

I. EXECUTIVE SUMMARY - APPROACHES TO INTEGRATED RISK ASSESSMENT

The goals of chemical safety programs encompass the prevention, assessment, and management of both short-term and long-term adverse effects to humans and the environment resulting from the production, use, transport and disposal of chemicals. The tools used internationally to assess and manage the risks of chemicals on human health have generally developed independently from the tools used to assess risks to the environment for practical and historical reasons. However, with increased recognition of the need to protect both humans and the environment more effectively, an integrated approach to risk assessment that addresses situations of multichemical, multimedia, multiroute, and multispecies exposures holistically is needed.

The UNEP/ILO/WHO International Programme on Chemical Safety (IPCS), in collaboration with the US Environmental Protection Agency (US EPA), the European Commission (EC), the Organization for Economic Cooperation and Development Cooperation, and other international and national organizations developed a working partnership to foster the integration of assessment approaches to evaluate human health and ecological risks. The overall goal of this project was to promote international understanding and acceptance of the integrated risk assessment process. Three specific objectives were identified to meet this goal: 1) enhance understanding of the benefits of integration, 2) identify and understand obstacles to integration, and 3) engage key scientific organizations to promote discussion of an integrated approach to risk assessment.

The term "integration" can have many meanings, and several opportunities exist within risk assessment generically for integration. For this effort, integrated risk assessment was taken to be "a science-based approach that combines the processes of risk estimation for humans, biota, and natural resources in one assessment." Although risk from chemical exposures was a primary concern, this definition does not limit the integrated risk assessment process to evaluation of chemical risks. It did, however, focus the efforts of the project on the scientific issues and needs of integrated risk assessment, and away from the varied regulatory and jurisdictional mandates and processes of individual governmental agencies.

Two fundamental reasons for integrated risk assessment are: 1) to improve the quality and efficiency of assessments through the exchange of information between human health and environmental risk assessors; and 2) to provide more coherent inputs to the decision-making process. With respect to the latter, human health and ecological risk assessors often provide decision makers with inconsistent input that results in contradictory impressions of the nature of risks. This results from differences in approach that should be eliminated in an integrated approach.

A generic framework and associated documentation were developed to communicate how an integrated risk assessment could be conducted. Recognizing the similarities in risk assessment frameworks currently in use internationally, the integrated risk assessment framework is based on US EPA's framework for ecological risk assessment and its associated terminology (US EPA 1998). Ecological risk assessment frameworks have greater general applicability than do human health frameworks (or those environmental frameworks derived directly from human health frameworks) in that they 1) were developed to deal with a range of environmental stressors beyond toxic chemicals, 2) must describe the nature and role of the environment in the risk assessment process, and 3) must explicitly identify the endpoint to be assessed. Further, a well developed body of concepts and terminology exist in the literature treating ecological risk assessment that support integration.

The integrated framework consists of three primary assessment phases. During the first of these, *Problem Formulation*, the overall goals, objectives, scope, and activities of the assessment are delineated. The *Analysis* step consists of data collection and modeling exercises to characterize exposure in time and space, and to define the effects on humans and ecological systems resulting from exposure. The methods appropriate for the Analysis step may be stressor-specific, but also depend upon the nature of the systems identified to be at risk. Exposure and effect information are synthesized as estimates of risk in the *Risk Characterization* step. Ideally, these estimates are quantitative with respect to the level of risk expected under different exposure scenarios, although only qualitative estimates of risk may be possible in some circumstances. The integrated risk assessment framework treats the relationships among risk assessment, risk management, stakeholder input, and data collection activities in a general, parallel and concurrent manner. These activities may interact in various ways depending on the regulatory context and the nature of the assessment problem. Documentation developed to describe the framework details the purpose and activities of each assessment phase, identifies points of integration, describes perceived advantages of integration, offers examples clarifying key concepts, and defines relevant terminology. This integrated risk assessment framework received international peer review by diverse organizations and scientific experts prior to finalization.

Case studies were developed to help communicate the integrated risk assessment approach, to illustrate how assessments might be conducted, and to highlight the benefits of integration. Four assessment problems were selected for initial case study development based on 1) known linkages between human health and ecological effects and exposure to stressors, 2) the sufficiency of available knowledge of human and ecological effects, 3) the adequacy of information describing the stressor(s) and exposure to humans and ecological receptors, and 4) the degree of commonality in conceptual models relating stressors to ecological and human receptors with respect to time and spatial scale.

Using these criteria, the following case studies were developed by panels of scientific experts: 1) the risks of persistent organic pollutants (POPS) to humans and wildlife; 2) ultraviolet radiation effects on amphibians, coral, humans, and oceanic primary productivity; 3) risks of tributyltin and triphenyltin compounds; and 4) organophosphorous pesticides in the environment. Each case study describes integrated assessment activities relevant to all parts of the framework, identifying key points of integration, critical information needs, and the benefits of integration. Although not actual risk assessments from the standpoint of completeness and rigor of analysis, the intent behind their development was to demonstrate that integrated risk assessment leads to enhanced scientific understanding that facilitates high quality regulatory decisions, assists in the identification of emerging issues and therefore may be predictive, provides a resource-effective alternative to independent assessments, and improves the response time of regulatory decisions.

The concepts, approaches, and framework for integrated risk assessment were evaluated at an international workshop held in Ispra, Italy in April 2001. Sponsored by the IPCS and the EC, the overall objectives of the workshop were to promote international understanding and acceptance of integrated risk assessment as a decision support tool for environmental policy and regulation, and to identify the science needed to conduct integrated risk assessments. This workshop was attended by over 40 invited participants, representing diverse international and national organizations and expertise. Using the framework and four case studies to focus deliberations, workshop participants were asked to identify: 1) the benefits of and obstacles to integrated risk assessment, 2) the research needed to facilitate implementation of integrated risk assessment and how an integrated approach informs the international research agenda, and 3) mechanisms and actions that can be taken to facilitate practical application of integrated risk assessment by regulatory bodies.

A principle benefit of integrated risk assessment identified by workshop participants was the improved effectiveness of the assessment process through exploitation of shared data and models, and the transferability of knowledge of mechanisms and modes of actions across risk endpoints and stressors. Participants also concluded that there would be general reductions in assessment uncertainties, an increased likelihood of identifying unexpected and emerging risks, and reductions in overall assessment costs relative to independent ecological and health assessments. However, several obstacles hindering acceptance and implementation of integrated risk assessment were identified, including the traditional disciplinary barriers that exist between ecological and human health research and assessment that are emphasized by differences in terminology, and the institutional, political, and cultural barriers that are codified in law and regulation in most countries. Concern also was expressed that integrated risk assessments would be perceived as inherently more complex, and that they might result in higher costs initially as integrated assessment protocols are worked out. Few insurmountable barriers of a strictly technical nature were identified.

With respect to the research needed for effective integrated risk assessments, workshop participants identified harmonization of exposure characterization and surveillance methods and models as critical. Further, they recommended development of common risk

endpoints across taxa, and improved understanding of mechanisms of action at multiple scales of biological organization as means to improve extrapolations of data and information. Development of methods and measures that facilitate comparison of risks among endpoints was identified as a way to improve the value of assessment conclusions to risk management decisions. Participants also recommended development of improved cost/benefit methods both to support decision-making and to be used to demonstrate the benefits of integrated risk assessment.

Finally, workshop participants expressed their commitment to promote and facilitate acceptance and implementation of integrated risk assessment, suggesting that removal of terminological and other non-scientific barriers might be accomplished through integration of educational and training experiences. Enhanced funding of integrated risk research, and continued communication of the advantages and benefits of integrated risk assessment to key organizations and the scientific community as a whole were recommended as important in this regard. Several communication activities were suggested, ranging from presentation at scientific meetings and publication in the scientific literature, to development of a web-based clearinghouse of relevant information. We hope that these collaborative efforts of the IPCS, EC, and other international and national organizations will help to establish the foundation of internationally-accepted guidance for integration of risk assessment.