Message

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Risk Policy Report - 04/08/2014

Pending NAS Report Expected To Reignite Debate Over Reforming IRIS

Posted: April 7, 2014

The National Academy of Sciences (NAS) is preparing to release a congressionally requested report on EPA's Integrated Risk Information System (IRIS) program, an assessment that is expected to reinvigorate efforts to reform the program, which industry has criticized for being too conservative and opaque while others have faulted its slow pace.

The report, which NAS says is expected to be released this month, is intended to be the culmination of EPA's ongoing effort to overhaul the IRIS program, which has already seen the agency revise its procedure and review structure to increase the program's output, form a separate review committee to enhance the quality of the assessments, and reduce the number of assessments underway.

But advocates on all sides are expected to call for additional reforms. Industry officials, for example, say they hope the report renews focus on their calls for EPA to clarify how IRIS chemical managers perform their weight of evidence analyses of toxicity information and other issues.

Environmentalists did not return requests for comment but in the past they have urged EPA to take steps to increase IRIS' output, in part by not waiting for "perfect" scientific information before completing an assessment. They argue that doing so further delays health-protective decisions.

IRIS is EPA's premiere chemical hazard assessment program with its analyses being used by state and federal regulators to develop scores of regulatory standards and cleanup levels across all media. But the program has been plagued by criticism, especially after the Government Accountability Office (GAO) in 2008 listed IRIS as a "high risk" program in need of reform.

The GAO report prompted some early reforms. Former EPA research chief Paul Anastas, for example, created a new standing committee within the Science Advisory Board (SAB) to review IRIS assessments.

The criticism continued when Congress asked EPA to seek the NAS review after a 2011 NAS report on the agency's draft assessment of formaldehyde renewed high-profile attention and prompted new calls for reform.

During a handful of public meetings, the NAS committee appeared to focus largely on one of industry critics' long-standing concerns with the assessments: how IRIS chemical managers perform their weight of evidence analyses of toxicity information.

EPA is also taking additional steps to reform the program before the NAS report is released. Ken Olden, the director of EPA's National Center for Environmental Assessment, has promised to do away with the program's opaque inner workings by inviting stakeholders to meet to discuss assessments or general concerns.

Olden also sought to prioritize assessments underway in the program, and increase its efficiency by altering the process slightly. Olden has also sought to boost the quality of the assessments, in part by creating teams

of staff with specialized expertise to work on parts of the assessments, as well as teams of senior scientists to review all of the assessments as they are underway.

Top EPA science officials are also considering a series of responses to an earlier set of NAS recommendations on how to improve the agency's risk assessment practices, an effort that officials have long struggled to adopt but is now gaining ground as the report's lead author, Johns Hopkins University Associate Dean Thomas Burke, is awaiting Senate confirmation to lead EPA's research office.

Earlier this year, EPA's Science Technology and Policy Council (STPC), a group of science policy makers chaired by the agency's Science Advisor, Glenn Paulson, was reviewing a lengthy list of efforts the agency could undertake to implement various recommendations in the NAS' 2009 report, "Science and Decisions: Advancing Risk Assessment," agency sources said.

The 2009 report suggests improvements to EPA risk assessment ranging from better scoping an assessment's goals and potential solutions before beginning the assessment to technical issues such as unifying how assessments of cancer and non-cancer risks are conducted

In an interview shortly after the report's release, Burke described it as an effort to break logjams that often occur in risk assessment as the agency and others seek more and more information to reduce uncertainties in the analyses, but also delay decisionmaking.

Agency sources said late last year that the document they were crafting seeks to improve the utility of its assessments by scoping its risk assessments at their outset, and even consider what risk management options are available before starting an assessment so that an assessment is most relevant to the questions and risk management decisions at issue. They are also launching an effort to better link risk assessment and the economic analysis required for many rulemakings.

While industry representatives and other stakeholders have responded positively to Olden's efforts, many are seeking further changes to IRIS, and more may stem from the recommendations in the closely watched NAS report.

"The scope of the [NAS] review is two-fold: review EPA's implementation of the 2011 [NAS] committee review of the formaldehyde assessment and focus on weight of evidence and how EPA can do a better job" with that, says one source with the American Chemistry Council (ACC), a chemical industry association. "First off, we hope that the report takes some time to evaluate how EPA's [incorporated] those recommendations [from the 2011 formaldehyde report] so far with the program."

Issues related to how EPA selects studies to include in its IRIS assessments, and how that information is weighed in reaching conclusions about whether chemicals are carcinogenic, or how to calculate various risk estimates are key issues in the debate over the IRIS program. "Specifically with weight of evidence, we'd like to see recommendations related to data acquisition, how to select studies for inclusion in IRIS and data evaluation, data quality and what EPA does to evaluate study quality and ... data integration," the ACC source says.

During a handful of meetings, the NAS committee appeared to focus in on those topics. Among other efforts, the committee requested presentations from National Toxicology Program (NTP) staff who are developing a new approach called systematic review to gathering and evaluating data for assessments and other environmental health questions. Modeled after the evidence-based medicine process, systematic review is intended to assist risk assessors in scoping an assessment, methodically formulating a literature search and evaluating the results, as well as transparently communicating that process.

Olden has already expressed interest in the NTP approach, suggesting that IRIS staff will use it as a model and adapt it for use in developing IRIS assessments.

A second ACC source says that if the NAS committee gives EPA recommendations on how to perform systematic reviews, "that would be great. Right now, they do a literature search [regarding a chemical's toxicity] and stop. We want to see *a priori* criteria [for selecting studies to include in an assessment] and [how to] integrate [that data into the assessment] ... we want to see the next steps."

ACC representatives and those of other industry groups have already expressed concerns with NTP's approach, particularly at a systematic review workshop that EPA held last August. There, ACC representatives argued that NTP's approach to systematic review does not include mechanistic data -- information about the molecular process by which a chemical produces a health effect -- early enough or sufficiently in the process.

But environmentalists, including representatives of the Environmental Defense Fund (EDF), argued at the same meeting that mechanistic data should not be a central organizing approach for chemicals, since mechanism is unknown for many chemicals. They said that mechanistic data should not be required in order to complete a risk or toxicological hazard assessment, or few would ever be finalized (*Risk Policy Report*, Sept. 10).

EDF's Richard Denison also raised a more basic concern with NAS committee members early in their review of the IRIS program: he pressed committee members to think practically and consider ensuring how EPA can release scientifically vigorous assessments in a timely way (*Risk Policy Report*, April 2, 2013).

"My greatest fear about this committee's IRIS review has been that it would run the risk of becoming a quest for the perfect science, yielding recommendations for enhancing IRIS' process that in an ideal world would be great, but in practice would make it harder, not easier, for EPA to do its job of protecting human health," he told the panel during a March 2013 workshop. -- *Maria Hegstad*