

Highlights of [GAO-13-369](#), a report to the Chairman, Committee on Environment and Public Works, U.S. Senate

## Why GAO Did This Study

EPA created the IRIS database in 1985 to help develop consensus opinions within the agency about the health effects from chronic exposure to chemicals. The health effects information in IRIS—referred to as IRIS toxicity assessments—provides fundamental scientific information EPA needs to develop human health risk assessments. GAO was asked to review the effectiveness of EPA's implementation of its IRIS toxicity assessment process. This report determines the extent to which (1) EPA has evaluated demand for IRIS toxicity assessments from users inside and outside EPA; (2) EPA's process for nominating and selecting chemicals for IRIS toxicity assessment accurately reflects demand; and (3) EPA has implemented a strategy for addressing any unmet agency needs when IRIS toxicity assessments are not available, applicable, or current. To do this work, GAO reviewed and analyzed IRIS nomination data, among other things, and interviewed EPA officials. GAO did not evaluate the scientific content or quality of IRIS toxicity assessments.

## What GAO Recommends

GAO recommends that EPA evaluate demand for IRIS assessments; document how the agency applies its selection criteria, including the circumstances under which an IRIS toxicity assessment is or is not needed and; develop an agencywide strategy including, at a minimum, coordination across EPA offices, as well as with other federal agencies, to identify and fill data gaps, and providing guidance that describes alternative sources of toxicity information. EPA agreed with the first two recommendations and partially agreed with the third.

View [GAO-13-369](#). For more information, contact J. Alfredo Gómez at (202) 512-3841 or [gomezj@gao.gov](mailto:gomezj@gao.gov).

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## CHEMICAL ASSESSMENTS

### An Agencywide Strategy May Help EPA Address Unmet Needs for Integrated Risk Information System Assessments

## What GAO Found

The Environmental Protection Agency (EPA) has not conducted a recent evaluation of demand for Integrated Risk Information System (IRIS) toxicity assessments with input from users inside and outside EPA. Specifically, EPA issued a needs assessment report in 2003, which estimated that 50 new or updated IRIS toxicity assessments were needed each year to meet users' needs. However, GAO did not find sufficient support for the estimate. In addition, IRIS Program officials recognize that the 2003 estimate does not reflect current conditions, but the agency does not plan to perform another evaluation of demand. Without a clear understanding of current demand for IRIS toxicity assessments, EPA cannot adequately measure the program's performance; effectively determine the number of IRIS toxicity assessments required to meet the needs of IRIS users; or know the extent of unmet demand.

The IRIS Program's chemical nomination and selection process, which the agency uses to gauge interest in the IRIS Program from users inside and outside of EPA, may not accurately reflect current demand for IRIS toxicity assessments. The 75 chemicals that were nominated in response to EPA's most recent 2011 nomination period may not reflect demand for a number of reasons. For example, given the long-standing challenges the IRIS Program has had in routinely starting new assessments, according to some EPA IRIS users, they chose not to nominate new chemicals for assessment. Also, EPA has not clearly articulated how the IRIS Program applies the criteria it uses to prioritize the selection of chemicals for IRIS toxicity assessment—including how it determines the circumstances under which an IRIS toxicity assessment is or is not needed. Consequently, for chemicals that were nominated but not selected for assessment, it is not clear how many, if any, were excluded from consideration because they did not meet the IRIS Program's selection criteria because the IRIS Program determined that an IRIS toxicity assessment was not needed—or, alternatively, if they were not selected due to resource constraints or other reasons.

EPA has not implemented an agencywide strategy for addressing the unmet needs of EPA program offices and regions when IRIS toxicity assessments are not available, applicable, or current. Specifically, EPA does not have a strategy for identifying and filling data gaps that would enable it to conduct IRIS toxicity assessments for nominated chemicals that are not selected for assessment because sufficient data from health studies are not available. IRIS Program officials stated that no agencywide mechanism exists for EPA to ensure that chemicals without sufficient scientific data during one nomination period will have such information by the next nomination period or even the one after that. These officials acknowledged that better coordination across EPA and with other federal agencies could help address the issue. EPA also does not have agencywide guidance for addressing unmet needs when IRIS toxicity assessments are not available, applicable, or current. In the absence of agencywide guidance, officials from select EPA offices stated that they used a variety of alternatives to IRIS toxicity assessments to meet their needs, including using toxicity information from other EPA offices or other federal agencies.