## Assessing Cumulative Impact and Risk – Approaches at the U.S. Environmental Protection Agency<sup>1</sup>

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The U.S. Environmental Protection Agency (EPA) has a mission and regulatory mandate to protect human health and the environment. EPA's primary role is to implement environmental laws by developing and enforcing national regulation. Cogent to the goals of this workshop, key environmental laws that EPA administers include the Clean Water Act, the Clean Air Act, and the Marine Protection, Research and Sanctuaries Act.<sup>2,3</sup> EPA also has a unique responsibility in the National Environmental Policy Act (NEPA) process, in that under the Clean Air Act, it is required to review and publicly comment on the environmental impacts of major federal actions. EPA's regulatory mission is supported by the research conducted by its Office of Research and Development.

In the late 1980s and early 1990s, EPA regulatory programs began adopting risk assessment as a primary decision informing tool for evaluating the potential impacts of anthropogenic stressors on humans and the environment. Ecological risk assessment is a process for evaluating the likelihood that adverse ecological effects will occur or are occurring as a result of exposure to one or more stressors (U.S. EPA 1992, 1998). It is intended to be a general, organizing process for science-based evaluations of the environmental consequences of human activity. Its concepts and approaches can be applied to problems involving any environmental stressor and the attributes of any species, community, or ecological system or process (the "assessment endpoint" in risk assessment parlance). As practiced historically by EPA (see Suter et al. 2003 for a history of ecological risk assessment), however, ecological risk assessment has been used for regulatory purposes primarily to inform decisions pertaining to the management of chemicals, and usually for single chemicals in isolation or classes of chemicals that act similarly. Further, the majority of past ecological risk assessments have focused on survival, reproduction or individual growth of organisms as their primary measures of effect. Such practices served EPA well in informing the actions that led to control of overt problems of chemical pollution.

Environmental policy and management goals in EPA regulatory programs are evolving. Ecological emphasis is shifting toward protection of populations, habitats, and whole ecosystems in the context of multiple stressors and their cumulative impacts. Parallel evolution is occurring with respect to human health risks. With these changes comes the need for more sophisticated risk assessment planning and methods, ones that can account for environmental complexity and

<sup>&</sup>lt;sup>1</sup> This abstract has not been subjected to Agency-level review, and therefore do not necessary reflect the views of the U.S. EPA. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

<sup>&</sup>lt;sup>2</sup> Although EPA has responsibilities under the Endangered Species Act, management of that Act is primarily the responsibility of the U.S. Fish and Wildlife Service.

<sup>&</sup>lt;sup>3</sup> EPA, under the Noise Control Act of 1972, had promulgated regulations that set maximum noise limits on a number of household, industrial and vehicular sources to protect against adverse effects on humans. However, primary responsibility for regulating noise was shifted to state and local governments in the early 1980s. Although the Noise Control Act and the Quiet Communities Act of 1978 were not rescinded by Congress and remain in effect today, they essentially are unfunded.

realistic context more effectively than can single-stressor, single-endpoint approaches. Assessments that consider the cumulative risks of multiple stressors provide the arrays of information needed to support the objectives of regulatory, resource management and conservation more comprehensively than do traditional single-stressor impact and risk assessments.

Many specific definitions of *cumulative impact or risk assessment* exist, but all reflect the notion of explicitly considering the aggregate impacts of multiple important agents or stressors on the endpoint or receptor of concern through time. In 2003, EPA released its Framework for Cumulative Risk Assessment (U.S. EPA 2003) to articulate an analytic-deliberative process and considerations for performing cumulative risk assessments (CRA) within the Agency. As with EPA's Framework for Ecological Risk Assessment (U.S. EPA 1992) before it, this process is intended to be applicable to broad array of environmental problems, and informative to a variety of environmental decisions, including those associated with NEPA. The basic steps of CRA (mirroring those of ecological risk assessment) are: 1) Planning, Scoping and Problem Formulation, within which the risk problem is defined and the assessment is planned; 2) Analysis, primarily an analytic process evaluating the risk problem at hand; and 3) Interpretation and Risk Characterization, focused on integration and interpretation of the results of the Analysis phase. Although CRA as framed by the Framework is oriented primarily toward human risk, its approach and considerations can serve as models for assessing cumulative risk to nonhuman receptors and populations, including marine mammals. EPA has begun a process of developing more explicit guidance for performing cumulative risk assessments, which is intended to be vetted and released in the near future.

Importantly, the CRA *Framework* identifies a number of research and development needs that address gaps in the knowledge and methodology required to perform CRA effectively. Included are methods for understanding the timing of exposure to stressors and its relationship to effects, methods for understanding how multiple stressors and their mechanisms of effect interact to result in risk, and methods for combining different types of risk. Such deficiencies in the science supporting CRA surely will affect our ability to assess the cumulative risk of noise and other stressors to marine mammal populations. However, because protection of populations necessarily requires appreciation of the contributions of multiple stressors to risk, increasing emphasis by EPA's Office of Research and Development and other organizations on development of tools to assess population-level risk to wildlife and aquatic life (e.g., U.S. EPA 2004, Munns 2004; also see Barnthouse et al. 2007) should continue to address these deficiencies.

## References

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