REPORT HIGHLIGHTS

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Review of EPA's Integrated Risk Information System (IRIS) Process

CHANGES TO THE IRIS PROCESS THAT EPA has proposed and implemented to various degrees in response to recommendations from the National Research Council constitute substantial improvements. If current trajectories are maintained, inconsistencies are addressed, and objectives still to be implemented are successfully completed, the IRIS process will become much more effective and efficient in achieving the program's basic goal of developing assessments that provide an evidence-based foundation for ensuring that chemical hazards are assessed and managed optimally.

Why did the National Research Council do this study?

Over the last decade, the National Research Council (NRC) has been asked to review some of the more complex and challenging of EPA's IRIS assessments, including those of formaldehyde, dioxin, and tetrachloroethylene. Several of the committees convened to conduct those studies identified deficiencies in some of EPA's general approaches and specific methods. The committee that produced the formaldehyde report, released in 2011, provided general suggestions for improving the IRIS process and a roadmap for its revision in case EPA decided to move forward with changes to the process.

After the release of the formaldehyde report, Congress held several hearings to examine the IRIS program, and then directed EPA to follow the NRC recommendations regarding general revisions to the IRIS methods. Congress requested this study to assess EPA's progress and to recommend modifications or additional changes as appropriate to improve the performance of the IRIS program. The study also reviews current methods for evidence-based reviews and recommends approaches for weighing scientific evidence for chemical hazard and dose-response assessments.

The Integrated Risk Information System (IRIS)

is a program within the US Environmental Protection Agency (EPA) that is responsible for developing toxicologic assessments of environmental contaminants. A wide range of federal agencies, various state and international agencies, and other organizations have come to rely on IRIS assessments for setting regulatory standards, establishing exposure guidelines, and estimating risks to exposed populations. At the request of Congress, this study evaluates EPA's progress in responding to recommendations from the National Research Council for improving the IRIS process.

EPA Has Strengthened the IRIS Process

Substantial improvements in the IRIS process have been made, and it is clear that EPA has embraced and is acting on the recommendations in the NRC formaldehyde report regarding general changes to the IRIS methods. The NRC formaldehyde committee recognized that its suggested changes would take several years and an extensive effort by EPA staff to implement, but substantial progress has been made in a short time.

EPA has made a number of positive changes to the IRIS process in response to general recommendations from the NRC. They have implemented a new document structure that streamlines the assessments, made greater use of evidence tables and graphic displays that improve clarity and transparency, added a standard preamble to all assessments that describes the IRIS process and its underlying principles, drafted a handbook that provides a more detailed description of the IRIS process, formed chemical assessment support teams (CASTs) to oversee the assessment-development process and ensure consistency among assessments, established tracking procedures, and implemented several initiatives to increase stakeholder input.

This study reviews the progress made at each of the specific steps in the IRIS process as depicted in Figure 1. Materials and examples provided by EPA indicate that the agency is incorporating systematic-review principles[1] into the IRIS process; the way

[1] A report released by the Institute of Medicine (IOM) in 2011 defined systematic review as "a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies."

systematic review fits into the IRIS process is shown in the figure. The study finds that EPA has made notable progress and is still in the process of making changes in many of the specific steps. Additional suggestions for further strengthening the IRIS process are provided in the report.

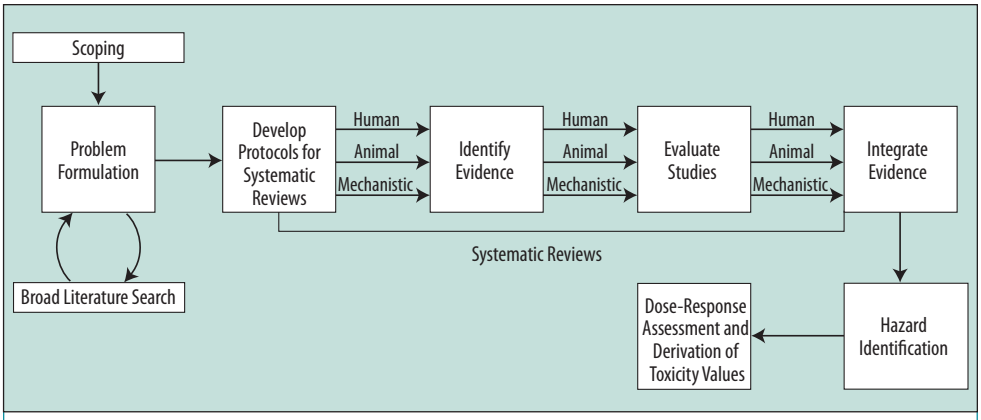

Figure 1. Steps in the IRIS process. The report's authoring committee views public input and peer review as integral parts of the IRIS process, although they are not specifically noted in the figure.

Future Directions

This study identifies three "lessons learned" from past IRIS reviews that are deemed critical for ensuring that the IRIS program provides the best assessments possible in the future:

1. **Assessment methods should be updated in a continuing fashion.** Even as the IRIS program undergoes revision, consideration needs to be given to how methods relevant to all elements of the process will evolve continuously and how relevant progress in toxicologic assessment and other domains will be tracked and incorporated.

2. **Inefficiencies in the IRS program need to be systematically identified and addressed.** Some of the most controversial assessments have had long histories with multiple cycles of revision and review. Although many factors that cause delay are beyond the program's control, EPA is urged to consider systematically how delay occurs so that it can be anticipated and addressed.

3. **Evolving competences that reflect new scientific directions are needed.** An IRIS assessment, by necessity, involves multiple scientific disciplines and requires attention to changing research methods and data streams. EPA management needs to continually evaluate whether its chemical-assessment teams have appropriate expertise and training.

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The National Academies appointed the above committee of experts to address the specific task requested by the U.S. Environmental Protection Agency. The members volunteered their time for this activity; their report is peer-reviewed and the final product signed off by both the committee members and the National Academies. This report brief was prepared by the National Research Council based on the committee's report.

EXPERT CONSENSUS REPORT

For more information, contact the Board on Environmental Studies & Toxicology at (202) 334-2347 or visit http://dels.nas.edu/best. Copies of *Review of EPA's Integrated Risk Information System (IRIS) Process* are available from the National Academies Press, 500 Fifth Street, NW, Washington, D.C. 20001; (800) 624-6242; www.nap.edu.