News Headline: New Report Notes Progress, Recommends Additional Improvements to Strengthen EPA's Chemical Assessment Program |

News Date: 05/06/2014
Outlet Full Name: Targeted News Service
Contact Name:
News Text: The American Chemistry Council issued the following news release:

The National Academy of Sciences (NAS) released today a report detailing their review of the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS). This congressionally-mandated report evaluated EPA's progress for improving the IRIS program by implementing the recommendations made by the National Research Council after their review of the draft formaldehyde assessment in 2011.

The following statement can be attributed to the American Chemistry Council (ACC):

"We welcome this important report and are particularly encouraged that the NAS has recognized the need for EPA to address fundamental issues with the IRIS program. Importantly, the NAS report also singles out the valuable contributions made under the leadership of Dr. Ken Olden to address some of these concerns.

"The NAS report outlines several continuing concerns with the IRIS assessment methodology, including the lack of clear criteria for evaluating the available scientific information. Over the past several years, a strong case has been made detailing the critical need for improving IRIS in order to provide better support for public health decisions.

"The U.S. Government Accountability Office has listed IRIS as a 'high risk program,' and Congress has been compelled to act in a bipartisan fashion to call for this review by the NAS. This report marks yet another important milestone for identifying and addressing areas for improving the IRIS program. However, the release of this report should not be viewed as a stopping point.

"ACC has strongly supported improvements in stakeholder engagement that Dr. Olden has implemented. Unfortunately, progress toward more substantive improvements, such as in data evaluation and evidence integration, has lagged. Today's report reiterates the need for continued improvement for EPA to achieve the scientific accuracy and transparency necessary for the development of high quality, reliable IRIS assessments.

"A number of NAS recommendations align well with ACC's own principles for enhancing chemical assessments. For example, the NAS report calls on EPA to develop and implement consistent and transparent protocols for evaluating data for relevance, reliability and quality. It also advises EPA to improve study integration methods and recommends that the Agency move away from overreliance on single point estimates of toxicity values.

"We hope that EPA will take quick steps to adopt the recommendations of the report, including the development of a structured process to integrate the scientific evidence into assessments. Work on assessments currently in progress will benefit from a more transparent and systematic approach.

"ACC and our members are committed to strengthening the process for conducting assessments under IRIS and other government assessment programs. We look forward to continuing our constructive work with EPA, including the adoption of many of the concepts outlined in our principles and this report."

- Learn more about chemical assessments http://www.americanchemistry.com/Policy/Chemical-Safety/Chemical-Assessments

News Headline: National Research Council Releases Report Praising EPA's IRIS Program Enhancements |

News Date: 05/06/2014
Outlet Full Name: Targeted News Service
Contact Name:
News Text: The Environmental Protection Agency issued the following news release:

Today, the U.S. Environmental Protection Agency's (EPA) actions to improve its Integrated Risk Information System (IRIS) program, which provides information on the health effects of environmental contaminants, were applauded in a report by the National Academies' National Research Council (NRC).

"I'm proud of the hard work our scientists have put into improving our IRIS program, and encouraged to see their efforts result in such tremendous progress which translates to greater transparency and improved efficiency to the benefit of the American public," said Lek Kadeli, acting assistant administrator for EPA's Office of Research and Development. "EPA is grateful to the Academies for their review, their recognition of the progress that's been made, and for their recommendations that will help us make IRIS a much more effective and efficient program."

The NRC announced that the program has moved forward steadily in planning for and implementing changes in each element of the IRIS assessment process. The report commends EPA for its substantive new approaches, continued commitment to improving the process, and successes to date. While recognizing the IRIS program is still implementing changes, the NRC notes in its report that, "overall, the committee expects that EPA will complete its planned revisions in a timely way and that the revisions will transform the IRIS program."

EPA's IRIS program provides health assessments of chemicals to which the public may be exposed from releases to air, water, and land and, additionally, through the use and disposal of chemicals. IRIS assessments inform EPA rulemakings, and the release of final IRIS assessments is consistent with EPA's ongoing efforts to improve the health of Americans and protect the environment.

EPA has been strengthening IRIS for several years and in 2013 announced broad changes through a series of enhancements designed to help the Agency produce more high quality assessments in a timely and transparent manner. A key feature of the enhancements is increased stakeholder engagement throughout the assessment development process, which EPA is achieving by holding bimonthly public science meetings to discuss specific assessments.

In the past few years, EPA has made many changes to the IRIS program. Assessments are now written using a streamlined document structure that includes:

A preamble describing how EPA applies guidance, methods, and criteria to develop assessments;

An executive summary highlighting major assessment conclusions;

A detailed literature search strategy and study evaluation process used to develop the assessment; and

Distinct sections on hazard identification and dose-response analysis.

The NRC notes that the IRIS program has made substantial progress in a short time, and the recommendations in their most recent report should be seen as building further on the progress that EPA has already made. EPA plans to convene a workshop later this year to address some of the NRC's recommendations.

News Headline: Vitter Statement on National Academies Review of EPA Chemical Assessment |

News Date: 05/06/2014
Outlet Full Name: Targeted News Service
Contact Name:
News Text: The ranking Republican member of the Senate Environment and Public Works Committee issued the following news release:

U.S. Sen. David Vitter (R-La.), top Republican on the Environment and Public Works (EPW) Committee, made the following statement regarding the National Academies review of the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) process for chemical assessments.

"Overall, the changes that EPA has proposed show's some initial improvements in their chemical assessment process, but by no means is this report a reason to spike the football," Vitter said. "Chemical safety is a top priority, and we need to ensure that the EPA's basic goals are to develop assessments that provide an evidence-based foundation for ensuring that chemical hazards are assessed and managed well. If the EPA actually implements the National Academies suggestions, the process will slowly move to becoming much more effective and credible but this is just a first step and they have a long way to go."

Vitter has long been pushing to have the EPA implement recommendations from the National Academies on chemical assessments and has been affective on several accounts including the 2011 formaldehyde assessment review which led to the ongoing changes in the IRIS program. Additional efforts to improve EPA's chemical science include forcing EPA to withdraw using work from the Ramazzini Institute in multiple chemical assessments, including methanol. Vitter raised additional concerns when EPA continued to have problems with its inorganic arsenic assessment in 2013.

In December 2013, Dr. Burke, President Obama's nominee to lead EPA's Office of Research and Development had positive comments saying he shared the same goals to promote better science at the agency. Click here to read his comments (http://www.epw.senate.gov/public/index.cfm?FuseAction=PressRoom.PressReleases&ContentRecord_id=a82e15b9-e8dc-87f2-cafe-b743f43ce85a).

You can access the National Academies of Science review here (http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=512014).

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News Headline: Report to US Congress finds 'substantial improvements' in IRIS |

News Date: 05/06/2014
Outlet Full Name: Chemical Watch
Contact Name:
News Text: Report recommends use of systematic review principles
6 May 2014

The National Research Council (NRC) has credited the US EPA with making “substantial improvements” to its Integrated Risk Information System (IRIS) process.

In a report, which was requested by Congress, the NRC evaluates progress made by the agency in implementing the 2011

recommendations, made after the Council's review of the IRIS formaldehyde assessment. The review had found deficiencies in the assessment, as well in the EPA's general methods, which Congress directed the agency to remedy.

The "trajectory of changes" in the IRIS process has been very positive, says Jonathan Samet, who chaired the NRC committee.

While acknowledging the improvements, the report offers further guidance and recommendations to improve the overall scientific and technical performance of the IRIS programme.

The report notes that the EPA has:
developed a document structure that "improves the organisation of, and streamlines, the assessments and reduces redundancies"; added a standard preamble to all assessments that describes the IRIS process; drafted a handbook that provides a more detailed description of underlying principles; formed chemical assessment support teams to oversee the process; and provided more opportunities for stakeholder input.
The NRC suggests that the handbook be peer reviewed. It wants IRIS assessments to clearly identify the members of all teams involved and that outside expertise is utilised when needed. It suggests the agency provide technical assistance to "under-resourced" stakeholders to help them develop and provide input into the process.

In problem formulation, a major challenge for the EPA is deciding what adverse health outcomes should be evaluated in a specific IRIS assessment, the report says. It suggests the agency take an approach that includes making a broad literature search, creating a table that organises the lines of evidence and possible health outcomes, and then examining the table to decide which outcomes call for a review.

The EPA has also implemented a standardised approach to evaluating evidence, the report notes. And while it correctly identifies attributes that can be used to judge study quality, the method does not "describe how it will access risk of bias" in the study. Without suggesting any particular approach to assessing bias, the NRC says the agency should fully describe its method in IRIS assessments.

Dr Samet, who is the director of global health at the University of Southern California, cites the development of a preamble and handbook to guide the process as positive steps to augment stakeholder involvement. The handbook is still incomplete in areas where quantification of risk is required, he said. On the content of the IRIS reports, the agency is moving to an approach that "very much mimics" systematic review such as in the "evidence-based medicine paradigm", he says. "Our report urges the agency to use the systematic review principles which lead to transparency."

News Headline: New Report Notes Progress, Recommends Additional Improvements to Strengthen EPA's Chemical Assessment Program |

News Date: 05/06/2014
Outlet Full Name: American Chemistry - Online
Contact Name:
News Text: Contact: Scott Jensen, (202) 249-6511
Email: Scott_Jensen@americanchemistry.com

WASHINGTON (May 6, 2014) – The National Academy of Sciences (NAS) released today a report detailing their review of the U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS). This congressionally-mandated report evaluated EPA's progress for improving the IRIS program by implementing the recommendations made by the National Research Council after their review of the draft formaldehyde assessment in 2011.

The following statement can be attributed to the American Chemistry Council (ACC):

"We welcome this important report and are particularly encouraged that the NAS has recognized the need for EPA to address fundamental issues with the IRIS program. Importantly, the NAS report also singles out the valuable contributions made under the leadership of Dr. Ken Olden to address some of these concerns.

"The NAS report outlines several continuing concerns with the IRIS assessment methodology, including the lack of clear criteria for evaluating the available scientific information. Over the past several years, a strong case has been made detailing the critical need for improving IRIS in order to provide better support for public health decisions.

"The U.S. Government Accountability Office has listed IRIS as a 'high risk program,' and Congress has been compelled to act in a bipartisan fashion to call for this review by the NAS. This report marks yet another important milestone for identifying and addressing areas for improving the IRIS program. However, the release of this report should not be viewed as a stopping point.

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» Learn more about chemical assessments

News Headline: Substantial Improvements Made in EPA's IRIS Program, Report Says |

News Date: 05/06/2014
Outlet Full Name: ScienceNewsline
Contact Name:
News Text: WASHINGTON – A new congressionally mandated report from the National Research Council says that changes EPA has proposed and implemented into its Integrated Risk Information System (IRIS) process are "substantial improvements." While acknowledging the progress made to date, the report offers further guidance and recommendations to improve the overall scientific and technical performance of the program, which is used to assess the hazards posed by environmental contaminants.

In 2011, a Research Council committee reviewed EPA's IRIS assessment for formaldehyde and found deficiencies both in the particular assessment as well as more broadly in EPA's general assessment methods. EPA was directed by Congress to implement the report's general recommendations on the IRIS process, and the Research Council was then tasked with assessing the changes made and recommending additional modifications.

In response to the recommendations in the formaldehyde report, EPA developed a new document structure, added a standard preamble to all assessments that describes the IRIS process, drafted a handbook that provides a more detailed description of this process and its underlying principles, formed chemical assessment support teams to oversee the process and ensure consistency, and increased opportunities for stakeholder input.

The Research Council committee that wrote the new report found the improved documentation better organizes and streamlines IRIS assessments, and the preamble is useful although it doesn't fulfill the need for a description in each assessment that indicates how the general principles are applied. The report recommends that the handbook be peer-reviewed, that IRIS assessments clearly identify the members of all teams involved, and that outside experts be engaged when needed. It adds that EPA should provide technical assistance to stakeholders who might not have the resources to provide input into the IRIS process.

EPA's progress indicates that the agency is incorporating principles of systematic review, a method for synthesizing scientific evidence that focuses on a specific question and uses predefined methods to identify, select, assess, and summarize the findings of the full body of literature relevant to the question. The committee agreed that using this approach would strengthen the IRIS process, and used published systematic-review standards as a reference point to evaluate the changes that EPA has made.

A major challenge for EPA in problem formulation is determining which adverse health outcomes should be evaluated in a specific IRIS assessment, the report says. The committee suggested a process that includes conducting a broad literature search, creating a table that organizes the lines of evidence and possible health outcomes, and then examining the table to decide which outcomes warrant a review. Once a systematic-review question is specified, a protocol should be developed that makes the methods of the review transparent.

The protocol should include descriptions of the literature search strategy for each question and explicitly state the criteria for including or excluding studies, and should be reviewed by an information specialist. Such a standardized search strategy is essential for evidence identification, the report says. EPA has also implemented a standardized approach to evaluating evidence, and while it correctly identifies attributes that can be used to judge study quality, it does not describe how it plans to assess the risk of bias in the identified studies. The committee did not recommend any specific approach to assessing bias, but said that the approach chosen by EPA and its results should be fully described and reported in the IRIS assessment.

After systematic review is completed, an IRIS assessment must combine all the individual lines of evidence to come to a judgment about whether a chemical is hazardous to human health, a process the committee referred to as "evidence integration." EPA currently relies on a guided expert judgment process for evidence integration. EPA should either make this process more transparent if it chooses to continue using this approach or adopt a structured process for evidence integration. EPA should also develop templates for narrative justifications of the evidence integration process and its conclusions, and work to ensure that its guidelines for integration are uniform for cancer and noncancer outcomes, the report says.

In addition to hazard identification, IRIS assessments derive toxicity values for given substances when data allow. The committee was encouraged by the improvements that EPA has made in this area, particularly the shift away from choosing one study as the "best" study for deriving a toxicity value and toward deriving and graphically presenting multiple candidate values. EPA, however, should develop formal methods for combining results of multiple studies and selecting the final IRIS

values with an emphasis on achieving a transparent and replicable process.

To ensure that the IRIS program provides the best assessments possible, the committee recommended that EPA develop a plan for strategically updating its methodology, systematically addressing any identified inefficiencies, and continually evaluating whether the IRIS teams have the appropriate expertise and training.

News Headline: Substantial improvements made in EPA's IRIS Program, report says |

News Date: 05/06/2014
Outlet Full Name: e! Science News
Contact Name:
News Text: A new congressionally mandated report from the National Research Council says that changes EPA has proposed and implemented into its Integrated Risk Information System (IRIS) process are "substantial improvements." While acknowledging the progress made to date, the report offers further guidance and recommendations to improve the overall scientific and technical performance of the program, which is used to assess the hazards posed by environmental contaminants. In 2011, a Research Council committee reviewed EPA's IRIS assessment for formaldehyde and found deficiencies both in the particular assessment as well as more broadly in EPA's general assessment methods. EPA was directed by Congress to implement the report's general recommendations on the IRIS process, and the Research Council was then tasked with assessing the changes made and recommending additional modifications.

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To ensure that the IRIS program provides the best assessments possible, the committee recommended that EPA develop a plan for strategically updating its methodology, systematically addressing any identified inefficiencies, and continually evaluating whether the IRIS teams have the appropriate expertise and training.

Report: http://www.nap.edu/catalog.php?record_id=18764

News Headline: US EPA plans workshop to address IRIS improvements |

News Date: 05/07/2014
Outlet Full Name: Chemical Watch
Contact Name:
News Text: 7 May 2014

The US EPA will convene a workshop, later this year, to address recommendations for further improvements to the Integrated Risk Information System. The recommendations were made by the National Research Council (NRC) in its latest IRIS review report (CW 6 May 2014 /).

While applauding the “substantial improvements” to IRIS, the report provides further guidance and recommendations to enhance the overall scientific and technical performance of the programme. “The NRC notes that the IRIS programme has made substantial progress in a short time, and the recommendations in their most recent report should be seen as building further on the progress that the EPA has already made,” the agency says. Stakeholders agree with the NRC assessment and say they looked forward to further improvements.

The report outlines “several continuing concerns with the IRIS assessment methodology, including the lack of clear criteria for evaluating the available scientific information,” says the American Chemistry Council (ACC). Supporting the advancements made to increase stakeholder engagement, the group adds that “progress towards more substantive improvements, such as in data evaluation and evidence integration, has lagged.”

The ACC urged the EPA to take quick steps to implement the report recommendations, including developing a structured process to integrate the scientific evidence into assessments. "Work on assessments currently in progress will benefit from a more transparent and systematic approach."

The Environmental Defense Fund (EDF) agrees with, and is encouraged by, the NRC's assessment, says Jennifer McPartland, EDF health scientist. "We look forward to additional recommended enhancements, including more explicit consideration of risk of bias in study evaluations, technical support for under-resourced stakeholders and continuing enforcement of firm stopping rules."

Jennifer Sass, senior scientist at the Natural Resources Defense Council, says she shares the NRC's "overall praise and enthusiasm for the improved IRIS progress." Among "particularly pleasing" aspects of the report are its support for "firm stopping rules at key points throughout the process to guard against delay," she says. "These stopping rules should help prevent industry tactics that delay chemical assessments."

News Headline: National Research Council Releases Report Praising EPA's IRIS Program Enhancements |

News Date: 05/07/2014
Outlet Full Name: Water Online
Contact Name:
News Text: Recently, the U.S. Environmental Protection Agency's (EPA) actions to improve its Integrated Risk Information System (IRIS) program, which provides information on the health effects of environmental contaminants, were applauded in a report by the National Academies' National Research Council (NRC).

"I'm proud of the hard work our scientists have put into improving our IRIS program, and encouraged to see their efforts result in such tremendous progress which translates to greater transparency and improved efficiency to the benefit of the American public," said Lek Kadeli, acting assistant administrator for EPA's Office of Research and Development. "EPA is grateful to the Academies for their review, their recognition of the progress that's been made, and for their recommendations that will help us make IRIS a much more effective and efficient program."

The NRC announced that the program has moved forward steadily in planning for and implementing changes in each element of the IRIS assessment process. The report commends EPA for its substantive new approaches, continued commitment to improving the process, and successes to date. While recognizing the IRIS program is still implementing changes, the NRC notes in its report that, "overall, the committee expects that EPA will complete its planned revisions in a timely way and that the revisions will transform the IRIS program."

EPA's IRIS program provides health assessments of chemicals to which the public may be exposed from releases to air, water, and land and, additionally, through the use and disposal of chemicals. IRIS assessments inform EPA rulemakings, and the release of final IRIS assessments is consistent with EPA's ongoing efforts to improve the health of Americans and protect the environment.

EPA has been strengthening IRIS for several years and in 2013 announced broad changes through a series of enhancements designed to help the Agency produce more high quality assessments in a timely and transparent manner. A key feature of the enhancements is increased stakeholder engagement throughout the assessment development process, which EPA is achieving by holding bimonthly public science meetings to discuss specific assessments.

In the past few years, EPA has made many changes to the IRIS program. Assessments are now written using a streamlined

document structure that includes:
A preamble describing how EPA applies guidance, methods, and criteria to develop assessments;
An executive summary highlighting major assessment conclusions;
A detailed literature search strategy and study evaluation process used to develop the assessment; and
Distinct sections on hazard identification and dose-response analysis.

The NRC notes that the IRIS program has made substantial progress in a short time, and the recommendations in their most recent report should be seen as building further on the progress that EPA has already made. EPA plans to convene a workshop later this year to address some of the NRC's recommendations.

Information on IRIS: www.epa.gov/iris

Link to NRC report: http://www.nationalacademies.org/newsroom/index.html

News Headline: Academies Report Praises EPA's Progress Improving Process, Content of IRIS Reviews |

News Date: 05/07/2014
Outlet Full Name: BNA's Daily Environment Report
Contact Name: Rizzuto, Pat
News Text: May 6 —

The Environmental Protection Agency has made substantial improvements in how it develops toxicological assessments of chemicals under its Integrated Risk Information System (IRIS) program and has upgraded the content of those assessments, the National Academies reported May 6. The congressionally mandated report from the academies' Committee to Review the IRIS Process offered recommendations about how the agency can build on the progress it has made and continue to improve the scientific and technical information in its toxicological assessments.

As the EPA already has begun to do, the committee suggested the IRIS program increase its use of systematic review. The committee urged the EPA to expand its analysis of how different types of biases could affect the results of scientific studies and to provide more information to help readers of IRIS documents understand the uncertainties surrounding estimates of doses at which disease or health injuries could occur.

IRIS assessments evaluate the hazards posed by environmental contaminants and the doses at which the hazards manifest. Increased Participation Companies, trade associations, health advocates, state officials and other organizations now have more opportunities to participate in and offer information for the IRIS assessments as they are developed, the committee noted as one of the positive changes. Federal, state, local and international governments use the assessments to determine whether regulations or other forms of risk management are needed.

The academies' National Research Council prepared the report, following up on criticisms from several academies committees reviewing draft IRIS assessments. An academies committee summarized the consistent problems the committees found in a 2011 critique of the EPA's draft assessment of formaldehyde (69 DEN A-1, 4/11/11).
In response, a House report that accompanied the Consolidated Appropriations Act of 2012 (Pub. L. No. 112-74) directed the EPA to revise IRIS in accordance with that critique.

The House Report (No. 112-151) also directed the agency to hire the National Academies to convene a committee that would oversee the agency's efforts to improve IRIS. The May 6 report was published by that committee.

Public Participation

Jonathan Samet, chairman of the committee that reviewed the changes the EPA is making to IRIS, told reporters May 6 that the committee lauded the fundamental, very positive changes the agency has been making since 2011 to the process of developing IRIS documents and their content. Samet also was chairman of the committee that issued the 2011 critique of EPA's draft formaldehyde assessments, which spurred the changes.

Samet commended the agency for offering interested parties more opportunities to participate in the development of IRIS assessments. For example, broadcasting IRIS meetings online is offering people an opportunity to participate even when they are unable to fly to EPA headquarters, he said.

"However, not all stakeholders who have an interest in the IRIS process have the same scientific or financial resources to provide timely comments, and expanded opportunities for stakeholder involvement might lead to a further imbalance of public input" the report said.

"Therefore, similar to other EPA technical-assistance programs, EPA should consider ways to provide technical assistance to under-resourced stakeholders to help them to develop and provide input into the IRIS process," the report said.
At an April IRIS meeting, Vincent Cogliano, acting director of IRIS, said the number of participants representing diverse perspectives and organizations had increased compared with a December IRIS program meeting. He said the EPA would continue to reach out to ensure broad-based participation in IRIS.

Easier to Use, Understand

Other changes the National Academies report commended include EPA producing IRIS assessments that are easier to read and the agency's increased use of tables, charts and other visual tools to present information.
Such changes should help regulatory offices within the agency, state agencies and other organizations better use the information in IRIS assessments, Samet said.

The committee urged the EPA to maintain the trajectory of progress and to periodically have the general process and content of IRIS documents peer reviewed, Samet said.

Early Reaction

The American Chemistry Council, which represents major U.S. chemical manufacturers, issued a statement echoing the praise in the academies report for ways the EPA is revising the IRIS program.

"Today's report reiterates the need for continued improvement for EPA to achieve the scientific accuracy and transparency necessary for the development of high quality, reliable IRIS assessments," the chemistry council said.

"We hope that EPA will take quick steps to adopt the recommendations of the report, including the development of a structured process to integrate the scientific evidence into assessments," the council said.

Jennifer Sass, a senior scientist with the Natural Resources Defense Council, told Bloomberg BNA she was pleased that the academies report recognized the extensive work the EPA has undertaken to revise IRIS.

"The National Academies basically gave the EPA an A+," Sass said.

Sass said NRDC supports recommendations the report made on issues such as "stopping rules" and bias assessments.
Much has been done, and the committee has very helpfully identified next steps that enhance the rigor of the IRIS process, said George Gray, director of the Center for Risk Science and Public Health at George Washington University.

Gray, who served as assistant administrator for the EPA's Office of Research and Development and as the agency's science adviser during the George W. Bush administration, said he supports recommendations the committee made on expanding the IRIS program's use of uncertainty analyses and presenting toxicity dose information in multiple ways.

Stopping Rules

Among the changes the EPA has made to IRIS since 2011 is its concept that "stopping rules" are needed to prevent delays in completing assessments. Stopping rules would provide a definite end date for submitting data for individual chemical reviews. The idea is to speed the completion of IRIS assessments, some of which have continued for 10 or more years (148 DEN A-1, 8/1/13).

The committee said it agreed with the EPA that stopping rules are needed, because the process for some IRIS assessments has become too long as revisions are repeatedly made to the assessments to accommodate new evidence and to review comments. However, "the stopping rules should be explicit and transparent, should describe when and why the window for evidence inclusion should be expanded, and should be sufficiently flexible to accommodate truly pivotal studies," the academies report said.

Systematic Review

The committee urged the EPA to use systematic review principles as it continues to revise the IRIS process.
"Critical elements of conducting a systematic review include formulating the specific question that will be addressed (problem formulation) and developing the protocol that specifies the methods that will be used to address the question (protocol development)," the report said.

The agency should consider using or adapting systematic review procedures that are available or being developed to determine which would be most appropriate for IRIS purposes, the report said.
Participants at a recent IRIS meeting encouraged the agency to hold a workshop on ways the IRIS program could use systematic review (80 DEN A-10, 4/25/14).

Bias

The report urged the IRIS program to consider many different types of biases that could influence a scientific study's results. For example, the methods used to give laboratory animals a chemical dose and the ways they are exposed to it, such as through inhalation, ingestion, or contact with the skin, could lead to bias, the report said.
Incorporating risk-of-bias assessments into the IRIS process might take additional time, the report said.
The agency's ability to do so will vary depending on the extent of data on the chemical being analyzed and the complexity of the assessment, it said.

A key problem the EPA faces is that the information it would need for bias assessments may not be available in the studies published in scientific journals, the report said. Addressing this problem may require a coordinated effort by government agencies, researchers, publishers and professional societies, the report said. If scientific journals require bias assessment information to be reported, it will be, the report said.

'Weight of Evidence.'

The draft Chemicals in Commerce Act circulated by a House Energy and Commerce Subcommittee would require the EPA to use a weight-of-evidence approach to decisions on chemicals. The proposed legislation, however, does not define the term. The committee said the phrase weight-of-evidence has become too vague and is of little scientific use.

"An IRIS assessment must come to a judgment about whether a chemical is hazardous to human health and must do so by integrating a variety of lines of evidence. Therefore, the committee found the term evidence integration to be more useful and more descriptive of the process that occurs after completion of systematic reviews," the report said.

Uncertainties

On uncertainties, the report said: "Uncertainty analysis should be conducted systematically and coherently in IRIS assessments. To that end, EPA should develop IRIS-specific guidelines to frame uncertainty analysis and uncertainty

communication."

In sections of the report that provide toxicity values, the report said EPA should provide multiple toxicity-value estimates under different assumptions, options, models and methods.

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