities may be recognized and require the collection of additional data or further analysis. Similarly, during the conduct of a CRA, unanticipated risk management options may become apparent that could entail additional analysis or reconsideration of the risk assessment approach. These are simple examples of the role that an iterative approach may have during a CRA. In its recommendations for improving the utility of risk assessment, the National Research Council (2009) also identified this as being an important risk assessment practice.

The *Clinch and Powell Valley Ecological Risk Assessment* exemplifies the iterative conduct of a CRA (Diamond et al., 2002; US EPA, 2002a). The assessment goal was to determine whether mining, urbanization, and agricultural activities in the watershed were adversely impacting fish and mussel species. The conceptual models for this assessment provided the following: (1) identify the exposed populations (i.e., fish, mussels); (2) identify possible sources of stressors (e.g., runoff from mining activities); (3) specify adverse effects (e.g., unacceptable losses of native fish); and (4) conceptualize the pathways by which the stressors impact assessment endpoints (e.g., runoff enters water bodies where fish reside). The relationships depicted in these conceptual models provided the initial inputs to the analysis plan. As the assessment progressed, unanticipated gaps were identified for specific stressor and effects data (e.g., a lack of water chemistry data prevented the analysis of relationships between water quality stressors and land uses, including urbanization). To overcome this challenge, the analytical approach was modified; nearby land-use activities along with habitat quality information served as surrogates for water quality stressor levels (US EPA, 2002a).