Basic Information about the Integrated Risk Information System

On this page:

EPA's mission is to protect human health and the environment. EPA's IRIS Program supports this mission by identifying and characterizing the health hazards of chemicals found in the environment. Each IRIS assessment can cover a chemical, a group of related chemicals, or a complex mixture. IRIS assessments are an important source of toxicity information used by EPA, state and local health agencies, other federal agencies, and international health organizations.

The IRIS Program is located within EPA's Center for Public Health and Environmental Assessment (CPHEA) in the Office of Research and Development (ORD). The placement of the IRIS Program in ORD is intentional. It ensures that IRIS can develop impartial toxicity information independent of its use by EPA's program and regional offices to set national standards and clean up hazardous sites.

- About the Center for Public Health & Environmental Assessment <https://epa.gov/aboutepa/about-center-public-health-and-environmental-assessment-cphea>
- About the Office of Research and Development <https://epa.gov/aboutepa/about-office-research-and-development-ord>

IRIS Toxicity Values

IRIS assessments provide the following toxicity values for health effects resulting from chronic exposure to chemicals.

More information on deriving RfD and RfC values can be found in *EPA's 2002 A Review of the Reference Dose and Reference Concentration Processes* <https://epa.gov/risk/review-reference-dose-and-reference-concentration-processes-document>.

Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark concentration, with uncertainty factors generally applied to reflect limitations of the data used.

Reference Dose (RfD): An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. It can be derived from a NOAEL, LOAEL, or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used.

More information on deriving cancer risk estimates can be found in *EPA's 2005 Guidelines for Carcinogen Risk Assessment* <https://epa.gov/risk/guidelines-carcinogen-risk-assessment>.

Cancer descriptors characterize the chemical as:

- Carcinogenic to Humans
- Likely to Be Carcinogenic to Humans
- Suggestive Evidence of Carcinogenic Potential
- Inadequate Information to Assess Carcinogenic Potential
- Not Likely to Be Carcinogenic to Humans

Oral slope factor **(OSF)** is an estimate of the increased cancer risk from oral exposure to a dose of 1 mg/kg-day for a lifetime. The OSF can be multiplied by an estimate of lifetime exposure (in mg/kg-day) to estimate the lifetime cancer risk.

Inhalation unit risk **(IUR)** is an estimate of the increased cancer risk from inhalation exposure to a concentration of 1 µg/m^3 for a lifetime. The IUR can be multiplied by an estimate of lifetime exposure (in µg/m^3) to estimate the lifetime cancer risk.

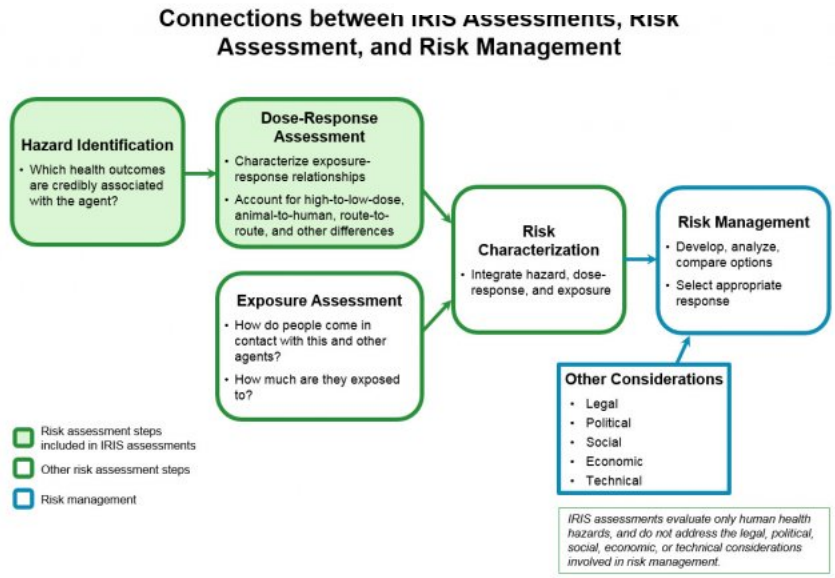
- Find other IRIS terminology in the IRIS Glossary.

What's the Role of IRIS Assessments in Risk Assessment?

Risk assessment is a four-step process described by the National Research Council (NRC) in 1983 as "the characterization of the potential adverse health effects of human exposures to environmental hazards." Characterizing risk involves integrating information on hazard, dose-response, and exposure.

Connection between IRIS, Risk Assessment, and Risk Management

<https://epa.gov/sites/default/files/2015-09/iris_rm.jpg>



Click to enlarge: Connection Between IRIS and Risk Management

An IRIS assessment includes the first two steps of the risk assessment process:

- Hazard Identification, which identifies credible health hazards associated with exposure to a chemical, and
- Dose-Response Assessment, which characterizes the quantitative relationship between chemical exposure and each credible health hazard. These quantitative relationships are then used to derive toxicity values.

EPA's program and regional offices identify human exposure pathways and estimate the amount of human exposure under different exposure scenarios (Exposure Assessment). Then they combine their exposure assessment with the hazard information and toxicity values from IRIS to characterize potential public health risks (Risk Characterization).

Guidance & Tools

IRIS Glossary

IRIS's Glossary has been moved to the EPA shared terminology service database. Would you like to search the IRIS Glossary for a definition?

EPA follows Agency guidance in developing IRIS assessments. Key guidelines, technical documents and a few popular tools used by the IRIS Program for developing assessments are listed below. Additional Agency guidance, models and tools are available at the EPA Risk Assessment website <https://epa.gov/risk>.

EPA Guidance Documents

- EPA Cancer Guidelines
- EPA Risk Assessment Guidelines
- EPA Science Policy Council Guidelines
- Other Guidance Documents and Technical Panel Reports
- References Cited in Older Assessment Documents but Superseded by More Recent Guidance

Tools

- Health and Environmental Research Online (HERO)
- Benchmark Dose Software (BMDS)

EPA Guidance Documents

EPA Cancer Guidelines

- U.S. EPA. 2005. Guidelines for Carcinogen Risk Assessment <https://epa.gov/risk/guidelines-carcinogen-risk-assessment> EPA/630/P-03/001F, Mar 2005.
- U.S. EPA. 2005. Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens <https://epa.gov/risk/supplemental-guidance-assessing-susceptibility-early-life-exposure-carcinogens> EPA/630/R-03/003F, Mar 2005.

EPA Risk Assessment Guidelines

- U.S. EPA. 2012. Guideline for Microbial Risk Assessment: Pathogenic Microorganisms with Focus on Food and Water <https://epa.gov/risk/microbial-risk-assessment-guideline-pathogenic-microorganisms-focus-food-and-water>. EPA/100/J-12/001, Jul 2012.
- U.S. EPA. 2000. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. EPA/630/R-00/002, Aug 2000.
- U.S. EPA. 1998. Guidelines for Neurotoxicity Risk Assessment <https://epa.gov/risk/guidelines-neurotoxicity-risk-assessment> EPA/630/R-95/001F, Apr 1998.
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- U.S. EPA. 1991. Guidelines for Developmental Toxicity Risk Assessment <https://epa.gov/risk/guidelines-developmental-toxicity-risk-assessment> EPA/600/FR-91/001, Dec 1991.
- U.S. EPA. 1986. Guidelines for Mutagenicity Risk Assessment <https://epa.gov/risk/guidelines-mutagenicity-risk-assessment> EPA/630/R-98/003, Sep 1986.
- U.S. EPA. 1986. Guidelines for the Health Risk Assessment of Chemical Mixtures <https://epa.gov/risk/guidelines-health-risk-assessment-chemical-mixtures> EPA/630/R-98/002, Sep 1986.

EPA Science Policy Council Guidelines

- U.S. EPA. 2015. Science Policy Council Handbook: Peer Review. Fourth Edition. Office of Science Policy, Office of Research and Development, Washington, DC. EPA/100/B-15/001, Oct 2015.
- U.S. EPA. 2000. Science Policy Council Handbook: Risk Characterization. Office of Science Policy, Office of Research and Development, Washington, DC. EPA 100-B-00-002, Dec 2000.

Other Guidance Documents and Technical Panel Reports

- U.S. EPA. 2014. Guidance for Applying Quantitative Data to Develop Data-Derived Extrapolation Factors for Interspecies and Intraspecies Extrapolation <https://epa.gov/risk/guidance-applying-quantitative-data-develop-data-derived-extrapolation-factors-interspecies>. EPA/100/R-14/022F, Sep 2014.
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- U.S. EPA. 2006. Approaches for the Application of Physiologically Based Pharmacokinetic (PBPK) Models and Supporting Data in Risk Assessment. EPA/600/R-05/043F, Sep 2006.
- U.S. EPA. 2006. A Framework for Assessing Health Risks of Environmental Exposure to Children. EPA/600/R-05/093F, Sep 2006.
- U.S. EPA. 2002. A Review of the Reference Dose and Reference Concentration Processes <https://epa.gov/risk/review-reference-dose-and-reference-concentration-processes-document>. EPA/630/P-02/002F, Dec 2002.
- U.S. EPA. 1994. Methods for Derivation of Inhalation Reference Concentrations and Application of Inhalation Dosimetry <https://epa.gov/risk/methods-derivation-inhalation-reference-concentrations-and-application-inhalation-dosimetry>. EPA/600/8-90/066F, Oct 1994.
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References Cited in Older Assessment Documents but Superseded by More Recent Guidance

- U.S. EPA. 2006. Science Policy Council Handbook: Peer Review. Third Edition. Office of Science Policy, Office of Research and Development, Washington, DC. EPA/100/B-06/002, Jan 2006.
- U.S. EPA. 2000. Science Policy Council Handbook: Peer Review. Second Edition. Office of Science Policy, Office of Research and Development, Washington, DC. EPA EPA/100/B-00/001
- U.S. EPA. 2000. Benchmark Dose Technical Guidance Document External Review Draft. EPA/630/R-00/001, Oct 2000.
- U.S. EPA. 1999. Guidelines for Carcinogen Risk Assessment Review draft. NCEA-F-0644, Jul 1999.
- U.S. EPA. 1996. Proposed Guidelines for Carcinogen Risk Assessment. EPA/600/P-92/003C, Apr 1996.
- U.S. EPA. 1993. Reference Dose (RfD): Description and Use in Health Risk Assessments <https://epa.gov/iris/reference-dose-rfd-description-and-use-health-risk-assessments>, Mar 1993.
- U.S. EPA. 1992. EPA's Approach for Assessing the Risks Associated with Chronic Exposures to Carcinogens <https://epa.gov/iris/epas-approach-assessing-risks-associated-chronic-exposure-carcinogens>, Jan 1992.
- U.S. EPA. 1986. Risk Assessment Guidelines of 1986. EPA/600/8-87/045, Sep 1987.
- U.S. EPA. 1986. Guidelines for Carcinogen Risk Assessment. EPA/630/R-00/004, Sep 1986.

Tools

Health and Environmental Research Online (HERO)

HERO is a searchable database of more than 1.6 million scientific studies and other references used to support the development of EPA assessments. Each HERO record provides detailed bibliographic information. Since 2010, all citations in new IRIS assessments are linked to entries in the HERO database.

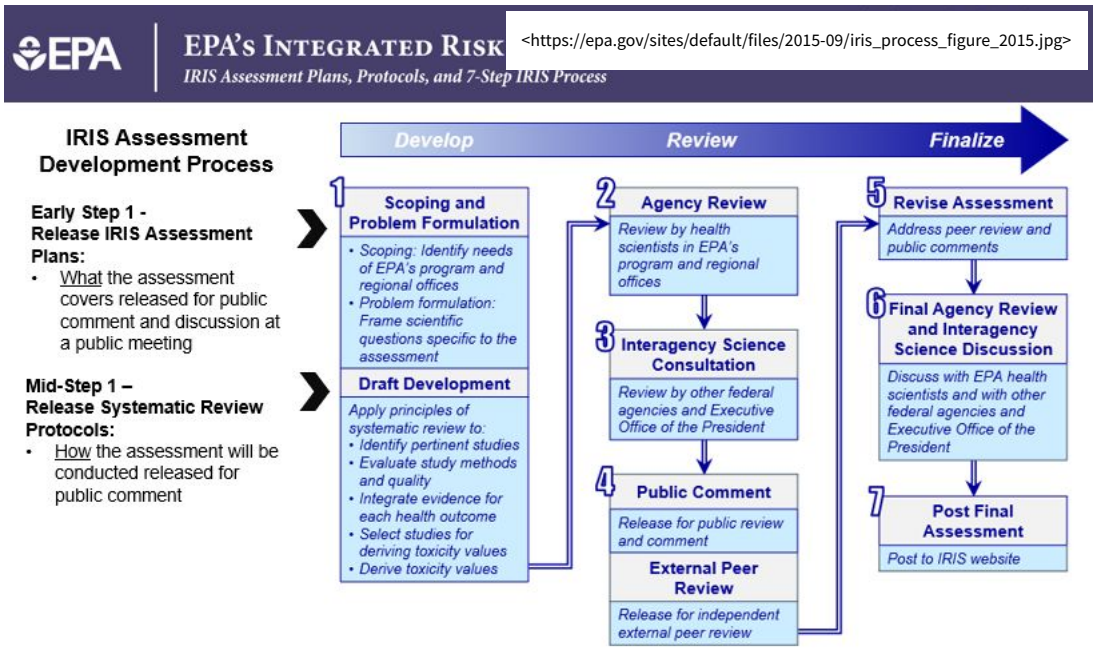
- Learn more about the HERO Database <https://hero.epa.gov/hero/>

Benchmark Dose Software (BMDS)

Benchmark dose (BMD) modeling is EPA's preferred approach for deriving points of departure (PODs) used to develop toxicity values. Use of BMD modeling involves fitting a set of mathematical models to dose-response data from human and animal studies. EPA's benchmark dose software (BMDS) was designed to facilitate the application of BMD methods in dose-response assessment.

- Learn more about Benchmark Dose Software <https://epa.gov/bmds>

IRIS Process for Developing Human Health Assessments



Click to enlarge: IRIS Process Figure

Step 1. Draft Development

Beginning an assessment, EPA's Office of Research and Development (ORD) undertakes scoping and problem formulation to ensure that the product meets the scientific needs of the EPA program or regional office(s) requesting the assessment. These activities help focus the assessment by describing the routes of exposure, potential health effects, types of studies, and key science issues to be considered in the assessment. EPA ORD also develops an assessment protocol which presents the systematic review and dose-response methods being used to develop the draft assessment. EPA releases these preliminary assessment materials to obtain input from the scientific community and general public. A public science meeting may be held to obtain additional input.

For more detailed information on the methods used to develop a draft IRIS assessment, visit the "ORD Staff Handbook for Developing IRIS Assessments," or "IRIS Handbook" webpage.

Step 2. Agency Review

Scientists in EPA's program offices and regions review the draft assessment.

Step 3. Interagency Science Consultation

EPA ORD leads other federal agencies and departments in a review of the draft assessment.

Step 4. Public Comment and External Peer Review

After revising based on Agency and Interagency comments, a draft assessment and charge questions are released for public comment and peer review.

Step 5. Revise Assessment

The assessment is revised to address public comments and peer review recommendations, and a disposition of peer reviewer and public comments is developed.

Step 6. Final Agency Review/Interagency Science Discussion

The revised assessment is reviewed by EPA's program offices and regions and other federal agencies and departments.

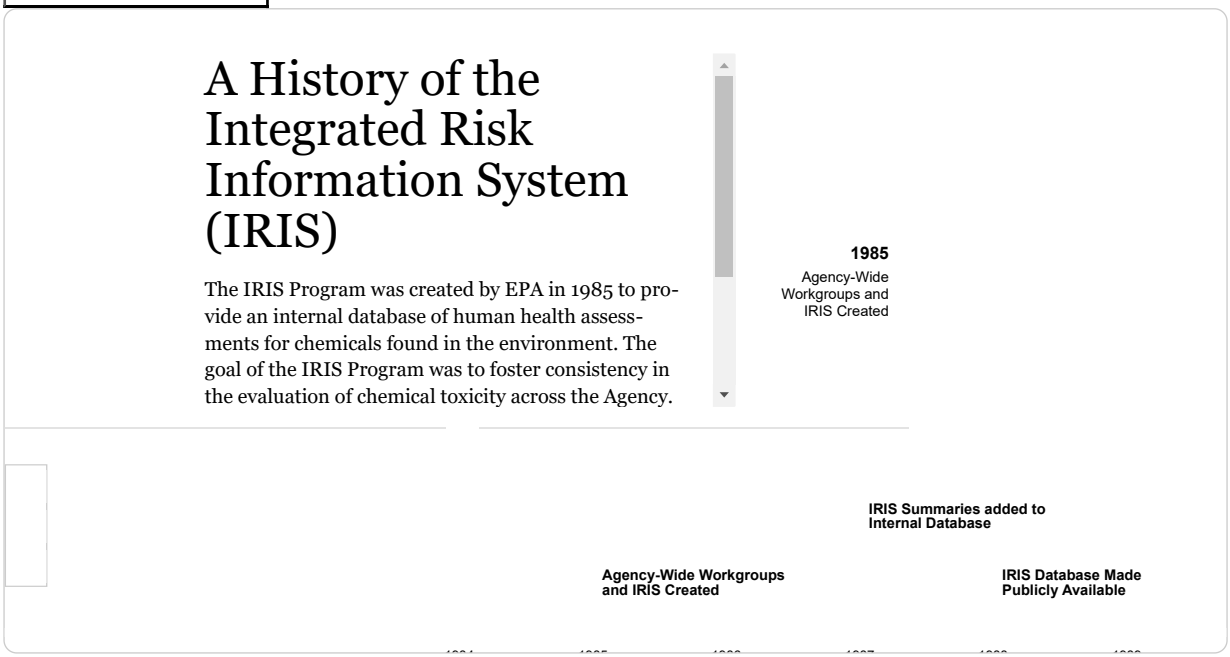
Step 7. Final Assessment

The final IRIS assessment is posted to the IRIS website.

Note: To learn more about the historical development of the IRIS Process, see the history of IRIS.

History of IRIS

View the list of milestones



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