Message

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EPA Backs Industry-Sought Changes To Chemical Assessment Program

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Top officials overseeing EPA's Integrated Risk Information System (IRIS) program say they are planning additional changes to the controversial chemical hazard assessment program, including gathering public input before assessments are drafted and generating new data for analyses -- both changes which have been sought by industry critics.

Kenneth Olden, recently appointed as director of EPA's National Center for Environmental Assessment (NCEA), which oversees IRIS, and Vincent Cogliano, the acting director of the IRIS program, outlined the changes Sept. 17 at the first meeting of the National Research Council's (NRC) Committee to Review IRIS.

The event provided Olden, who assumed his position 10 weeks ago, his first opportunity to publicly discuss his plans for the beleaguered program, and he promised an aggressive effort to address long-time concerns with the program.

Administrator Lisa Jackson and acting research chief Lek Kadeli "didn't hire me to sit in [EPA's Potomac Yard headquarters] for two years, they hired me to lead," he said. "This is a new day for NCEA," Olden added. "Openness and transparency will be the hallmarks of EPA going forward."

Olden's NCEA houses both the IRIS program, whose assessments are often the basis for EPA and state decisions and regulations, and the Integrated Science Assessment program that produces the assessments of criteria pollutants required by the Clean Air Act.

He said that he will seek to "elevate the dialogue" with stakeholders and to craft a long-term strategic plan that emphasizes strong science, stakeholder engagement and public policy.

While both Olden and Cogliano outlined several new changes to the program, Cogliano also cautioned that there is limited data available for many of the chemicals that IRIS staff are assessing, and that assessments "need to be made in a reasonable amount of time, at a reasonable cost," he said, noting that the agency is facing a shrinking budget. "It's not always feasible to wait for new studies."

Olden and Coliagno's comments drew early praise from representatives of the American Chemistry Council (ACC), who have been advocating for many of the changes. "We've already seen improvement," said ACC's Rick Becker. "We've seen new things today that continue to show improvement."

The IRIS program has drawn considerable criticism from industry and other critics since a 2011 report from an NRC panel charged that EPA's draft assessment of formaldehyde failed to justify its conclusion that the chemical poses leukemia risks and called for a host of reforms to the program.

In response, Congress requested EPA to seek NRC review of its pending arsenic assessment and as many as two others but the NRC convinced lawmakers to allow them to conduct a comprehensive review of the program's scientific practices in lieu of reviewing two additional chemical assessments.

EPA and NRC have also agreed on a unique review for the draft arsenic assessment.

Since the criticisms, EPA has adopted several steps to reform the program -- including creation of a standing scientific panel to review its draft assessments, as well as related policy and methodology questions -- and is crafting other changes to comply with NRC advice, such as an upcoming weight-of-evidence framework to use in drafting assessments.

Additional Reforms

But Becker and others have urged the agency to go further, including gathering public input before starting assessments and generating new data for assessments, rather than relying on existing data.

For example, on the issue of public scoping prior to the launch of assessments, Becker said recently that EPA could have avoided problems with its pending assessment of trimethylbenzenes (TMBs) if it had gathered public input prior to the launch of the assessment. In that case, EPA drafted an assessment of only three chemicals in the class -- while leaving out data that industry had provided the agency's EPA's toxics office a decade ago on the rest of the class -- data that industry says is essential to understanding the substances' toxicities.

Industry officials have long sought pre-assessment access to IRIS staff, arguing that it will actually speed the assessments because fewer reviews and rewrites will be necessary.

And on the issue of new toxicity data, ACC battled for months to get EPA to accept new data its consultants generated on the risks posed by hexavalent chromium (Cr6), data that the group says undermines the need for the agency's conservative assessment method.

In his appearance before the panel, Olden voiced his support for including stakeholders at the very beginning of scoping and planning an IRIS assessment, usually a multi-year project for the program. "We need to include stakeholder participation in planning and scoping," Olden said. "If we don't agree on a problem, we aren't going to agree on the" outcome of the assessment.

He extended this comment to suggest that such early meetings could also lead to agreements on missing data that would be critical for assessing its risks. "If we could agree at the beginning that there are data gaps, maybe we could agree to commission a new study," Olden said, adding, "We've done this before." He indicated that EPA could undertake some studies or offer grants for some studies, while others could be jointly funded by EPA and industry through joint agreements.

Olden also responded to long-standing industry accusations that IRIS assessments "cherry-pick" data, selecting only studies showing the greatest risk to include in the IRIS assessments. Olden suggested that establishing rules for which studies are selected during an IRIS assessment's initial literature review and also using a computer algorithm to accelerate the speed of these literature searches.

"Can we generate some rules up front to evaluate the literature, make the process more objective?" Olden asked.

"We've done a study and it looks like we can do this." Olden also indicated the possibility of using computer algorithms in IRIS literature searches. He added that he is meeting soon with Linda Birnbaum, director of the National Institute of Environmental Health Sciences to discuss the idea, because that agency uses such a tool. Olden held Birnbaum's position from 1991-2005.

That suggestion may go some way toward meeting ACC calls for EPA to craft standardized methods of data evaluation and selection, and greater inclusion of industry in its assessment process. In a Sept. 13 letter to NRC staff, ACC said EPA should develop "a formal protocol for each IRIS assessment that should include the literature search strategy and study inclusion/exclusion criteria, . . . develop and follow a transparent, systematic approach when evaluating each individual study for quality, reliability and relevance."

Peer Reviews

Olden also addressed other industry concerns regarding peer review of draft assessments, which are usually conducted by contractor-run panels of experts or EPA Science Advisory Board panels. Olden said that "Whether we've responded to public comments is not included in peer review. Let's respond and have the peer review consider that. Have one of the peer review questions be, 'Have we responded to the public?'"

Olden further indicated that he will invite other agencies' involvement in the decision-making process during the drafting of assessments. The approach has merit because it should reduce disagreement between agencies over assessments, he said. "Everybody will have ownership [of the assessment] because they will have contributed to it."

Olden also described some challenges he sees for the IRIS program, such as including new hazard assessment tools and information such as that gleaned from "omics" studies and high throughput screening. He also points to the need to address varying susceptibilities within the population to risk.

"There are a few challenges that are very obvious. We need to rebuild the strong reputation of IRIS for timely, quality support of agency decision-making. . . . We need to modernize hazard assessment and risk assessment by employing our [current] knowledge and tools," Olden said. "We need to develop models to integrate knowledge of susceptibility. We know that will make our [job] more difficult. But we need to integrate models related to stage of development, genetics, behavior and socioeconomic factors. It will add to uncertainty but we need to do it."

Cogliano, too, outlined new plans for the IRIS program, which he said are based upon recommendations in the critical 2011 formaldehyde report. He said that NAS report recommended that IRIS staff calculate multiple reference values based on multiple health effects. "So we've done that," Cogliano said adding that an overall reference dose or reference concentration can then be selected by averaging the values, picking the best value, or by meta analysis. Cogliano argued that this new approach is important because "it gives decision-makers a bigger picture of health hazard of the chemical."

This new approach of multiple values for multiple relevant health effects will also allow greater comparison among chemicals and assist in hazard assessments of chemical mixtures, Cogliano suggested. "When we go to sites, the community will often say, "We're not just exposed to one chemical. Now, we can add up all [chemicals' reference values for the] same effect. Hopefully it will lead to more robust decisions."

An agency source says the next IRIS assessment released will include multiple reference values. The NRC committee is scheduled to meet again in December. -- *Maria Hegstad*