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Updated September 12, 2022

U.S. Environmental Protection Agency's Integrated Risk Information System (IRIS): Toxicity Assessment of Chemicals

The U.S. Environmental Protection Agency (EPA) established the Integrated Risk Information System (IRIS) program in 1985 to consolidate human health toxicity assessments that the agency had prepared in order to implement various pollution control statutes (e.g., Clean Air Act and Clean Water Act). Specific incidents, such as the 1984 leak of methyl isocyanate from a Union Carbide facility in Bhopal, India, reinforced the need for a better understanding of human health toxicity from exposure to various chemicals. Over time, findings from IRIS assessments have informed many different agency actions, including regulatory requirements that EPA has established under various pollution control statutes. Given that these actions may require regulated entities to incur significant compliance costs and determine the extent of health benefits, the process that EPA follows to conduct IRIS assessments and the findings of such assessments have received considerable attention.

EPA's IRIS program is not authorized explicitly in statute, but multiple pollution control statutes include general research provisions intended for the agency to generate information that may be useful in the implementation of such statutes. Additionally, EPA continues to receive annual appropriations to its Science and Technology (S&T) account that largely funds its research efforts, including the IRIS program.

EPA maintains a public IRIS website that provides more than 560 assessments on a range of chemicals. EPA completed more than 80% of these assessments before 1995. However, assessments completed more than 25 years ago may still be relevant if no new information is available to warrant a revision of the existing assessment.

Selection of Chemicals to Assess

EPA focuses on a select number of assessments at any given time. EPA staff managing the IRIS program select chemicals for IRIS assessments through a prioritization process, which involves soliciting internal input from EPA program and regional offices on which assessments may be useful and evaluating the extent to which resources and expertise are available to complete the assessments. EPA began issuing an *IRIS Program Outlook* in December 2018 to provide periodic updates on the development of IRIS assessments.

Assessments that examine multiple pathways of exposure (e.g., ingestion, inhalation, or direct contact) and potential associated health effects typically take many years to prepare. In some instances, EPA may decide to conduct an assessment with a more narrow scope, focusing on a specific pathway of exposure or health effect. According to EPA, this approach allows the agency to finalize an assessment more quickly. EPA's selection of which chemicals to assess has received scrutiny on occasion. For example, after some of EPA's announcements of upcoming IRIS assessments, observers have raised questions about whether the agency's plans reflect an appropriate assessment of high priorities. In some instances, EPA has withdrawn an initiated assessment before it is completed due to a change in priorities.

Assessment Process

Since 2016, EPA has included a preamble in each IRIS assessment that summarizes the objectives and scope of the IRIS program, general principles and systematic procedures used in developing assessments, and the overall development process and document structure. The preamble is accompanied by the preface, which is chemical-specific and describes procedures in the assessment that differ from the general procedures described in the preamble. In the preamble of each IRIS assessment since 2016, EPA describes seven steps for developing IRIS assessments: (1) draft development; (2) agency review; (3) interagency science consultation; (4) public comment, followed by external peer review; (5) assessment revision; (6) final agency reviews and interagency science discussion; and (7) post final assessment.

EPA staff preparing IRIS assessments may revisit prior steps of the process based on input from program and regional offices, other agencies, peer reviewers, or the public. The process, from start to finish for assessments completed since 2013, has typically spanned at least five years, with the ethylene oxide carcinogenicity assessment taking 17 years. EPA now states that it aims to complete an assessment within three years.

After selecting a chemical to assess and prior to developing a draft assessment, EPA generally prepares a series of documents that detail how the agency plans to develop the draft. EPA practice is to issue each of these documents for public comment, which may help to inform how the agency performs the assessment. The first document that EPA prepares for an assessment is the scoping document, which describes the chemical being assessed, potential routes and durations of exposure to examine, considerations for susceptible populations and different life stages, and other topics of interest. After receiving public comment for the scoping document and finalizing it, EPA prepares a problem formulation that identifies the scientific issues that the agency expects to address based on a preliminary literature search. Additionally, EPA generally identifies protocols that the agency intends to use for the specific

assessment. The problem formulation and description of protocols are published for public comment.

After the development of a draft IRIS assessment, the agency's IRIS staff generally seeks input on the draft from EPA program and regional offices, other federal agencies, external peer reviewers, and the public. Since 2014, EPA has submitted draft IRIS assessments to the Chemical Assessment Advisory Committee within its Science Advisory Board for external peer review. Final IRIS assessments generally include a list of authors, contributors, intra- and inter-agency reviewers, and external peer reviewers who contributed to the review of the assessment at various stages of its development.

After EPA posts a final assessment, the Information Quality Act (44 U.S.C. 3516 note) provides a mechanism for interested persons to request that EPA correct parts of the assessment that do not meet the agency's own *Information Quality Guidelines.* EPA has received requests for corrections to certain IRIS assessments. Generally, the agency has found that these requests reiterate concerns expressed and already considered earlier in the process. If EPA relies on the findings of a final IRIS assessment in rulemaking, that assessment becomes part of the rulemaking record, which is subject to public comment upon the proposal of the rule. Upon promulgation of a rule, the Administrative Procedure Act (5 U.S.C. 500 et seq.) and various environmental pollution control statutes provide the opportunity for judicial review of the rule, including the rulemaking record.

In January 2021, the U.S. Government Accountability Office (GAO) found that EPA has not produced timely assessments. GAO also noted that EPA has not identified the resources needed by the IRIS program to meet user needs for chemical assessments.

Use of Toxicity Information to Evaluate Risk

EPA may use the findings of IRIS assessments to inform various agency actions, including

- the registration of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act;
- the establishment of National Emission Standards for Hazardous Air Pollutants under the Clean Air Act;
- the establishment of Effluent Guidelines and Human Health Ambient Water Quality Criteria under the Clean Water Act;
- the establishment of a maximum contaminant level under the Safe Drinking Water Act; and
- the selection of screening levels and cleanup standards in the federal remediation of contaminated sites under the Comprehensive Environmental Response, Liability, and Compensation Act.

Congressional Action

Congress has included language focused on improving the IRIS program in explanatory statements accompanying multiple annual appropriations acts. For example, in the FY2001 appropriations process, Congress requested that EPA conduct "needs assessments" to determine the appropriate pace for completing IRIS assessments. Also, certain Members have requested GAO and EPA's Office of Inspector General examine aspects of EPA's IRIS program to provide recommendations for improving the program.

As part of the FY2018, FY2019, and FY2020 appropriations processes, the House and Senate Committees on Appropriations directed EPA to maintain funding for IRIS at FY2017 levels. The committees also urged expedited completion of an IRIS handbook and directed the agency to provide an opportunity for public comment on the IRIS handbook before formally adopting it for use. The IRIS handbook is intended to provide standard operating procedures for completing an IRIS assessment. Upon preparing a draft IRIS handbook, EPA requested the National Academies of Science, Engineering, and Medicine (NASEM) to review the procedures and considerations outlined in the handbook for completing an IRIS assessment. NASEM completed its review in November 2021, and EPA anticipates issuing a final IRIS handbook by 2023. For FY2022 appropriations, the House and Senate Committees on Appropriations directed EPA to "continue the IRIS program within the Office of Research and Development and to utilize the IRIS program to support the Agency's mission to protect human health and the environment."

Legislation in the 117th Congress

In the 117th Congress, one bill focuses on making changes to the administrative aspects of completing an IRIS assessment. H.R. 62 would amend Section 7 of the Environmental Research, Development, and Demonstration Act of 1978 (42 U.S.C. 4364) to decentralize IRIS assessment activities from EPA's Office of Research and Development to the agency's program and regional offices. H.R. 62 would also establish a hazard identification and dose-response steering committee within EPA to coordinate relevant assessments. These assessments would be subject to certain scientific standards.

Concluding Observations

In December 2018, EPA's IRIS program office announced its selection of 13 chemical assessments to prepare. The office also announced its plans to discontinue or suspend certain ongoing assessments not identified as priorities. Given limited resources to assess chemicals, EPA must choose specific assessments to complete over others. In some cases, prioritizing certain assessments may delay the dissemination of assessment findings that may help to inform specific agency actions. In June 2021, EPA announced it would reinitiate the development of four chemical assessments that had been previously suspended. Many past IRIS assessments have gained near-consensus approval, but others have led to disagreement among stakeholders. As a result, stakeholders are expected to continue their scrutiny of the program.

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IF11680

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