LONG-TERM GOAL 4 Evaluation of Public Health Outcomes

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Overview

Evaluating public health outcomes from risk management actions is clearly linked to assessing human health risks. Under an initiative begun by previous Administrator Whitman, EPA has started a process to better assess the "state of the environment" that may result from its policies and actions to improve environmental quality. A centerpiece of this effort has been the publication of an initial Draft Report on the Environment (ROE) (US EPA, 2003) that will be supplemented by periodic updates- the next edition is due in 2006. In the Health chapter of the ROE, a number of data gaps are identified that relate to the need for improved indicators of the actual public health impact associated with Agency decisions and actions. ORD has implemented a research initiative that will lead to the development and validation of such environmental public health indicators (EPHIs). These indicators, while complementing traditional process indicators such as decreases in emissions, discharges and pollutant levels in environmental media, are intended to reflect more closely the actual impact on public health that result from environmental decision-making and contribute to clarifying the benefits and costs associated with further incremental environmental improvements. The research program builds upon the current research programs in Human Health that improve the risk assessment process and improve the linkages discussed above.

The Long-Term Goal for research Evaluation of Public Health Outcomes is that risk assessors and risk managers use ORD's methods and models to evaluate public health outcomes, which in turn determines the effectiveness of Agency regulatory and risk management decision. The key questions that guide research in this area are

- What public health outcomes need to be examined to evaluate Agency regulatory decisions?
- What approaches are needed to evaluate (and attribute) changes in public health outcomes to Agency actions?
- Did Agency actions have an impact on public health outcomes?

Selected Examples of Research on Evaluation of Public Health Outcomes

The key to using outcome-based indicators is a clear understanding of the sequence of events that link changes in the environmental conditions to health. Critical to the eventual employment of outcome-based indicators is a clearer understanding of the sequence of events that link predictive changes in environmental conditions to health outcomes.

Understanding the determinants of the events that comprise this continuum and the linkages between them has always been a key priority for EPA. In fact, these determinants underlie the science upon which the Agency bases the risk assessment process for making regulatory decisions and implementing risk management actions for a given pollutant and/or condition. It is precisely the same understanding of this sequence of events and the attendant human health outcomes from which the Agency will draw in assessing the impact of regulatory decisions and actions. In addition, these insights will aid EPA in proactively identifying opportunities to protect public health. As Agency risk assessors and risk managers must consider the uncertainties associated with the risk assessment process, they must increasing take into account the uncertainties associated with various risk management actions and their intended outcomes. The degree of certainty and directness of these links between source, exposure, and effect influence the validity of both types of determinations. If these linkages were better delineated scientifically, then the assessment of risk and the accurate prediction of risk management effectiveness would be greatly enhanced. To achieve such goals, the actual impacts will need to be measured to evaluate whether the predictions (or the prediction approach) are correct. The optimal approach is to compare a health condition (risk before and after the risk management action has been employed.

In considering the design and subsequent implementation of this research program, the methodologies that form the current state-of-the-science are recognized to be in varying stages of maturity. In many cases, a clear need for the development of the proper tools or assays may be required, hence the link to the three other areas of the Human Health Risk Research Program. The program has been initiated in FY05 with an

innovative approach through the solicitation of actions and policies to be considered for research in this program. ORD will form design teams to prepare proposals for scientific peer review. Based on available resources and a successful peer review projects will be initiated. ORD is also preparing to a solicitation for proposals from the academic community on research to development indicators through the linkage of existing databases.

Other activities supporting the Accountability program include the close consultation between EPA and the Centers for Disease Control and Prevention (CDC) on the National Environmental Information Network and National Environmental Public Health Tracking efforts, respectively. A memorandum of understanding (MOU) was established between CDC and EPA to partner in data sharing and exchange to help facilitate the development of a national environmental public health tracking network. ORD and the Office of Environmental Information have taken a lead role for EPA within this MOU agreement. The MOU's activities include working with partners to improve management and use of environmental and public health data, collaborate on e-commerce practices for sharing data, collaborate on development and validation of additional environmental public health indicators, and create a timely and reliable data access. The Public Health Air Surveillance Evaluation (PHASE) Project was established by this MOU. The PHASE Project is a collaboration between EPA (National Exposure Research Laboratory and Office of Air Quality, Standards, and Planning), CDC, New York State Department of Health, Maine Bureau of Health, and the Wisconsin Division of Public Health. The project's main goals are to link air quality characterization surveillance data with routinely available public health surveillance data and evaluate the advantages and limitations of this process including evaluating the different types of data used and the methods to link the data.

Two indicator efforts are already well underway and will benefit from both the Accountability Research effort and the joint PHASE program between EPA and CDC. Indicators are a major focus of the U.S.-Mexico Border program for which a draft strategic framework is being developed jointly with Mexico. An initial Request for Proposals has been issued through the Pan American Health Organization. The Report on the Environment (ROE) next report due out in 2006 continues evaluation of health

indicators proposed in the ROE, with a focus on providing information and evaluation of indicators on a regional scale. It is expected the Accountability program will provide better methods and tools for both the development new data for indicators as well as the further evaluation of current data that has not been used as an indicator.

The long-term strategy is that the Public Health Benefits program will continue to build upon research conducted in Use of Mechanistic Information in Risk Assessment, Aggregate and Cumulative Risk, and Susceptible Populations. The research will also be a centerpiece in bridging the chasm that has existed since the environmental community was separated from the traditional public health community in the 1970s when EPA was formed.

References

US EPA. Draft Report on the Environment. Office of Research and Development, Washington, DC, 2004. EPA 600/R-03/050.

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Evaluating Public Health Outcome: An Overview

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Science Question:

This research addresses several science questions, including the following:

- What public health outcomes need to be examined to evaluate Agency regulatory decision?
- What public health outcomes need to be examined to evaluate Agency regulatory decision?
- What approaches and tools are needed to evaluate and attribute changes in public health outcomes to Agency actions?
- Have Agency actions had an impact on public health outcomes?

The Research:

The overall goal of ORD's Public Health Outcomes Research Program is to develop tools and methodologies and apply those to evaluating the Agency's regulatory and environmental management program. Under an initiative begun by previous Administrator Whitman, the Agency has started a process to better assess the "state of the environment" that may result from its policies and actions to improve environmental quality. ORD has implemented a research program that will lead to the development and validation of such environmental public health indicators (EPHIs). These indicators, while complementing traditional process indicators such as decreases in emissions, discharges and pollutant levels in environmental media, are intended to reflect more closely the actual impact on public health that result from environmental decision-making and to help clarify the benefits and costs associated with further incremental environmental improvements. The current lexicon that is ascribed to this overall effort is accountability, i.e., the Agency's desire to be more accountable to the public in demonstrating true environmental progress. This research program is called the "Accountability Research Program".

A centerpiece of this effort has been the publication of an initial Draft Report on the Environment (ROE) in 2003 (EPA publication # 600-R-03-050) that will be supplemented by periodic updates- the next report is due in 2006. The report outlines the key to using outcome-based indicators is a clear understanding of the sequence of events that link changes in the environmental conditions to health. Critical to the eventual employment of outcome-based indicators is a clearer understanding of the sequence of events that link predictive changes in environmental conditions to health outcomes. In the Health chapter of the ROE, a number of data gaps are identified that relate to the need for improved indicators of the actual public health impact associated with Agency decisions and actions.

ORD has identified three strategic objectives for the Accountability Research Program. First, research is needed to develop improved linkages across the source to outcome continuum. Understanding those linkages will better identify appropriate methodologies and approaches to making public health benefit evaluations. Key to accomplishing the work in the first objective will be the development of tools, assays, study methodologies or models that will allow the better understanding of the linkages in the source to outcome continuum. The programs in the first and second objective will be essential to conducting work in the third objective in actually conducting studies that attempt to quantify public health benefit associated with Agency action. ORD has solicited from regions and program offices proposed policies, regulations, or other Agency action that was based on some predicted human health risk. Design teams have been formed to design studies to evaluate those proposed actions. ORD is in the process of selecting the first projects to be completed under this research program.

Impact and Outcomes:

- Research on public health outcomes is a relatively new effort in ORD.
- This research is a key component in the Agency's ability to protect the human health and the environment.
- With the advent of the Government Program Review Act, it is critical for the Agency to be able to demonstrate measures of success.
- Research on public health outcomes will provide the methods and models necessary to enable evaluation of actual public health outcomes for risk management actions.
- The Report on the Environment had identified data gaps and research needs to describe environmental conditions and human health concerns.