Risk Assessment
Shift of EPA Risk Program May Disrupt Other Agency Needs

Snapshot

• President's fiscal year 2018 budget request would eliminate the EPA's Integrated Risk Information System of chemical hazard values
• Ideas include relocating lengthy IRIS analyses into those the agency's chemicals office must perform under new statutory deadlines

By Pat Rizzuto

Behind the president's budget proposal to eliminate an EPA-wide chemical evaluation program may be the goal of shifting its function to another part of the agency.

But a shift from the agency's research arm to its chemicals office could jeopardize the EPA's ability to meet new statutory deadlines under a toxics law Congress amended last June or preclude the program from serving the diverse agency offices and outside professionals that need it, consultants and environmental scientists say.

The chemical hazard analyses the Environmental Protection Agency's Integrated Risk Information System, or IRIS, program, performs for the agency's waste, air and other regulatory offices may be transferred to the EPA Office of Chemical Safety and Pollution Prevention, Jennifer Sass, a senior scientist with the Natural Resources Defense Council, who tracks IRIS told Bloomberg BNA.

The chemical safety office is regulatory and oversees the Toxic Substances Control Act. The IRIS program is housed in the EPA's Office of Research and Development, which is non-regulatory. A former EPA official Bloomberg BNA spoke with also said he has heard the IRIS program may be reinvented in the chemicals or another agency office.

The specifics are "very much in flux," Sass said. But multiple agency scientists have told her they are discussing ways to fold a lot of IRIS' services into implementation of the 2016 TSCA amendments, she said.
Placing IRIS' analytic functions within the chemicals office could make sense but would have to be carefully planned to avoid bogging down the chemicals office, Lorenz Rhomberg, a former EPA risk assessor working with Gradient, an environmental consulting firm, told Bloomberg BNA. He added that IRIS currently supports many programs, offices and states by producing chemical hazard values that can be applied in multiple environmental scenarios, support that may be constrained if chemical risk evaluations are only geared for TSCA's purposes.

Eliminating IRIS

The President's fiscal year 2018 budget request proposes to eliminate IRIS, according to a March 21 memo.

Since its creation in 1985, the IRIS program has generated consensus estimates of the human health hazards of about 540 chemicals and the doses at which those hazards could manifest.

Other EPA offices, federal agencies, the private sector, consultants and state agencies combine the hazard information and dose-response values IRIS generates with exposure information in setting cleanup, air toxics, water and other regulatory standards. The database also can be leveraged to compare the hazards of multiple chemicals under consideration in product formulations.

State officials make broad use of IRIS in their day-to-day work.

IRIS provides the primary source of toxicity information to set air, water and waste cleanup standards for Washington state, Holly Davies, chemical policy coordinator in the state's Department of Ecology.

The case of perfluorinated chemicals—which help chemical manufacturers produce chemicals that are heat, oil and water resistant, but which contaminate water and soil across the U.S.—illustrate the value of IRIS assessments, she said.

The IRIS program hasn't evaluated perfluorinated chemicals, so states are doing it on their own and coming up with different health, cleanup and other numbers, Davies said. "We're not going to stop protecting human health and the environment" just because IRIS has yet to evaluate a chemical, she said, underlying the value of consensus IRIS numbers.

For years, companies, trade associations, some members of Congress and scientific panels convened by the agency and the National Academies of Science have criticized the IRIS program.

Concerns surrounding the program relate to the length of time that reviews take, that program analysts sometimes fail to provide clear study selection rationales, and that IRIS assessors fall short of clearly explaining the reasoning for their conclusions.

The IRIS program has repeatedly been redesigned, most recently in 2012. In a 2014 report, an academies committee wrote: "the changes that EPA has proposed and implemented to various degrees constitute substantial improvements in the IRIS process."

Possible Results Vary

The transfer could improve IRIS' efficiency and/or bog down the agency's goal of implementing the 2016 TSCA amendments, Rhomberg said.

IRIS' functions have to be located somewhere, according to Rhomberg.

The EPA created IRIS in 1985, because different offices within the agency were generating divergent risk values for the same chemical, George Gray, who served as assistant administrator for research and development at EPA under the George W. Bush administration, told Bloomberg BNA. Gray teaches risk assessment in the George Washington University's Department of Environmental and Occupational Health.

Yet, Rhomberg said, a renamed IRIS program can't simply be moved wholesale. "There will have to be more to it than that."

Any change must be designed to make the chemical evaluation program more efficient and allow it to take advantage of advanced toxicity and exposure modeling programs within EPA's research office, Rhomberg said.

Broad TSCA Mandate

The broad mandate Congress gave EPA through the 2016 TSCA amendments could make the agency's chemicals office a logical place to relocate IRIS functions, Rhomberg said.

The 2016 TSCA amendments require the EPA to evaluate chemical risks, the conditions of their use, and aggregate exposures to them, he said.

The statute defines conditions of use as meaning "the intended, known, or reasonably foreseeable circumstances the administrator determines a chemical substance is manufactured, processed, distributed in commerce, used, or disposed of."

The statute directed the EPA to describe "aggregate exposures, or significant subsets of exposures, to a chemical substance under the conditions of use will be considered, and explain the basis for that consideration in the final safety assessment."

"There'd have to be a lot of coordination," to provide information useful to other agency offices, Rhomberg added.

The EPA's Science and Technology Policy Council, which oversees agencywide risk policy issues that go beyond regional and program boundaries, could oversee a reinvented IRIS, Rhomberg said. But others note that the STPC is composed of volunteers and has limited support staff, which may constrain its ability to manage such a shift.

Not only would the EPA's air, waste and water offices need to work with its chemicals office, but other agencies also would need to be involved, Rhomberg said.

For example, the TSCA amendments direct the EPA to protect vulnerable and potentially highly exposed populations including children, pregnant women and workers.

That suggests the Occupational Health and Safety Administration would need to work with the EPA to address workers' exposures, Rhomberg said.

The two agencies might not agree on the exposure concentration that would trigger regulatory action, but they should agree on how to characterize the workplace exposures, he said.

Timing

The IRIS program's slow pace has been criticized so much over the years that it's not surprising the Trump administration is proposing to eliminate it, Richard Denison, lead senior scientist, and Jennifer McPartland, a health scientist, both with the Environmental Defense Fund, told Bloomberg BNA.

"A large share of the blame [for the slow pace] falls squarely on industry, which has hijacked the process at every possible stage," Denison said.

Yet the timing is unfortunate, McPartland said.

The IRIS program has made substantial improvements since 2012, Denison and McPartland agreed.

Kris Thayer, who became IRIS' director earlier this year, brings impressive experience with systematic approaches to assessing chemicals from her previous job at the National Toxicology Program, McPartland said.

Eliminating IRIS won't do away with the need for the information it provides, Denison said.

Undermining TSCA?

Moving it into one regulatory office also may not work, because the information IRIS has provided is designed to serve all of EPA, state agencies and other federal departments, Denison said.

Rhomberg said "the cynical view" could foresee the IRIS functions being transferred into the chemicals office and getting stuck by not completing the first 10 chemicals being assessed under TSCA in a timely way.
That would undermine the goal of TSCA reform, he said, having continual progress in completing evaluations of the risks chemicals pose.

To contact the reporter on this story: Pat Rizzuto in Washington at prizzuto@bna.com
To contact the editor responsible for this story: Larry Pearl at lpearl@bna.com