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Risk Assessment

Data, Computational Tools for Risk Analysts Key in 2016

By Pat Rizzuto

Jan. 12 — The Environmental Protection Agency will generate chemical bioactivity and exposure data in 2016 and design computational tools to save risk assessors throughout the agency time while improving their analyses.

"We have unprecedented amounts of information that we can combine to help solve problems," Thomas Burke, deputy assistant administrator for research and development at EPA, told Bloomberg BNA.

"We're finding quicker, more-efficient ways to do that," said Burke, who also serves as science adviser for the agency.

The National Toxicology Program will deepen the amount of gene-activity information it obtains through robotic tests while also establishing methods scientists can use to evaluate the quality of gene-activity, cellular and other mechanistic data.

Both agencies will work together and with institutions such as the World Health Organization to keep adapting systematic review procedures for environmental health analyses.

"We're expecting a lot of strides in that area," John Bucher, associate director of the National Toxicology Program, told Bloomberg BNA.

BNA Snapshot

Top Risk Assessment Issues in 2016

- The agency will make existing data from many sources easier to access.
- The agency will develop databases and software to save risk assessors time and improve analytic quality.
- The agency will examine ways to ensure quality of mechanistic data.
- The agency will strive to adapt systematic review for environmental health assessments.

Many Diverse Projects

Bucher, Burke, and Tina Bahadori, national program director for chemical safety and sustainability in EPA's Office of Research and Development, discussed many efforts their offices are undertaking to generate information for various types of risk assessments, to ensure data quality and to cut analytic time. A few examples include:

- providing better chemical structure and physical chemical property information on an easier-to-use version of the interactive Chemical Safety for Sustainability (iCSS) Dashboard, a web-based portal to access chemical data derived from high throughput screens;
- reworking high throughput screens—equipment that simultaneously tests hundreds or thousands of experimental samples—so they account for chemical metabolism, which largely is omitted with present techniques;
- designing quicker ways to validate high throughput screens for potential uses;
- redesigning ultra high throughput screens so they generate even more gene activity data;
- expanding and improving the information in the EPA's Chemical Product Category Database, which lists chemicals and the types of products in which they are used; and
- developing computerized methods to predict chemical exposures incurred by many different demographic groups.

Status of Ongoing IRIS Assessments

Step in IRIS Process	Assessments
Problem formulation	
	Arsenic, inorganic Butyl benzyl phthalate Chromium VI

Draft development	Dibutyl phthalate Diethyl phthalate Di-isobutyl phthalate Di-isononyl phthalate Ethylbenzene Hexabromocyclododecane Naphthalene Polychlorinated biphenyls (PCBs; noncancer)
Agency Review	
Interagency Science Consultation	t-Butyl alcohol Ethyl t-butyl ether (ETBE) Hexahydro-1,3,5-trinitro-1,3,5-triazine (RDX)
Assessments released prior to EPA's IRIS reforms that will be re-released to step 4.	Acrylonitrile n-Butyl alcohol Formaldehyde Polycyclic aromatic hydrocarbons (PAH) relative potency factors
Public comment; Peer review	Benzo[a]pyrene
Revise assessment	Ammonia (inhalation) Ethylene oxide (inhalation, cancer) Trimethylbenzenes
Final Agency Review/Interagency Science Discussion	
Note: IRIS assessments are prepared through a multistep process that consists of scoping and problem formulation, development of a draft assessment, agency review of the draft, interagency science consultation, public comment, external peer review, revision of draft, final agency review and interagency science discussion and issuance of final assessment.	

Source: EPA

Embracing Complexity

Bahadori described a different type of research effort that is in its early stages.

Traditionally, chemical safety research involves carefully controlled experiments that don't reflect the complexity in which human and ecological populations live, she told Bloomberg BNA.

A researcher will analyze blood and urine samples, for example, to determine whether they contain specific chemicals.

"You look for what you think is a problem," Bahadori said.

The researcher is "looking under the lamppost" and doesn't identify other chemicals that also are in the blood or urine sample, she said.

ORD and its academic grant recipients are working to develop "non-targeted" analytical chemistry approaches.

Instead of looking for specific chemicals in the blood or urine samples, the researchers identify every chemical they can, Bahadori said.

The labs are working with samples spiked by EPA to ensure the labs find the chemicals the agency knows are in the sample, she said.

> ***'We have unprecedented amounts of information that we can combine to help solve problems.'***
>
> ***—Thomas Burke, EPA science adviser***

The researchers also are working to standardize the analytic methods to be sure that when two different labs say they have found a particular chemical, it really is the same chemical, Bahadori said.

In a separate approach to the same idea, researchers receive samples of Great Lakes water.

First, they identify as many chemicals as they can in the samples, then they run the samples through high throughput screens.

The goal is to understand whether the mixture has a toxic effect different than what would be expected based on its individual components, she said.

The water office suggested ORD undertake the project because it is interested in understanding the effects of mixtures and exploring whether it is feasible to set water standards for more than one chemical at a time, Bahadori said.

Bridging Emerging Data, Regulatory Decisions

The EPA and toxicology program are building bridges to bring the wealth of new data that technologies are making possible to regulators who are unaccustomed to using such data to make decisions.

ORD and the EPA's Office of Chemical Safety and Pollution Prevention will continue to use high-throughput screening data and high-throughput exposure predictions to prioritize chemicals that companies would have to test for potential endocrine disruption.

In 2015, the agency began to accept data from high-throughput screens on a chemical's potential to mimic, block or alter estrogen, the female reproductive hormone (118 DEN A-20, 6/19/15).

In 2016, the agency anticipates being able to accept high-throughput data about chemicals' potential to mimic, block or alter androgen, the male reproductive hormone (224 DEN A-6, 11/20/15).

RapidTox Program

EPA researchers are working with the agency's regional offices and its Office of Solid Waste and Emergency Response and Office of Pesticides Programs to develop decision-support tools called RapidTox.

For the waste office, the EPA's goal is to help officials dealing with Superfund sites that are contaminated with hundreds of chemicals, Rusty Thomas, director of the agency's National Center for Computational Toxicology, said at a Society for Risk Analysis meeting in December.

Of those hundreds of contaminants, only a few have toxicity values the officials can use to make cleanup decisions, he said.

The RapidTox program would combine a wide variety of data including a chemical's properties and how it moves through the environment. The software would then develop numerical toxicity values while letting the risk manager know how uncertain the estimates were, he said.

A similar computer decision-support tool will be developed for the EPA's Office of Pesticide Programs so it can decide which inert ingredients in non-food use pesticides warrant additional study, Thomas said.

The RapidTox computer program would "enable screening-level assessments to be performed for hundreds to thousands of data-poor chemicals," he said.

Initial prototypes will be available by the end of fiscal year 2016, Thomas said.

ExpoFIRST Database

Also coming in 2016 will be a database and software program called the Exposure Factors Interactive Resource for Scenarios Tool or ExpoFIRST, said Michelle Cawley, a technical specialist for ICF International Inc., a contractor working with the EPA to design the system.

The many different numerical values from EPA's Exposure Factors Handbook are plugged into the database from which ExpoFIRST draws its information, Cawley said. These factors include details such as drinking water, soil ingestion and inhalation rates for different ages; the amounts of time different age groups spend crawling on floors and touching their mouths; skin area for different parts of the body; and vapor intrusion rates.

The database also taps into details such as a chemical's molecular weight and the time the chemical takes be absorbed through the skin, she said.

Instead of manually entering such information for each analysis project, the ExpoFIRST user can spend his or her time altering the assumptions and possible scenarios, she said.

'NTP is working on ways to present information. We're creating visualization tools.'

—John Bucher, National Toxicology Program

Data Presentation, Data Quality

Meanwhile, the National Toxicology Program is working to define ways researchers can evaluate the quality of mechanistic—detailed cellular, genetic and other studies—data, Bucher said.

To help people understand that mechanistic and other data, the NTP is working on ways to present information, he said. "We're creating visualization tools."

Mary Wolfe, deputy division director for policy at NTP's Office of Liaison, Policy, and Review, said in an e-mail that the toxicology program also is updating what it calls its "Levels of Concern" framework.

The program uses six phrases, ranging from "serious concern" to "negligible concern" or "insufficient data," to provide a science-informed opinion as to whether an environmental substance may cause adverse effects on human health given what is known about its toxicity and current human exposure.

Over the years, there has been confusion about some of the terms and questions about the number of categories.

The program is working with epidemiologists, risk communicators and other experts to determine the optimal number of categories, words and other means to better communicate what different concern levels mean, she said.

Systematic Review

In partnership with the EPA and the World Health Organization, NTP also is working to adapt systematic review to the chemical evaluations it conducts, Bucher said.

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Systematic review techniques were designed for physicians examining clinical studies about specific therapeutic approaches. The goal is to adapt them to environmental health assessments.

"We're expecting a lot of strides in that area," Bucher said.

Systematic reviews attempt to bring rigor and transparency to reviews of scientific evidence.

Elements of Systematic Review
• defining the questions to be analyzed;
• developing criteria to include or exclude scientific studies;
• identifying studies through literature searches and other means;
• assessing study quality and risk of bias;
• synthesizing findings from individual studies; and
• interpreting those findings.

IRIS Program

The Integrated Risk Information System program, which evaluates the health effects of chemicals and the doses at which those effects may manifest, will be wrestling with many questions relating to systematic review following a two-day workshop the EPA held in mid-December.

The program also will be analyzing chemicals identified in the IRIS Agenda it released Dec. 15 (241 DEN A-1, 12/16/15)(241 DEN, 12/16/15)(242 DEN A-15, 12/17/15)(242 DEN 1, 12/17/15)(242 DEN, 12/17/15).

Nancy Beck, a toxicologist with the American Chemistry Council, told Bloomberg BNA that such silence has been frustrating in 2015, a year in which the IRIS program also canceled several public meetings.

"I think they are struggling internally. I don't know what's happening in that program. It would be nice if they could communicate along the way what they are trying to do," Beck said.

When IRIS program staff members speak at public meetings, they sound as if the program is making improvements, she said.

But with few materials having been released in 2015, it is hard to know, she said.

ORD's Burke said "IRIS is source of frustration. I would like to see it move much quicker, and we're working in that direction."

But the IRIS program is going through a time of transition as it responds to changes recommended by the National Academies of Sciences, Engineering, and Medicine, Burke said.

Kenneth Olden, director of EPA's National Center for Environmental Assessment, which oversees IRIS, launched a series of initiatives in 2012 to revamp it (134 DEN A-10, 7/13/12).

Olden told a House subcommittee in 2014 that it could take three to five more years to overhaul the program (137 DEN A-6, 7/17/14).

Burke said improving a product sometimes slows production. "We're in a transition stage, where we're looking to push that process."

"Every new bar we set takes time to adapt to," he said.

Connecting the Dots

Although IRIS is going through a transition, ORD is providing as many tools and as much assistance as it can so state, EPA and public health officials can connect the dots that lead from one or more exposures through many different environmental and biological systems to, ultimately, affect public health, Burke said.

"Risk assessment is a really important public health tool that synthesizes public health information from so many different sources to guide decisions," Burke said.

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