{In Archive} Re: Review of ADME section in draft formaldehyde assessment

Sury Vulimiri to: Paul Schlosser 12/02/2011 01:09 PM
Cc: Barbara Glenn, Ravi Subramaniam
Bcc: Kate Guyton

Archive: This message is being viewed in an archive.

Hi Paul,

Thank you very much for taking time to review the Toxicokinetics section. I will incorporate the paragraph you suggested. I will look forward for your complete review and then get back to you if I have any questions.
Thanks again.
Have a nice weekend.

Sury

Suryanarayana (Sury) Vulimiri, B.V.Sc., PhD, DABT
Biologist, National Center for Environmental Assessment, ORD, USEPA
(P) 703.308.7949, (F) 703.347.8692, E-mail: vulimiri.sury@epa.gov
Mailing Address: USEPA (8623-P), 1200 Pennsylvania Ave. NW, Washington, D.C. 20460
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-----Paul Schlosser/RTP/USEPA/US wrote: -----
To: Barbara Glenn/DC/USEPA/US@EPA
From: Paul Schlosser/RTP/USEPA/US
Date: 12/02/2011 12:57PM
Cc: Ravi Subramaniam/DC/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA
Subject: Re: Review of ADME section in draft formaldehyde assessment

Barbara, Ravi, Sury,

I'm part way through reviewing the chapter, should finish this afternoon. I'm suggesting some added text on inhalation distribution that I'm copying below, so you can begin to consider this sooner. I remember Henry Heck saying this to me (not the numbers but the qualitative conclusion) at some point ... well after the '85 paper. Added text (suggested) is in bold below.

I also recall Henry relating that he was one of the subjects and that the eye irritation from this exposure was extremely high -- it was hard to stay in the chamber that long. Most human exposure are below the eye irritation threshold, 0.5 mg/m3 = 0.5 ug/L. At that level, assuming 20 L/m daily average for a 70 kg person, you'd inhale 206 ug/kg-day, or 0.2 ug/g of blood assuming even distribution. Given the SDs below, even that would be barely detectable, if there were no removal by chemical reactions, etc. At the odor threshold, 0.1 mg/m3, it's down to 1/5th of that. So I think that your considerations of possible impact also have to

include such calculations of how much of an increase they would cause over normal endogenous levels, and how that compares to normal variation.

-Paul

> Heck et al (1985) conducted a controlled inhalation study with six healthy volunteers and measured the blood formaldehyde levels by GC-MS analysis before and after exposure to 1.9 ppm formaldehyde for 40 minutes. They observed that the pre- and post-exposure levels of formaldehyde (2.61 ± 0.14 vs. 2.77 ± 0.28 µg/g of blood) were not significantly different in these individuals, suggesting that the inhaled formaldehyde is possibly completely absorbed in the nasal cavity and **conducting airways and reacts with those tissue constituents, hence** did not reach blood (Table 3-4). **But if one assumes a somewhat high resting ventilation rate of 9 liters per minute for a 70 kg adult, the total mass of formaldehyde inhaled at 1.9 ppm in 40 minutes (21 C, 1 atm) would be 6.5 µg/kg BW. Assuming an even distribution throughout the body, this would correspond to an increase of 0.0065 ug/g of blood. Thus the total mass of formaldehyde inhaled in this experiment was not sufficient to result in a significant increase in blood levels, even if there was no removal by any chemical reaction or clearance process. Thus the data are inconclusive as to whether inhaled formaldehyde reaches the blood or not, but the mass balance calculation shows that the amount inhaled with air concentrations in the low ppm range is not sufficient to significantly increase systemic levels, even if it does distribute there.**

Barbara Glenn---11/04/2011 09:09:32 AM---Hi Paul, I think we could live with an early Dec date for your review. We really appreciate your wi

From: Barbara Glenn/DC/USEPA/US
To: Paul Schlosser/RTP/USEPA/US@EPA
Cc: Ravi Subramaniam/DC/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA
Date: 11/04/2011 09:09 AM
Subject: Re: Review of ADME section in draft formaldehyde assessment

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Hi Paul,
I think we could live with an early Dec date for your review. We really appreciate your willingness to spend some time on it given all of your other commitments. Thank you so much! Here is the document and if

you want to discuss any issues of clarification with Sury or Ravi, please feel free to do that.

-Barbara

[attachment "FA Chapter 3-ADME Revised 101511.doc" deleted by Paul Schlosser/RTP/USEPA/US]

Paul Schlosser---11/03/2011 05:45:14 PM---Barbara, cc: Ravi

From: Paul Schlosser/RTP/USEPA/US
To: Barbara Glenn/DC/USEPA/US@EPA
Cc: Ravi Subramaniam/DC/USEPA/US@EPA
Date: 11/03/2011 05:45 PM
Subject: Re: Review of ADME section in draft formaldehyde assessment

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Barbara,
cc: Ravi

Right now I need to focus on completing the revision of the methanol assessment, which I've delayed considerably for other work already. There are other balls that I need to keep in the air at the same time... I *think* that I could provide a review in 3 weeks, but I just completed a manuscript review that took over 3 weeks for me to get to. Also, 3 weeks from today is Thanksgiving, and I have a brother coming to visit that week, was planning to take at least one extra day of leave...

So I am willing, but I cannot commit to having it done in 3 weeks. It's possible that I could do sooner, but Dec. 2 is more likely.

-Paul

Barbara Glenn---11/03/2011 04:39:34 PM---Hello Paul, I am the chemical manager for revising the formaldehyde assessment. We have a draft rev

From: Barbara Glenn/DC/USEPA/US
To: Paul Schlosser/RTP/USEPA/US@EPA
Date: 11/03/2011 04:39 PM
Subject: Review of ADME section in draft formaldehyde assessment

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Hello Paul,
I am the chemical manager for revising the formaldehyde assessment. We have a draft revision of the ADME section in Chapter 2 written by Sury Vulimiri. Both Sury and Ravi Subramaniam suggested that it would be valuable if you would review this revision and provide comments. I would really appreciate it if you are willing to do that.

Would you have time to do this over the next 3 weeks or so? I am happy to discuss this on the phone if you would like.

Thanks for considering, Barbara Glenn

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

{In Archive} reference to NRC in revised formaldehyde document

Ravi Subramaniam to: Kate Guyton, Barbara Glenn 09/09/2011 07:52 AM

History: This message has been replied to.

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This is re: formaldehyde. I would like to refer to an argument in the NRC review in the MAIN body of the revised formaldehyde assessment and cite NRC 2011. I am assuming that, since NRC 2011 is a published and citable (peer-reviewed) document, such citation would be appropriate. I dont recall us doing so in perc, so I thought I would check if there are any considerations against doing so.

Ravi

Ravi Subramaniam
Environmental Health Scientist
NCEA-Washington, ORD, EPA
N-7934, Two Potomac Yard, Crystal City
(703) 347-8606, (301) 515-2701 (alternate office)

{In Archive} Re: Comments? Slides for IO briefing on Formaldehyde Assessment

Barbara Glenn to: Kate Guyton 06/09/2011 06:08 PM

Archive: This message is being viewed in an archive.

I think we all agree with that assessment and the central message of this briefing should be that no change in direction is anticipated. Thanks.

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

Kate Guyton | Hi Barbara, I realize I am coming in after the mo... | 06/09/2011 06:04:14 PM

From: Kate Guyton/DC/USEPA/US
To: Barbara Glenn/DC/USEPA/US@EPA
Date: 06/09/2011 06:04 PM
Subject: Re: Comments? Slides for IO briefing on Formaldehyde Assessment

Hi Barbara,

I realize I am coming in after the movie already started... but I suggest deleting reference to potential additional peer review on the last slide. I would endorse a strong team opinion that additional peer review will not be needed, given that the major conclusions will not change... whether this is politically viable, however, I don't know. But if you go back for another peer review, that will add years to your pain.
Thanks,
Kate

Kate Z. Guyton, PhD DABT
Toxicologist, NCEA, ORD, US EPA
703-347-8562 | guyton.kate@epa.gov
Mailing Address: US EPA (8623-P), 1200 Pennsylvania Ave. NW, Washington DC 20460
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Barbara Glenn | I attached some slides for our Thursday briefing... | 06/09/2011 05:37:39 PM

{In Archive} Re: Comments? Slides for IO briefing on Formaldehyde Assessment

Sury Vulimiri to: Barbara Glenn 06/09/2011 05:58 PM

Cc: Andrew Kraft, Barbara Glenn, Danielle DeVoney, David Bayliss, Jennifer Jinot, John Whalan, Kate Guyton, Mary Ross, Ravi Subramaniam, Susan Euling, Susan Makris, Thomas Bateson

Archive: This message is being viewed in an archive.

Hi Barbara,

Here are my edits.

Sury

formaldehyde next steps_BClark_9Jun2011_SV edits.pptx

Barbara Glenn | I attached some slides for our Thursday briefing... | 06/09/2011 05:37:39 PM

From: Barbara Glenn/DC/USEPA/US
To: Andrew Kraft/DC/USEPA/US@EPA, Barbara Glenn/DC/USEPA/US@EPA, Danielle DeVoney/DC/USEPA/US@EPA, David Bayliss/DC/USEPA/US@EPA, Jennifer Jinot/DC/USEPA/US@EPA, John Whalan/DC/USEPA/US@EPA, Ravi Subramaniam/DC/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA, Susan Euling/DC/USEPA/US@EPA, Susan Makris/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA, Mary Ross/RTP/USEPA/US@EPA, Kate Guyton/DC/USEPA/US@EPA
Date: 06/09/2011 05:37 PM
Subject: Comments? Slides for IO briefing on Formaldehyde Assessment

I attached some slides for our Thursday briefing of the IO for your comments and suggestions. The intent is to illustrate our understanding of the NAS comments, our approach to responding to them, and how much work it will take.

Mary and I are prebriefing David, Bob and Paul on Tuesday morning. I appreciate any comments you have and would like to receive them by Monday afternoon so I can incorporate them for the morning meeting.

thanks, Barbara

[attachment "formaldehyde next steps_BClark_9Jun2011.pptx" deleted by Sury Vulimiri/DC/USEPA/US]

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

{In Archive} Re: Formaldehyde staffing list

Barbara Glenn to: Christina Bonanni 12/09/2011 10:42 AM
Cc: Gina Perovich, Bob Sonawane, Kate Guyton

Archive: This message is being viewed in an archive.

Hi Christina,
Here is the staffing for the formaldehyde assessment. -Barbara

Staffing:
Barbara Glenn - Chemical manager; epidemiology
John E. Whalan – respiratory toxicology
Danielle DeVoney – toxicology and mode-of-action
Thomas Bateson – epidemiology
Jennifer Jinot –dose-response modeling, human data, cancer and noncancer
Susan Makris – developmental and reproductive toxicology
Jackie Moya – exposure
Ravi Subramaniam – cancer dose-response modeling, animal data; BBDR modeling; toxicokinetics/inhalation dosimetry
Sury Vulimiri – genotoxicity and cancer mode-of-action; toxicokinetics, ADME
Glinda Cooper – epidemiology, immunology
Andrew Kraft – neurotoxicity

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

Christina Bonanni Hi Barbara, I'm compiling a list of all of the staff... 12/08/2011 03:17:33 PM

From: Christina Bonanni/DC/USEPA/US
To: Barbara Glenn/DC/USEPA/US@EPA
Date: 12/08/2011 03:17 PM
Subject: Formaldehyde staffing list

Hi Barbara,
I'm compiling a list of all of the staff members working on each IRIS chemical, and their expertise, as well as any needed expertise. Gina told me you were the head of formaldehyde. Can you send the names and expertise of people working on formaldehyde with you? Also, if you need any expertise areas, please indicate this as well. We're working to assess the IRIS Staffing program as a whole. I'll attach a list of expertise titles that we are using. Thank you!
Christina

[attachment "Expertise Titles.docx" deleted by Barbara Glenn/DC/USEPA/US]
Christina Bonanni
Student Services Contractor
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U.S. Environmental Protection Agency

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House GOP looks to portray EPA toxics assessments as job killers

Jeremy P. Jacobs, E&E reporter

Published: Thursday, October 6, 2011
U.S. EPA's system for evaluating the toxicity of chemicals will come under fire today from Republicans and industry representatives who question its scientific methodologies and argue it is hurting businesses through overregulation.

The House Energy and Commerce Subcommittee on Environment and the Economy today will delve into EPA's Integrated Risk Information System (IRIS), which is tasked with assessing the effects of chemicals on human health and the environment.

And, according to written testimony submitted to the subpanel, IRIS will be the latest arm of EPA targeted by congressional Republicans as a job killer.

Michael Honeycutt of the Texas Council on Environmental Quality will assert that IRIS assessments are not based on the best available science and that they are overly precautionary.

"The heart of the matter is that EPA is moving toward the philosophy that there is no safe level of exposure to a chemical, which is contrary to the cornerstone of the science of toxicology," Honeycutt will testify. "This change in philosophy results in unrealistically low levels that they consider safe. As a result, naturally occurring levels of chemicals will be higher than EPA's safe level."

Honeycutt will also say his organization's frustrations with IRIS have led it to develop its own method for chemical assessments.

The committee will focus largely on a National Academy of Sciences (NAS) review of IRIS's formaldehyde assessment this year. The NAS panel found significant problems with EPA's methodologies and recommended it undergo several changes (*Greenwire* , April 8).

"EPA's recent conclusion that formaldehyde causes leukemia in humans is based on one study that did not show effects at occupational levels, much less environmental levels," Honeycutt will testify. "However, a wealth of solid scientific data show that formaldehyde cannot cause cancer outside of the respiratory tract, but EPA dismissed these data."

EPA Assistant Administrator for the Office of Research and Development Paul Anastas will be on hand to defend IRIS. His testimony will highlight changes in the IRIS program since 2009. He also plans to lay out how EPA is responding to the recommendations of the NAS panel.

"EPA welcomed those suggestions and is addressing all of them," says his written testimony. "The academy recognized that implementing these changes would require a phased-in approach. Although the public will not see the changes for some time, EPA is already implementing many of the NAS recommendations and EPA has a plan for implementing them all."

Some of those changes include more rigorous editing and streamlining of the scientific process.

IRIS has long been criticized by industry. After the NAS formaldehyde report, the American Chemistry Council (ACC) said all controversial IRIS assessments should be sent to NAS for review (*E&ENews PM* , April 19).

"ACC is concerned that an entire generation of IRIS assessments due to be completed in the next nine to 12 months will suffer from the very same shortcomings that plagued the draft formaldehyde assessment," ACC President Cal Dooley said yesterday in a statement.

Anastas, however, will point out that the NAS recommendations did not call for EPA to stall its formaldehyde report.

David Dorman of North Carolina State University, and a member of the NAS formaldehyde panel, will reinforce that point.

"The committee recognized that any revision of the approach would involve an extensive effort by EPA staff and others and consequently, it did not recommend that EPA delay the revision of the formaldehyde assessment while revisions of the approach are undertaken," Dorman will say. "In fact, we provided specific guidance as to the steps needed to revise the existing draft."

However, Dorman will also testify that problems with "clarity and transparency of the methods appear to be a repeating theme over the years."

That sentiment is also present in the written testimony of Harvey Clewell of the Hamner Institutes for Health Science.

The committee will also hear from Jerry Cook, technical director of the Chemical Products Corp., who will testify on how EPA's IRIS assessment of barium "is much more interested in bureaucratic expediency than in sound science."

As a result, EPA's Resource Conservation and Recovery Act (RCRA) standards on barium are hurting his customers' business. Cook's customers use his barium chemicals to manufacture ceramic bricks and tiles.

"Many of our customers are small and medium-sized U.S. companies, which are literally fighting

for survival," Cook will testify. "Our customers tell us that the costs associated with RCRA regulation of barium are a substantial burden on them."

Elizabeth Erwin
Communications Assistant
National Center for Environmental Assessment
Office of Research and Development
U.S. Environmental Protection Agency
Office: (703) 347-0205
Fax: (703) 347-8699

{In Archive} a clearance-related argument

Ravi Subramaniam to: Bob Frederick, Glinda Cooper, Jacqueline Moya, Kate Guyton, Matthew Lorber, Susan Euling, Weihsueh Chiu, 09/22/2011 09:27 AM

Cc: Barbara Glenn

Archive: This message is being viewed in an archive.

I am back to griping again! Our management has insisted with us that it is necessary to share highly visible NCEA journal papers with other ORD labs and Program Offices before publication. In many cases, we have been asked to elicit comments and address them from these other folks who have strong opinions about what we do.

So, here we are in the middle of this extremely visible revision of the formaldehyde assessment, and there is new paper on formaldehyde from the Conolly and others that has come out in Inhal Tox. No one shared a word with anyone. It takes care not to say anything bad about us but the conclusions are still the same.

Note the "received" and "accepted" dates. They are 2 days apart. But that is a different matter indeed!!

I am inclined to send an email to Darrell to point this out as an example of a key argument that we had made. . . that NCEA management actions often put NCEA scientists who are at odds with others in ORD at a major disadvantage from getting their points of view expressed soon. Let me know if you think otherwise.

Miller et al 2011.pdf

Ravi

Ravi Subramaniam
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N-7934, Two Potomac Yard, Crystal City
(703) 347-8606, (301) 515-2701 (alternate office)

{In Archive} NEWS UPDATES: Key Adviser Warns EPA To Improve Agency Science Or Face A 'Crisis' (Risk Policy Report)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew Hotchkiss, Andrew 07/06/2011 02:39 PM

Archive: This message is being viewed in an archive.

Key Adviser Warns EPA To Improve Agency Science Or Face A 'Crisis'

Posted: July 1, 2011

A key EPA science adviser is warning that the agency must succeed in making its scientific research programs more transparent and sound in order to to bring credibility back to agency science, or EPA will risk increased scrutiny from House Republicans and industry that could prompt a "crisis."

"You can't fail this time," Thomas Burke, associate dean of The Johns Hopkins Bloomberg School of Public Health who also chaired a recent National Academy of Sciences (NAS) panel on ways to improve EPA risk assessments, told EPA officials and other scientific advisers during a discussion on the agency's new chemical safety research program June 30.

"The sleeping giant is that EPA science is on the rocks . . . if you fail, you become irrelevant, and that is kind of a crisis," Burke told a joint meeting of EPA's Science Advisory Board and EPA's Board of Scientific Counselors (BOSC) charged with looking at the reorganization of the agency's research programs.

Burke, who chaired a recent NAS panel that recommended a host of steps for EPA to improve its risk assessment process, pointed in particular to the agency's risk assessment process, calling it EPA's "Achilles heel."

The recommendations that stemmed from Burke's NAS panel -- contained in a 2009 report titled *Science and Decisions: Advancing Risk Assessment* -- have taken on heightened significance over the past few months since another NAS panel urged EPA to quickly implement the recommendations in light of problems the panel found with the agency's assessment of formaldehyde.

While faulting the agency's draft formaldehyde assessment, the panel also devoted a chapter of their report to fixing its risk assessment process, including calls for EPA to develop a standardized weight-of-evidence approached, establish clear guidelines for selecting studies to justify risk estimates and standardize the review process for assessments. Many of those recommendations were also contained in *Science and Decisions* .

In the wake of the NAS review of the formaldehyde assessment, EPA is under fire from industry and GOP lawmakers, who have also urged the agency to quickly implement the NAS' recommended approaches, not just in its chemical risk assessments but in EPA air programs (*see related story*).

In light of this intense scrutiny, Burke urged officials from the Office of Research and Development at the SAB- BOSC meeting to tread carefully as it reorganizes its 21 research programs into six, and pay particular attention to how that system and other challenges levied by Paul Anastas, head of ORD, will play in to the IRIS program.

Among other things, the agency needs to better define sustainability, have metrics for which innovative idea the agency should pursue, develop a cross cutting transdisciplinary approach and provide funding to universities to better prepare students for the agency's future needs, Burke said. While some of those recommendations "sound kind of bureaucratic … that revolution has to happen because the status quo is not working," Burke added. -- *Jenny Hopkinson*

Elizabeth Erwin
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National Center for Environmental Assessment
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Office: (703) 347-0205
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{In Archive} Re: Formaldehyde Topics

Sury Vulimiri to: Barbara Glenn 06/20/2011 09:11 PM

Cc: Andrew Kraft, Danielle DeVoney, David Bayliss, Jennifer Jinot, John Whalan, Kate Guyton, Ravi Subramaniam, Susan Euling, Susan Makris, Thomas Bateson

Archive: This message is being viewed in an archive.

Hi Barbara,
I have PPRTV meetings every alterenate Wednesday from 1 pm to 4 pm. So 2 pm would not work for me.

Sury

Suryanarayana (Sury) Vulimiri, B.V.Sc., PhD, DABT
Biologist, National Center for Environmental Assessment, ORD, USEPA
(P) 703.308.7949, (F) 703.347.8692, E-mail: vulimiri.sury@epa.gov
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FedEx and Ground Deliveries: Two North Potomac Yard, 7th Floor, N-7333, 2733 S. Crystal Dr. Arlington, VA 22202

-----Barbara Glenn/DC/USEPA/US wrote: -----
To: Andrew Kraft/DC/USEPA/US@EPA, Danielle DeVoney/DC/USEPA/US@EPA, David Bayliss/DC/USEPA/US@EPA, Jennifer Jinot/DC/USEPA/US@EPA, John Whalan/DC/USEPA/US@EPA, Kate Guyton/DC/USEPA/US@EPA, Ravi Subramaniam/DC/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA, Susan Euling/DC/USEPA/US@EPA, Susan Makris/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA
From: Barbara Glenn/DC/USEPA/US
Date: 06/20/2011 10:00AM
Subject: Formaldehyde Topics

Hi Formaldehyde Team,

I am setting up weekly meetings (you will get an invite soon) to get us going on revising the assessment. I am trying Wednesday at 2 pm but let me know if that is a terrible day or time for you. Wednesday seems to be the best option for the long term because some of us are not in the office on other days. We will not meet this week - I will be out of the office Tu - Fri this week.

At our first meeting we will go over organizing our topic workgroups, the draft table of contents that I have attached here, and timelines.

Thanks very much for your assistance putting together the briefing slides for Becki's briefing last week. I think it went well.

-Barbara

(See attached file: Formaldehyde Assessment Topic Workgroups_20Jun.docx)
(See attached file: TOC_10June2011.docx)

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

[attachment "Formaldehyde Assessment Topic Workgroups_20Jun.docx" removed by Sury Vulimiri/DC/USEPA/US]
[attachment "TOC_10June2011.docx" removed by Sury Vulimiri/DC/USEPA/US]

{In Archive} Slides for IO briefing on Formaldehyde Assessment

Barbara Glenn to: David Bussard, Bob Sonawane, Paul White 06/13/2011 06:03 PM

Cc: Andrew Kraft, Barbara Glenn, Danielle DeVoney, David Bayliss, Jennifer Jinot, John Whalan, Ravi Subramaniam, Sury Vulimiri, Susan Euling, Susan Makris, Thomas Bateson, Mary Ross, Kate

Archive: This message is being viewed in an archive.

David, Bob and Paul,

Attached are some briefing slides for discussion at our meeting tomorrow morning.

-Barbara

formaldehyde next steps_BClark_13Jun2011.pptx

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

{In Archive} Re: Comments? Slides for IO briefing on Formaldehyde Assessment

Danielle DeVoney to: Barbara Glenn 06/13/2011 03:48 PM

Cc: Andrew Kraft, Barbara Glenn, David Bayliss, Jennifer Jinot, John Whalan, Kate Guyton, Mary Ross, Ravi Subramaniam, Sury Vulimiri, Susan Euling, Susan Makris, Thomas Bateson

Archive: This message is being viewed in an archive.

Barbara -

Hi - here are some specific suggestions and edits. suggestions are in blue text, and imbedded in some of the comments. You may already have an overview slide, but I made some suggestions if you find it helpful.

Thanks,
Danielle

formaldehyde next steps_BClark_9Jun2011_ddComments_13june2011.pptx

Danielle DeVoney, PhD, DABT, PE
National Center for Environmental Assessment
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1200 Pennsylvania Ave., NW (8623P)
Washington, DC 20460
703.347.8558
FAX: 703.347.8692

Barbara Glenn | I attached some slides for our Thursday briefing... | 06/09/2011 05:37:39 PM

From: Barbara Glenn/DC/USEPA/US
To: Andrew Kraft/DC/USEPA/US@EPA, Barbara Glenn/DC/USEPA/US@EPA, Danielle DeVoney/DC/USEPA/US@EPA, David Bayliss/DC/USEPA/US@EPA, Jennifer Jinot/DC/USEPA/US@EPA, John Whalan/DC/USEPA/US@EPA, Ravi Subramaniam/DC/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA, Susan Euling/DC/USEPA/US@EPA, Susan Makris/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA, Mary Ross/RTP/USEPA/US@EPA, Kate Guyton/DC/USEPA/US@EPA
Date: 06/09/2011 05:37 PM
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Mary and I are prebriefing David, Bob and Paul on Tuesday morning. I appreciate any comments you have and would like to receive them by Monday afternoon so I can incorporate them for the morning meeting.

thanks, Barbara

[attachment "formaldehyde next steps_BClark_9Jun2011.pptx" deleted by Danielle

DeVoney/DC/USEPA/US]

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

{In Archive} Re: Comments? Slides for IO briefing on Formaldehyde Assessment

Thomas Bateson to: Barbara Glenn 06/13/2011 02:50 PM

Cc: Andrew Kraft, Barbara Glenn, Danielle DeVoney, David Bayliss, Jennifer Jinot, John Whalan, Kate Guyton, Mary Ross, Ravi Subramaniam, Sury Vulimiri, Susan Euling, Susan Makris

Archive: This message is being viewed in an archive.

Barbara,

Looks good.

My comments are embedded in the ppt. On my copy, they show up as light blue boxes.

formaldehyde next steps_BClark_9Jun201.tb.pptx

On the face of it, Dec 2011 appears reasonable for a team draft to be reviewed by management. But that might be hard if further analyses of the NCI were desired.

With so many other projects underway and due by 9/30, and knowing the level of scrutiny that will be directed at the next draft, I would be hesitant to commit to a date without answering more questions about the scope of changes.

Tom

Thomas F. Bateson, ScD MPH
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Effects Identification & Characterization Group
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1200 Pennsylvania Ave. NW (Mail Code 8623P)
Washington, DC 20460

Phone: 703-347-8570

Barbara Glenn I attached some slides for our Thursday briefing... 06/09/2011 05:37:39 PM

From: Barbara Glenn/DC/USEPA/US
To: Andrew Kraft/DC/USEPA/US@EPA, Barbara Glenn/DC/USEPA/US@EPA, Danielle DeVoney/DC/USEPA/US@EPA, David Bayliss/DC/USEPA/US@EPA, Jennifer Jinot/DC/USEPA/US@EPA, John Whalan/DC/USEPA/US@EPA, Ravi Subramaniam/DC/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA, Susan Euling/DC/USEPA/US@EPA, Susan Makris/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA, Mary Ross/RTP/USEPA/US@EPA, Kate Guyton/DC/USEPA/US@EPA
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thanks, Barbara

[attachment "formaldehyde next steps_BClark_9Jun2011.pptx" deleted by Thomas Bateson/DC/USEPA/US]

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

{In Archive} Re: Comments? Slides for IO briefing on Formaldehyde Assessment

Susan Euling to: Barbara Glenn 06/13/2011 01:45 PM

Cc: Andrew Kraft, Ravi Subramaniam, Danielle DeVoney, David Bayliss, Jennifer Jinot, John Whalan, Kate Guyton, Mary Ross, Sury Vulimiri, Susan Makris, Thomas Bateson

Archive: This message is being viewed in an archive.

One more comment on slide 6: The last bullet (see below) about repro/dev effects needs to be qualified - this comment refers to the text for the epidemiological literature regarding the "relationship between occupational exposure to FA and adverse reproductive outcomes in women." This bullet has nothing to do with either developmental effects in animals or humans, or repro animal studies. In fact, I suggest adding a bullet about NAS' comments about the repro/dev animal studies: NAS asks for a discussion of study quality and distinguish between "high quality" studies for use in the risk assessment vs. studies of not high enough quality.

•Reproductive/developmental effects

—NAS concluded evidence is “suggestive”

Ravi Subramaniam Barbara: The presentations looks very good. I... 06/13/2011 11:56:40 AM

From: Ravi Subramaniam/DC/USEPA/US
To: Barbara Glenn/DC/USEPA/US@EPA
Cc: Andrew Kraft/DC/USEPA/US@EPA, Danielle DeVoney/DC/USEPA/US@EPA, David Bayliss/DC/USEPA/US@EPA, Jennifer Jinot/DC/USEPA/US@EPA, John Whalan/DC/USEPA/US@EPA, Kate Guyton/DC/USEPA/US@EPA, Mary Ross/RTP/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA, Susan Makris/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA, Susan Euling/DC/USEPA/US@EPA
Date: 06/13/2011 11:56 AM
Subject: Re: Comments? Slides for IO briefing on Formaldehyde Assessment

Barbara:

The presentations looks very good. I have a couple of changes to suggest

Slide 5. I realize you need to be brief. But on the whole the NAS was much more critical of EPA's treatment of systemic availability of formaldehyde than is suggested in this presentation. I would add the following:
The NAS concluded that hcho was unlikely to appear in the blood as an intact molecule. The NAS argued strongly that the hydration of formaldehyde to methanediol should not be used as basis for its delivery beyond the portal of entry.

Slide 10. Second bullet or elsewhere. Add: The NAS recommended that EPA use the CIIT computational fluid dynamics modeling of the dosimetry for low dose extrapolation also.
Third bullet: The NAS used much stronger language than what is said here. So instead of "NAS disagreed with some of the sensitivity analyses of the BBDR model", I suggest: "NAS agreed with the need for a sensitivity analysis but found EPA's parameter and model variations to be extreme and inconsistent with the available epidemiological data."

Ravi Subramaniam
Environmental Health Scientist
NCEA-Washington, ORD, EPA
N-7934, Two Potomac Yard, Crystal City
(703) 347-8606, (301) 515-2701 (alternate office)

Susan Euling	Hi Barbara, Thank you for circulating.	06/13/2011 10:42:12 AM
Barbara Glenn	I attached some slides for our Thursday briefing...	06/09/2011 05:37:40 PM

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Ravi Subramaniam to: Barbara Glenn 06/13/2011 11:56 AM

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Date: 06/13/2011 10:42 AM
Subject: Re: Comments? Slides for IO briefing on Formaldehyde Assessment

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Slide 1 could be improved by using the language verbatim from p. 11 of the report. Right now some

important details are missing such as for #1 --- what needs to be accomplished by the rigorous editing? It is the reduction of volume and get rid of redundancies and inconsistencies; #2 -- the critique is of Chapter 1.

Overall, the other slides are very nice. I would use a different font color for what the team decisions have been so that they stand out -- otherwise it can get confusing about what NAS recommends, vs. what we are thinking. For example, on slide 6: •Team considers original literature sufficient for hazard id

and slides 7 and 8, •Re-evaluation of the RfC is being considered

could be in blue font so it is clear that this is the team.

Some of the material may be easier to digest as tables -- you could have NRC recommendation, what team is considering as columns and rows with different issues or endpoints.

Sue

Barbara Glenn	I attached some slides for our Thursday briefing...	06/09/2011 05:37:40 PM

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[attachment "formaldehyde next steps_BClark_9Jun2011.pptx" deleted by Susan Euling/DC/USEPA/US]

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

{In Archive} Re: reference to NRC in revised formaldehyde document

Kate Guyton to: Ravi Subramaniam 09/09/2011 09:21 AM

Cc: Barbara Glenn

Archive: This message is being viewed in an archive.

Hi Ravi,

We did that in perc (you can search for "NRC") and also in TCE....when we strayed from standard practice or added substantial analysis at the NRC'a behest (e.g. Ppar alpha, mcl tumors, and the extra cancer modeling).

-----Ravi Subramaniam/DC/USEPA/US wrote: -----

==========
To: Kate Guyton/DC/USEPA/US@EPA, Barbara Glenn/DC/USEPA/US@EPA
From: Ravi Subramaniam/DC/USEPA/US
Date: 09/09/2011 07:52AM
Subject: reference to NRC in revised formaldehyde document
==========

This is re: formaldehyde. I would like to refer to an argument in the NRC review in the MAIN body of the revised formaldehyde assessment and cite NRC 2011. I am assuming that, since NRC 2011 is a published and citable (peer-reviewed) document, such citation would be appropriate. I dont recall us doing so in perc, so I thought I would check if there are any considerations against doing so.

Ravi Subramaniam
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CHEMICALS: Dem floats amendment to protect IRIS program (07/26/2011)

Jeremy P. Jacobs, E&E reporter

Rep. Brad Miller (D-N.C.) is planning to offer an amendment to the U.S. EPA spending bill currently on the House floor that would strip some Republican provisions restricting the agency's chemical risk assessment program.

EPA's Integrated Risk Information System (IRIS) is charged with evaluating the health effects of chemicals and substances in commerce and the environment. The program's assessments typically serve as the foundation of EPA's regulations.

Republicans included changes to the IRIS program in the 2012 appropriations bill that would require EPA to implement reforms outlined in an April National Academy of Sciences (NAS) review of IRIS's formaldehyde assessment. The NAS review sharply criticized EPA's scientific methodologies and devoted a chapter to recommendations for the program.

"Overall, the committee found that EPA's draft assessment was not prepared in a logically consistent fashion, lacks clear links to an underlying conceptual framework and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies," NAS said (*Greenwire* , April 8).

The appropriations bill would effectively stop the IRIS program from taking any action on any assessment that does not follow the NAS recommendations (*Greenwire* , July 6).

Miller's amendment would make three changes to the bill. First, noting that EPA recently said it plans to implement the NAS recommendations, it would grant the agency the necessary time to put them in place.

Paul Anastas, EPA's assistant administrator who directs the Office of Research and Development, said earlier this month that the agency "welcomes those suggestions and [is] committed to incorporating them fully" (*E&ENews PM* , July 12).

Miller's amendment also would strike Republican language that could halt all final or draft IRIS assessments until those NAS recommendations are implemented. His office pointed out that those NAS guidelines will likely take multiple years for EPA to integrate, so the Republican language would effectively put IRIS on hold for one or two years.

Finally, Miller is seeking to change a provision in the bill that would require formal NAS reviews of three current IRIS assessments. That would put an undue burden on NAS scientists, Miller's office said. The Democrat's amendment would require a NAS review of only one current IRIS assessment.

IRIS has increasingly become a focus of Republicans recently, particularly since the critical formaldehyde report. At a hearing earlier this month, House Science, Space and Technology Subcommittee for Investigations and Oversight Chair Paul Broun (R-Ga.) had sharp words for the program.

"Time and time again," Broun said, "draft assessments were sent to NAS for review, only to be severely criticized. Rather than adopting the recommendations of the academy and updating their processes, EPA continued to churn out assessments that were summarily rebuked" (*E&E Daily* , July 15).

Green groups, on the other hand, have largely defended the program, arguing that without IRIS, EPA cannot move forward with regulating controversial chemicals like hexavalent chromium, dioxin and formaldehyde. The assessments and regulations that could come from the program, they argue, are critical to public health.

It is unclear whether Miller's amendment will come up for a vote and, given the Republican majority and the GOP's recent focus on IRIS, it appears unlikely it would pass.

The IRIS program has come under criticism before. Earlier this year, the Government Accountability Office added it to its annual "high risk list" of troubled federal programs (*Greenwire* , Feb. 16).

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Communications Assistant
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{In Archive} NEWS UPDATES: Eying 'High Priority' Risk Studies, EPA Sets Ambitious FY12 IRIS Schedule (Risk Policy Report)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew Hotchkiss, Andrew 07/06/2011 01:28 PM

Archive: This message is being viewed in an archive.

Eying 'High Priority' Risk Studies, EPA Sets Ambitious FY12 IRIS Schedule

Posted: July 1, 2011

EPA has set an ambitious schedule aimed at completing at least 10 major risk assessments for its Integrated Risk Information System (IRIS) database by the end of fiscal year 2012, at the same time as the agency is looking ahead to the next round of "high priority" assessments that its regional and program offices are urging officials to conduct, including assessments for manganese, ammonia, ethylbenzene and ethanol. But industry officials, who are already urging the White House to step in and revise EPA's risk assessment process, are raising concerns that that the agency will now be completing assessments with significant regulatory impacts but without revisions to how the agency conducts the assessments.

Prioritizing chemicals for new assessment is "just the start," says a source with the American Chemistry Council (ACC), "but one of they key problems with the IRIS program . . . is the fact that the policies and practices of the program are lagging behind the science of chemical toxicology and risk assessment."

Still, another industry source says completing the pending assessments is important if EPA is to move on to the next round of risk studies. "It always comes down to resources, and they obviously have a fair amount of controversial" assessments that are gaining a lot of attention, the source says. "I think it's a matter of can they finalize some of the ones they have in the process and free up some resources?"

In a presentation to a joint meeting of EPA's Science Advisory Board and Board of Scientific Counselors June 29 in Cary, NC, Rebecca Clark, acting head of the National Center for Environmental Assessment, indicated that the agency hopes to post its long-awaited and high-profile assessments for a host of major chemicals in the coming months, including assessments for tetrachloroethylene (July), arsenic cancer (August), chromium VI (September), platinum salts (September) and trichloroethylene (September).

This schedule follows in part the schedule suggested by Vince Coliagno, the acting IRIS program director, who told *Inside EPA* in a recent interview that the agency hopes to complete the assessments for arsenic and dioxin this year (*Risk Policy Report*, April 5). *The list is available on InsideEPA.com.* (*Doc ID:* 2368849)

For the remainder of this year, EPA hopes to post assessments on dioxin and polycyclic aromatic hydrocarbons. The presentation indicates that EPA has set target dates to complete three additional assessments by the end of FY12, including PCBs (noncancer), phthalates and an assessment of the risks posed by asbestos from Libby, MT.

The only uncertainty in the list is when the agency expects to complete its controversial

assessment of formaldehyde, which a National Academy of Sciences (NAS) panel has strongly criticized. EPA says the target date for completion of the formaldehyde assessment is still "to be determined."

In its April 8 review of EPA's draft formaldehyde assessment, an NAS panel strongly faulted EPA's methodology in crafting its draft assessment, while warning of a broader pattern of problems in how the agency crafts assessments for its IRIS database that could continue to hamper future risk studies. "The committee is concerned about the persistence of problems encountered with IRIS assessments over the years, especially given the multiple groups that have highlighted them . . . If the methodologic issues are not addressed, future assessments may still have the same general and avoidable problems that are highlighted here."

But EPA's schedule is now likely to intensify criticism of EPA's risk assessments which many industry officials fear will drive costly new cleanup and regulatory requirements. Late last month, ACC urged the White House to step in an address the issue, in part by requiring EPA to revise its assessment process along the lines recommended by NAS and to subject all its risk assessments to NAS review.

And industry officials are also looking to GOP lawmakers on the House Science Committee to conduct vigorous oversight of EPA's risk assessment process, though one House source cautioned that the committee may not be willing to push EPA to seek NAS reviews as industry is seeking. "The goal should be getting EPA to do the assessments correctly, not having the [NAS] do EPA's job," one House source said (*Risk Policy Report* , June 28).

Industry groups and GOP lawmakers have also lobbied administration officials over concerns with agency assessments over arsenic, platinum salts, dioxin and chromium VI.

Agency officials, meanwhile, are defending the process, with Administrator Lisa Jackson telling a Senate environment committee panel June 15 that the agency had revised the IRIS process since the draft formaldehyde review was completed, though she acknowledged that the agency is considering additional fixes. Clark, meanwhile, recently told industry officials that "IRIS is a model for openness, transparency, scientific integrity and scientific quality" (*Risk Policy Report* , June 28).

Even before EPA completes the current round of assessments, officials are looking ahead to its next round. According to Clark's presentation, the agency has identified a list of 12 high priority chemicals as a result of a 2010 request to the regions and program offices to nominate substances for IRIS assessments, part of a broader effort to align EPA research priorities with program priorities.

″ We asked the programs and regions to provide information on their needs for the assessments, including the regulatory context and what types of toxicity values they would need," according to an agency spokeswoman. "This information is being used to help us set priorities to begin work on the chemicals as staff time becomes available."

The high priority list identified by the regions includes several substances that could prompt controversy, including ethanol, the transportation fuel that EPA recently approved for expanded use that is also used in hydraulic fracturing operations; ethylbenzene, a compound used in fracking operations; cobalt, cadmium, manganese and antimony, all common contaminants at Superfund sites; ammonia, which is used in air quality control systems; and RDX, a chemical present in munitions that EPA says is

a common contaminant.
While EPA has also asked for public comment on the next round of IRIS assessments, the only overlap is on manganese, where industry officials say the agency's current risk value is too conservative (*Risk Policy Report* , Jan 11).
A second industry source says EPA's focus on addressing contaminants at Superfund sites is misguided. Superfund has "been the driver for a lot of this stuff for a long time," the source says, "but as far as a real public health concern," the offices should be focused on common contaminants in consumer products, such as Bisphenol A (BPA). "If you really want to get a lot of bang for your buck you really want to look at the chemicals that are in consumer products."
Those chemicals are largely unregulated, but are gaining attention as they to show up in blood and body fat. "A lot of the activists say we've got all these chemicals in our blood stream, they all need to be banned, but I don't think that's a sound or appropriate reaction," the source says. "But the dose makes the poison." IRIS could be a tool for addressing that issue, the source adds.
The first industry source, however, noted that those contaminants deemed priorities by the offices and regions "make sense" in light of high profile cleanups. "A lot of these… are a response to concerns addressed by members of congress and members of the public." -- *Jenny Hopkinson*

Elizabeth Erwin
Communications Assistant
National Center for Environmental Assessment
Office of Research and Development
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Office: (703) 347-0205
Fax: (703) 347-8699

{In Archive} Re: Comments? Slides for IO briefing on Formaldehyde Assessment

Kate Guyton to: Barbara Glenn 06/09/2011 06:04 PM

Archive: This message is being viewed in an archive.

Hi Barbara,

I realize I am coming in after the movie already started... but I suggest deleting reference to potential additional peer review on the last slide. I would endorse a strong team opinion that additional peer review will not be needed, given that the major conclusions will not change... whether this is politically viable, however, I don't know. But if you go back for another peer review, that will add years to your pain.
Thanks,
Kate

Kate Z. Guyton, PhD DABT
Toxicologist, NCEA, ORD, US EPA
703-347-8562 | guyton.kate@epa.gov
Mailing Address: US EPA (8623-P), 1200 Pennsylvania Ave. NW, Washington DC 20460
FedEx and Ground Deliveries: Two Potomac Yard (North Building), 2733 S. Crystal Drive, Arlington VA 22202

Barbara Glenn | I attached some slides for our Thursday briefing... | 06/09/2011 05:37:39 PM

From: Barbara Glenn/DC/USEPA/US
To: Andrew Kraft/DC/USEPA/US@EPA, Barbara Glenn/DC/USEPA/US@EPA, Danielle DeVoney/DC/USEPA/US@EPA, David Bayliss/DC/USEPA/US@EPA, Jennifer Jinot/DC/USEPA/US@EPA, John Whalan/DC/USEPA/US@EPA, Ravi Subramaniam/DC/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA, Susan Euling/DC/USEPA/US@EPA, Susan Makris/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA, Mary Ross/RTP/USEPA/US@EPA, Kate Guyton/DC/USEPA/US@EPA
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Barbara Glenn to: Andrew Kraft, Barbara Glenn, Danielle DeVoney, David Bayliss, Jennifer Jinot, John Whalan, Ravi Subramaniam, Sury Vulimiri, 06/09/2011 05:37 PM

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formaldehyde next steps_BClark_3Jun2011.pptx

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EPA says it's revamping risk-assessment program

Jeremy P. Jacobs, E&E reporter

Published: Thursday, February 2, 2012

U.S. EPA said today that it's working quickly "behind the scenes" to implement the National Academy of Sciences' recommendations for improving assessments of chemicals' health effects.

In its review of EPA's Integrated Risk Information System (IRIS) assessment of formaldehyde last April, a NAS panel criticized the agency's methodologies and made several recommendations for all IRIS chemical reviews.

Vincent Cogliano, the acting director of IRIS, said the recommendations were reasonable, EPA agrees with them and it is moving in that direction every day.

"We embrace all of these recommendations," Cogliano said at a Toxicology Forum conference. "These are things we need to do, and these are things we are doing right now."

The NAS review faulted EPA's assessment of formaldehyde, finding the agency's methodologies confusing. Reviewers dedicated a chapter to recommendations for future IRIS assessments (*Greenwire* , April 8, 2011).

The NAS report spurred attacks on EPA by industry groups and congressional Republicans, who called for halting assessments while the agency implements the panel's recommendations. IRIS assessments are the foundation for EPA and other agencies' regulations.

David Dorman of North Carolina State University, a member of the NAS panel, said today the formaldehyde assessment was a mixed bag. In particular, he said it wasn't clear why EPA included some studies in its assessment but excluded others. He also said the method the agency used to find studies wasn't properly articulated.

"Overall, what we felt was there was an opportunity for improvement in some areas and drastic improvement in others rather than a complete do-over," Dorman said.

IRIS has been frequently criticized. The Government Accountability Office included it in its

annual list of troubled federal programs last year. Last month, GAO said IRIS had made improvements but that challenges remain, including speeding up its laggard pace for issuing assessments (*E&ENews PM* , Jan. 9).

Cogliano, who came to EPA last year after working at the World Health Organization, has pledged to reform the IRIS system (*Greenwire* , March 30, 2011).

Among his top priorities, he said today, is making IRIS assessments more succinct. Many of the reports have grown to more than 400 pages, which he said "isn't sustainable." Consequently, IRIS is "rigorously editing" the assessments in hopes of making them more streamlined.

To address the methodology concerns that Dorman noted, Cogliano said, the agency is drafting a preamble that will describe how it evaluates and selects studies. These criteria, he said, are taken directly from the NAS review.

The assessments will now include standardized evidence tables and criteria for each study included.

Cogliano also said the agency is implementing ways to include peer reviews earlier in the drafting process. EPA's Science Advisory Board is currently forming a new Chemical Assessment Advisory Committee that will provide a consistent source of peer reviewers for all IRIS reports.

"That, over the next one and two years, will be very key to our progress," Cogliano said.

Cogliano did not say, however, when the long-awaited formaldehyde assessment will be finalized.

Elizabeth Erwin
National Center for Environmental Assessment
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{In Archive} Re: Review of ADME section in draft formaldehyde assessment

Sury Vulimiri to: Paul Schlosser 12/02/2011 05:40 PM
Cc: Barbara Glenn, Paul White, Ravi Subramaniam
Bcc: Kate Guyton
Archive: This message is being viewed in an archive.

Thanks Paul for your comments/suggestions. I will get back to you should I need some clarifications.
Have a nice weekend.

Sury

Suryanarayana (Sury) Vulimiri, B.V.Sc., PhD, DABT
Biologist, National Center for Environmental Assessment, ORD, USEPA
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-----Paul Schlosser/RTP/USEPA/US wrote: -----
To: Barbara Glenn/DC/USEPA/US@EPA
From: Paul Schlosser/RTP/USEPA/US
Date: 12/02/2011 04:42PM
Cc: Ravi Subramaniam/DC/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA, Paul White/DC/USEPA/US@EPA
Subject: Re: Review of ADME section in draft formaldehyde assessment

OK, so both of the attached have comments from me. Also copying Paul White on this.

(See attached file: Response_Toxicokinetics_111411_pms.docx)
(See attached file: FA Chapter 3-ADME Revised 101511pms.doc)

Given the total mass balance/distribution calculations that I've shown, I really, really think that you cannot argue for a direct effect of exogenous HCHO on bone marrow in humans at typical exposure levels, or those occurring in the epi study which reports the association with leukemia. The total mass inhaled is just not large enough and the idea that the body somehow keeps exogenous HCHO separate from endogenous anyplace but at the POE cannot be supported.

As mentioned in a previous note that just went to Ravi (I think), it seems possible to me that the ongoing irritation and immune response in the RT could induce lymphocytic proliferation, which could be a risk factor -- hence a pharmacodynamic distal effect.

But I also believe that, given that the association was only seen in one study, and is not strong (if I remember correctly), 'good science' requires more than just a hypothetical mechanism to support it. If you believe there's enhanced lymphocytic proliferation, then that would be data supporting that hypothesis. Otherwise that's just 'hand waving'.

I've said this to Ravi before and will again here... please understand that this is with a collegial "tone" and intent: to me it appears that there is a base assumption that the leukemia association is 'fact', and there has been a grasping at explanations or mechanisms by which it might be true. That is not good science and (going beyond what I've said before) I think it's fairly plain that the current storm of criticism, congressional hearings, etc., is the fallout of trying to maintain that position/assumption in this assessment (and similar overly-precautionary approaches in others). Associations can occur by random chance, or because of other correlating factors (e.g., co-exposures). Is think the apparent association deserves future research. But I don't think that the preponderance of the mechanistic data support it. The PK data do not.

-Paul

[attachment "Response_Toxicokinetics_111411_pms.docx" removed by Sury Vulimiri/DC/USEPA/US]
[attachment "FA Chapter 3-ADME Revised 101511pms.doc" removed by Sury Vulimiri/DC/USEPA/US]

{In Archive} NEWS UPDATES: Responding to critics, EPA plans update of screening program (E&E News PM)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew Hotchkiss, Andrew 07/13/2011 09:12 AM

Archive: This message is being viewed in an archive.

Responding to critics, EPA plans update of screening program (07/12/2011)

Jeremy P. Jacobs, E&E reporter

U.S. EPA today announced steps to improve its assessment of health threats posed by chemicals, a program that has come under fire from a National Academy of Sciences panel.

Paul Anastas, the agency's assistant agency administrator who directs the Office of Research and Development, said EPA is making changes to its Integrated Risk Information System (IRIS) that will make assessments "shorter, clearer, more concise and more transparent."

In addition, Anastas said EPA will create a new scientific peer review panel that will be charged with reviewing the science behind IRIS assessments.

"We feel an obligation to make these as accessible and transparent as possible," Anastas said on a conference call with reporters.

IRIS assessments serve as the basis for all EPA regulatory actions that limit chemicals in the environment or commerce.

The announcement responds to a recent NAS panel review of IRIS's formaldehyde assessment. While it agreed with some of the conclusions EPA made in the report, the panel criticized IRIS's scientific methodologies and dedicated an entire chapter to recommending ways IRIS should improve.

"Overall, the committee found that EPA's draft assessment was not prepared in a logically consistent fashion, lacks clear links to an underlying conceptual framework and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies," the NAS panel said (*Greenwire* , April 8).

Anastas said EPA is planning to follow through on the NAS panel's recommendations.

"We welcome those suggestions and are committed to incorporating them fully," he said.

In addition to the new panel, Anastas said future IRIS assessments will be shorter and will include more graphs and tabular representations of data. EPA will also evaluate the strengths and weakness of important studies that are used in IRIS assessments in a more uniform way.

EPA's announcement also comes two days before Anastas is set to testify before Congress on IRIS (*E&E Daily* , July 11).

Cal Dooley, the president of the American Chemistry Council, said he welcomed EPA's move because most of the group's concerns with IRIS were articulated in the NAS review.

"We're pleased that EPA recognizes they have a problem and that their IRIS program is in need of reform," Dooley said in an interview.

Anastas' announcement, however, stopped short of the council's call for all IRIS assessments to be submitted to NAS for review.

"We would also suggest that EPA should still submit IRIS assessments to NAS for peer review," Dooley said.

Elizabeth Erwin
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{In Archive} Re: Comments? Slides for IO briefing on Formaldehyde Assessment

Danielle DeVoney to: Barbara Glenn 06/13/2011 02:46 PM
Cc: Andrew Kraft, David Bayliss, Jennifer Jinot, John Whalan, Kate Guyton, Mary Ross, Ravi Subramaniam, Sury Vulimiri, Susan Euling, Susan Makris, Thomas Bateson

Archive: This message is being viewed in an archive.

Barbara,

Hi - I just got back to the office today and am reviewing the materials. A few general comments/questions. I will forward some specific track changes in a few minutes:

1) I would suggest an intro slide - outlining the flow of the briefing.

2) The wording of the six topic areas on slide 1 come from the executive summary of the report. However, the wording in Chapter 7 is more detailed and clear as each point is set out as a bullet statement. Also this section is titled "Critical Revisions..." so it might be useful to tie the briefing to this material in Chapter 7 which may be of interest to management. I would suggest perhaps a little more specific and linking these points to the "Critical Revisions" (even if just by ref) so it is clear these are the same general topics.

3) I think it would be useful to point out where our response to the NAS report may not necessitate a document change (e.g. where the text/tables already exist, or we are not(or cannot) execute the recommendation.) I think this would be helpful in explaining the overall LOE needed for document revisions.

4) It might be useful to show the range of RfCs in the NAS draft - versus the range of RfCs if we exclude the two studies. Essentially there is little change.

5) It might be useful to summarize the major specific comments in a second slide following the "Path Forward" as you do address some of the specific comments in the following slides. This could also be done as an "impact" slide - e.g. what are the bottom line impacts of document changes and new analyses.

Danielle DeVoney, PhD, DABT, PE
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FAX: 703.347.8692

Barbara Glenn | I attached some slides for our Thursday briefing... | 06/09/2011 05:37:39 PM

From: Barbara Glenn/DC/USEPA/US
To: Andrew Kraft/DC/USEPA/US@EPA, Barbara Glenn/DC/USEPA/US@EPA, Danielle DeVoney/DC/USEPA/US@EPA, David Bayliss/DC/USEPA/US@EPA, Jennifer Jinot/DC/USEPA/US@EPA, John Whalan/DC/USEPA/US@EPA, Ravi Subramaniam/DC/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA, Susan Euling/DC/USEPA/US@EPA, Susan Makris/DC/USEPA/US@EPA, Thomas Bateson/DC/USEPA/US@EPA, Mary Ross/RTP/USEPA/US@EPA, Kate Guyton/DC/USEPA/US@EPA

Date: 06/09/2011 05:37 PM
Subject: Comments? Slides for IO briefing on Formaldehyde Assessment

I attached some slides for our Thursday briefing of the IO for your comments and suggestions. The intent is to illustrate our understanding of the NAS comments, our approach to responding to them, and how much work it will take.

Mary and I are prebriefing David, Bob and Paul on Tuesday morning. I appreciate any comments you have and would like to receive them by Monday afternoon so I can incorporate them for the morning meeting.

thanks, Barbara

[attachment "formaldehyde next steps_BClark_9Jun2011.pptx" deleted by Danielle DeVoney/DC/USEPA/US]

Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

{In Archive} IRIS email re Formaldehyde , and revisions to our assessments

David Bussard to: Susan Makris, Susan Euling, Danielle DeVoney, Ghazi Dannan, Weihsueh Chiu, Jane Caldwell, Henry Kahn, Thomas Bateson, 04/13/2011 06:10 AM

Cc: Paul White, Bob Sonawane, Jeff Frithsen, Gina Perovich, Charles Ris

Archive: This message is being viewed in an archive.

I can't tell if Cogliano's "NCEA IRIS" group includes all working on IRIS assessments, or just those reporting through the NCEA IO.

So, my apoligies if you have already received the below email.

I thought all might be interested to see Vince's message and if any don't have a copy of the recent NRC report, one is attached.

David

----- Forwarded by David Bussard/DC/USEPA/US on 04/13/2011 06:01 AM -----

From: Vincent Cogliano/DC/USEPA/US
To: NCEA IRIS
Cc: Becki Clark/DC/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Annette Gatchett/CI/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Jamie_B._Strong@ceq.eop.gov, Martin Gehlhaus/DC/USEPA/US@EPA
Date: 04/12/2011 07:11 PM
Subject: Formaldehyde, and revisions to our assessments

Hello everyone -- You've probably heard about the review of our formaldehyde assessment released last Thursday by the National Academy of Sciences. I would like everyone to read the NAS report, attached here.

Formaldehyde Prepub.pdf

Many of the NAS's comments on formaldehyde apply equally to our other assessments. Their report includes a section, "Future assessments and the IRIS process" (pp 113-123), which offers suggestions for how we complete draft IRIS assessments.

This week's all-hands meeting will discuss the proposed IRIS reorganization with union officials invited. At the next all-hands meeting I would like to begin our discussion of the NAS's general recommendations for IRIS. We have discussed some of these themes before, particularly streamlining our assessment documents, and there are other specific recommendations. Although it is painful to read the NAS's criticisms, I am appreciative -- even excited -- about their general recommendations and am confident that we can use them to improve our process and our assessments.

I remain a pragmatist and do not wish to restructure documents already drafted. That said, all chemical managers should give immediate attention to two recommendations: for strengthened discussions of weight of evidence and for expanded rationales for study selection in calculating toxicity values. To illustrate the urgency, appended to this message is the NAS press release,

and I will forward the stories that ran in Greenwire and in InsideEPA. We cannot leave ourselves open to further criticism on these points.

Thank you all for your dedication to IRIS. See you soon,
Vincent

Date: April 8, 2011

EMBARGOED: NOT FOR PUBLIC RELEASE BEFORE 11 A.M. EDT FRIDAY, APRIL 8

EPA's Draft Health Assessment for Formaldehyde Needs Improvement

WASHINGTON — A U.S. Environmental Protection Agency draft assessment of the potential health effects associated with formaldehyde exposure needs substantial revision, says a new report from the National Research Council, which recommends improvements for EPA's final assessment. The report finds that EPA supports its conclusions that formaldehyde can cause irritation to the eyes, nose, and throat; lesions in the respiratory tract; and genetic mutations at high concentrations. Furthermore, the report finds that the evidence is sufficient for EPA to conclude that formaldehyde exposures are a cause of cancers of the nose, nasal cavity, and upper throat. However, the draft assessment has not adequately supported its conclusions that formaldehyde causes other cancers of the respiratory tract, leukemia, or several other noncancer health outcomes. Also, the assessment should consider additional studies to derive noncancer reference concentrations (RfCs), which are estimates of lifetime concentrations to which someone could be exposed without appreciable risk of particular adverse health effects.

Formaldehyde is an important industrial chemical used to produce a wide array of materials, but it is also generated naturally by the human body. When inhaled, it is absorbed primarily at the site of first contact, where it is metabolized and reacts with cellular components; thus, inhaled formaldehyde remains predominantly in the tissue that lines the airways.
Given the pervasive exposure of the general population to some concentration of formaldehyde, federal agencies tasked with protecting public health are concerned about the health effects. In June 2010, EPA released its draft health assessment of formaldehyde, and a Research Council committee that wrote the report reviewed the assessment and key literature to determine whether EPA's conclusions were supported. The committee did not perform its own assessment or conduct additional literature searches.

Overall, the committee found that EPA's draft assessment was not prepared in a logically consistent fashion, lacks clear links to an underlying conceptual framework, and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies.
Moreover, many of the general problems with the EPA formaldehyde health assessment have been identified by other Research Council committees that reviewed other EPA chemical assessments in recent years. For instance, there have been recurring problems with clarity and transparency of the methods, even though the documents have grown considerably in length. The committee concluded that if the methodologic issues are not addressed, future assessments may suffer from the same general problems highlighted in this report.

Various cancerous and noncancerous health effects attributed to formaldehyde were evaluated in EPA's draft assessment, including:

Leukemia and lymphoma. The committee did not support EPA's

grouping of all types of leukemias and lymphomas because it combined diverse cancers that are not closely related. Although EPA presented an exhaustive description of studies and speculated extensively on how formaldehyde reacts in the body, the determinations of causality are not supported in the assessment. EPA should revisit its arguments and include detailed descriptions of the criteria that were used to weigh evidence and assess causality.

Respiratory tract cancers. The committee found that EPA's assessment had sufficient evidence to conclude that formaldehyde causes cancer in the nose, nasal cavity, and nasopharnyx (upper throat). However, the evidence regarding the chemical's relationship to cancer in other sites in the respiratory tract was considered insufficient.

Asthma. EPA should strengthen its discussion of asthma to reflect current understanding of the disease, as the term "asthma" is commonly applied to a broad category of respiratory diseases, the committee said. EPA's assessment provides little discussion about how asthma could be caused or exacerbated by formaldehyde exposure.

Nervous system function. EPA's conclusion that formaldehyde harms the nervous system was overstated, the committee said. The human data used as evidence are insufficient and the candidate animal studies deviate substantially from testing guidelines and common practice.

Reproduction and development. The report finds that the evidence is insufficient to support EPA's conclusion that there is a "convincing" relationship between formaldehyde exposure and adverse reproductive outcomes, such as infertility in women. Rather, the human data suggest a pattern of association -- meaning the evidence indicates there could be an increased risk for an adverse reproductive outcome but uncertainty limits any conclusion. Although the animal data also suggest an effect, EPA should weigh the positive and negative results more rigorously, evaluate study quality more critically, and consider carefully potential confounding factors.

In addition, the report suggests improvements to the development and presentation of EPA's calculated RfC values and strongly encourages a more informative approach similar to that previously proposed by other Research Council committees and used in other recent EPA assessments. The committee recommended that EPA use an appropriate graphical display to help identify a central value, isolate especially high or low values that might not be consistent with the literature, and improve the ability of the assessment to make a compelling case that the RfC proposed is appropriate.

The report also offers general recommendations to help revise the formaldehyde draft assessment, including rigorously editing to reduce the volume of text, adding clear and concise statements on the methods used, standardizing evidence tables, and thoroughly evaluating all critical studies for strengths and weaknesses. The committee also provided a "road map" for improving the assessment process in general.

The study was sponsored by the U.S. Environmental Protection Agency. The National Academy of Sciences, National Academy of Engineering, Institute of Medicine, and National Research Council make up the National Academies. They are independent, nonprofit institutions that provide science, technology, and health policy advice under an 1863 congressional charter.
Committee members, who serve pro bono as volunteers, are chosen by the Academies for each study based on their expertise and experience and must

satisfy the Academies' conflict-of-interest standards. The resulting consensus reports undergo external peer review before completion. For more information, visit http://national-academies.org/studycommitteprocess.pdf. A committee roster follows.

Contacts:
Jennifer Walsh, Media Relations Officer
Luwam Yeibio, Media Relations Assistant
Office of News and Public Information
202-334-2138; e-mail news@nas.edu

Pre-publication copies of Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde are available from the National Academies Press; tel. 202-334-3313 or 1-800-624-6242 or on the Internet at http://www.nap.edu. Reporters may obtain a copy from the Office of News and Public Information (contacts listed above).

# # #

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Division on Earth and Life Studies
Board on Environmental Studies and Toxicology

Committee to Review the Draft IRIS Assessment on FormaldehydeReview of EPA's Draft Assessment of Formaldehyde - page 3

(MORE)
(MORE)

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Ellen Mantus
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(See attached file: Formaldehyde Prepub.pdf)

{In Archive} NEWS UPDATES: House GOP finds another EPA target -- toxicity assessments (E&E Daily)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew Hotchkiss, Andrew 07/15/2011 10:25 AM

Archive: This message is being viewed in an archive.

CHEMICALS: House GOP finds another EPA target -- toxicity assessments (07/15/2011)

Jeremy P. Jacobs, E&E reporter

House Republicans appear to have found yet another bone to pick with U.S. EPA: how the agency conducts chemical toxicity assessments.

At issue is EPA's Integrated Risk Information System (IRIS), which is the primary program for the agency to determine the health and environmental effects of chemicals in commerce or the environment.

IRIS assessments serve as the basis of EPA regulations.

Rep. Paul Broun (R-Ga.) said yesterday that recent reviews of the IRIS program by the National Academy of Sciences and Government Accountability Office have found IRIS's scientific methodologies to be fundamentally flawed.

"Time and time again," Broun said at a House Science, Space and Technology Subcommittee for Investigations and Oversight hearing, "draft assessments were sent to NAS for review, only to be severely criticized. Rather than adopting the recommendations of the academy and updating their processes, EPA continued to churn out assessments that were summarily rebuked."

The focus of Broun and other Republicans' fire was EPA Office of Research and Development Assistant Administrator Paul Anastas, who oversees the IRIS program.

Republicans homed in on a recent NAS review of IRIS's formaldehyde assessment. The NAS panel, whose chairman testified at the hearing, roundly criticized IRIS's scientific methodologies, saying the IRIS assessment lacked clarity and transparency (*Greenwire* , April 8).

They also highlighted several GAO reports criticizing IRIS, including GAO adding the program to its annual "high risk list" of troubled federal programs (*Greenwire* , Feb. 16).

Anastas started off on particularly shaky ground, as Broun criticized EPA for being tardy in turning in its testimony for the hearing.

"Dr. Anastas, this is unacceptable. I expect EPA's testimony to be on time," Broun said. "EPA has obstructed the committee's ability to conduct oversight."

Anastas began by apologizing for the late testimony and then went on to highlight changes to the IRIS program since 2009. In particular, he noted that IRIS has completed 16 assessments in two years, more than had been finished in the four years before that. The program, he said, has also shortened the amount of time taken to complete its assessments.

He also pointed to his announcement earlier this week that EPA is planning improvements to the IRIS program, including putting into place the recommendations of the NAS report to increase accountability and transparency (*E&ENews PM* , July 12).

"EPA welcomes and accepts their recommendations," Anastas said yesterday.

Broun and other Republicans appeared unmoved. Their arguments were bolstered by GAO's David Trimble, who said "EPA still faces significant management challenges."

Further, Cal Dooley, the president of the American Chemistry Council (ACC), testified that the IRIS program is not rooted in the most modern scientific methods and lacks a comprehensive peer review process. Consequently, Dooley repeated industry's call for all IRIS assessments to be sent to NAS for review.

"Not only has IRIS failed to keep pace with modern science, the program lacks the scientific accountability needed to be considered objective and credible," Dooley said.

Democrats and other witnesses came to Anastas' -- and EPA's -- defense. Rena Steinzor, the president of the liberal Center for Progressive Reform, sharply criticized industry for delaying IRIS assessments and Dooley's call for further NAS reviews.

"What is in fact a sober, well-informed and carefully conducted scientific effort to synthesize existing research ... for the most toxic chemicals is portrayed by industry lobbyists as an anti-scientific effort to 'demonize' such ostensibly benign substances as arsenic, formaldehyde and dioxin," Steinzor said.

Steinzor added that the current IRIS database and pace is "woefully inadequate," in large part because EPA "has reacted to constant harassments."

Requiring NAS reviews of all assessments, she said, would "paralyze the IRIS program for the foreseeable future."

That sentiment was echoed by Rep. John Sarbanes. The Maryland Democrat said that most Americans would be shocked at the current state of chemical regulation. Stalling IRIS, he said, would not be an adequate solution.

"If the average person understood how little information we have about the chemicals being put out there in the stream of commerce, they'd be amazed and appalled," Sarbanes said. "I think they have the expectation that our level of knowledge is much, much higher than it is."

Elizabeth Erwin
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{In Archive} Re: a clearance-related argument

Matthew Lorber to: Ravi Subramaniam 09/22/2011 09:33 AM

Cc: Barbara Glenn, Bob Frederick, Glinda Cooper, Jacqueline Moya, Kate Guyton, Ravi Subramaniam, Susan Euling, Weihsueh Chiu

Archive: This message is being viewed in an archive.

Us scientists care about doing good work and getting this work out, certainly in a responsible manner and not until we are happy with the validity and presentation of our products. Managers, on the other hand, care much more about stepping on toes and fighting fires - good and timely science be damned. Simply stated and there is more, but there you have it.

Ravi Subramaniam | I am back to griping again! Our management ha... | 09/22/2011 09:27:46 AM

From: Ravi Subramaniam/DC/USEPA/US
To: Bob Frederick/DC/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA, Jacqueline Moya/DC/USEPA/US@EPA, Kate Guyton/DC/USEPA/US@EPA, Matthew Lorber/DC/USEPA/US@EPA, Susan Euling/DC/USEPA/US@EPA, Weihsueh Chiu/DC/USEPA/US@EPA, Ravi Subramaniam/DC/USEPA/US@EPA
Cc: Barbara Glenn/DC/USEPA/US@EPA
Date: 09/22/2011 09:27 AM
Subject: a clearance-related argument

I am back to griping again! Our management has insisted with us that it is necessary to share highly visible NCEA journal papers with other ORD labs and Program Offices before publication. In many cases, we have been asked to elicit comments and address them from these other folks who have strong opinions about what we do.

So, here we are in the middle of this extremely visible revision of the formaldehyde assessment, and there is new paper on formaldehyde from the Conolly and others that has come out in Inhal Tox. No one shared a word with anyone. It takes care not to say anything bad about us but the conclusions are still the same.

Note the "received" and "accepted" dates. They are 2 days apart. But that is a different matter indeed!!

I am inclined to send an email to Darrell to point this out as an example of a key argument that we had made. . . that NCEA management actions often put NCEA scientists who are at odds with others in ORD at a major disadvantage from getting their points of view expressed soon. Let me know if you think otherwise.

Miller et al 2011.pdf

Ravi

Ravi Subramaniam
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NCEA-Washington, ORD, EPA
N-7934, Two Potomac Yard, Crystal City
(703) 347-8606, (301) 515-2701 (alternate office)

{In Archive} NEWS UPDATES: EPA Faces New Pressure On Chromium 6 Cancer Risk After Panel Critique (Inside EPA)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew Hotchkiss, Andrew 08/01/2011 11:29 AM

Archive: This message is being viewed in an archive.

EPA Faces New Pressure On Chromium 6 Cancer Risk After Panel Critique

Posted: July 29, 2011

Most members of the scientific panel reviewing EPA's draft assessment of the risks posed by hexavalent chromium (Cr6) are detailing their strong criticisms of the document, putting new pressure on the agency to revise or delay its draft finding that ingestion of the compound causes cancer just weeks before its slated completion.

In written comments on the draft assessment released July 16, at least seven of the nine panelists said EPA had not demonstrated that ingestion of the compound can cause cancer. Three of the nine panelists also urged EPA to consider an upcoming industry study sponsored by the American Chemistry Council (ACC) that is also likely to undercut its cancer claim before proceeding with its assessment, echoing industry calls.

While the panelists' call to delay the assessment bolsters industry efforts, the industry group suffered a setback July 27 when California regulators finalized a strict health goal for Cr6 in drinking water that uses a method similar to EPA's and did not consider the upcoming industry data (*see related story*).

The panelists' criticisms appears likely to make it difficult for the agency to finalize the draft assessment in its current form, particularly given broad criticism from industry groups and many Republican lawmakers over the agency's Integrated Risk Information System (IRIS) process in the wake of a similar critique from a National Academy of Sciences panel over the agency's draft formaldehyde assessment.

Despite criticism from most panelists, the remaining panelists backed EPA's draft conclusion and urged the agency to complete the assessment with the available data.

EPA was not immediately available for comment.

Cr6 has long been considered a carcinogen when inhaled. Then a 2008 study by the National Toxicology Program reported stomach and mouth tumors in lab animals exposed to Cr6 in drinking water. That controversial study is the principal study EPA relies on in its strict calculations of risk in its draft assessment.

EPA's draft assessment of Cr6 -- the first to assess cancer risks from ingestion -- produced a stringent cancer slope factor, or estimate of cancer potency, of 0.5 milligrams per kilogram per day. If finalized, the draft assessment could help EPA justify a first-time drinking water standard and other regulations for Cr6, a substance that is widely used as an anti-corrosive agent in pigments, dyes, paints and plastics. The substance is also used in the production of stainless steel and formed as a byproduct in metal finishing work.

The draft assessment – which EPA is slated to finalize in September -- concludes that Cr6 is a mutagen and requires a conservative linear modeling of cancer risk. The two conclusions are linked, because EPA's cancer guidelines require the agency to perform the linear modeling from high dose animal data to the lower doses humans are expected to receive in the environment when a chemical causes cancer by mutagenic means -- or when it is unknown how the chemical causes cancer. The linear modeling is considered the strictest and most health protective because it assumes there is no safe level of exposure to the chemical.

But industry and some states, including Texas, have raised concerns about EPA's draft assessment, in particular its conclusion that it causes cancer by mutagenic means. At an EPA-sponsored listening session on the draft assessment late last year, industry toxicologists shared preliminary results that suggest there is insufficient data available on low levels of Cr6 exposure to indicate a mode of action (MOA), mutagenic or otherwise.

EPA though has said it plans to finalize the Cr6 risk assessment by September, and Administrator Lisa

Jackson has promised lawmakers that the draft assessment will be the basis for the agency's decision whether and how to regulate Cr6 in drinking water. Congressional interest in the metal sparked early in the year after environmentalists published a study showing elevated levels of the metal in tap water in dozens of cities.

Reviewers Echo Industry

Now the agency has released written comments from its peer reviewers, some of which echo industry criticisms. Joshua Hamilton, a senior scientist with the Marine Biological Laboratory in Woods Hole, MA, writes, “In this reviewer's strong opinion -- and in the consensus opinion of the external reviewers who are experts in this area and who discussed this at the May 12, 2011 meeting -- [Cr6] is highly unlikely to act via a mutagentic mode of action [MOA] in vivo.”

He adds that EPA's conclusions that Cr6 acts via a mutagenic MOA by all routes of exposure “is illogical given the current state of knowledge of chromium biology and toxicology as already presented in this draft report” and the emerging data from the ACC study.

Steven Patierno, executive director of the George Washington University Cancer Institute, notes that he has spent more than 25 years studying the genotoxic properties of Cr6 and has “frequently contributed to the plethora of studies showing DNA damage and what we thought was associated mutagensis.” But in hindsight, Patierno says he and other scientists have come to appreciate that DNA damage is only observed at very high doses that kill a lot of cells. “[W]hat we thought was 'mutagensis' is actually selection for stochastic cell survivors of massive toxic insult.”

Patierno says “EPA may be under certain historical regulatory precedents and pressures to deem [Cr6] with a mutagenic mode of action simply because there are published studies that have '[Cr6]' and 'mutation' equated in the title (some of these papers are my own), but this decisions would not be based on science.”

John Wise Sr., a professor at the University of Southern Maine, raises similar criticisms in his comments, saying EPA appears to fail to clearly consider that Cr6 is a weak mutagen when defined as an agent that can directly change the primary DNA sequence. The draft assessment is “inconsistent and thus, EPA has not presented and synthesized the scientific evidence for noncancer and cancer hazard in a clear manner.”

“Perhaps, the data will indicate [Cr6] is a mutagen, but, perhaps, the data indicate that one only gets mutations in the DNA sequence when systems are forced experimentally to do so at very high concentrations, due to species specific factors or by non-physiological exposure routes” -- a possibility that would make the mutations unlikely to occur in humans, Wise writes.

Toby Rossman, a professor at the New York University School of Medicine, is critical of EPA's interchanging use of the terms genotoxic and mutagenic in discussing Cr6's MOA. “[T]he human tumor data support an epigentic mechanism more than a mutagenic one,” Rossman writes.

Konstantin Salnikow of the National Institutes of Health says that while EPA's assessment concludes Cr6 is carcinogenic by a mutagenic MOA, very few publications show frequent mutations in chromium-induced tumors.

The panel chair, Anatoly Zhitkovich of Brown University, however, says that in general the draft assessment is well prepared and balanced in its presentation of various aspects of Cr6 toxicology and carcinogenesis.

Three of the nine reviewers -- Janusz Byczkowski, an independent consultant; Patierno; and Rossman -- specifically urge EPA to consider the ACC-funded research before finalizing the assessment.

Monica Nordberg, a professor at the Karolinska Institute in Sweden, however, says that while it would be worthwhile to await the outcome of these studies, it is important to set risk numbers now with the data available. “[I]t is important to draw conclusions now and on data available now and not to wait,” she says.

Elizabeth Erwin
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{In Archive} NEWS UPDATES: EPA chemical risk assessment program , though broken, is not beyond repair (ACC blog)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allan Marcus, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew 01/20/2012 12:23 PM

Archive: This message is being viewed in an archive.

EPA chemical risk assessment program, though broken, is not beyond repair

http://blog.americanchemistry.com/2012/01/epa-chemical-risk-assessment-program-though-broken-is-not-beyond-repair/

By Mike Walls on January 11, 2012 in Policy

In the latest of a series of concerns regarding EPA's Integrated Risk Information System, or IRIS, the U.S. Government Accountability Office (GAO) reported on Monday that EPA continues to face "both long-standing and new challenges" in bringing this critical part of our chemical regulatory system to working order. In other words, there is still more work to be done.

The IRIS program produces chemical assessments that are relied upon by federal and state government agencies to establish regulatory standards. As President Obama has noted, it's critical that the federal government develop or rely on the best science available – and that it evaluate the data fairly and accurately.

It's evident from the GAO report that comprehensive improvements are still needed in the scientific process EPA employs to evaluate data and weight of evidence when determining the strengths and weaknesses of studies. In addition, the Agency needs to improve the review process to ensure that IRIS adequately incorporates changes in response to peer review and public comment.

The GAO report did acknowledge that EPA has already taken some steps to improve IRIS – thanks, in part, to outgoing EPA research chief Paul Anastas. As E&E News' Jeremy Jacobs reported, Dr. Anastas "took several steps to bolster IRIS during his tenure. Most notably, he announced that the agency would implement recommendations from a National Academy of Sciences review of IRIS's formaldehyde assessment."

We were encouraged by Dr. Anastas' pledge to improve IRIS and believe the bipartisan legislation recently approved by Congress will help EPA follow through on Dr. Anastas' commitment and adopt the National Academy of Sciences' (NAS) recommendations in a timely manner. As the GAO reports points out, EPA has yet to make known exactly how it will implement all of the recommendations. Congress, meanwhile, has set a clear timetable for EPA to fix IRIS and to provide a progress report to ensure all ongoing and future assessments benefit from changes to the program.

We need to get the IRIS process right so that we can all have confidence in the results of its chemical assessments. IRIS is an important program that must improve to complete assessments more efficiently and to provide answers to the public, public health professionals and industry in a far more timely way. ACC will continue to work with Congress, EPA and other stakeholders to seek further improvements to ensure IRIS delivers timely and credible science-based assessments.

Photo *via panelworldmag.com*

Elizabeth Erwin
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Omnibus Appropriations Bill Directs EPA To Adopt Recommended Changes to IRIS

By Amena H. Saiyid

The Environmental Protection Agency would have to make changes to its chemical risk assessment program, us recommendations by the National Academies, under a congressional directive as part of the fiscal 2012 spending

The nine-bill omnibus appropriations package (H.R. 2055) includes a manager's report directing the agency to a recommended changes to the Integrated Risk Information System.

In the manager's report, EPA is directed to incorporate, as appropriate, recommendations to improve IRIS based the National Academies' National Research Council April review of the IRIS assessment of formaldehyde.

The IRIS directive is one of a number of policy riders in the appropriations bill. (See related story in this issue.)

The IRIS program has been assailed by congressional Republicans and industry advocates, who claim it lacks transparency, particularly when deciding on which studies to consider when setting inhalation exposure limits kn as reference concentrations.

By March 1, 2012, EPA must report to Congress on its efforts to make improvements to IRIS, and to explain it reasoning if it has not incorporated any recommended changes. Within 18 months of the omnibus bill's passage, is ordered to set up a contract with the National Academies to review up to three IRIS assessments to determine whether they incorporate the NAS recommendations.

The managers' report also emphasized the need for EPA to use sound, objective, and peer-reviewed science in th IRIS assessments.

One of the three IRIS assessments the academies must review is EPA's assessment of the carcinogenic and non-carcinogenic hazards of inorganic arsenic.

NAS Recommendations

The NAS critique of the formaldehyde assessment generally faulted it for including long descriptions of individu studies, and said the descriptions should be replaced with concise statements of findings and tables presenting evidence. More detailed descriptions should be included in appendices, NAS said (69 DEN A-1, 4/11/11).

NAS also said the opening section should more fully describe the methods used in the assessment, in particular t explanations of the criteria for including or excluding certain studies and the explanations of the weight-of-evide approaches used for non-cancer outcomes. These also should be expressed through concise statements and tables NAS said.

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Finally, stronger, more integrative, and more transparent discussions of the weight of evidence is needed in IRIS assessments, NAS said.

The bill also authorizes the EPA administrator to collect and obligate pesticide registration service fees in accor with the provisions of the Pesticide Registration Improvement Renewal Act (Pub. L. No. 110-94), which was en to help reduce a backlog of EPA pesticide registration decisions.

The full text of House Report 112-331 and the manager's reports are available at http://appropriations .house.gov/News/DocumentSingle.aspx?DocumentID=272625
The summary of the omnibus spending bill is available at http://appropriations .house.gov/UploadedFiles/12.14.11_Final_FY_2012_Appropriations_Legislation_-_Detailed_Summary.pdf.
The text of Interior, Environment and Related Agencies bill is available at http://rules.house.gov/Media/file/PDF_112_1/HR2055CRbill/pcConferenceDivE-BillOCR.pdf.

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{In Archive} Re: reference to NRC in revised formaldehyde document

Barbara Glenn to: Kate Guyton 09/09/2011 12:03 PM
Cc: Ravi Subramaniam

Archive: This message is being viewed in an archive.

Hi Ravi and Kate,
It seems kind of awkward to cite the NRC 2011 in general, because one doesn't say they did an extra analysis or discuss an issue because of a peer review comment. But I can see that when we wouldn't otherwise have done something (e.g., it doesn't really make sense) then perhaps citing the NRC 2011 is the reason that should be given.

-Barbara
Barbara S. Glenn, PhD | 703-347-8658
National Center for Environmental Assessment
U.S. Environmental Protection Agency

Kate Guyton | Hi Ravi, We did that in perc (you can search for... | 09/09/2011 09:21:13 AM

From: Kate Guyton/DC/USEPA/US
To: Ravi Subramaniam/DC/USEPA/US@EPA
Cc: Barbara Glenn/DC/USEPA/US@EPA
Date: 09/09/2011 09:21 AM
Subject: Re: reference to NRC in revised formaldehyde document

Hi Ravi,

We did that in perc (you can search for "NRC") and also in TCE....when we strayed from standard practice or added substantial analysis at the NRC'a behest (e.g. Ppar alpha, mcl tumors, and the extra cancer modeling).

-----Ravi Subramaniam/DC/USEPA/US wrote: -----

==========
To: Kate Guyton/DC/USEPA/US@EPA, Barbara Glenn/DC/USEPA/US@EPA
From: Ravi Subramaniam/DC/USEPA/US
Date: 09/09/2011 07:52AM
Subject: reference to NRC in revised formaldehyde document
==========

This is re: formaldehyde. I would like to refer to an argument in the NRC review in the MAIN body of the revised formaldehyde assessment and cite NRC 2011. I am assuming that, since NRC 2011 is a published and citable (peer-reviewed) document, such citation would be appropriate. I dont recall us doing so in perc, so I thought I would check if there are any considerations against doing so.

Ravi Subramaniam
Environmental Health Scientist
NCEA-Washington, ORD, EPA
N-7934, Two Potomac Yard, Crystal City
(703) 347-8606, (301) 515-2701 (alternate office)

EPA Plans New Peer Review To Address Industry Concerns Over IRIS

Posted: January 30, 2012

EPA officials say they are adding an additional peer review step at the start of its process for crafting its Integrated Risk Information System (IRIS) chemical risk assessments -- the latest in a series of new measures the agency is taking to improve its IRIS program and one long sought by industry before the agency's draft assessments are issued for review.

"We're . . . adding an early peer consultation step for some assessments before a draft [IRIS assessment] is written so we can have a fuller discussion" of the science, Becki Clark, acting director of EPA's National Center for Environmental Assessment, which oversees the IRIS program, told the National Academy of Sciences (NAS) Board on Environmental and Toxicological Studies (BEST) Jan. 25.

She added that the first of these consultations is under consideration for the summer of 2012, and would consider a toxicological issue regarding mouse lung tumors relevant to three ongoing IRIS assessments of ethylbenzene, napthalene and styrene.

Industry representatives have long complained that EPA's IRIS assessments, often the basis for agency regulations and other decisions, are overly stringent and ignore data that suggests lower risks. As a result, groups like the American Chemistry Council have long pushed the agency to hold scientific meetings with stakeholders before they get too far along in assessing chemicals.

Since the release last spring of the NAS' review of EPA's draft assessment of formaldehyde risks, industry has used the recommendations to argue for delays and re-writes of major IRIS assessments including the ubiquitous contaminant dioxin. The NAS formaldehyde report was particularly notable because its authors devoted a chapter of recommendations to EPA's overall process and scientific approach for drafting the documents, beyond just the formaldehyde assessment.

EPA has already announced numerous changes intended to address the NAS formaldehyde report. Many seek to make IRIS documents more transparent and easier to read. During the Jan. 25 meeting at NAS, EPA officials reiterated several additional ideas for addressing the formaldehyde report's recommendations on their scientific approach to creating the IRIS documents, including the pre-draft scientific meetings and adopting a standardized weight of evidence framework to use in drafting the assessments.

Vincent Cogliano, the acting IRIS director, said that EPA will be hosting a workshop to explore various weight of evidence approaches later this year, during remarks at the Society for Risk Analysis annual meeting in Charleston, SC, last month (*Risk Policy Report* , Dec. 13).

Clark reiterated the agency's interest in the approach, telling the NAS the program is "moving toward a standardized weight of evidence characterization for all health effects" in future IRIS documents. She added that, "keeping the IRIS program strong is a priority for EPA."

One of the board members, consultant Gail Charnley, asked during the Jan. 25 meeting whether "there would be an advantage" if BEST convened the workshop. But Cogliano disagreed, explaining that he is hoping to get the new framework in place "quickly." NAS reports often take 18 months or more to complete.

"We're still getting comments [on IRIS assessments] saying we're not doing this [weight of evidence assessment]," Cogliano replied. "I'm hoping to have the workshop, review by [EPA's Science Advisory Board] and implement . . . I think we can do it by the agency within the year."

Additionally, Clark said that all new IRIS assessments will include a new 15-page preamble explaining the agency's approach to the IRIS assessment. Each preamble is "responsive to the [NAS] recommendations by describing methods and criteria used to develop the assessments" and will address five topics, according to slides Clark presented, including "identifying and selecting pertinent studies"; "evaluating the quality of individual studies"; "weighing the overall evidence for each effect"; "selecting studies for derivation of toxicity values" and "deriving toxicity values." *Relevant documents are available on InsideEPA.com.* (*Doc ID:* 2388735) -- *Maria Hegstad*

Elizabeth Erwin
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{In Archive} Fw: EPA finds a common industrial solvent causes cancer - From E&E News

Kate Guyton to: Weihsueh Chiu 09/29/2011 09:14 AM

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In case this didn't come through to you...

----- Forwarded by Kate Guyton/DC/USEPA/US on 09/29/2011 09:14 AM -----

From: "Ginsberg, Gary" <Gary.Ginsberg@po.state.ct.us>
To: Bob Sonawane/DC/USEPA/US@EPA
Cc: "chiu.wiehsueh@epamail.epa.gov" <chiu.wiehsueh@epamail.epa.gov>, Kate Guyton/DC/USEPA/US@EPA
Date: 09/28/2011 06:53 PM
Subject: RE: EPA finds a common industrial solvent causes cancer - From E&E News

Congrats to all - it looks great on IRIS - Gary

_____

From: Sonawane.Bob@epamail.epa.gov [Sonawane.Bob@epamail.epa.gov]
Sent: Wednesday, September 28, 2011 6:22 PM
To: Ginsberg, Gary; david.eastmond@ucr.edu
Subject: Fw: EPA finds a common industrial solvent causes cancer - From E&E News

----- Forwarded by Bob Sonawane/DC/USEPA/US on 09/28/2011 06:21 PM -----

From: Bob Sonawane/DC/USEPA/US
To: birnbaumls@niehs.nih.gov
Date: 09/28/2011 06:20 PM
Subject: Fw: EPA finds a common industrial solvent causes cancer - From E&E News

EPA finds a common industrial solvent causes cancer

Jeremy P. Jacobs, E&E reporter

Published: Wednesday, September 28, 2011

U.S. EPA declared today that trichloroethylene (TCE), one of the country's most common environmental contaminants, causes cancer in humans -- a finding that will likely spur tighter regulation of the chemical.

EPA's assessment of TCE has been more than a decade in the making and has been strongly opposed by industry.

In an interview, Paul Anastas, assistant administrator of EPA's Office of Research and Development, called the TCE report one of the most complex and far-reaching reviews the agency has undertaken in recent years.

"This is among the most important assessments that we'll be releasing this year," Anastas said. "Trichloroethylene is one of the very large-volume chemicals out there. It's in all different kinds of industries."

The assessment came from the agency's Integrated Risk Information System (IRIS), which is supposed to assess health and environmental risks posed by chemicals. IRIS assessments provide a scientific basis for EPA regulations.

TCE is a chlorinated solvent widely used in industrial settings as a metal degreaser. It is one of the most common man-made chemicals detected in the environment and has been found at more than 1,500 hazardous waste sites. It has also been identified as a contaminant at 761 cleanups of hazardous waste sites in EPA's Superfund program.

EPA also found TCE causes damage to the nervous system, kidneys, liver and immune system. It can also pose threats to developing fetuses.

The release of the TCE assessment comes two weeks after reports that EPA had delayed finalizing the review and criticism from environmentalists who accused the White House of meddling in the IRIS program to placate industry as President Obama ramps up his re-election campaign (Greenwire , Sept. 16).

Anastas said there was no delay.

"At EPA, when we are doing scientific assessment, it's the science, the science, the science and the data, data, data," he said. "I know there has been a lot of talk about delays, but this is being released exactly on time because on time is when the science dictates."

Anastas was careful to note that the IRIS assessment is not a regulatory determination. Rather, he said, it provides the scientific data on which EPA, as well as state and local agencies, may take regulatory action.

The assessment's release was hailed by Daniel Rosenberg, a senior attorney at the Natural Resources Defense Council.

"The update of the TCE health assessment is a significant achievement for which Administrator Lisa Jackson, the EPA science staff and local activists from across the country deserve credit," Rosenberg said.

EPA must continue moving forward with finalizing IRIS assessments for other chemicals, he added.

"Ideally," Rosenberg said, "EPA will be allowed to continue its work in

addressing the backlog of health assessments for major high-volume chemicals without interference from the chemical industry, their allies in Congress or the White House."

The final TCE assessment will be used to establish cleanup procedures at Superfund sites and to improve the understanding of how vapors migrate from contaminated groundwater and soil into the indoor air of overlying building, EPA said.

It will also be used to revise EPA limits on TCE in drinking water and to develop new standards for limiting atmospheric emissions of the chemical under the Clean Air Act.

Industry, which opposed the release of the TCE report, has been a fierce critic of the IRIS program.

After a National Academy of Sciences (NAS) review of IRIS's formaldehyde assessment found significant shortcomings in the program's methodologies, industry groups called for all controversial IRIS assessments to be put on hold and reviewed by an NAS panel (E&ENews PM, April 19).

Environmentalists point out that the NAS panel did not call for holding up the IRIS formaldehyde assessment or any other studies. They also note that an NAS panel reviewed the draft TCE assessment in 2006 and urged EPA to finalize it.

{In Archive} Fw: NEWS UPDATES: Group accuses industry of slowing EPA assessments (Greenwire)

Kate Guyton to: iir 07/08/2011 01:33 PM

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The beat goes on!
Enjoy,
Kate

CHEMICALS: Group accuses industry of slowing EPA assessments (07/08/2011)

Jeremy P. Jacobs, E&E reporter

The chemical industry's recent call for an independent review of U.S. EPA's chemical toxicity assessments is a "thinly veiled attempt" to block new federal standards on dangerous substances, a group promoting chemical testing and regulation said today.

At issue, the Center for Progressive Reform (CPR) says, is a letter sent last month by the American Chemistry Council (ACC) sent to the White House that said a recent independent review of EPA's Integrated Risk Information System (IRIS) assessment of formaldehyde revealed significant scientific problems with the program (*Greenwire* , June 23).

In their own letter to the White House Office of Management and Budget, CPR's Rena Steinzor and Wendy Wagner imply that the ACC request that the National Academy of Sciences review all IRIS assessments is a bid to stall regulations.

"ACC," the wrote, "aggressively extrapolates from the review and argues that NAS review should be required for all IRIS assessments without any regard for the disastrous effects such a requirement would have on human health and the environment."

A NAS review of every IRIS assessment, they go on, "would grind" the assessment "process to a slow walk at the expense of the health and safety of everyone in the United States."

In response, ACC emphasized that the NAS review showed that IRIS needs significant improvements.

"We agree that IRIS is critical to protecting public health and the environment, which is why it is so important to make sure the program is effective," said ACC's Scott Jensen. "As the NAS stated in their latest review, 'persistent problems' with IRIS will only continue to lead to flawed risk assessments. Until EPA fixes these problems with IRIS, we believe the NAS must ensure the quality of ongoing risks assessments."

The NAS report on IRIS's formaldehyde assessment did take several issues with the scientific methodologies used by EPA. "Overall," the NAS panel said, "the committee found that EPA's draft assessment was not prepared in a logically consistent fashion, lacks clear links to an

underlying conceptual framework and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies" (*Greenwire*, April 8).

The IRIS program was also listed this year in the Government Accountability Office's annual "high risk list" of troubled federal programs (*Greenwire*, Feb. 16).

CPR cites cost of industry proposal

The CPR scholars argue that the current framework at EPA is set up to address the concerns noted in the NAS and GAO reports. Currently, they wrote, EPA is in charge of scientific assessments while OMB reviews draft regulations "with an eye to the budget, not the scientific underpinnings."

"[OIRA] employs just two scientists," CPR wrote, "and hence is not designed to conduct scientific peer review."

Further, they also argue that a NAS review for every IRIS assessment would cost thousands, "if not millions," of dollars for each new IRIS assessment.

ACC's Jensen countered that argument by insisting that paying for NAS reviews would be a good investment because funding flawed IRIS reviews are a waste of resources.

Steinzor and Wagner concluded by noting that currently about nine new or updated assessments are promulgated by IRIS each year -- a mere drop in the bucket of assessments that need to be done.

"IRIS work needs to be accelerated, not delayed," they wrote. "At this rate, the work needed to develop profiles for statutorily-identified 'hazardous air pollutants' and other chemicals that Congress and the agency have identified as needing more effective controls is already pushed back several decades in the future."

Click here to read the CPR letter.

{In Archive} NEWS UPDATES: Group accuses industry of slowing EPA assessments (Greenwire)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew Hotchkiss, Andrew 07/08/2011 01:24 PM

History: This message has been forwarded.

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Jeremy P. Jacobs, E&E reporter

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Click here to read the CPR letter.

Elizabeth Erwin
Communications Assistant
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Fax: (703) 347-8699

{In Archive} Fw: NEWS UPDATES: Omnibus Appropriations Bill Directs EPA To Adopt Recommended Changes to IRIS (BNA)

Kate Guyton to: iir 12/19/2011 04:57 PM

Archive: This message is being viewed in an archive.

See page 34 (or search for "IRIS") at:
http://rules.house.gov/Media/file/PDF_112_1/legislativetext/HR1540crSOM/psConference%20Div%20E%20-%20SOM%20OCR.pdf
Enjoy!
Kate

Omnibus Appropriations Bill Directs EPA To Adopt Recommended Changes to IRIS

By Amena H. Saiyid

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The full text of House Report 112-331 and the manager's reports are available at http://appropriations .house.gov/News/DocumentSingle.aspx?DocumentID=272625
The summary of the omnibus spending bill is available at http://appropriations .house.gov/UploadedFiles/12.14.11_Final_FY_2012_Appropriations_Legislation_-_Detailed_Summary.pdf.
The text of Interior, Environment and Related Agencies bill is available at http://rules.house.gov/Media/file/PDF_112_1/HR2055CRbill/pcConferenceDivE-BillOCR.pdf.

{In Archive} Fw: NEWS UPDATES: Group accuses industry of slowing EPA assessments (Greenwire)

Kate Guyton to: woodrufft, Lauren Zeise, Daniel Axelrad 07/08/2011 01:32 PM

Archive: This message is being viewed in an archive.

FYI...

----- Forwarded by Kate Guyton/DC/USEPA/US on 07/08/2011 01:30 PM -----

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Jeremy P. Jacobs, E&E reporter

The chemical industry's recent call for an independent review of U.S. EPA's chemical toxicity assessments is a "thinly veiled attempt" to block new federal standards on dangerous substances, a group promoting chemical testing and regulation said today.

At issue, the Center for Progressive Reform (CPR) says, is a letter sent last month by the American Chemistry Council (ACC) sent to the White House that said a recent independent review of EPA's Integrated Risk Information System (IRIS) assessment of formaldehyde revealed significant scientific problems with the program (*Greenwire* , June 23).

In their own letter to the White House Office of Management and Budget, CPR's Rena Steinzor and Wendy Wagner imply that the ACC request that the National Academy of Sciences review all IRIS assessments is a bid to stall regulations.

"ACC," the wrote, "aggressively extrapolates from the review and argues that NAS review should be required for all IRIS assessments without any regard for the disastrous effects such a requirement would have on human health and the environment."

A NAS review of every IRIS assessment, they go on, "would grind" the assessment "process to a slow walk at the expense of the health and safety of everyone in the United States."

In response, ACC emphasized that the NAS review showed that IRIS needs significant improvements.

"We agree that IRIS is critical to protecting public health and the environment, which is why it is so important to make sure the program is effective," said ACC's Scott Jensen. "As the NAS stated in their latest review, 'persistent problems' with IRIS will only continue to lead to flawed risk assessments. Until EPA fixes these problems with IRIS, we believe the NAS must ensure the quality of ongoing risks assessments."

The NAS report on IRIS's formaldehyde assessment did take several issues with the scientific methodologies used by EPA. "Overall," the NAS panel said, "the committee found that EPA's draft assessment was not prepared in a logically consistent fashion, lacks clear links to an

underlying conceptual framework and does not sufficiently document methods and criteria used to identify evidence for selecting and evaluating studies" (*Greenwire*, April 8).

The IRIS program was also listed this year in the Government Accountability Office's annual "high risk list" of troubled federal programs (*Greenwire*, Feb. 16).

CPR cites cost of industry proposal

The CPR scholars argue that the current framework at EPA is set up to address the concerns noted in the NAS and GAO reports. Currently, they wrote, EPA is in charge of scientific assessments while OMB reviews draft regulations "with an eye to the budget, not the scientific underpinnings."

"[OIRA] employs just two scientists," CPR wrote, "and hence is not designed to conduct scientific peer review."

Further, they also argue that a NAS review for every IRIS assessment would cost thousands, "if not millions," of dollars for each new IRIS assessment.

ACC's Jensen countered that argument by insisting that paying for NAS reviews would be a good investment because funding flawed IRIS reviews are a waste of resources.

Steinzor and Wagner concluded by noting that currently about nine new or updated assessments are promulgated by IRIS each year -- a mere drop in the bucket of assessments that need to be done.

"IRIS work needs to be accelerated, not delayed," they wrote. "At this rate, the work needed to develop profiles for statutorily-identified 'hazardous air pollutants' and other chemicals that Congress and the agency have identified as needing more effective controls is already pushed back several decades in the future."

Click here to read the CPR letter.

{In Archive} NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew Hotchkiss, Andrew 07/06/2011 02:13 PM

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GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process

Posted: July 1, 2011

Two key GOP senators are stepping up their attacks on EPA science by criticizing "defects" in the scientific review process for EPA's national ambient air quality standards (NAAQS), drawing parallels between flaws in the NAAQS program and criticisms of scientific errors in EPA's risk assessment for the chemical formaldehyde.

Sens. James Inhofe (R-OK), ranking member on the Environment & Public Works Committee, and panel member David Vitter (R-LA) sent a June 30 letter to EPA Administrator Lisa Jackson asking more than a dozen "important questions of scientific integrity" targeting several aspects of the NAAQS process, including how EPA selects scientific studies for reviews of its standards, the weight of evidence methodology EPA uses, and uncertainties in the process.

Inhofe and other Republicans have long criticized the agency for pursuing stricter NAAQS, which regulate six criteria pollutants including ozone and fine particulate matter (PM2.5). States must craft air quality plans that outline the pollution cuts they will impose on industry to come into, or stay in, attainment with the standards. Critics say that ever-tightening standards lead to increasingly expensive pollution controls that harm states' economies.

Industry, Republicans and others have, for example, criticized EPA's proposal to tighten the Bush EPA's 2008 ozone standard of 75 parts per billion (ppb) to a range within 60 to 70 ppb as supported by its science advisers.

Under the Clean Air Act EPA is barred from considering costs when setting NAAQS, and must propose changes to its standards based on science on the risks of exposure to a criteria pollutant. But Vitter and Inhofe say there are "fundamental problems to assuring high-quality, unbiased scientific results" in the NAAQS process.

The letter signals the senators stepping are up their broad attacks on EPA data, after touting recent a National Academy of Sciences' (NAS) critique of EPA's risk assessment of formaldehyde, to raise broad questions about the validity of other agency science, such as the data that EPA uses to justify its air quality standards. For example, speaking at a June 8 hearing of several Senate Environment & Public Works subcommittees on the impacts of EPA's air quality rules, Vitter questioned the legitimacy of EPA air rules and the agency's actions in general based on the NAS' conclusions in its review of the Integrated Risk Information System assessment of formaldehyde.

The NAS review, released in April, found that EPA did not provide sufficient evidence to

support its conclusions that human exposure to formaldehyde can cause leukemia or Hodgkin lymphoma, and raised additional concerns about the agency's process for reaching weight of evidence conclusions in its risk assessments.

Industry and Republicans have called on EPA to adopt NAS' recommendations for the chemical risk assessment program, including putting pending assessments on hold until the changes have been made.

"The same scientific defects noted in the formaldehyde assessment are also present in EPA's evaluations of the science used to establish and revise" NAAQS, the senators write in their June 30 letter. Their critiques over the NAAQS process come despite the fact that NAS praised EPA's updated risk assessment practices for setting criteria pollutant standards. *The letter is available on InsideEPA.com.* (*Doc ID: 2368871*)

The senators question the process EPA uses to decide which studies to cite when determining air quality standards, arguing that "Current methods for selecting studies appear to systematically exclude or discount well conducted, peer reviewed studies that show no adverse health effects from air pollution at or below current air quality standards."

They add that, "Current methods for weighing evidence allow EPA to discount multiple no-effect studies and rely instead on single studies showing an effect," and that "Current practices do not provide for a comprehensive analysis of uncertainty and variability as a way to make risk assessments more useful for decision makers."

The letter points to a number of specific examples where the senators charge that "EPA has discounted or ignored studies" that find no association between a pollutant and a particular health outcome -- including between ozone and asthma, ozone and cardiovascular morbidity and PM2.5 and chronic mortality.

Vitter and Inhofe also raise concerns with use of a 2006 study that found asthma symptoms for nitrogen dioxide (NO_2) but not for ozone. "In the NO_2 NAAQS review, EPA states that this study provides strong evidence for the health effects of NO_2 . . . whereas in the 2008 ozone NAAQS review and reconsideration, EPA notes many reasons why the results of the study should be ignored, including the fact that only 12 children per day were evaluated and that the authors did not clearly define the severity of asthma in the study subjects."

The senators ask Jackson more than a dozen questions, including asking whether EPA has "a policy of consistently disregarding studies misinforms the public and leads to inflated and highly uncertain estimates of public health risks" and why EPA has failed to conduct a quantitative uncertainty analysis on PM2.5 exposure.

The senators ask for a reply by July 8. With EPA planning to release its revised ozone standard later this month and other NAAQS reviews pending, the senators say, "Given the timeframe with which we are dealing the need for your prompt response to these important questions of scientific integrity cannot be understated. The economy and many of our fellow Americans are suffering. To further perpetuate the problems of high unemployment and poverty without strong scientific and economic support for EPA's calculated efforts would be unwise."

Elsewhere in the letter, the senators also note that EPA has not yet replied to their May 10 letter asking how EPA has implemented recommendations from NAS to address concerns with the formaldehyde assessment. -- *Victoria Finkle*

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EPA Agrees To GAO Calls To Further Improve Risk Assessment Program

Posted: January 9, 2012

EPA is backing new calls from the Government Accountability Office (GAO) to further enhance the transparency and efficiency of its chemical risk assessment program, after GAO warned EPA may face new challenges to timely release of its assessments, such as its failure to win White House approval to respond to industry data quality challenges.

Among other things, outgoing EPA research chief Paul Anastas says the agency plans to reconstitute an interagency working group to help improve coordination with other agencies and provide participants more detailed deadlines so that reviewers of draft EPA documents can still provide their advice in a timely fashion.

"In reconstituting the interagency workgroup, EPA will also communicate time commitments for reviewers to ensure that the interagency review step of the IRIS process are not an impediment to completing assessments in a timely manner," according to a letter Anastas sent to GAO late last year that was published in GAO's just-released study.

Anastas was responding to an earlier version of a GAO report, "Challenges Remain with EPA's Integrated Risk Information System (IRIS) Program," which was issued in final form Jan. 9. The report recommends that EPA's Office of Research and Development (ORD) determine the feasibility of the time frame for each step in the IRIS process and alter as necessary; submit a plan on how it will implement National Academy of Sciences (NAS) recommendations for reforming the IRIS program to "an independent entity with scientific and technical credibility;" publish the IRIS agenda in the *Federal Register* each fiscal year; describe in the agendas which chemicals remain under review and when the agency will begin new assessments; and update EPA's IRIS Track website and keep it current.

GAO's recommendations are the latest in a series of calls to revise the controversial program. In a 2009 report, GAO listed IRIS as a high risk program in need of reform. That report criticized the Bush administration's process for other agencies and the public to review draft assessments that allowed years to complete assessments and removed EPA from the lead role in crafting the assessments.

In the wake of the initial GAO report, Administrator Lisa Jackson unveiled a series of changes, limiting the review period and restoring EPA's lead role. While those reforms have resulted in

speedier release of some assessments, the program is also facing heated criticisms from industry and many lawmakers who have challenged the integrity of the science behind a host of high-profile draft assessments, including those for formaldehyde, arsenic, platinum, hexavalent chromium, dioxin and others.

An NAS panel was especially critical of the agency's draft formaldehyde assessment and reiterated calls for the agency to reform the IRIS program -- calls that have become a rallying cry for industry and other critics.

The new GAO report generally praises some of the changes that Jackson made in the agency's process for producing the IRIS assessments. The current report is also silent on whether the congressional investigation office continues to consider the IRIS program a "high-risk" government program in need of reform, as GAO did in its 2009 study.

Nevertheless, the report notes that while EPA released 16 final IRIS assessments in fiscal year 2010, the agency published only four reports in FY2011. "EPA's initial gains in productivity under the revised process have not been sustained," according to the GAO report. "Further, the increase in productivity does not appear to be entirely attributable to the revised IRIS assessment process and instead came largely from (1) clearing the backlog of IRIS assessments that had undergone work under the previous IRIS process and (2) issuing assessments that were less challenging to complete."

'New Challenges'

EPA "faces both long-standing and new challenges in implementing the IRIS Program," including implementing the NAS recommendations and providing reliable information on ongoing and planned assessments to IRIS users.

For example, the report warns that "unresolved discussions with [the White House Office of Management and Budget (OMB)] regarding EPA's responses to Data Quality Act challenges may impede EPA's ability to issue completed IRIS assessments."

GAO explains that some of those discussions -- as in the case of industry challenges to EPA assessments for methanol and non-cancer risks of inorganic arsenic -- have lasted for more than one year "without resolution."

GAO also highlights a third assessment which EPA had expected to complete in 2011, the draft assessment of platinum, noting that it also was subject to a DQA challenge in August. "For reasons that remain unclear, EPA now projects that this assessment will not be finalized until fiscal year 2012 . . . EPA asked interagency reviewers to submit written comments by August 26, 2011, but as of September 2011, OMB reviewers have not yet submitted comments."

These could contribute to further delays in the program, GAO adds. The report notes that EPA officials believe that OMB must clear its responses to DQA petitions. "According to EPA officials, OMB is delaying a decision because OMB would like to return to its role in the prior assessment process, in which it managed interagency reviews and made the final determination

as to whether EPA has satisfactorily responded to comments from OMB and officials in other federal agencies," according to the report.

But GAO states "no law or guidance specifically provides for such reviews."

While the report faults OMB for some delays, it also faults EPA for not clarifying which ongoing IRIS assessments will undergo how much revision in accordance with the NAS recommendations. "EPA has not provided a more detailed description of how the [NAS]' suggestions will apply to each of the assessments in its current inventory of IRIS assessments. Without a more precise description . . . it is too soon to provide a comprehensive assessment of EPA's approach. In addition, it is not transparent to stakeholders and other interested parties which assessments will be subject to these changes and which will not."

Still, GAO found that the agency was taking steps to comply with some of the NAS recommendations. For example, it found that the agency shortened an assessment of urea, and better described how it selected principal studies in its draft assessment of diisobutyl phthalate -- all recommendations from NAS.

"For these two assessments, it appears that EPA has begun to enhance the readability of its assessments by making changes that appear to be in line with the suggestions made by the [NAS]."

The American Chemistry Council (ACC), which has led industry challenges to EPA's risk assessment program, said in a statement that the GAO report affirms the need to improve the program along the lines recommended by NAS. "The [GAO] report shows that these longstanding problems have yet to be addressed and EPA has not developed a clear plan for fixing IRIS," ACC said.

"Specifically, it's evident from the report that comprehensive improvements are still needed in the scientific process EPA employs to evaluate data and weight of evidence when determining the strengths and weaknesses of studies. In addition, the Agency needs to improve the review process to ensure that IRIS adequately incorporates changes in response to peer review and public comment," ACC said.

But Rep. Brad Miller (D-NC), the ranking member of the House science committee's energy and environment panel, in a Jan. 9 statement, agreed that IRIS needs further reforms but cautioned that EPA needs to ensure speedy release of assessments. "We desperately need a reliable, scientific assessment of the effects of exposure to the thousands of chemicals now on the market," Miller said in a statement.

Miller, who requested the GAO report, cautioned that GAO found IRIS "has yet to make operational all the reforms promised by the new Administration" and officials are still working to adopt NAS recommendations. "The delays in fully reforming the program have produced a situation where new assessments are still not being released as promptly as promised," he said. -- *Maria Hegstad* (mhegstad@iwpnews.com This e-mail address is being protected from spambots. You need JavaScript enabled to view it)

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{In Archive} NEWS UPDATES: EPA, Key Adviser Oppose House Bid To Halt Chemical Risk Assessments (Inside EPA)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew Hotchkiss, Andrew 10/07/2011 09:15 AM

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EPA, Key Adviser Oppose House Bid To Halt Chemical Risk Assessments

Posted: October 6, 2011

Backed by a key scientist, EPA's research chief Paul Anastas is resisting language House lawmakers have included in the agency's pending spending bill that would halt the release of major chemical risk assessments until the National Academy of Sciences (NAS) has had a chance to review them and has backed recently announced program reforms.

At a House subcommittee hearing Oct. 6 to review EPA's Integrated Risk Information System (IRIS) program, Anastas drew strong support from Thomas Burke, an associate dean of The Johns Hopkins Bloomberg School of Public Health who also chaired a 2009 NAS panel that issued recommendations on ways to improve EPA risk assessments, with both men providing separate arguments to why the assessments shouldn't be delayed until the program is reformed.

A subsequent 2011 NAS panel that faulted EPA's draft assessment of formaldehyde reiterated some of the recommendations contained in the 2009 panel report, that Burke chaired. Many industry groups and GOP lawmakers are touting the formaldehyde report – and urging EPA to delay issuing new risk assessments until it has adopted the panel's suggestions.

To pressure the agency to adopt the NAS recommendations, House Republicans have also included language in EPA's fiscal year 2012 spending bill that would require the agency to implement the recommendations, have the NAS review any changes EPA makes to the IRIS program and have the NAS review several pending and future risk assessments, including the controversial assessment of arsenic. The House began considering the bill before the summer recess but lawmakers are scheduled to resume consideration later this year.

Sens. James Inhofe (R-OK) and David Vitter (R-LA) have also called on EPA Administrator Lisa Jackson to “suspend” issuance of controversial assessments until the reforms have been implemented and subjected to NAS review.

But at the Oct. 6 hearing of the House Energy and Commerce's energy and environment subcommittee to examine what subcommittee Chairman John Shimkus (R-IL) said is the “underlying bias present in the program and the impact of science manipulation on jobs and the economy” Anastas and Burke pushed back against efforts to halt the assessments until the NAS recommendations are adopted.

In written testimony at the hearing, Anasatas, assistant administrator of EPA's Office of Research and Development, reiterated that the agency is making changes to the program, but noted that NAS was clear that the program should continue to issue risk assessments despite the needed improvements.

“It is important to note that the NAS report viewed the implementation of their recommendations as a multi-year process,” he said. “For example, the NAS stated ‘it is not recommending that EPA delay the revision of the formaldehyde assessment to implement a new approach.”

Burke went even further, warning that language in the bill delaying the program would cause problems for public health programs that depend on the assessments to set standards to protect human health. “I think it would be a disservice to public health agencies throughout the country and even around the world” if we brought the IRIS program to a halt, Burke said in response to a question from Rep. Gene Greene (D-TX), the subcommittee's ranking Democrat.

Burke also clarified remarks he made last summer, first reported by *Inside EPA* , that EPA's IRIS program is in “crisis” and is in need of reform the program. At a June 30 meeting on the agency's new chemical safety research program, Burke warned EPA officials and other scientific advisers that “the sleeping giant is that EPA science is on the rocks . . . if you fail, you become irrelevant, and that is kind of a crisis.”

"You can't fail this time," Burke said.

In response to questions from Greene, Burke said that, “Obviously there is a lot of criticism and the credibility of science is really important,” Burke continued. “So why is EPA in crisis? Because of the incessant attacks on their credibility.”

“We owe it to the American public, we owe it to the scientific community” to have risk assessments based in sound science, Burke told the committee. “It would be better to do it right than destroy the credibility of the process.”

Focus On IRIS

The hearing was held to gather input on the IRIS program and its effects on regulations. IRIS has come under fire recently from industry and Republicans who argue that the assessments are overly conservative and not based in sound science, and who are pointing to the NAS' criticism of the program in chapter 7 of its review of the formaldehyde risk assessment as further need for improvement.

In the wake of such concerns, the agency in early July unveiled a series of reforms designed to strengthen the program and respond to the NAS concerns, including the development of a standing IRIS Advisory Committee at the Science Advisory Board (SAB) to address thorny scientific questions and review risk assessments that have provoked controversy among industry and other critics who fear they are too conservative.

EPA also announced a series of additional plans to clarify the information presented in IRIS assessments, provide better rationale for which studies EPA relies on in its assessments, streamline the documents and increase transparency, but industry groups viewed these plans as falling short of the necessary revision of a program they have long disliked.

EPA is moving forward with a host of IRIS assessments and has recently released several assessments, including one for trichloroethylene (TCE) -- a common groundwater contaminant -- and continues to defend the science behind the documents.

When Anastas issued the TCE assessment, he strongly touted the public health benefits of the program, saying the TCE assessment “underscores the importance of EPA's science and, in particular, the critical value of the IRIS database for ensuring that government officials and the American people have the information they need to protect their health and the health of their children."

But the agency has so far issued only one assessment -- for acrylonitrile -- that Inhofe and Vitter have urged EPA to “suspend,” leaving the agency with a series of major tests on upcoming future assessments, including one for hexavalent chromium, which environmentalists are pushing the agency to quickly issue.

Anastas told the Oct. 6 hearing that the agency is moving forward with applying the NAS' recommendations to assessments, but pointed out that “these improvements will have a greater impact on our new assessments as opposed to those already in the pipeline.”

Anastas also defended the IRIS review process, noting that assessments “are held to the highest Agency standards,” receiving considerable internal and external review and comment. “These standards are among the best in the federal government and the scientific community.”

OMB Review

However, Rep. Bill Cassidy (R-LA) called for increased oversight of IRIS assessments from the White House Office of Management and Budget (OMB), and advocated reinstating the OMB-led review process that was in place during the Bush Administration.

EPA Administrator Lisa Jackson reversed the Bush review process shortly after taking office, putting EPA back in the lead after the Government Accountability Office (GAO) called the IRIS program a “high risk” program due to the lengthy delays inherent in the OMB-led review process.

But Cassidy called for reinstating the OMB-led process. IRIS assessments, while not regulatory by themselves, are used to inform policy, Cassidy said, adding that he is concerned that “policy is manipulating science to achieve advocacy as opposed to truth.”

“Why in the world are we basing decisions that affect a number of jobs” on questionable science, Cassidy said. “I'm struck how sometimes processes are used to manipulate the response to the finding.”

The congressman added that cost-benefit analyses should be conducted for IRIS assessments and “I'm thinking OMB needs to be involved.”

But GAO is is expected to reach the opposite conclusion in a soon-to-be-released review of the 2009 changes to IRIS. In testimony to the subcommittee, David Trimble, director of GAO's natural resources and the environment program, reiterated earlier comments that the Obama Administration's reforms “appeared to represent a significant improvement over the previous IRIS process and, if implemented effectively, with sustained management and oversight, could help EPA restore the credibility and increase

the timeliness of this program." The reforms, he said, streamlined the IRIS process, consolidating and eliminating unnecessary steps and reducing delay; established transparency; and restored control of the process to EPA, taking the management of reviews away from OMB to considerably speed up the release of assessments.
However, Trimble added, a lack of statutory deadline; ever changing science and methodologies; delays; challenges from industry, environmentalists and lawmakers; and what are becoming frequent changes to the IRIS process will continue to hamper the program. -- *Jenny Hopkinson* (jhopkinson@iwpnews.com
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{In Archive} NEWS UPDATES: Industry Cautious On EPA's IRIS Reform But Seeks Additional Verifications (Risk Policy Report)

Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew Hotchkiss, Andrew 07/26/2011 02:16 PM

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Industry Cautious On EPA's IRIS Reform But Seeks Additional Verifications

Posted: July 25, 2011

Industry officials are cautiously welcoming EPA's recently announced efforts to improve its risk assessment process by implementing changes recommended by the National Academy of Sciences (NAS) but are still calling for more independent oversight than what the agency is proposing to ensure the improvements are properly implemented.

"I think they pretty much follow the NAS recommendations" in the proposed changes, says one industry source. "But I would use Ronald Reagan's terms…which is 'trust but verify.'"

Environmentalists are applauding EPA's proposals, with one source charging that industry's skepticism over EPA's actions to implement the recommendations could be a sign that industry's efforts are not aimed at improving the process, but rather an attempt to bring risk assessments to a halt. "I honestly don't think that's the goal, to get EPA to follow the recommendations," the source said. "I think it goes much deeper than that."

At issue are recommendations for reforming EPA's Integrated Risk Information System (IRIS) risk assessment process put forward by the NAS panel that reviewed the agency's draft assessment of formaldehyde. The panel strongly criticized the formaldehyde assessment for inadequately justifying its strict assessment while also calling for broad reforms to the program.

Since the review's release this spring, industry and Republican lawmakers have used the document to not only question the IRIS process, but also agency science as a whole, with industry calling for future assessments to be reviewed by NAS and for a halt to all pending assessments until the problem are resolved.

House Republicans have also included language in the agency's fiscal year 2012 spending bill that would require the agency to implement the recommendations, have the NAS review any changes EPA makes to the IRIS program and have the NAS review several pending and future risks assessments, including the assessment of arsenic.

EPA research chief Paul Anastas July 12 detailed a series of steps the agency plans for implementing NAS suggestions. He detailed a series of changes to IRIS that EPA is making in response to the NAS recommendations, including enhancing guidelines for transparency in data evaluation; streamlining documents; and providing improved explanation for why it selects certain health studies as the basis for its assessments.

"EPA will evaluate the overall weight of evidence for each health outcome, identify plausible approaches for developing toxicity values; select the most pertinent data and develop toxicity values for each health hazard; and portray toxicity values graphically," according to the IRIS Progress Report, which EPA released July 12 along with Anastas' announcement.

To better indicate what criteria were used in weighing studies, EPA will be "augmenting its current analysis of data to indicate which criteria were most influential in evaluating the weight of evidence," according to the report. Anastas said EPA seeks to be more transparent about how the criteria are applied and how the agency comes to its conclusions. "If it's not transparent and we do not do our best to make it transparent, there will be questions," Anastas said.

In addition to these changes, Anastas also detailed the agency's plan to create the new standing SAB panel, which he said would focus on scientific issues, including weight-of-evidence questions and how the agency selects key studies, rather than process issues (*Risk Policy Report* , July 18).

But several industry sources say that the agency will need independent oversight to ensure the proposals are properly implemented.

One industry attorney questions Anastas's announcement and says Congress is going to need to keep the pressure on the agency to reform the program based on ongoing assessments by the NAS.

The attorney says EPA officials will likely not follow through with the changes "unless their feet are held to the fire," and points to language in the FY12 appropriations bill that would require the agency to submit reports to Congress on the status of the reforms.

"I think Congress is going to have to do it and think they are going to have to rely on what NAS tells them," the source says. "If EPA is in charge of this, I don't have a lot of confidence . . . we've been down this road before."

The source says of Anastas' proposal, "When you look at their responses here . . . it's largely basically regurgitating what the NAS has said and then some of the phrasing is 'we are already working towards this,' and that seems a little disingenuous to me." If the agency were already making some of these changes as part of its 2009 IRIS reforms, why aren't they apparent in more recent assessments, the source asks.

"To some extent, what is [Anastas] going to say?" the source says. "I think it was largely lip service."

The first industry source says that another way to ensure EPA is moving ahead with the changes would be to have NAS review the program once the agency has put in place the reforms. "Until EPA gets this right, what's wrong with halting them," the source asks. "I don't think the delay will be that long . . . and poor work is not very helpful."

A third industry source says the agency needs to go beyond the recommendations of NAS if it wants to really improve the risk assessment process, in particular with regard to the peer review process. All assessments should go for NAS review, the source says, and EPA should be held accountable for making sure it responds to the concerns raised in the peer review.

Meanwhile, environmentalists say the efforts outlined by Anastas and the IRIS Progress Report fall in line with what NAS recommended. "It should satisfy any reasonable person," the first environmental source says. "I think it's very consistent with what NAS recommended and they have shown they are very responsive."

"They clearly read the report and took it clearly and I think that theses will be improvements," a second environmental source adds.

But a third environmental source says that the calls for more oversight are just a delay tactic. "I think there are always going to be parties who have a financial interest in the outcome of EPA's risk assessment" process, and it's not a surprise that industry and Republican lawmakers are trying to use NAS to further bolster their mission. The source accuses industry and Republicans of exaggerating the recommendations laid out by NAS and, despite their lofty language, picking and choosing which of the academy's studies they choose to support.

While industry and Republicans have lined up behind NAS on the formaldehyde assessment review, the groups largely ignored a 2009 NAS report *Science and Decisions: Advancing Risk Assessment* . "They don't like what *Science and Decisions* says" because it calls for EPA to include the latest scientific methods and knowledge, which would include things like genetics and other more sensitive endpoints, and could result in much more stringent risk assessments. "The current method suits them fine," the source says. -- *Jenny Hopkinson*

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{In Archive} NTP Expected To List Formaldehyde As Carcinogen , Bolstering EPA

Kate Guyton to: Bob Sonawane 03/15/2011 01:21 PM

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NTP Expected To List Formaldehyde As Carcinogen, Bolstering EPA
Posted: March 15, 2011
Health and Human Services Secretary Kathleen Sebelius is poised to release the National Toxicology Program's (NTP) twelfth report on chemicals the agency deems carcinogenic to humans, and is expected to list formaldehyde for the first time -- a move that could further solidify EPA's stance that the chemical is a carcinogen just as a National Academy of Sciences (NAS) panel moves closer to unveiling their review of the agency's draft risk assessment.

Congress first ordered NTP to produce the Report on Carcinogens (RoC) in 1978, according to the program's website. The documents provide information on chemicals that NTP deems carcinogenic or reasonably anticipates to be human carcinogens, along with people's potential for exposure to them, whether they are genotoxic and how they cause cancer.

NTP Director Linda Birnbaum said during remarks at the Society of Toxicology annual meeting in Washington, D.C. March 10 that Sebelius could release the 12th RoC as early as this month.

"We are supposed to release the RoC every two years. The last one was released in 2005; there was a lot of back and forth with the [White House Office of Management and Budget]," Birnbaum said. "They finally approved our new [RoC] review process in 2008."

NTP's 12th RoC has long been expected to list formaldehyde as a carcinogen. An expert panel reviewing NTP's background document on formaldehyde unanimously voted the chemical -- both naturally produced and widely used in industry -- a human carcinogen after considering a controversial study of Chinese workers published in early 2010 that indicated that exposure to formaldehyde caused certain types of leukemia.

EPA researchers considered the same study when writing their June 2010 draft Integrated Risk Information System (IRIS) assessment of formaldehyde, as did the International Agency for Research on Cancer when it voted formaldehyde a human carcinogen in late 2009.

EPA's draft IRIS assessment of formaldehyde is undergoing review by the NAS, under an agreement that Administrator Lisa Jackson struck with Sen. David Vitter (R-LA) in 2009. Vitter placed a hold on the nomination of EPA research chief until Jackson agreed to fund an NAS review of the formaldehyde assessment.

NAS' report is also expected to be released this month, according to the NAS website.

Release of the NTP report and the NAS review of EPA's draft assessment comes amid growing disputes over the chemical's risks and EPA regulation.

EPA in its latest national-scale air toxics assessment based on 2005 data finds that cancer risks from hazardous air pollutants (HAPs) have grown from 36 in a million to 50 in a million and that formaldehyde is now the biggest "driver" of overall air toxic cancer risks, despite what they agency says is an overall reduction in HAP levels.

But the chemical industry is resisting EPA efforts to strictly regulate the chemical. For example, industry officials last month urged EPA to stall a proposed air toxics rule for wood furniture manufacturing facilities until the NAS completes its review, saying the 1991 risk assessment that EPA was relying on is "overly conservative."

NTP's new process for drafting the RoC documents includes requesting nominations from the public for chemicals to be added to the listing, or re-examined. NTP staff then select those studies to potentially include, and drafts a background document relating each substance's carcinogenic potential. Each of these documents is reviewed by an external panel of experts, who recommend whether and how to list the substance in the RoC. NTP updates the background documents, which are then sent to two additional review committees for consideration before NTP presents them to its Board of Scientific Counselors for final peer review. The final draft is then reviewed by the NTP director and NTP executive committee before it is submitted to Secretary Sebelius for final review and submission to Congress.

NTP initially proposed to include eight substances in the 12th RoC, including Aristolochic Acids, Captafol, Cobalt-Tungsten Carbide Powders and Hard Metals, Glass Wool Fibers, ortho-Nitrotoluene, Riddelliine and Styrene in addition to formaldehyde. -- Maria Hegstad

EPA Weighs NAS Call To Improve IRIS By Unifying Risk Assessment Methods

Posted: February 6, 2012

EPA's Integrated Risk Information System (IRIS) staff is weighing a National Academy of Sciences' (NAS) call to improve risk assessments by unifying the program's approach to assessing cancer risks and other health effects from substances, according to a top IRIS official, as part of the agency's broader ongoing efforts to reform its controversial risk analysis program.

During a presentation at the Toxicology Forum's annual winter meeting in Washington, DC, Feb. 2, **Vincent Cogliano**, acting director of the IRIS program, said that a unified risk approach is one of many short- and long-term NAS recommendations in a 2009 report on steps for improving the agency's risk assessment program.

The report, "Science and Decisions: Advancing Risk Assessment," said EPA should unify dose-response for cancer and non-cancer risk assessments. Such an approach could help the agency address criticism about its current process for using one method to risk studies to assess cancer risks and another for non-cancer risks. Critics say that creates problems including making it harder to compare various risk numbers and other factors.

Cogliano said that among the long-term improvements to IRIS under consideration is how to unify dose-response for cancer and non-cancer risk assessments. "We will be looking at that again," Cogliano said.

Cogliano noted at the event there are concerns that the existing cancer risk assessment approach does not consider variation in human susceptibility, as the non-cancer assessment approach does.

Non-cancer assessments include uncertainty factors -- multiples of as much as 10 intended to introduce an extra margin of safety for uncertainties in risk assessment. Some of the more common factors are included for differences between lab animals and humans, or differences among humans.

Cogliano added that any unified approach adopted by IRIS would probably have elements of both existing practices, but declined to elaborate. He added that before updating EPA assessment guides, he would prefer to test the elements of a new unified dose-response approach in some data-rich assessments.

Cogliano also defended the IRIS program and EPA's efforts to respond to recommendations in a separate NAS report from 2011 on the agency's formaldehyde risk assessment noting among other things that the NAS report indicated that overhauling a program similar to IRIS took the agency more than two years.

"I don't know of any other agency that goes through so many steps of review and comment [as IRIS]," Cogliano said. "A lot is going on behind the scenes at EPA that we'll [unveil] soon . . . We embrace all the [NAS formaldehyde report] recommendations. These are things we need to do and are doing now."

NAS' report on formaldehyde was critical of the agency's risk study for the substance. Cogliano said EPA is taking steps to address various short- and long-term recommendations in the report, and provided tables from the agency's ongoing revisions to its formaldehyde assessment, indicating the group of studies included in the assessment and various measures of study strength and quality. "We'll do a systemic evaluation of each study on each of these criteria," Cogliano said. "Then we'll look at which of these studies go into which tiers one through three."

The tiers are intended to group the studies by quality, and help EPA staff determine how much weight to accord to the studies under consideration in IRIS assessments, he added.

The program is also developing a risk assessment training program, which all staff and contractors will undergo, Cogliano said. He said IRIS staff have held a number of meetings to discuss issues with ongoing assessments that are broadly applicable to the program. And he said the group is exploring ways to gather more scientific involvement and input from external scientists as EPA assessors are developing their analyses.

One of those is an effort to hold public scientific meetings early in the assessment process, before a draft is written and released publicly. Cogliano explained that the "workshop goals will vary" of these meetings: some will be early listening sessions on individual chemicals, while others will address toxicological issues relevant to more than one chemical under assessment. -- *Maria Hegstad*

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Faulting EPA's Vanadium Risk Study, Industry Calls For Early Data Review

Posted: December 12, 2011

Industry is urging EPA to follow the National Academy of Sciences' (NAS) advice to better identify at the start of its risk assessment process studies that are of low quality or lack consistent data, pointing to flaws in a pending assessment of vanadium pentoxide (V2O5) as an example of why the agency needs more confidence in the data it uses.

For EPA's V205 Integrated Risk Information System (IRIS) assessment, which is currently undergoing public comment, industry groups are questioning EPA's reliance on studies that they say used questionable procedures and yielded inconsistent results. The uncertainty factor of 3,000 -- the highest EPA can use -- that is attached to the inhalation dose is evidence of the agency's lack of confidence in the data, the groups argue.

"Do you take a bad study and apply a large uncertainty factor and say it's OK," asked Andrey Nikiforov, a toxicologist with Toxicology Research Services and consultant with the Vanadium Producers and Recyclers Association (VPRA), during a Dec. 8 listening session on the V2O5 IRIS assessment. "I would say you don't."

V2O5 is made from the spent catalysts from oil refineries and power plants and is used as a strengthener in steel and titanium alloys, making the metal lighter and stronger, qualities that have made the substance attractive to the military for uses in weapons, vehicles and other equipment. The material is also finding uses as pigment in some yellow paints and in rechargeable batteries.

The risk assessment comes as the agency is weighing how to regulate spent refinery catalyst under its pending amendments to the definition of solid waste. The VPRA in presentations during the listening session in Arlington, VA, and other groups are calling on EPA to exclude catalyst from the broad rule to ensure it is not regulated under strict hazardous waste provisions and can still be processed by third-party recyclers.

In its new risk assessment for V2O5, which was released in September, EPA sets a reference concentration (RfC), or safe limit for inhalation, of 1 × 10-5 mg/m3; an oral reference dose (RfD), or safe limit for ingestion, of 9 × 10-4 mg/kg-day; and further concludes that the substance is "likely to be carcinogenic to humans." *Relevant documents are available on InsideEPA.com. See page 2 for details.* (*Doc ID:* 2384571)

However, industry is arguing that those conclusions are overly conservative, pointing out that the limits are orders of magnitude below naturally occurring background levels, and are skewed by flawed data the agency used in crafting the assessment.

"Some of the studies [used] should have been deemed low quality or inconsistent," said Kimberly Wise, a toxicologist with the American Chemistry Council, during the listening session. Wise called on EPA to identify how it does quality assessment of relevant studies, "being very clear and transparent about what you deem the quality of those studies," a recommendation that NAS had made in chapter 7 of it's review of the draft formaldehyde assessment -- a document that is at the fore of industry's push for change to the IRIS program.

If the agency had done that for the V2O5 assessment, it would likely have not chosen the National Toxicology Program (NTP) 2002 study as the basis of its RfC and the 1953 Mountain study -- which VPRA argued is outdated -- used to determine the RfD, she added.

The NTP study has come under criticism in the past, Nikiforov said, pointing to a review paper, Duffus (2007), that audited NTP's study record and "found major issues that question the integrity of the results."

Among other things, researchers never accounted for the fact that the bulk test material of V2O5 dramatically changed colors -- going from yellow to violet -- over the course of the two year study, a change that "should have raised red flags," Nikiforov said.

There were other issues with the way the animals were dosed, Nikiforov added, including that considerable heat was used to break the V2O5 into inhalable particles, which could have changed the make up of the material, making the study "just fraught with problems."

In addition, the data produced by NTP looked at such high doses that the agency then attempted to model down to levels that humans would be exposed to, said Thomas Starr, of TBS Associates, speaking on behalf of the VPRA. Extrapolating the data down that far, however, is inappropriate and "has no biological basis to support" the results, Starr added, leading to a very conservative dose that "trumped objective science criteria." EPA's attempt to compensate for the problems with the study was to give the RfC a very high uncertainty factor, making the assessment even more conservative, Starr said.

What's more, the study recorded high incidence of lesions of the larynx in rats, conclusions that are not applicable to humans, Nikiforov continued, "because these lesions seen in rats are not predicative for what is seen in humans, [thus] they are not reliable for forming an RfC."

"The critical effect is not scientifically supported to derive an inhalation RfC," he added.

Representatives from the VPRA found similar issues with the cancer assessment, which was also based on NTP's 2002 study. "Given the complete lack of knowledge regarding the shape of the dose response at low V2O5 doses, EPA should withdraw its draft quantitative cancer risk assessment from further consideration," Starr said. "EPA should call for additional mechanistic

research to determine the modes of action by which V2O5 causes lung tumors in mice but not rats. Only when modes of action are better understood will it be possible to evaluate the relevance of theses mouse tumors to potential cancer risks arising from far lower human exposures to V2O5."

The study results on the issue were largely inconsistent, continued Douglas McGregor of Toxicity Evaluation Consultants, who pointed out that there was considerably high prevalence of tumors in mice and almost none in rats. What's more, the study did not determine a mode of action, nor find a bio marker that would indicate a human endpoint.

Given all of the questions surrounding those results, "the designation of a likely human carcinogen as a description is likely too severe to use in this case," McGregor concluded.

Michael Woolery, a toxicologist with Evraz Stratcor, a V2O5 producer, further added that the agency would have been better off by using existing human cohort studies, of which "none of them have shown any carcinogenic effects."

"It's hard for me to see that in the absence of any indication of human data that you can assume" it is likely to be a human carcinogen, Woolery added. The unnecessarily conservative assessment would put the vanadium industry in the U.S. out of business, "but it would not improve the health, the safety of the human people because it won't change what they are exposed to." -- *Jenny Hopkinson*

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{In Archive} NEWS UPDATES: Summer Reruns: More Debate Over EPA's Integrated Risk Information System (Georgetown Public Policy Review)
Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew Hotchkiss, Andrew 10/27/2011 12:38 PM

Summer Reruns: More Debate Over EPA's Integrated Risk Information System

http://gppreview.com/2011/10/20/summer-reruns-more-debate-over-epa%E2%80%99s-integrated-risk-information-system/

This summer featured the latest installment of the ongoing EPA Integrated Risk Information System (IRIS) reform saga. EPA's IRIS program produces chemical assessments that evaluate the health effects of chemicals in the environment and commerce, specifically determining the level at which a given chemical presents a potential public health risk. These assessments serve as the underpinnings of EPA's regulations, so it should come as no surprise that the release of an assessment (or draft assessment) is often accompanied by a tide of opposition from interested parties who stand to be impacted by potential regulation.

Since its inception in 1985, IRIS has faced a series of roadblocks. Under the Bush Administration, IRIS confronted heavy-handed involvement by external parties, particularly the Office of Management and Budget (OMB). OMB's far-reaching oversight and review contributed to the production of assessments being slowed to a glacial pace. In fact, an April 2008 Government Accountability Office (GAO) report warned that under the Bush administration, IRIS was at serious risk of becoming obsolete because of its inability to complete timely, credible assessments or reduce its backlog: only four assessments were completed in fiscal years 2006 and 2007 combined.

At the dawn of the Obama Administration, EPA Administrator Lisa Jackson introduced a set of reforms in 2009, which included streamlining the IRIS review schedule, ensuring that the majority of assessments would be posted within two years of the start date, restricting the ability of other federal agencies to request suspension of an assessment process, making public all written comments from other agencies and White House offices, and generally increasing EPA's autonomy.

Fast-forward to this summer's round of debates over IRIS reform, prompted by the June 2010 release of the draft assessment of formaldehyde, which, among other things, concluded that the chemical is a human carcinogen. Unsurprisingly, the draft assessment was met by uproar from the chemical industry, as well as from Senator David Vitter (R-La), who in 2009 requested that the National Academy of Sciences (NAS) examine the formaldehyde draft assessment process. (Interestingly, Vitter was recently awarded the American Chemistry Council's "distinguished leadership award".) The NAS review of the draft assessment, points out some methodological shortcomings, but ultimately supports EPA's determination that formaldehyde is known to cause cancer in humans. While the NAS review *never* called for halting of assessments or doing away

with the program, industry (and its Congressional allies), has made this particularized debate a referendum on the IRIS program writ large. Until the formaldehyde assessment is finalized, EPA will continue to list formaldehyde as only a "probable" carcinogen, which prevents it from issuing more rigorous regulations on the chemical – a delay that has very real public health consequences.

In mid-July, the House Committee on Science, Space, and Technology, Subcommittee on Investigations and Oversight held a hearing on IRIS. Among the individuals offering testimony were representatives from EPA itself, other federal agencies, industry, and public interest groups. Overall, the tenor of the hearings was in keeping with historical commentary on IRIS, with industry calling for more "independent" review of assessments, more involvement by other federal agencies (OMB review in particular has historically had a nearly paralyzing effect on the assessment process), and the use of more timely, scientific data – an attempt to corner EPA into using industry-backed studies.

And so, as is all too often the case in regulatory endeavors, a discussion about reform that should have been for the benefit of the public has been hijacked by industry. Thus, there appears to be little hope for untangling industry's use of vague (and at first glance, even beneficial) concepts like improving procedure and using the latest science, from the fact that they are in actuality a guise for altering a regulatory process in its own favor. Ultimately, we would hope that Congress and the Administration would see through the veneer, exposing what such calls for reform truly seek to accomplish. Unfortunately, such bold moves seem extremely unlikely in light of the Administration's latest concession in favor of industry and in abandonment of the public interest.

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EPA, Key Adviser Oppose House Bid To Halt Chemical Risk Assessments

Posted: October 6, 2011

Backed by a key scientist, EPA's research chief Paul Anastas is resisting language House lawmakers have included in the agency's pending spending bill that would halt the release of major chemical risk assessments until the National Academy of Sciences (NAS) has had a chance to review them and has backed recently announced program reforms.

At a House subcommittee hearing Oct. 6 to review EPA's Integrated Risk Information System (IRIS) program, Anastas drew strong support from Thomas Burke, an associate dean of The Johns Hopkins Bloomberg School of Public Health who also chaired a 2009 NAS panel that issued recommendations on ways to improve EPA risk assessments, with both men providing separate arguments to why the assessments shouldn't be delayed until the program is reformed.

A subsequent 2011 NAS panel that faulted EPA's draft assessment of formaldehyde reiterated some of the recommendations contained in the 2009 panel report, that Burke chaired. Many industry groups and GOP lawmakers are touting the formaldehyde report – and urging EPA to delay issuing new risk assessments until it has adopted the panel's suggestions.

To pressure the agency to adopt the NAS recommendations, House Republicans have also included language in EPA's fiscal year 2012 spending bill that would require the agency to implement the recommendations, have the NAS review any changes EPA makes to the IRIS program and have the NAS review several pending and future risk assessments, including the controversial assessment of arsenic. The House began considering the bill before the summer recess but lawmakers are scheduled to resume consideration later this year.

Sens. James Inhofe (R-OK) and David Vitter (R-LA) have also called on EPA Administrator Lisa Jackson to “suspend” issuance of controversial assessments until the reforms have been implemented and subjected to NAS review.

But at the Oct. 6 hearing of the House Energy and Commerce's energy and environment subcommittee to examine what subcommittee Chairman John Shimkus (R-IL) said is the “underlying bias present in the program and the impact of science manipulation on jobs and the economy” Anastas and Burke pushed back against efforts to halt the assessments until the NAS recommendations are adopted.

In written testimony at the hearing, Anasatas, assistant administrator of EPA's Office of

Research and Development, reiterated that the agency is making changes to the program, but noted that NAS was clear that the program should continue to issue risk assessments despite the needed improvements.

“It is important to note that the NAS report viewed the implementation of their recommendations as a multi-year process,” he said. “For example, the NAS stated ‘it is not recommending that EPA delay the revision of the formaldehyde assessment to implement a new approach.”

Burke went even further, warning that language in the bill delaying the program would cause problems for public health programs that depend on the assessments to set standards to protect human health. “I think it would be a disservice to public health agencies throughout the country and even around the world” if we brought the IRIS program to a halt, Burke said in response to a question from Rep. Gene Greene (D-TX), the subcommittee's ranking Democrat.

Burke also clarified remarks he made last summer, first reported by *Inside EPA* , that EPA's IRIS program is in “crisis” and is in need of reform the program. At a June 30 meeting on the agency's new chemical safety research program, Burke warned EPA officials and other scientific advisers that “the sleeping giant is that EPA science is on the rocks . . . if you fail, you become irrelevant, and that is kind of a crisis.”

"You can't fail this time," Burke said.

In response to questions from Greene, Burke said that, “Obviously there is a lot of criticism and the credibility of science is really important,” Burke continued. “So why is EPA in crisis? Because of the incessant attacks on their credibility.”

“We owe it to the American public, we owe it to the scientific community” to have risk assessments based in sound science, Burke told the committee. “It would be better to do it right than destroy the credibility of the process.”

Focus On IRIS

The hearing was held to gather input on the IRIS program and its effects on regulations. IRIS has come under fire recently from industry and Republicans who argue that the assessments are overly conservative and not based in sound science, and who are pointing to the NAS' criticism of the program in chapter 7 of its review of the formaldehyde risk assessment as further need for improvement.

In the wake of such concerns, the agency in early July unveiled a series of reforms designed to strengthen the program and respond to the NAS concerns, including the development of a standing IRIS Advisory Committee at the Science Advisory Board (SAB) to address thorny scientific questions and review risk assessments that have provoked controversy among industry and other critics who fear they are too conservative.

EPA also announced a series of additional plans to clarify the information presented in IRIS assessments, provide better rationale for which studies EPA relies on in its assessments,

streamline the documents and increase transparency, but industry groups viewed these plans as falling short of the necessary revision of a program they have long disliked.

EPA is moving forward with a host of IRIS assessments and has recently released several assessments, including one for trichloroethylene (TCE) -- a common groundwater contaminant -- and continues to defend the science behind the documents.

When Anastas issued the TCE assessment, he strongly touted the public health benefits of the program, saying the TCE assessment "underscores the importance of EPA's science and, in particular, the critical value of the IRIS database for ensuring that government officials and the American people have the information they need to protect their health and the health of their children."

But the agency has so far issued only one assessment -- for acrylonitrile -- that Inhofe and Vitter have urged EPA to "suspend," leaving the agency with a series of major tests on upcoming future assessments, including one for hexavalent chromium, which environmentalists are pushing the agency to quickly issue.

Anastas told the Oct. 6 hearing that the agency is moving forward with applying the NAS' recommendations to assessments, but pointed out that "these improvements will have a greater impact on our new assessments as opposed to those already in the pipeline."

Anastas also defended the IRIS review process, noting that assessments "are held to the highest Agency standards," receiving considerable internal and external review and comment. "These standards are among the best in the federal government and the scientific community."

OMB Review

However, Rep. Bill Cassidy (R-LA) called for increased oversight of IRIS assessments from the White House Office of Management and Budget (OMB), and advocated reinstating the OMB-led review process that was in place during the Bush Administration.

EPA Administrator Lisa Jackson reversed the Bush review process shortly after taking office, putting EPA back in the lead after the Government Accountability Office (GAO) called the IRIS program a "high risk" program due to the lengthy delays inherent in the OMB-led review process.

But Cassidy called for reinstating the OMB-led process. IRIS assessments, while not regulatory by themselves, are used to inform policy, Cassidy said, adding that he is concerned that "policy is manipulating science to achieve advocacy as opposed to truth."

"Why in the world are we basing decisions that affect a number of jobs" on questionable science, Cassidy said. "I'm struck how sometimes processes are used to manipulate the response to the finding."

The congressman added that cost-benefit analyses should be conducted for IRIS assessments and

“I'm thinking OMB needs to be involved.”

But GAO is is expected to reach the opposite conclusion in a soon-to-be-released review of the 2009 changes to IRIS. In testimony to the subcommittee, David Trimble, director of GAO's natural resources and the environment program, reiterated earlier comments that the Obama Administration's reforms “appeared to represent a significant improvement over the previous IRIS process and, if implemented effectively, with sustained management and oversight, could help EPA restore the credibility and increase the timeliness of this program.” The reforms, he said, streamlined the IRIS process, consolidating and eliminating unnecessary steps and reducing delay; established transparency; and restored control of the process to EPA, taking the management of reviews away from OMB to considerably speed up the release of assessments.

However, Trimble added, a lack of statutory deadline; ever changing science and methodologies; delays; challenges from industry, environmentalists and lawmakers; and what are becoming frequent changes to the IRIS process will continue to hamper the program. -- *Jenny Hopkinson*

{In Archive} RE: EPA finds a common industrial solvent causes cancer - From E&E News

Ginsberg, Gary to: Bob Sonawane 09/28/2011 06:53 PM
Cc: "chiu.wiehsueh@epamail.epa.gov", Kate Guyton

History: This message has been forwarded.
Archive: This message is being viewed in an archive.

Congrats to all - it looks great on IRIS - Gary

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From: Sonawane.Bob@epamail.epa.gov
[Sonawane.Bob@epamail.epa.gov]
Sent: Wednesday, September 28, 2011 6:22 PM
To: Ginsberg, Gary; david.eastmond@ucr.edu
Subject: Fw: EPA finds a common industrial solvent causes cancer - From E&E News

----- Forwarded by Bob Sonawane/DC/USEPA/US on 09/28/2011 06:21 PM -----

From: Bob Sonawane/DC/USEPA/US
To: birnbaumls@niehs.nih.gov
Date: 09/28/2011 06:20 PM
Subject: Fw: EPA finds a common industrial solvent causes cancer - From E&E News

EPA finds a common industrial solvent causes cancer

Jeremy P. Jacobs, E&E reporter

Published: Wednesday, September 28, 2011

U.S. EPA declared today that trichloroethylene (TCE), one of the country's most common environmental contaminants, causes cancer in humans -- a finding that will likely spur tighter regulation of the chemical.

EPA's assessment of TCE has been more than a decade in the making and has been strongly opposed by industry.

In an interview, Paul Anastas, assistant administrator of EPA's Office of Research and Development, called the TCE report one of the most complex and far-reaching reviews the agency has

undertaken in recent
years.

"This is among the most important assessments that
we'll be releasing
this year," Anastas said. "Trichloroethylene is one
of the very
large-volume chemicals out there. It's in all
different kinds of
industries."

The assessment came from the agency's Integrated Risk
Information System
(IRIS), which is supposed to assess health and
environmental risks posed
by chemicals. IRIS assessments provide a scientific
basis for EPA
regulations.

TCE is a chlorinated solvent widely used in
industrial settings as a
metal degreaser. It is one of the most common
man-made chemicals
detected in the environment and has been found at
more than 1,500
hazardous waste sites. It has also been identified as
a contaminant at
761 cleanups of hazardous waste sites in EPA's
Superfund program.

EPA also found TCE causes damage to the nervous
system, kidneys, liver
and immune system. It can also pose threats to
developing fetuses.

The release of the TCE assessment comes two weeks
after reports that EPA
had delayed finalizing the review and criticism from
environmentalists
who accused the White House of meddling in the IRIS
program to placate
industry as President Obama ramps up his re-election
campaign (Greenwire
, Sept. 16).

Anastas said there was no delay.

"At EPA, when we are doing scientific assessment,
it's the science, the
science, the science and the data, data, data," he
said. "I know there
has been a lot of talk about delays, but this is
being released exactly

on time because on time is when the science dictates."

Anastas was careful to note that the IRIS assessment is not a regulatory determination. Rather, he said, it provides the scientific data on which EPA, as well as state and local agencies, may take regulatory action.

The assessment's release was hailed by Daniel Rosenberg, a senior attorney at the Natural Resources Defense Council.

"The update of the TCE health assessment is a significant achievement for which Administrator Lisa Jackson, the EPA science staff and local activists from across the country deserve credit," Rosenberg said.

EPA must continue moving forward with finalizing IRIS assessments for other chemicals, he added.

"Ideally," Rosenberg said, "EPA will be allowed to continue its work in addressing the backlog of health assessments for major high-volume chemicals without interference from the chemical industry, their allies in Congress or the White House."

The final TCE assessment will be used to establish cleanup procedures at Superfund sites and to improve the understanding of how vapors migrate from contaminated groundwater and soil into the indoor air of overlying building, EPA said.

It will also be used to revise EPA limits on TCE in drinking water and to develop new standards for limiting atmospheric emissions of the chemical under the Clean Air Act.

Industry, which opposed the release of the TCE report, has been a fierce critic of the IRIS program.

After a National Academy of Sciences (NAS) review of IRIS's formaldehyde assessment found significant shortcomings in the program's methodologies, industry groups called for all controversial IRIS assessments to be put on hold and reviewed by an NAS panel (E&ENews PM, April 19).

Environmentalists point out that the NAS panel did not call for holding up the IRIS formaldehyde assessment or any other studies. They also note that an NAS panel reviewed the draft TCE assessment in 2006 and urged EPA to finalize it.

EPA Weighs NAS Call To Improve IRIS By Unifying Risk Assessment Methods

Posted: February 6, 2012

EPA's Integrated Risk Information System (IRIS) staff is weighing a National Academy of Sciences' (NAS) call to improve risk assessments by unifying the program's approach to assessing cancer risks and other health effects from substances, according to a top IRIS official, as part of the agency's broader ongoing efforts to reform its controversial risk analysis program.

During a presentation at the Toxicology Forum's annual winter meeting in Washington, DC, Feb. 2, **Vincent Cogliano**, acting director of the IRIS program, said that a unified risk approach is one of many short- and long-term NAS recommendations in a 2009 report on steps for improving the agency's risk assessment program.

The report, "Science and Decisions: Advancing Risk Assessment," said EPA should unify dose-response for cancer and non-cancer risk assessments. Such an approach could help the agency address criticism about its current process for using one method to risk studies to assess cancer risks and another for non-cancer risks. Critics say that creates problems including making it harder to compare various risk numbers and other factors.

Cogliano said that among the long-term improvements to IRIS under consideration is how to unify dose-response for cancer and non-cancer risk assessments. "We will be looking at that again," Cogliano said.

Cogliano noted at the event there are concerns that the existing cancer risk assessment approach does not consider variation in human susceptibility, as the non-cancer assessment approach does.

Non-cancer assessments include uncertainty factors -- multiples of as much as 10 intended to introduce an extra margin of safety for uncertainties in risk assessment. Some of the more common factors are included for differences between lab animals and humans, or differences among humans.

Cogliano added that any unified approach adopted by IRIS would probably have elements of both existing practices, but declined to elaborate. He added that before updating EPA assessment guides, he would prefer to test the elements of a new unified dose-response approach in some data-rich assessments.

Cogliano also defended the IRIS program and EPA's efforts to respond to recommendations in a separate NAS report from 2011 on the agency's formaldehyde risk assessment noting among other things that the NAS report indicated that overhauling a program similar to IRIS took the agency more than two years.

"I don't know of any other agency that goes through so many steps of review and comment [as IRIS]," Cogliano said. "A lot is going on behind the scenes at EPA that we'll [unveil] soon . . . We embrace all the [NAS formaldehyde report] recommendations. These are things we need to do and are doing now."

NAS' report on formaldehyde was critical of the agency's risk study for the substance. Cogliano said EPA is taking steps to address various short- and long-term recommendations in the report, and provided tables from the agency's ongoing revisions to its formaldehyde assessment, indicating the group of studies included in the assessment and various measures of study strength and quality. "We'll do a systemic evaluation of each study on each of these criteria," Cogliano said. "Then we'll look at which of these studies go into which tiers one through three."

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Top Official Vows More EPA Risk Reforms While Defending IRIS Program

Posted: December 12, 2011

CHARLESTON, S.C. -- The head of EPA's Integrated Risk Information System (IRIS) program is vowing to make additional reforms to the controversial program while also defending the agency's approach to adopting recommendations from the National Academy of Sciences (NAS) to improve it.

Vincent Cogliano, the program's acting director, told attendees during a session of the Society for Risk Analysis annual meeting here Dec. 7, that the agency is seeking to address concerns with how IRIS assessments are drafted and peer-reviewed, as well as how agency assessors weigh the evidence of data as the documents are created.

But industry groups are calling for additional reforms beyond Cogliano's proposals.

The IRIS program is under fire from industry and congressional Republicans who charge that the agency is rushing to complete a host of assessments for major chemicals expected to result in strict new regulatory requirements, without adequate scientific backing.

The critics point especially to EPA's draft assessment of formaldehyde, which an NAS panel strongly criticized for not containing adequate justification for its finding that the chemical is a leukemogen. In the report's chapter seven, the panel urged EPA to revise its IRIS assessment process, noting that the agency had revised its process for assessing air quality risks in just two years. The way EPA revised its process for drafting Integrated Science Assessments for criteria air pollutants is an example of how the agency "was able to revise an entrenched process in a relatively short time," the NAS panel said.

Since the issuance of the NAS panel report last April, critics have raised concerns that EPA has yet to adopt the overall process recommendations included in the document. Some have been pushing EPA to delay issuing any new risk assessments until the agency adopts the NAS panel's recommended reforms.

Public health activists and environmentalists, however, regularly complain that the program moves too haltingly to stay up to date, or to begin to address the vast number of chemicals in the environment.

But Cogliano urged attendees to remember the uncertainty that existed before IRIS, when various EPA programs and states had different risk values that could be used as the basis for various regulations, and often disagreed over which should be used, when and how.

He also pushed back against calls for EPA to delay issuance of IRIS assessments until the reforms have been adopted, noting that the NAS report urges EPA to continue to operate the IRIS program, and envisions a multi-year effort to implement all of the recommendations. "They did not tell us to stop doing assessments and they envisioned a multi-year improvement process and they encouraged us to go forward as we implement these improvements," Cogliano said.

He also downplayed industry suggestions that most IRIS assessments result in more conservative risk values than current assessments. He said that in a recent review of 20 chemicals with updated assessments, nine were more stringent than the earlier estimates. But, eight were less strict and 23 included first-time estimates, Cogliano said.

Cogliano also touted the agency's completion in late September of its long-awaited assessment of trichloroethylene (TCE), which had been some 20 years in the making. He contrasted the agency's experience with the formaldehyde assessment with the TCE assessment, where, he noted, that not only did staff complete the long-running TCE assessment, it also received positive reviews from its peer reviewers.

And he praised the IRIS review process that Administrator Lisa Jackson introduced shortly after her arrival at EPA. Cogliano noted that it contained far fewer steps that the process developed during the Bush administration. He also noted that the new process contains four separate periods for review and comment from other federal agencies, peer reviewers or the public. And Cogliano described the IRIS process as "one of the most transparent risk assessment processes ever."

Nevertheless, Cogliano detailed a series of new and ongoing reforms the agency is developing to further improve the process. He said the agency will hold a workshop in the first half of 2012 to consider various weight of evidence (WoE) approaches. IRIS staff will use public and stakeholder input at the workshop to select a WoE framework or approach to test in a pilot with a handful of upcoming IRIS assessments, he said.

Cogliano had earlier expressed interest in adopting a WoE framework for use in crafting IRIS assessments during a October listening session of the chemical n-butanol, though he also raised concern that doing so could cause delays in the program. Representatives of the American Chemistry Council (ACC), a chemical industry organization, had urged EPA to adopt such a tool at that meeting (*Risk Policy Report* , Nov. 1).

Cogliano also outlined plans to "create an earlier peer review step in the process to improve the [IRIS] documents so the peer review document is better," and described measures taken to improve the clarity of new IRIS documents. Cogliano said they will be significantly shorter than documents of the last few years have been, will include a short, introductory preamble and more tables and charts. "The first step in the IRIS assessment is draft development, we'll be seconding

that with a peer review workshop . . . on focused issues involving that chemical early in the IRIS assessment so we can get the benefit of public comment, stakeholder input and expert scientific advice so we can improve the assessment so the peer review draft will be much better."

And Cogliano indicated the new standing committee of EPA's Science Advisory Board (SAB) will review more than just individual IRIS assessments. The new standing committee is one of the reforms to the IRIS process that EPA research chief Paul Anastas announced in a series of reforms to the IRIS process in July, following the NAS formaldehyde report's release last April (*Risk Policy Report* , July 19). SAB staff are currently seeking nominations for members for the new subcommittee, which are due Jan. 6 (*Risk Policy Report* , Nov. 22).

"We are forming a dedicated [SAB] committee," Cogliano said. "We'll be going to take some assessments to this committee, we'll also be able to use the committee to give us advice on our [IRIS] process and how we are implementing the NAS recommendations."

But stakeholders are questioning the agency's approach. Matt Shudtz of the Center for Progressive Reform, a think tank that favors strict environmental rules, urged the agency to further simplify the process, arguing that having just one simultaneous comment period for all parties would enhance efficiency.

Cogliano, however, said, "We've streamlined already, reducing the [IRIS] process to a seven-step process," from the much longer process under the Bush administration.

And Jennifer Sass of the Natural Resources Defense Council also questioned the amount of time it has taken EPA to complete some of its more controversial IRIS assessments, including those of formaldehyde and TCE. She blamed industry for most of these delays, arguing that industry often uses new research programs as a way to delay ongoing assessments. She noted that the TCE assessment, for example, started in 1989. "I know some people think it's reasonable. But I think it's ridiculous," Sass said. "States and communities rely on those [assessments.]"

But the American Chemistry Council (ACC), the chemical industry trade association, called for further reforms than Cogliano outlined. Rick Becker, a senior toxicologist at ACC, acknowledged Cogliano's announcements, but argued that EPA has yet to address some major advice in the NAS formaldehyde report -- and urged the agency to do so.

Becker thanked Cogliano for his announcements of the WoE workshop and the earlier review step intended to improve the draft IRIS documents that undergo peer review. But he outlined a number of NAS recommendations that he argues EPA has yet to address, including standardized methods for literature reviews and selecting principal studies that are the basis for the risk estimates, use of a mode of action WoE framework and established protocols for analyzing major study types.

"Maintaining the status quo in IRIS is not tenable. I'm pleased to hear there are changes, but more needs to be done," Becker said. "We need to ask the right questions up front. Articulate the strategy to collect relevant information, and include an opportunity for stakeholder discussion at that early point. There may be some science that is needed to improve the assessment that can be

done relatively quickly."

Becker adds that EPA explaining the purpose of the IRIS assessment and what possible regulations it is intended to support would also be helpful to stakeholders. Stepping through the assessment process, Becker continues, "if defaults are used, there should be a clear rationale [in the document]. Information gaps and uncertainty need to be disclosed. These recommendations will help the risk management stage." -- *Maria Hegstad*

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{In Archive} NEWS UPDATES: Credibility On The Line: EPA's chemical hazard assessment program remains under scrutiny (C&E News)
Elizabeth Erwin to: Abdel Kadry, Alan Sasso, Allen Davis, Amanda Boone-Edwards, Amanda Persad, AmandaM Evans, Andrew Hotchkiss, Andrew 08/02/2011 10:55 AM

Credibility On The Line

EPA's chemical hazard assessment program remains under scrutiny

Cheryl Hogue

As picnics draw ants, the Environmental Protection Agency's assessments of a chemical's hazards attract critics.

Those assessments include EPA's scientific judgment on the safe level of exposure to a substance. They aren't regulations; but a lot rides on them.

The safe level of exposure set in an assessment affects regulatory decisions that determine cleanup levels for pollution in air, water, and soil. Thus, a polluter's financial liability in part hinges on the outcome of these assessments. So do the affordability and degree of cleanups faced by cities or regions stigmatized by pollution. Assessments also provide information to people who live near pollution sources and worry about how exposure could affect the health of their children and themselves.

Industry, politicians, environmental activists, and even the National Research Council (NRC) for years have critiqued this EPA assessment program, called the Integrated Risk Information System. IRIS has produced assessments on some 540 chemicals to date, and EPA is working on 70 more. The assessments in process are examining the hazards from several metals and commercially produced chemicals, including a half-dozen phthalates, vinyl acetate, styrene, and methanol.

A major complaint about IRIS is that assessments take years to complete, with those for some chemicals seemingly stuck in a cycle of review, redrafting, and review again. The most notorious example is EPA's work to revise its 1984 assessment of 2,3,7,8-tetrachlorodibenzo-*p* -dioxin (TCDD), the most toxic form of dioxin. The agency has been working on this reassessment for 20 years, and it still isn't done (C&EN, Nov. 15, 2010, page 30).

In recent years, IRIS has received more high-level political attention than any other EPA scientific effort. Congress has held oversight hearings about the program, with the latest one taking place last month. The Government Accountability Office (GAO), the investigative arm of Congress, has a close eye on IRIS. The office determined in 2008 that the IRIS database is at serious risk of becoming obsolete because EPA is unable to complete credible chemical assessments in a timely manner.

Also in 2008, the Administration of President George W. Bush made changes to IRIS that raised concerns at GAO and among congressional Democrats and environmentalists. The Bush Administration established an official role in IRIS assessments for the White House Office of Management & Budget (OMB), which reviews the economic impacts of federal regulation. The Bush Administration also provided agencies facing pollution liability—notably the Defense Department and the National Aeronautics & Space Administration—with channels to influence EPA's assessments shielded from public scrutiny.

As a result of these controversial policy moves and the delays in assessment completion, GAO in 2009 put IRIS on its list of some two-dozen government programs in greatest need of reform. That year, President Barack Obama's EPA Administrator, Lisa P. Jackson, struck down the Bush Administration's policy

changes and pledged to speed up the assessment process (C&EN, June 1, 2009, page 7).

But criticism of IRIS continues. In April of this year, NRC released a report that found fault with EPA's draft assessment of formaldehyde (C&EN, April 18, page 10). The report also took the IRIS program to task and recommended reforms, including better editing and streamlining of assessments, which have grown in length over the years. In July, the agency announced that it is implementing the recommendations to improve IRIS (C&EN, July 18, page 10).

Demand for assessments is growing in EPA regulatory programs.

In light of these recent moves, a House of Representatives panel held a hearing on July 14 to check up on IRIS. Members of the House Science, Space & Technology Subcommittee on Investigations & Oversight got an earful from witnesses who had plenty to say about EPA's chemical assessment program and the changes they think it needs.

"IRIS is broken," Calvin M. Dooley, president and chief executive officer of the American Chemistry Council, a chemical industry group, told the congressional panel. EPA's chemical assessment process lags behind scientific advances and relies too much "on outdated assumptions formulated in the 1970s," he said. In comments on several draft assessments, ACC has attacked the agency's standard assumption that no dose of a carcinogen is safe. Chemical makers and NRC, in reviews of draft assessments for some chemicals, have recommended that EPA consider whether these compounds cause cancer below a certain threshold of exposure.

At the hearing, Dooley called on Congress to require NRC to review all draft IRIS assessments. The trade association chief made a similar request to the White House in June.

NRC review of all draft assessments should continue "until we have confidence" that the deficiencies in IRIS are fixed, he said. Improvements in the EPA program would also be validated through NRC review, Dooley said. "We want to have an IRIS process that meets a gold standard," he added.

Also testifying at the hearing was Jonathan M. Samet, chairman of the NRC committee that reviewed EPA's draft formaldehyde assessment and professor of preventive medicine at the University of Southern California. Although Samet didn't directly counter Dooley's recommendation for NRC reviews, he told lawmakers that because the effort involved in such reviews is substantial, requiring an NRC review of every IRIS assessment would stress the community of scientists with the expertise to carry them out.

The top Democrat on the subcommittee, Rep. Donna F. Edwards (D-Md.), said she suspects that requiring NRC to peer-review all EPA draft chemical assessments would be "impracticable."

The job of reviewing EPA's draft chemical assessments often falls to the agency's Science Advisory Board. Samet chairs EPA's Clean Air Scientific Advisory Committee and is an ex officio member of the Science Advisory Board. He spoke supportively of the board's reviews of draft assessments, telling the subcommittee that they are carried out in complete openness and are not influenced by EPA staffers.

Paul T. Anastas, EPA assistant administrator for research and development, was also on hand to testify before the congressional panel. He told the subcommittee that he welcomes the NRC criticism. "We take those recommendations extremely seriously," he said. "We will always engage in continuous improvement because that's what scientists do."

The agency has completed 16 IRIS assessments since 2009, which is more than it completed during the previous three-year period from 2005 to 2008, Anastas said. EPA has cut the time to complete an assessment from an average of three or four years before 2009 to the current average of 23 months, he said.

"One reason why IRIS profiles have ballooned into unmanageable

length is the reaction of EPA staff to constant harassment by industry."

While EPA institutes reforms, House Republican leaders are acting too. The House is targeting IRIS in legislation (H.R. 2584) to fund EPA in fiscal 2012. The bill, which is expected to pass the House, would prohibit EPA from spending money on any regulation, cleanup guidance, or pollution permit that relies on a chemical assessment that doesn't hew to the NRC recommendations.

If enacted, this provision could force EPA to stop work on assessments that are now in progress and revise the hundreds of existing chemical profiles completed before the NRC issued its recommendations, said Rena I. Steinzor, president of the Center for Progressive Reform, a research and education organization.

In his testimony, Samet also discussed the specifics of the evaluation of EPA's work on formaldehyde in the April NRC report. The review backed EPA's conclusion that formaldehyde causes cancer in the nose, nasal cavity, and upper throat. But NRC found fault with part of the draft assessment that linked formaldehyde exposures to cancers of the lymphatic system and blood, including leukemias. The report directed EPA to rework this part of the assessment and describe how and why the agency picked particular studies as the basis of this conclusion.

Samet stressed that although EPA failed to communicate how it selected scientific studies as the basis for the formaldehyde assessment, there was nothing purposefully deceptive about the agency's actions.


EPA Anastas

Other problems that the report identified "were not unique and have been reported over the last decade by other NRC committees tasked with reviewing EPA's IRIS assessments for other chemicals," Samet said.

Steinzor of the Center for Progressive Reform said industry regularly submits to EPA the scientific studies it thinks are most important for a particular chemical assessment, "repeatedly advocating their view of the research to IRIS staff, more senior EPA officials, sympathetic federal agencies [other than EPA], and the White House." She continued, "One reason why IRIS profiles have ballooned into unmanageable length is the reaction of EPA staff to constant harassment by industry."

Another issue raised at the hearing was whether the White House should assume a bigger role in chemical assessments. In a June 22 letter to OMB Director Jacob J. Lew, ACC's Dooley asked OMB to take greater responsibility in the coordination and review of chemical assessments, similar to the Bush Administration's policy for chemical assessments.

Steinzor pointed out that OMB is staffed almost exclusively by economists and thus lacks the scientific and technical expertise to assess chemical hazards. ACC's recommendation that OMB take on a greater role in this work "is not designed to improve the program's scientific validity but rather is intended to give chemical manufacturers a sympathetic forum where they can tie IRIS in knots more easily," said Steinzor, a professor at the University of -Maryland School of Law.

Subcommittee member Rep. John P. Sarbanes (D-Md.) expressed concern about ACC's suggestions for

NRC and OMB review. “I’m worried your proposal would add more steps, with the potential to drag the process down,” Sarbanes said. He stressed the need for EPA to assess more pollutants.

Demand for assessments is growing in EPA regulatory programs, such as the part of the agency that handles water pollution and drinking water safety, said David Trimble, director of natural resources and environment at GAO. Yet regulators aren’t requesting what they need because of the backlog of incomplete IRIS assessments, Trimble told the subcommittee.

GAO investigators are monitoring EPA’s implementation of the NRC recommendations, Trimble continued. The office will report its findings to Congress later this year.

Rep. Paul Broun (R-Ga.), chairman of the subcommittee, said his panel will continue to keep an eye on the IRIS program, too. Broun said he wants “to ensure that EPA not only adopts the [NRC] recommendations but that it follows guidelines already in existence and continuously seeks to employ the most modern, credible methods and protocols to assess chemical risks.”

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{In Archive} RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

Kate Guyton to: Woodruff, Tracey 07/07/2011 12:06 PM
Cc: "Sutton, Patrice"

Archive: This message is being viewed in an archive.

YES. I think we need a GRADE overview as a start? Who would be best-- one of you, Lisa B, Holger, Kris? We can certainly link everyone in, but need someone to "teach" the principles and discuss how this can apply to evaluation of evidence mainly from animal studies. I can suggest this to Vince AND Mary Ross (NAAQS)? I am not certain it will reach Anastas, but...

Thanks,
Kate

"Woodruff, Tracey" YES, or Navigating, it is a perfect win to have P... 07/06/2011 11:55:10 PM

From: "Woodruff, Tracey" <WoodruffT@obgyn.ucsf.edu>
To: Kate Guyton/DC/USEPA/US@EPA, "Sutton, Patrice" <SuttonP@obgyn.ucsf.edu>
Date: 07/06/2011 11:55 PM
Subject: RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

YES, or Navigating, it is a perfect win to have Paul write back and say - YES, I have the tool that we are developing...

Do you have a way to engage with them on this? Of course the layers of bureaucracy do seem daunting - maybe you can talk with vince.

Would be good timing for a webinar.

tw

-----Original Message-----
From: Kate Guyton [mailto:Guyton.Kate@epamail.epa.gov]
Sent: Wednesday, July 06, 2011 11:31 AM
To: Woodruff, Tracey; Sutton, Patrice
Subject: Fw: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

Could GRADE help...?

Here's the letter:
(See attached file: June 30 letter.pdf)

Thanks,
Kate

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----- Forwarded by Kate Guyton/DC/USEPA/US on 07/06/2011 02:30 PM -----

GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process
Posted: July 1, 2011

Two key GOP senators are stepping up their attacks on EPA science by criticizing "defects" in the scientific review process for EPA's national ambient air quality standards (NAAQS), drawing parallels between flaws in the NAAQS program and criticisms of scientific errors in EPA's risk assessment for the chemical formaldehyde.

Sens. James Inhofe (R-OK), ranking member on the Environment & Public Works Committee, and panel member David Vitter (R-LA) sent a June 30 letter to EPA Administrator Lisa Jackson asking more than a dozen "important questions of scientific integrity" targeting several aspects of the NAAQS process, including how EPA selects scientific studies for reviews of its standards, the weight of evidence methodology EPA uses, and uncertainties in the process.

Inhofe and other Republicans have long criticized the agency for pursuing stricter NAAQS, which regulate six criteria pollutants including ozone and fine particulate matter (PM2.5). States must craft air quality plans that outline the pollution cuts they will impose on industry to come into, or stay in, attainment with the standards. Critics say that ever-tightening standards lead to increasingly expensive pollution controls that harm states' economies.

Industry, Republicans and others have, for example, criticized EPA's proposal to tighten the Bush EPA's 2008 ozone standard of 75 parts per billion (ppb) to a range within 60 to 70 ppb as supported by its science advisers.

Under the Clean Air Act EPA is barred from considering costs when setting NAAQS, and must propose changes to its standards based on science on the risks of exposure to a criteria pollutant. But Vitter and Inhofe say there are "fundamental problems to assuring high-quality, unbiased scientific results" in the NAAQS process.

The letter signals the senators stepping are up their broad attacks on EPA data, after touting recent a National Academy of Sciences' (NAS) critique of EPA's risk assessment of formaldehyde, to raise broad questions about the validity of other agency science, such as the data that EPA uses to justify its air quality standards. For example, speaking at a June 8 hearing of several Senate Environment & Public Works subcommittees on the impacts of EPA's air quality rules, Vitter questioned the legitimacy of EPA air rules and the agency's actions in general based on the NAS' conclusions in its review of the Integrated Risk Information System assessment of formaldehyde.

The NAS review, released in April, found that EPA did not provide sufficient evidence to support its conclusions that human exposure to formaldehyde can cause leukemia or Hodgkin lymphoma, and raised additional concerns about the agency's process for reaching weight of evidence conclusions in its risk assessments.

Industry and Republicans have called on EPA to adopt NAS' recommendations for the chemical risk assessment program, including putting pending assessments on hold until the changes have been made.

"The same scientific defects noted in the formaldehyde assessment are also present in EPA's evaluations of the science used to establish and revise" NAAQS, the senators write in their June 30 letter. Their critiques over the NAAQS process come despite the fact that NAS praised EPA's updated risk assessment practices for setting criteria pollutant standards. The letter is available on InsideEPA.com. (Doc ID: 2368871)

The senators question the process EPA uses to decide which studies to cite when determining air quality standards, arguing that "Current methods for selecting studies appear to systematically exclude or discount well conducted, peer reviewed studies that show no adverse health effects from air pollution at or below current air quality standards."

They add that, "Current methods for weighing evidence allow EPA to discount multiple no-effect studies and rely instead on single studies showing an effect," and that "Current practices do not provide for a comprehensive analysis of uncertainty and variability as a way to make risk assessments more useful for decision makers."

The letter points to a number of specific examples where the senators charge that "EPA has discounted or ignored studies" that find no association between a pollutant and a particular health outcome -- including between ozone and asthma, ozone and cardiovascular morbidity and PM2.5 and chronic mortality.

Vitter and Inhofe also raise concerns with use of a 2006 study that found asthma symptoms for nitrogen dioxide (NO2) but not for ozone. "In the NO2 NAAQS review, EPA states that this study provides strong evidence for the health effects of NO2 . . . whereas in the 2008 ozone NAAQS review and reconsideration, EPA notes many reasons why the results of the study should be ignored, including the fact that only 12 children per day were evaluated and that the authors did not clearly define the severity of asthma in the study subjects."

The senators ask Jackson more than a dozen questions, including asking whether EPA has "a policy of consistently disregarding studies misinforms the public and leads to inflated and highly uncertain estimates of public health risks" and why EPA has failed to conduct a quantitative uncertainty analysis on PM2.5 exposure.

The senators ask for a reply by July 8. With EPA planning to release its revised ozone standard later this month and other NAAQS reviews pending, the senators say, "Given the timeframe with which we are dealing the need for your prompt response to these important questions of scientific integrity cannot be understated. The economy and many of our fellow Americans are suffering. To further perpetuate the problems of high unemployment and poverty without strong scientific and economic support for EPA's calculated efforts would be unwise."

Elsewhere in the letter, the senators also note that EPA has not yet replied to their May 10 letter asking how EPA has implemented recommendations from NAS to address concerns with the formaldehyde assessment. -- Victoria Finkle

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Citing Congress' Report, Industry Urges EPA To Withdraw Dioxin Risk Limit

Posted: December 22, 2011

The chemical industry is urging EPA to withdraw its assessment of dioxin's non-cancer risks from interagency review, one of the last steps before issuing such estimates, arguing it is at odds with just-approved congressional report language urging the agency to revise its risk methods as recommended by the National Academy of Sciences (NAS).

"To comply with Congress' direction, EPA should withdraw the dioxin assessment from interagency review and take the necessary steps to implement the NAS recommendations," Cal Dooley, president and CEO of the American Chemistry Council (ACC), said in a Dec. 20 letter to Administrator Lisa Jackson.

An EPA spokeswoman says the agency is reviewing the ACC letter but agency officials have generally argued that NAS did not intend for them to delay risk assessments while it works to implement its recommendations.

EPA's risk assessment for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) -- the most toxic form of the compound -- has been in development for decades and under review for weeks. It includes a reference dose (RfD), the amount below which the agency does not anticipate adverse non-cancer health effects if consumed daily over a lifetime, of 0.7 picograms per kilogram bodyweight per day (pg/kg-day). The 0.7 pg/kg-day number is identical to the level EPA proposed and its science advisers generally endorsed.

The agency's proposal has riled ACC and other industry groups who fear it will drive significantly stricter regulatory limits. They charge that EPA's recommended limit is so strict it is set at a level lower than the amount of dioxin that would be ingested if consumers followed federal nutrition guidelines -- creating the possibility of confusion and poor dietary choices as consumers avoid dairy and meat in their diets -- the highest sources of dioxin.

The industry groups are particularly concerned because EPA is expected to unveil its non-cancer assessment in early 2012, and later, an even stricter cancer assessment -- which Dooley and others say will exacerbate consumer fears and confusion.

Industry groups have been lobbying administration officials to address their concerns. For example, Dooley and other industry representatives met with White House and EPA officials

Dec. 13 where they suggested that if EPA made less conservative policy choices in how it assessed the substance, it would result in an RfD of 3-10 pg/kg-day.

They also presented material to back their arguments that EPA's assessment would result in unsafe levels of ingestion if consumers follow federal nutrition guidelines. For example, they estimate that some toddlers and children up to age 8 could consume nearly 5 pg/kg-day daily, if they were to follow the Agriculture Department's recommended diet, while some adults 31 and older might consume nearly 2 pg/kg-day.

They also argued that it is out of line with other countries' limits. For example, Canada's limit, set in 1993 is 10 pg/kg-day while the World Health Organization and the United Kingdom have both recommended values of about 2 pg/kg-day.

At Odds With Report

Now Dooley is arguing that EPA's pending assessment is also at odds with report language Congress attached to EPA's portion of the fiscal year 2012 omnibus spending bill -- legislation that has passed both chambers of Congress and which President Obama is slated to sign in the coming days.

The language urges agency officials to revise its process and methods for how it conducts Integrated Risk Information System (IRIS) assessments along the lines recommended by the NAS. While legally not binding, EPA implements it as a matter of policy.

In particular, the report language urged EPA to adopt advice crafted by an NAS panel that had reviewed the agency's draft assessment of formaldehyde earlier this year. The panel strongly criticized the draft formaldehyde assessment and urged the agency to adopt a host of reforms to the IRIS program.

While EPA has adopted some of the NAS' recommendations, it is still working to craft others. But agency officials have resisted delaying pending assessments while they implement the NAS' recommendations. They have said that the NAS report urged EPA to continue to operate the IRIS program, and envisioned a multi-year effort to implement all of the recommendations.

"They did not tell us to stop doing assessments and they envisioned a multi-year improvement process and they encouraged us to go forward as we implement these improvements," Vincent Cogliano, IRIS's acting chief, said recently.

Among other things, Congress' report language requires EPA to issue a progress report by next March describing how it is implementing the NAS recommendations "for ongoing and new assessments." For draft assessments issued in FY12, EPA is required to document how the NAS' recommended reforms have been implemented or addressed, "including an explanation for why certain recommendations were not incorporated."

The report language also urges EPA to contract with NAS to review its upcoming assessment of arsenic and as many as two others. And it urges EPA to ensure that "any current and future IRIS

assessments must not only be grounded in sound, objective and peer-reviewed science and methodologies but should also provide risk managers with realistic values that will result in enhanced protection of human health."

Revise Assessment

In his letter to Jackson, Dooley cites the report language to argue that EPA should withdraw the draft dioxin assessment from interagency review and revise it to reflect Congress' call for the agency to revise the IRIS program along the lines recommended by NAS.

For example, he notes that the report language "directs EPA to include documentation describing how" NAS' recommendations "have been implemented or addressed in all IRIS assessments" released in FY12 -- although the report language only requires EPA to justify how it followed NAS for "draft" assessments.

He also charges that EPA's plan to issue the cancer and non-cancer portions of the assessment separately violates NAS' call to assess all harmful health effects simultaneously. "EPA's bifurcation of the dioxin assessment runs counter to the NAS' recommendation that IRIS assessments evaluate all relevant health endpoints based on a weight-of-evidence evaluation," he says.

Dooley adds that EPA has failed to apply a weight-of-evidence approach, along the lines recommended by NAS, to its RfD. "A failure to apply a weight-of-evidence approach was also evident in EPA's derivation of a [RfD] for dioxin. For example, EPA failed to consider the strengths and weaknesses of the underlying studies and whether these weaknesses affect the RfD determination."

In the material presented to the White House meeting, the industry groups urged the administration to consider what it calls "specific science policy choices, [which] result in an RfD value that is overly conservative." For example, they argue that these choices underestimate the RfD by multiple factors. "If these technical issues were corrected, the derived RfD would be approximately 3 [pg/kg-day] - 10 pg/kg-day," according to the document.

Among the technical issues are EPA decisions which industry argues underestimate the amounts of dioxin that resulted in what industry considers biological changes, but not necessarily adverse changes, in the population study that is the basis for EPA's RfD. The agency based that calculation on two studies of an Italian population exposed to dioxins following an industrial accident near Seveso, Italy, in 1976.

For example, the handout argues that "EPA underestimates children's exposures in Seveso. EPA's estimation of daily doses required to achieve the blood levels seen in the children in Seveso is too low, and conflicts with other published information for these children. Correctly estimating these exposures would increase the derived RfD by a factor of 2 to 3."

Similarly, the handout argues that "EPA over interprets the observed effects. Neither the subtle alterations in thyroid hormone levels nor the changes in sperm parameters observed in these

studies rise to the level of clinically relevant changes. However, in both cases, EPA counts the observed changes as fully adverse effects . . ." As a result, the document continues, EPA assigned its largest uncertainty factor -- an additional factor used in the risk estimate calculation to make it more conservative in the face of scientific unknowns -- of 10, when it could have used a smaller factor of 3 "effects considered to be 'minimally adverse.' This change would result in a 3-fold increase in the derived RfD."

"It sounds like small numbers . . . but they make a huge difference," an ACC source says. -- *Maria Hegstad*

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Citing Congress' Report, Industry Urges EPA To Withdraw Dioxin Risk Limit

Posted: December 21, 2011

The chemical industry is urging EPA to withdraw its assessment of dioxin's non-cancer risks from interagency review, one of the last steps before issuing such estimates, arguing it is at odds with just-approved congressional report language urging the agency to revise its risk methods as recommended by the National Academy of Sciences (NAS).

"To comply with Congress' direction, EPA should withdraw the dioxin assessment from interagency review and take the necessary steps to implement the NAS recommendations," Cal Dooley, president and CEO of the American Chemistry Council (ACC), said in a Dec. 20 letter to Administrator Lisa Jackson. *Relevant documents are available on InsideEPA.com. See page 2 for details.* (*Doc ID:* 2385534)

EPA did not respond to requests for comment but agency officials have generally argued that NAS did not intend for them to delay risk assessments while it works to implement its recommendations.

EPA's risk assessment for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) -- the most toxic form of the compound -- has been in development for decades and under review for weeks. It includes a reference dose (RfD), the amount below which the agency does not anticipate adverse non-cancer health effects if consumed daily over a lifetime, of 0.7 picograms per kilogram bodyweight per day (pg/kg-day). The 0.7 pg/kg-day number is identical to the level EPA proposed and its science advisers generally endorsed.

The agency's proposal has riled ACC and other industry groups who fear it will drive significantly stricter regulatory limits. They charge that EPA's recommended limit is so strict it is set at a level lower than the amount of dioxin that would be ingested if consumers followed federal nutrition guidelines -- creating the possibility of confusion and poor dietary choices as consumers avoid dairy and meat in their diets -- the highest sources of dioxin.

The industry groups are particularly concerned because EPA is expected to unveil its non-cancer assessment in early 2012, and later, an even stricter cancer assessment -- which Dooley and others say will exacerbate consumer fears and confusion (*Inside EPA* , Dec. 16).

Industry groups have been lobbying administration officials to address their concerns. For

example, Dooley and other industry representatives met with White House and EPA officials Dec. 13 where they suggested that if EPA made less conservative policy choices in how it assessed the substance, it would result in an RfD of 3-10 pg/kg-day.

They also presented material to back their arguments that EPA's assessment would result in unsafe levels of ingestion if consumers follow federal nutrition guidelines. For example, they estimate that some toddlers and children up to age 8 could consume nearly 5 pg/kg-day daily, if they were to follow the Agriculture Department's recommended diet, while some adults 31 and older might consume nearly 2 pg/kg-day.

They also argued that it is out of line with other countries' limits. For example, Canada's limit, set in 1993 is 10 pg/kg-day while the World Health Organization and the United Kingdom have both recommended values of about 2 pg/kg-day.

Now Dooley is arguing that EPA's pending assessment is also at odds with report language Congress attached to EPA's portion of the fiscal year 2012 omnibus spending bill -- legislation that has passed both chambers of Congress and which President Obama is slated to sign in the coming days (*see related story*).

The language urges agency officials to revise its process and methods for how it conducts Integrated Risk Information System (IRIS) assessments along the lines recommended by the NAS. While legally not binding, EPA implements it as a matter of policy.

In particular, the report language urged EPA to adopt advice crafted by an NAS panel that had reviewed the agency's draft assessment of formaldehyde earlier this year. The panel strongly criticized the draft formaldehyde assessment and urged the agency to adopt a host of reforms to the IRIS program.

While EPA has adopted some of the NAS' recommendations, it is still working to craft others. But agency officials have resisted delaying pending assessments while they implement the NAS' recommendations. They have said that the NAS report urged EPA to continue to operate the IRIS program, and envisioned a multi-year effort to implement all of the recommendations.

"They did not tell us to stop doing assessments and they envisioned a multi-year improvement process and they encouraged us to go forward as we implement these improvements," Vincent Cogliano, IRIS's acting chief, said recently.

Among other things, Congress' report language requires EPA to issue a progress report by next March describing how it is implementing the NAS recommendations "for ongoing and new assessments." For draft assessments issued in FY12, EPA is required to document how the NAS' recommended reforms have been implemented or addressed, "including an explanation for why certain recommendations were not incorporated."

The report language also urges EPA to contract with NAS to review its upcoming assessment of arsenic and as many as two others. And it urges EPA to ensure that "any current and future IRIS

assessments must not only be grounded in sound, objective and peer-reviewed science and methodologies but should also provide risk managers with realistic values that will result in enhanced protection of human health."

In his letter to Jackson, Dooley cites the report language to argue that EPA should withdraw the draft dioxin assessment from interagency review and revise it to reflect Congress' call for the agency to revise the IRIS program along the lines recommended by NAS.

For example, he notes that the report language "directs EPA to include documentation describing how" NAS' recommendations "have been implemented or addressed in all IRIS assessments" released in FY12 -- although the report language only requires EPA to justify how it followed NAS for "draft" assessments.

He also charges that EPA's plan to issue the cancer and non-cancer portions of the assessment separately violates NAS' call to assess all harmful health effects simultaneously. "EPA's bifurcation of the dioxin assessment runs counter to the NAS' recommendation that IRIS assessments evaluate all relevant health endpoints based on a weight-of-evidence evaluation," he says.

Dooley adds that EPA has failed to apply a weight-of-evidence approach, along the lines recommended by NAS, to its RfD. "A failure to apply a weight-of-evidence approach was also evident in EPA's derivation of a [RfD] for dioxin. For example, EPA failed to consider the strengths and weaknesses of the underlying studies and whether these weaknesses affect the RfD determination."

In the material presented to the White House meeting, the industry groups urged the administration to consider what it calls "specific science policy choices, [which] result in an RfD value that is overly conservative." For example, they argue that these choices underestimate the RfD by multiple factors. "If these technical issues were corrected, the derived RfD would be approximately 3 [pg/kg-day] - 10 pg/kg-day," according to the document.

Among the technical issues are EPA decisions which industry argues underestimate the amounts of dioxin that resulted in what industry considers biological changes, but not necessarily adverse changes, in the population study that is the basis for EPA's RfD. The agency based that calculation on two studies of an Italian population exposed to dioxins following an industrial accident near Seveso, Italy, in 1976.

For example, the handout argues that "EPA underestimates children's exposures in Seveso. EPA's estimation of daily doses required to achieve the blood levels seen in the children in Seveso is too low, and conflicts with other published information for these children. Correctly estimating these exposures would increase the derived RfD by a factor of 2 to 3."

Similarly, the handout argues that "EPA over interprets the observed effects. Neither the subtle alterations in thyroid hormone levels nor the changes in sperm parameters observed in these studies rise to the level of clinically relevant changes. However, in both cases, EPA counts the observed changes as fully adverse effects . . ." As a result, the document continues, EPA

assigned its largest uncertainty factor -- an additional factor used in the risk estimate calculation to make it more conservative in the face of scientific unknowns -- of 10, when it could have used a smaller factor of 3 "effects considered to be 'minimally adverse.' This change would result in a 3-fold increase in the derived RfD."

"It sounds like small numbers . . . but they make a huge difference," an ACC source says. -- *Maria Hegs*

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{In Archive} Re: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

Daniel Axelrad to: Kate Guyton 12/13/2011 12:22 PM

History: This message has been replied to.

Archive: This message is being viewed in an archive.

meanwhile, I hear that you have yet another week to go with perc? the fun never stops?

Kate Guyton Top Official Vows More EPA Risk Reforms Whil... 12/13/2011 11:38:34 AM

From: Kate Guyton/DC/USEPA/US
To: woodrufft@obgyn.ucsf.edu, Lauren Zeise <Lauren.Zeise@oehha.ca.gov>, Daniel Axelrad/DC/USEPA/US@EPA
Date: 12/13/2011 11:38 AM
Subject: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

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Posted: December 12, 2011

CHARLESTON, S.C. -- The head of EPA's Integrated Risk Information System (IRIS) program is vowing to make additional reforms to the controversial program while also defending the agency's approach to adopting recommendations from the National Academy of Sciences (NAS) to improve it.

Vincent Cogliano, the program's acting director, told attendees during a session of the Society for Risk Analysis annual meeting here Dec. 7, that the agency is seeking to address concerns with how IRIS assessments are drafted and peer-reviewed, as well as how agency assessors weigh the evidence of data as the documents are created.

But industry groups are calling for additional reforms beyond Cogliano's proposals.

The IRIS program is under fire from industry and congressional Republicans who charge that the agency is rushing to complete a host of assessments for major chemicals expected to result in strict new regulatory requirements, without adequate scientific backing.

The critics point especially to EPA's draft assessment of formaldehyde, which an NAS panel strongly criticized for not containing adequate justification for its finding that the chemical is a leukemogen. In the report's chapter seven, the panel urged EPA to revise its IRIS assessment process, noting that the agency had revised its process for assessing air quality risks in just two years. The way EPA revised its process for drafting Integrated Science Assessments for criteria

air pollutants is an example of how the agency "was able to revise an entrenched process in a relatively short time," the NAS panel said.

Since the issuance of the NAS panel report last April, critics have raised concerns that EPA has yet to adopt the overall process recommendations included in the document. Some have been pushing EPA to delay issuing any new risk assessments until the agency adopts the NAS panel's recommended reforms.

Public health activists and environmentalists, however, regularly complain that the program moves too haltingly to stay up to date, or to begin to address the vast number of chemicals in the environment.

But Cogliano urged attendees to remember the uncertainty that existed before IRIS, when various EPA programs and states had different risk values that could be used as the basis for various regulations, and often disagreed over which should be used, when and how.

He also pushed back against calls for EPA to delay issuance of IRIS assessments until the reforms have been adopted, noting that the NAS report urges EPA to continue to operate the IRIS program, and envisions a multi-year effort to implement all of the recommendations. "They did not tell us to stop doing assessments and they envisioned a multi-year improvement process and they encouraged us to go forward as we implement these improvements," Cogliano said.

He also downplayed industry suggestions that most IRIS assessments result in more conservative risk values than current assessments. He said that in a recent review of 20 chemicals with updated assessments, nine were more stringent than the earlier estimates. But, eight were less strict and 23 included first-time estimates, Cogliano said.

Cogliano also touted the agency's completion in late September of its long-awaited assessment of trichloroethylene (TCE), which had been some 20 years in the making. He contrasted the agency's experience with the formaldehyde assessment with the TCE assessment, where, he noted, that not only did staff complete the long-running TCE assessment, it also received positive reviews from its peer reviewers.

And he praised the IRIS review process that Administrator Lisa Jackson introduced shortly after her arrival at EPA. Cogliano noted that it contained far fewer steps that the process developed during the Bush administration. He also noted that the new process contains four separate periods for review and comment from other federal agencies, peer reviewers or the public. And Cogliano described the IRIS process as "one of the most transparent risk assessment processes ever."

Nevertheless, Cogliano detailed a series of new and ongoing reforms the agency is developing to further improve the process. He said the agency will hold a workshop in the first half of 2012 to consider various weight of evidence (WoE) approaches. IRIS staff will use public and stakeholder input at the workshop to select a WoE framework or approach to test in a pilot with a handful of upcoming IRIS assessments, he said.

Cogliano had earlier expressed interest in adopting a WoE framework for use in crafting IRIS assessments during a October listening session of the chemical n-butanol, though he also raised concern that doing so could cause delays in the program. Representatives of the American Chemistry Council (ACC), a chemical industry organization, had urged EPA to adopt such a tool at that meeting (*Risk Policy Report* , Nov. 1).

Cogliano also outlined plans to "create an earlier peer review step in the process to improve the [IRIS] documents so the peer review document is better," and described measures taken to improve the clarity of new IRIS documents. Cogliano said they will be significantly shorter than documents of the last few years have been, will include a short, introductory preamble and more tables and charts. "The first step in the IRIS assessment is draft development, we'll be seconding that with a peer review workshop . . . on focused issues involving that chemical early in the IRIS assessment so we can get the benefit of public comment, stakeholder input and expert scientific advice so we can improve the assessment so the peer review draft will be much better."

And Cogliano indicated the new standing committee of EPA's Science Advisory Board (SAB) will review more than just individual IRIS assessments. The new standing committee is one of the reforms to the IRIS process that EPA research chief Paul Anastas announced in a series of reforms to the IRIS process in July, following the NAS formaldehyde report's release last April (*Risk Policy Report* , July 19). SAB staff are currently seeking nominations for members for the new subcommittee, which are due Jan. 6 (*Risk Policy Report* , Nov. 22).

"We are forming a dedicated [SAB] committee," Cogliano said. "We'll be going to take some assessments to this committee, we'll also be able to use the committee to give us advice on our [IRIS] process and how we are implementing the NAS recommendations."

But stakeholders are questioning the agency's approach. Matt Shudtz of the Center for Progressive Reform, a think tank that favors strict environmental rules, urged the agency to further simplify the process, arguing that having just one simultaneous comment period for all parties would enhance efficiency.

Cogliano, however, said, "We've streamlined already, reducing the [IRIS] process to a seven-step process," from the much longer process under the Bush administration.

And Jennifer Sass of the Natural Resources Defense Council also questioned the amount of time it has taken EPA to complete some of its more controversial IRIS assessments, including those of formaldehyde and TCE. She blamed industry for most of these delays, arguing that industry often uses new research programs as a way to delay ongoing assessments. She noted that the TCE assessment, for example, started in 1989. "I know some people think it's reasonable. But I think it's ridiculous," Sass said. "States and communities rely on those [assessments.]"

But the American Chemistry Council (ACC), the chemical industry trade association, called for further reforms than Cogliano outlined. Rick Becker, a senior toxicologist at ACC, acknowledged Cogliano's announcements, but argued that EPA has yet to address some major advice in the NAS formaldehyde report -- and urged the agency to do so.

Becker thanked Cogliano for his announcements of the WoE workshop and the earlier review step intended to improve the draft IRIS documents that undergo peer review. But he outlined a number of NAS recommendations that he argues EPA has yet to address, including standardized methods for literature reviews and selecting principal studies that are the basis for the risk estimates, use of a mode of action WoE framework and established protocols for analyzing major study types.

"Maintaining the status quo in IRIS is not tenable. I'm pleased to hear there are changes, but more needs to be done," Becker said. "We need to ask the right questions up front. Articulate the strategy to collect relevant information, and include an opportunity for stakeholder discussion at that early point. There may be some science that is needed to improve the assessment that can be done relatively quickly."

Becker adds that EPA explaining the purpose of the IRIS assessment and what possible regulations it is intended to support would also be helpful to stakeholders. Stepping through the assessment process, Becker continues, "if defaults are used, there should be a clear rationale [in the document]. Information gaps and uncertainty need to be disclosed. These recommendations will help the risk management stage." -- *Maria Hegstad*

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Anastas' departure seen as blow to agency

Jeremy P. Jacobs, E&E reporter

Published: Friday, January 6, 2012

The "Father of Green Chemistry" is leaving U.S. EPA.

Paul Anastas, the assistant administrator of the agency's Office of Research and Development and EPA's science adviser, will return to Yale University in the middle of February, EPA announced yesterday afternoon.

The agency said Anastas is leaving to meet his obligations to Yale, where he leads its Center for Green Chemistry and Green Engineering.

"Paul put his academic career on hold and took a leave of absence from Yale University to serve at EPA the past two years," EPA said in an internal memo.

The Massachusetts native's departure comes at a time when regulators often leave administrations -- two years in. But Anastas' decision may be a blow to EPA's efforts to crack down on harmful chemicals in the environment and commerce. Anastas oversees EPA's Integrated Risk Information System (IRIS), which is charged with assessing the health risks posed by substances.

IRIS assessments are the scientific building blocks for EPA and other agency regulations. The program is currently finalizing controversial assessments of whether substances like formaldehyde, hexavalent chromium and dioxin cause cancer. It remains to be seen whether Anastas' departure will affect when those final assessments will be released.

Anastas also follows Steve Owens, EPA's assistant administrator for the Office of Chemical Safety and Pollution Prevention, in leaving the agency. Owens, who oversaw the agency's efforts to more effectively use its authority to regulate chemicals and pesticides under the 1976 Toxic Substances Control Act (TSCA), left the agency Nov. 30 (*Greenwire* , Oct. 26, 2011).

Anastas was considered a major addition to EPA when he was appointed shortly after President Obama took office. He is widely respected in the environmental and public health communities for his 12 principles of green chemistry, which he published with chemist John Warner in 1991 (*Greenwire* , June 20, 2011).

Since then, green chemistry -- which focuses on creating chemicals that pose no toxic risks to human health or the environment over their life cycle -- has grown into a major field, with universities around the world dedicating labs to it.

Anastas' tenure at EPA was applauded by environmental groups, which urged the agency to appoint a worthy successor.

"Dr. Anastas is a good scientist and a visionary leader in green chemistry," said Gina Solomon, a senior scientist at the Natural Resources Defense Council. "We look forward to his ongoing scientific contributions, while we also look ahead to the need for strong leadership at [the Office of Research and Development]."

But Anastas undoubtedly felt the political pressures of his job. He was frequently the target of strong criticism from Republicans at congressional hearings, both for perceived problems with the IRIS program and EPA's efforts to launch a long-term study on the environmental effects of hydraulic fracturing for natural gas.

Environmentalists also took aim at Anastas last year for what they perceived as a delay in releasing IRIS's assessment of trichloroethylene (TCE), an industrial solvent that is one of the most common Superfund hazardous waste site contaminants. The TCE assessment was strongly opposed by industry, and greens viewed the delay as politically motivated (*Greenwire* , Sept. 16, 2011).

Shortly thereafter, Anastas released the TCE assessment, which found the solvent causes cancer. Anastas said there was no delay in the release (*E&ENews PM* , Sept. 28, 2011).

Anastas also fielded a constant stream of criticism from industry, which typically opposed IRIS assessments and the program's scientific methodologies.

However, Mike Walls, the American Chemistry Council's vice president of regulatory and technical affairs, praised Anastas for steps taken to improve IRIS.

"During his tenure, Dr. Anastas has made an important contribution toward refocusing EPA's Office of Research and Development and advancing the protection of human health and environment," Walls said in an email. "We were encouraged by his commitment to improving the IRIS program."

Anastas took several steps to bolster IRIS during his tenure. Most notably, he announced that the agency would implement recommendations from a National Academy of Sciences review of IRIS's formaldehyde assessment (*E&ENews PM* , July 12, 2011).

Those efforts were also welcomed by green groups.

"In the face of misguided attacks by the chemical industry and its congressional allies, Paul Anastas provided strong leadership to the Office of Research and Development," said the

Environmental Working Group's director of government affairs, Jason Rano. "He ably defended and highlighted EPA's strong scientific work and when necessary, began implementing essential changes."

Other observers noted that while Anastas' departure is a blow to the agency, IRIS continues to be directly led by Vincent Cogliano, a veteran of the World Health Organization's International Agency for Research on Cancer (IARC) and a widely respected name in the scientific world.

EPA has given no indication of who may replace Anastas.

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Industries press White House to delay EPA dioxin assessment

Jeremy P. Jacobs, E&E reporter

Published: Wednesday, December 21, 2011
The dairy, fish and chemical industries are making a year-end push to delay U.S. EPA's release of its controversial dioxin health assessment early next year, arguing it would create a panic that would scare consumers away from safe food products.

Broad coalitions have ramped up their lobbying effort aimed at the White House in the last two weeks, hoping the administration will step in before EPA's Integrated Risk Information System (IRIS) issues its long-awaited report on dioxins -- a group of chemicals with similar structures that are produced naturally and as a byproduct of industrial processes such as paper production and waste incineration.

"This action is taking place without any agency outreach to the food industry or other key stakeholders who could suffer severe harm if the EPA proposal is implemented," a large coalition of agricultural trade groups wrote in a Dec. 7 letter to Melody Barnes, the assistant to the president for domestic policy.

"EPA's process over time has suffered from inaccuracy, questionable methodologies and inadequate scientific evidence," the coalition added.

The agency began its review of dioxin in 1985, and it has remained in limbo ever since. In 2003, EPA released a draft assessment, which was then sent to the National Academy of Sciences (NAS) for review. Three years later, NAS asked the agency to clarify sections of the report.

The Obama administration vowed to expedite the IRIS assessment, which would likely lead to new regulations. EPA issued another draft review in May 2010 that included many changes and classified dioxin as carcinogenic (*E&ENews PM* , May 21, 2010).

The agency then took an unusual step in August when it announced it would split up the assessment, opting to release its report on the non-cancer effects of dioxin next January and the cancer effects thereafter.

The coalition, which includes the American Farm Bureau Federation and the American Feed

Industry Association, criticized the agency for splitting up the assessment and said the draft review sets standards that are far too stringent.

"EPA's proposed standard is significantly out of alignment and far more stringent than current international science-based standards," they wrote. "It sets a dioxin exposure threshold lower than any government entity in the world, including the European Union."

The coalition said EPA's proposed non-cancer limit for dioxin is three times lower than the World Health Organization's. As a result, Americans, and especially children, could exceed the EPA's dioxin limit "after consuming a single meal or heavy snack."

"The implications of this action are chilling," they wrote. "EPA is proposing a situation in which most U.S. agricultural products could arbitrarily be classified as unfit for consumption."

Public health advocates have pushed strongly for EPA to finalize the dioxin assessment, noting that dioxin is one of the most studied substances in the world. The World Health Organization and U.S. National Toxicology Program have classified high exposure to dioxin as carcinogenic, and studies have linked it to neurodevelopment problems in children as well as effects on hormonal and reproductive systems.

In April, 72 members of the House sent EPA a letter urging the agency to complete the IRIS assessment.

"This much-needed assessment should not languish at the EPA as long as this dangerous chemical lasts in our food chain," Rep. Ed Markey (D-Mass.) said then. "The EPA should release its report without further delay" (*E&E Daily* , April 12).

However, the criticism of the draft assessment was echoed by the International Dairy Foods Association and the National Fisheries Institute, which both sent letters to the U.S. Department of Agriculture and the Department of Health and Human Services urging them to intervene.

"EPA's proposed values for evaluating dioxin, if translated publicly to a 'reference dose,' would scare consumers away from our products, and this would be contrary to the government's own dietary guidance to consume three servings of low-fat or fat-free dairy each day in order to get essential nutrients found in milk and dairy," wrote Connie Tipton of the International Dairy Foods Association.

The American Chemistry Council (ACC) also urged EPA to reconsider the assessment after Congress passed language in its $1 trillion spending package last weekend that requires EPA to implement changes to IRIS's scientific methodologies outlined in an April NAS review of IRIS's formaldehyde assessment (*Greenwire* , Dec. 16).

ACC President Cal Dooley said splitting up the IRIS assessment into cancer and non-cancer sections contradicts the NAS recommendations.

"EPA's bifurcation of the dioxin assessment runs counter to the NAS recommendation that IRIS

assessments evaluate all relevant health endpoints based on a weight-of evidence evaluation," Dooley wrote in a letter to Administrator Lisa Jackson.

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Democrats Increasingly Back GOP Calls For NAS Review Of Chemical Risks

Posted: November 16, 2011

A small but growing number of congressional Democrats are backing Republican calls for the National Academy of Sciences (NAS) to review Obama administration chemical risk assessments, putting pressure on an administration that has so far been reluctant to seek such reviews for assessments crafted by EPA and other agencies.

While the Democratic lawmakers are seeking NAS review for assessments conducted under the auspices of the Department of Health and Human Services (HHS), not EPA, any administration agreement to seek reviews could set a precedent for several pending EPA assessments that GOP lawmakers and industry are urging the agency to send to NAS.

In the most recent action, eleven senators, including five Democrats, sent Health and Human Services (HHS) Secretary Kathleen Sebelius a Nov. 15 letter urging her to engage the NAS to review the health risks of formaldehyde. Among the letter's 11 signatories are five Democrats: Sens. Sherrod Brown (OH), Max Baucus (MT), Jay Rockefeller (WV), Debbie Stabenow (MI) and Jon Tester (MT). The six Republicans signing the letter include Sens. Rob Portman (OH), Saxby Chamblis (GA), Johnny Isakson (GA), John Boozman (AR), and Dan Coats (IN).

The senators are concerned that in the National Toxicology Program's (NTP) Report on Carcinogens (RoC) that HHS released earlier this year, the program listed the chemical as a "known human carcinogen" -- even though an NAS panel had strongly criticized a similar EPA finding.

"The 12th RoC changed the listing of formaldehyde to a known human carcinogen. It is our understanding that [NAS] released a report in April that questioned both the process used to make this classification -- the original EPA health assessment on formaldehyde -- and the causal relationship between formaldehyde and certain types of cancer," the letter says.

"We respectfully request that the [HHS] work with the NAS to resolve the question of whether the known human carcinogen listing for formaldehyde is appropriate using the NAS' standard weight-of-the-evidence approach," the senators write Sebelius. "While the 12th RoC was published in June, it is our understanding that there is a precedent for new scientific findings resulting in modified RoC classifications." *Relevant documents are available on InsideEPA.com.* (*Doc ID:* 2382189)

Just a few days earlier, the bipartisan House Manufacturing Caucus asked the Obama administration to initiate an NAS review of the "potential health effects" of the widely-used industrial chemical styrene, after the 12th RoC listed the substance as "reasonably anticipated to be a human carcinogen."

Any NAS review could influence a long-pending EPA assessment of the risks posed by the ubiquitous chemical. EPA's last assessment of styrene, issued in 1993, said the agency lacked sufficient data to make a determination on the chemical's carcinogenicity -- though industry sources have said the agency is now crafting a cancer assessment.

The House caucus, led by Reps. Donald Manzullo (R-IL) and Tim Ryan (D-OH), sent a Nov. 8 letter to White House Chief of Staff William Daley asking the administration to contract with NAS for a study of styrene's health effects. Democrats signing the House letter include Ryan, along with Reps. Gene Green (TX), Dan Boren (OK), Sanford Bishop (GA), Jason Altmire (PA), Laura Richardson (CA) and Mike Ross (AR).

The congressional calls for the administration to seek NAS review of NTP findings comes as EPA is facing similar calls from Republicans for NAS to review some of its pending chemical assessments, which have drawn concern from industry and others that they could drive costly regulatory requirements.

Language included in the House version of EPA's spending bill for fiscal year 2012 seeks to halt the release of at least one major EPA chemical risk assessment -- for arsenic -- until NAS has had a chance to review it and has backed recently announced program reforms.

While it is not clear whether administration officials will agree to any requests for NAS reviews, EPA officials have so far opposed having any more of their draft risk assessments subjected to NAS review. During a hearing last month, EPA research chief Paul Anastas opposed the House spending bill language, noting that the NAS panel did not recommend EPA delay issuing additional risk assessments.

"It is important to note that the NAS report viewed the implementation of their recommendations as a multi-year process," he said in his testimony. "For example, the NAS stated 'it is not recommending that EPA delay the revision of the formaldehyde assessment to implement a new approach." -- *Maria Hegstad*

Elizabeth Erwin
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{In Archive} RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

Kate Guyton to: Woodruff, Tracey, Sutton, Patrice 07/07/2011 01:57 PM

Archive: This message is being viewed in an archive.

Well I think some background on Cochrane reviews and GRADE would be a good starting place? And focus on a better way to navigate the evidence for IRIS purposes... not all the way to clinician recommendations?

Do you think Lisa would be game for this?

I'll email Vince ASAP.
Thanks,
Kate

Kate Z. Guyton, PhD DABT
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703-347-8562 | guyton.kate@epa.gov
Mailing Address: US EPA (8623-P), 1200 Pennsylvania Ave. NW, Washington DC 20460
FedEx and Ground Deliveries: Two Potomac Yard (North Building), 2733 S. Crystal Drive, Arlington VA 22202

"Woodruff, Tracey" I think that is ok.... but do GRADE first? I would... 07/07/2011 01:43:06 PM

From: "Woodruff, Tracey" <WoodruffT@obgyn.ucsf.edu>
To: Kate Guyton/DC/USEPA/US@EPA
Cc: "Sutton, Patrice" <SuttonP@obgyn.ucsf.edu>
Date: 07/07/2011 01:43 PM
Subject: RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

I think that is ok.... but do GRADE first? I would suggest a Lisa/us combination

Ye s- email Vince - he must be involved in the response to Vitters

-----Original Message-----
From: Kate Guyton [mailto:Guyton.Kate@epamail.epa.gov]
Sent: Thursday, July 07, 2011 9:07 AM
To: Woodruff, Tracey
Cc: Sutton, Patrice
Subject: RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

YES. I think we need a GRADE overview as a start? Who would be best-- one of you, Lisa B, Holger, Kris? We can certainly link everyone in, but need someone to "teach" the principles and discuss how this can apply to evaluation of evidence mainly from animal studies. I can suggest this to Vince AND Mary Ross (NAAQS)? I am not certain it will reach Anastas, but...

Thanks,
Kate

From: "Woodruff, Tracey" <WoodruffT@obgyn.ucsf.edu>
To: Kate Guyton/DC/USEPA/US@EPA, "Sutton, Patrice" <SuttonP@obgyn.ucsf.edu>
Date: 07/06/2011 11:55 PM
Subject: RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

YES, or Navigating, it is a perfect win to have Paul write back and say - YES, I have the tool that we are developing...

Do you have a way to engage with them on this? Of course the layers of bureaucracy do seem daunting - maybe you can talk with vince.

Would be good timing for a webinar.

tw

-----Original Message-----
From: Kate Guyton [mailto:Guyton.Kate@epamail.epa.gov]
Sent: Wednesday, July 06, 2011 11:31 AM
To: Woodruff, Tracey; Sutton, Patrice
Subject: Fw: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

Could GRADE help...?

Here's the letter:
(See attached file: June 30 letter.pdf)

Thanks,
Kate

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----- Forwarded by Kate Guyton/DC/USEPA/US on 07/06/2011 02:30 PM -----

GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process
Posted: July 1, 2011
Two key GOP senators are stepping up their attacks on EPA science by criticizing "defects" in the scientific review process for EPA's national ambient air quality standards (NAAQS), drawing parallels between flaws in the NAAQS program and criticisms of scientific errors in EPA's risk assessment for the chemical formaldehyde.
Sens. James Inhofe (R-OK), ranking member on the Environment & Public Works Committee, and panel member David Vitter (R-LA) sent a June 30 letter to EPA Administrator Lisa Jackson asking more than a dozen "important questions of scientific integrity" targeting several aspects of the NAAQS process, including how EPA selects scientific studies for reviews of its standards, the

weight of evidence methodology EPA uses, and uncertainties in the process.
Inhofe and other Republicans have long criticized the agency for pursuing stricter NAAQS, which regulate six criteria pollutants including ozone and fine particulate matter (PM2.5). States must craft air quality plans that outline the pollution cuts they will impose on industry to come into, or stay in, attainment with the standards.
Critics say that ever-tightening standards lead to increasingly expensive pollution controls that harm states' economies.
Industry, Republicans and others have, for example, criticized EPA's proposal to tighten the Bush EPA's 2008 ozone standard of 75 parts per billion (ppb) to a range within 60 to 70 ppb as supported by its science advisers.
Under the Clean Air Act EPA is barred from considering costs when setting NAAQS, and must propose changes to its standards based on science on the risks of exposure to a criteria pollutant. But Vitter and Inhofe say there are "fundamental problems to assuring high-quality, unbiased scientific results" in the NAAQS process.
The letter signals the senators stepping are up their broad attacks on EPA data, after touting recent a National Academy of Sciences' (NAS) critique of EPA's risk assessment of formaldehyde, to raise broad questions about the validity of other agency science, such as the data that EPA uses to justify its air quality standards. For example, speaking at a June 8 hearing of several Senate Environment & Public Works subcommittees on the impacts of EPA's air quality rules, Vitter questioned the legitimacy of EPA air rules and the agency's actions in general based on the NAS' conclusions in its review of the Integrated Risk Information System assessment of formaldehyde.
The NAS review, released in April, found that EPA did not provide sufficient evidence to support its conclusions that human exposure to formaldehyde can cause leukemia or Hodgkin lymphoma, and raised additional concerns about the agency's process for reaching weight of evidence conclusions in its risk assessments.
Industry and Republicans have called on EPA to adopt NAS' recommendations for the chemical risk assessment program, including putting pending assessments on hold until the changes have been made.
"The same scientific defects noted in the formaldehyde assessment are also present in EPA's evaluations of the science used to establish and revise" NAAQS, the senators write in their June 30 letter. Their critiques over the NAAQS process come despite the fact that NAS praised EPA's updated risk assessment practices for setting criteria pollutant standards. The letter is available on InsideEPA.com. (Doc ID: 2368871) The senators question the process EPA uses to decide which studies to cite when determining air quality standards, arguing that "Current methods for selecting studies appear to systematically exclude or discount well conducted, peer reviewed studies that show no adverse health effects from air pollution at or below current air quality standards."
They add that, "Current methods for weighing evidence allow EPA to discount multiple no-effect studies and rely instead on single studies showing an effect," and that "Current practices do not provide for a comprehensive analysis of uncertainty and variability as a way to make risk assessments more useful for decision makers."
The letter points to a number of specific examples where the senators charge that "EPA has discounted or ignored studies" that find no association between a pollutant and a particular health outcome -- including between ozone and asthma, ozone and cardiovascular morbidity and PM2.5 and chronic mortality.
Vitter and Inhofe also raise concerns with use of a 2006 study that found asthma symptoms for nitrogen dioxide (NO_2) but not for ozone. "In the NO_2 NAAQS review, EPA states that this study provides strong evidence for the health effects of NO_2 . . . whereas in the 2008 ozone NAAQS review and reconsideration, EPA notes many reasons why the results of the study should be ignored, including the fact that only 12 children per day were evaluated and that the authors did not clearly define the severity of asthma in the study

subjects."
The senators ask Jackson more than a dozen questions, including asking whether EPA has "a policy of consistently disregarding studies misinforms the public and leads to inflated and highly uncertain estimates of public health risks" and why EPA has failed to conduct a quantitative uncertainty analysis on PM2.5 exposure.
The senators ask for a reply by July 8. With EPA planning to release its revised ozone standard later this month and other NAAQS reviews pending, the senators say, "Given the timeframe with which we are dealing the need for your prompt response to these important questions of scientific integrity cannot be understated. The economy and many of our fellow Americans are suffering. To further perpetuate the problems of high unemployment and poverty without strong scientific and economic support for EPA's calculated efforts would be unwise."
Elsewhere in the letter, the senators also note that EPA has not yet replied to their May 10 letter asking how EPA has implemented recommendations from NAS to address concerns with the formaldehyde assessment. -- Victoria Finkle

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Industry group boosted political spending last year -- and it paid off

Jeremy P. Jacobs, E&E reporter

E&E Daily: Tuesday, February 7, 2012

The American Chemistry Council significantly ramped up its lobbying efforts in the fourth quarter of last year, spending more than double its total for any quarter in recent history.

ACC, the chief lobbying arm of the chemical manufacturing industry, spent $5.37 million in the fourth quarter. The total represents the fifth most of any lobbying operation on Capitol Hill during that period, outspending the perennially deep-pocketed efforts of General Electric Co. and the Pharmaceutical Research and Manufacturers of America, according to a Center for Responsive Politics analysis conducted for *E&E Daily* .

A review of ACC's lobbying disclosure report shows the group was involved in a host of issues, ranging from efforts to update chemical regulations, to U.S. EPA's air pollution rules for boilers and incinerators, to EPA's long-delayed health assessments of substances like bisphenol A (BPA) and formaldehyde. The group also successfully pushed for inserting language into the $1 trillion omnibus spending package passed at the end of the year and aired its first television ads of the election cycle.

The spending is significant because it shows ACC, which public health advocates view as public enemy No. 1, is having an ever-growing role on regulatory and legislative issues.

Anne Kolton, an ACC spokeswoman, said the lobbying shows the group has a renewed and sharper focus on Capitol Hill.

"The spending is a reflection of our increasingly aggressive approach to advocacy," Kolton said. "Policies that will support economic growth and job creation are very important for the future of our industry."

For all of 2011, ACC spent almost $10.3 million, significantly more than the $8.1 million it spent the year before. Last year's total trumps what was doled out by Dow Chemical Co., the industry's other major lobbying operation, which spent $7.3 million. The American Petroleum

Institute, the largest trade association for the oil and gas industry, also spent far less than ACC in 2011 -- less than $6.3 million.

In some cases, the results of ACC's increased spending are crystal clear.

The group was most effective lobbying on the year-end omnibus spending package. Buried in the 1,200-page bill was language that requires EPA's Integrated Risk Information System (IRIS) to implement changes to its scientific methodologies outlined in a National Academy of Sciences review of the agency's formaldehyde risk assessment. It also requires EPA to submit a progress report to Congress by March and stipulates that EPA send three IRIS assessments to NAS for review next year.

ACC has long pushed for IRIS reforms, though critics argue that the group's goal is to delay the agency from finalizing assessments because they are the foundation of new, often stricter, regulations.

Notably, Democrats and some public health advocates touted the IRIS reforms in the omnibus as a compromise, implying that Republicans had sought stronger provisions to handcuff the IRIS program. Public health advocates have also noted that EPA is already in the process of implementing the NAS recommendations (*E&E Daily* , Dec. 20, 2011).

Kolton nevertheless called the language a "major victory."

"We saw a lot of success last year," she said. "It is a difficult environment, but we were able to move some key priorities."

The omnibus also contained $1 million to pay NAS for a scientific peer review of Department of Health and Human Services' "Report on Carcinogens." Last year, the document said styrene -- a common component of plastic food packaging -- is "reasonably anticipated" to cause cancer. The report also said formaldehyde, a common construction material, is a known carcinogen.

Industry has vocally criticized the report, and the styrene industry has sued HHS.

While ACC was clearly successful on the omnibus, the effects of its efforts were felt in other areas as well -- albeit less obviously.

The group criticized Sen. Frank Lautenberg's (D-N.J.) "Safe Chemicals Act" (S. 847), which would overhaul the 1976 Toxic Substances Control Act (TSCA) and require manufacturers to prove their substances are safe before they go on the market. Lautenberg's efforts appear to have stalled late last year after a hearing featuring ACC President Cal Dooley devolved into screaming when Democrats pressed Dooley, a former Democratic congressman, to submit legislative language (*Greenwire* , Nov. 17, 2011).

Similarly, ACC's disclosure forms show it lobbied EPA on its 27-year-old IRIS assessment of dioxin, a family of chemicals believed to cause cancer. EPA was supposed to finalize the non-cancer portion of its dioxin assessment in January but missed that deadline in the face of

significant industry opposition. The agency has yet to explain what is causing the delay (*Greenwire* , Feb. 1).

ACC has similarly pressed EPA on its formaldehyde assessment, which is also more than 20 years old and has been delayed indefinitely, and other controversial chemicals like hexavalent chromium and phthalates.

Those results have raised the ire of public health advocates.

"The greatest impediment to protecting the public from toxic chemicals in everyday products is the money spent by the chemical industry in Washington to block legislative action to reform TSCA, and to prevent government scientists from taking steps to better-inform the public," said Daniel Rosenberg of the Natural Resources Defense Council.

Jason Rano of the Environmental Working Group said that industry could have put those millions of dollars to better use.

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Wading into politics

ACC's lobbying total was also boosted because the group aired television and radio ads for the first time in recent history.

The group aired television spots that tout support for domestic energy production and small businesses in the districts of Republican Reps. John Shimkus of Illinois, Tim Murphy of Pennsylvania and Ed Whitfield of Kentucky, as well as Democratic Reps. Cedric Richmond of Louisiana and Gene Green of Texas. Whitfield and Shimkus are chairmen of House Energy and Commerce subpanels on issues relating to chemical manufacturing, and Green is a ranking member on one.

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Kolton said ACC intends to do more television ads this year but that it remains to be seen whether the group wades fully into election-year politics and backing specific candidates. "We are evaluating as we go," she said.

ACC's political action committee has been active so far this cycle as well. PAC dollars come from a different pot than lobbying funds and typically consist largely of employee contributions.

The PAC contributed nearly $78,500 to federal candidates through the end of 2011, according to the Center for Responsive Politics. That is significantly less than the $294,000 it gave to federal

candidates last cycle, the most ACC's PAC has ever dished out. It is likely, though, that ACC's campaign contributions will ramp up as the election approaches this year.

There has been a significant partisan shift in the contributions, however. The Center for Responsive Politics breakdown shows the ACC PAC has given nearly 70 percent of its contributions to Republicans. In the 2010 cycle, a narrow majority of its contributions -- 54 percent -- went to Democrats.

The shift may be partially explained by Republicans -- who are generally more sympathetic to ACC's agenda -- taking control of the House in 2010, giving them more control over the congressional agenda.

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E&ETV's OnPoint: ACC's Dooley discusses new advocacy campaign

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Seeing 'Erroneous' Industry View, Activists Urge EPA To Finish Dioxin Study

Posted: December 22, 2011

A progressive think tank is urging EPA to complete as planned its upcoming analysis of the non-cancer risks of dioxin, charging that chemical industry calls for the agency to withdraw and revise the assessment are misplaced because the industry is misinterpreting congressional report language recommending the agency revise some pending analyses.

The Center for Progressive Reform, a group that advocates for strict environmental and health safeguards, wrote EPA Administrator Lisa Jackson to ignore the calls of the American Chemistry Council (ACC) to withdraw its Integrated Risk Information System (IRIS) assessment of dioxin's non-cancer risks from interagency review because the industry group misinterpreted report language that it cited as the basis for its call.

"On [Dec. 20], the American Chemistry Council (ACC) wrote to you with an erroneous interpretation of the IRIS-related riders to [the fiscal year 2012 omnibus spending bill] and, based on that erroneous interpretation, suggested that you should send the ongoing dioxin assessment back to the drawing board," write CPR President Rena Steinzor and senior policy analyst Matthew Shudtz in their Dec. 22 letter.

"We urge you to disregard that suggestion and allow the IRIS program to continue on its charted path for releasing the dioxin assessment in 2012."

EPA's risk assessment for 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) -- the most toxic form of the compound -- has been in development for decades and under interagency review for weeks. It includes a reference dose (RfD), the amount below which the agency does not anticipate adverse non-cancer health effects if consumed daily over a lifetime, of 0.7 picograms per kilogram bodyweight per day (pg/kg-day), according to industry sources.

The 0.7 pg/kg-day number is identical to the level EPA proposed and its science advisers generally endorsed in the 2010 draft of the assessment.

But ACC and other industry groups are concerned that the agency's preferred limit will drive strict new regulatory burdens. They also charge that EPA's proposed limit is lower than the amount consumers would ingest if they were to follow federal nutrition guidelines -- creating confusion and poor nutritional choices.

The industry group is lobbying White House officials to soften the RfD -- to a range of 3-10 pg/kg-day.

Cal Dooley, president and CEO of the American Chemistry Council (ACC), wrote Jackson Dec. 20 urging her to withdraw the dioxin non-cancer assessment from interagency review. He charged that the assessment under review is at odds with report language that Congress attached to EPA's FY12 spending bill urging the agency to reform the IRIS program as recommended by the National Academy of Sciences (NAS) in its report reviewing the agency's draft formaldehyde IRIS assessment.

"To comply with Congress' direction, EPA should withdraw the dioxin assessment from interagency review and take the necessary steps to implement the NAS recommendations," Dooley said. The report language is not legally binding, but EPA has as longstanding policy treated report language as binding.

For example, Dooley notes that the report language "directs EPA to include documentation describing how" NAS' recommendations "have been implemented or addressed in all IRIS assessments" released in FY12 -- although the report language only requires EPA to justify how it followed NAS for "draft" assessments.

'False Reading Of The Bill'

CPR disagrees with ACC's reading of the report language, for precisely this reason.

“ACC inaccurately claims that H.R. 2055 directs EPA to include documentation of how the agency has implemented [NAS'] recommendations 'in all IRIS assessments released in Fiscal Year 2012' and then uses that false reading of the bill to suggest that the dioxin assessment would run afoul of the law if released in the form most recently published,” Steinzor and Shudtz write.

“EPA is only required to document its implementation of [NAS'] recommendations for draft assessments published in FY 2012. The upcoming final assessment for dioxin need not include such documentation.”

They outline the history of the rider language to make their argument, noting that earlier language would have prohibited EPA from making any regulatory decisions based on IRIS assessments that did not incorporate the NAS recommendations. This language failed and was replaced, CPR writes.

“The compromise reflects Congress’s recognition that near-complete assessments should not be held up unnecessarily, and it echoes NRC’s own argument that the IRIS program should focus first and foremost on completing ongoing assessments,” writes CPR. The letter notes that while the NAS formaldehyde report contained a “roadmap” intended to prove the IRIS program generally, it also urged the agency not to delay the release of the formaldehyde assessment until the roadmap had been fully adopted. -- *Maria Hegstad*

Elizabeth Erwin
Communications Assistant
National Center for Environmental Assessment
Office of Research and Development
U.S. Environmental Protection Agency
Office: (703) 347-0205
Blackberry: (571) 247-3051

{In Archive} Re: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

Daniel Axelrad to: Kate Guyton 12/16/2011 02:56 PM

History: This message has been replied to.
Archive: This message is being viewed in an archive.

hmmm. I don't see it yet :)

hope all is well!

Kate Guyton	Yup! We are slated for this Friday, but I just hea...	12/13/2011 12:31:29 PM

From: Kate Guyton/DC/USEPA/US
To: Daniel Axelrad/DC/USEPA/US@EPA
Date: 12/13/2011 12:31 PM
Subject: Re: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

Yup! We are slated for this Friday, but I just heard next week might be possible... not sure if that's because we are waiting for permission from on high or what... either way, it's a gift that just keeps on giving!!

Daniel Axelrad	meanwhile, I hear that you have yet another wee...	12/13/2011 12:22:40 PM
Kate Guyton	Top Official Vows More EPA Risk Reforms Whil...	12/13/2011 11:38:34 AM

{In Archive} Re: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

Kate Guyton to: Daniel Axelrad 12/13/2011 12:31 PM

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From: Daniel Axelrad/DC/USEPA/US
To: Kate Guyton/DC/USEPA/US@EPA
Date: 12/13/2011 12:22 PM
Subject: Re: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

---

meanwhile, I hear that you have yet another week to go with perc? the fun never stops?

Kate Guyton	Top Official Vows More EPA Risk Reforms Whil...	12/13/2011 11:38:34 AM

{In Archive} RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

Woodruff, Tracey to: Kate Guyton 07/07/2011 01:43 PM
Cc: "Sutton, Patrice"

History: This message has been replied to.
Archive: This message is being viewed in an archive.

I think that is ok.... but do GRADE first? I would suggest a Lisa/us combination

Ye s- email Vince - he must be involved in the response to Vitters

-----Original Message-----
From: Kate Guyton [mailto:Guyton.Kate@epamail.epa.gov]
Sent: Thursday, July 07, 2011 9:07 AM
To: Woodruff, Tracey
Cc: Sutton, Patrice
Subject: RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

YES. I think we need a GRADE overview as a start? Who would be best-- one of you, Lisa B, Holger, Kris? We can certainly link everyone in, but need someone to "teach" the principles and discuss how this can apply to evaluation of evidence mainly from animal studies. I can suggest this to Vince AND Mary Ross (NAAQS)? I am not certain it will reach Anastas, but...

Thanks,
Kate

From: "Woodruff, Tracey" <WoodruffT@obgyn.ucsf.edu>
To: Kate Guyton/DC/USEPA/US@EPA, "Sutton, Patrice" <SuttonP@obgyn.ucsf.edu>
Date: 07/06/2011 11:55 PM
Subject: RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

YES, or Navigating, it is a perfect win to have Paul write back and say
- YES, I have the tool that we are developing...

Do you have a way to engage with them on this? Of course the layers of bureaucracy do seem daunting -

maybe you can talk with vince.

Would be good timing for a webinar.

tw

-----Original Message-----
From: Kate Guyton [mailto:Guyton.Kate@epamail.epa.gov
]
Sent: Wednesday, July 06, 2011 11:31 AM
To: Woodruff, Tracey; Sutton, Patrice
Subject: Fw: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

Could GRADE help...?

Here's the letter:
(See attached file: June 30 letter.pdf)

Thanks,
Kate

Kate Z. Guyton, PhD DABT
Toxicologist, NCEA, ORD, US EPA
703-347-8562 | guyton.kate@epa.gov
Mailing Address: US EPA (8623-P), 1200 Pennsylvania Ave. NW, Washington DC 20460 FedEx and Ground Deliveries: Two Potomac Yard (North Building), 2733 S.
Crystal Drive, Arlington VA 22202

----- Forwarded by Kate Guyton/DC/USEPA/US on 07/06/2011 02:30 PM -----

GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process
Posted: July 1, 2011
Two key GOP senators are stepping up their attacks on EPA science by criticizing "defects" in the scientific review process for EPA's national ambient air quality standards (NAAQS), drawing parallels between flaws in the NAAQS program and criticisms of scientific errors in EPA's risk assessment for the chemical formaldehyde.
Sens. James Inhofe (R-OK), ranking member on the Environment & Public Works Committee, and panel member David Vitter (R-LA) sent a June 30 letter to EPA Administrator Lisa Jackson asking more than a dozen "important questions of scientific integrity" targeting several aspects of the NAAQS process, including how EPA selects scientific studies for reviews of its standards, the weight of evidence methodology EPA uses, and uncertainties in the process.
Inhofe and other Republicans have long criticized the

agency for pursuing stricter NAAQS, which regulate six criteria pollutants including ozone and fine particulate matter (PM2.5). States must craft air quality plans that outline the pollution cuts they will impose on industry to come into, or stay in, attainment with the standards.

Critics say that ever-tightening standards lead to increasingly expensive pollution controls that harm states' economies.

Industry, Republicans and others have, for example, criticized EPA's proposal to tighten the Bush EPA's 2008 ozone standard of 75 parts per billion (ppb) to a range within 60 to 70 ppb as supported by its science advisers.

Under the Clean Air Act EPA is barred from considering costs when setting NAAQS, and must propose changes to its standards based on science on the risks of exposure to a criteria pollutant. But Vitter and Inhofe say there are "fundamental problems to assuring high-quality, unbiased scientific results" in the NAAQS process.

The letter signals the senators stepping are up their broad attacks on EPA data, after touting recent a National Academy of Sciences' (NAS) critique of EPA's risk assessment of formaldehyde, to raise broad questions about the validity of other agency science, such as the data that EPA uses to justify its air quality standards. For example, speaking at a June 8 hearing of several Senate Environment & Public Works subcommittees on the impacts of EPA's air quality rules, Vitter questioned the legitimacy of EPA air rules and the agency's actions in general based on the NAS' conclusions in its review of the Integrated Risk Information System assessment of formaldehyde.

The NAS review, released in April, found that EPA did not provide sufficient evidence to support its conclusions that human exposure to formaldehyde can cause leukemia or Hodgkin lymphoma, and raised additional concerns about the agency's process for reaching weight of evidence conclusions in its risk assessments.

Industry and Republicans have called on EPA to adopt NAS'
recommendations for the chemical risk assessment program, including putting pending assessments on hold until the changes have been made.

"The same scientific defects noted in the formaldehyde assessment are also present in EPA's evaluations of the science used to establish and revise" NAAQS, the senators write in their June 30 letter. Their critiques over the NAAQS process come despite the fact that NAS praised EPA's updated risk assessment practices for setting criteria pollutant standards. The letter is available on InsideEPA.com. (Doc ID: 2368871) The senators question the process EPA uses to decide which studies to cite when determining air quality standards, arguing that "Current methods for selecting studies appear to systematically exclude or discount well conducted, peer reviewed studies that show no adverse health

effects from air pollution at or below current air quality standards."
They add that, "Current methods for weighing evidence allow EPA to discount multiple no-effect studies and rely instead on single studies showing an effect," and that "Current practices do not provide for a comprehensive analysis of uncertainty and variability as a way to make risk assessments more useful for decision makers."
The letter points to a number of specific examples where the senators charge that "EPA has discounted or ignored studies" that find no association between a pollutant and a particular health outcome -- including between ozone and asthma, ozone and cardiovascular morbidity and PM2.5 and chronic mortality.
Vitter and Inhofe also raise concerns with use of a 2006 study that found asthma symptoms for nitrogen dioxide (NO2) but not for ozone. "In the NO2 NAAQS review, EPA states that this study provides strong evidence for the health effects of NO2 . . . whereas in the 2008 ozone NAAQS review and reconsideration, EPA notes many reasons why the results of the study should be ignored, including the fact that only 12 children per day were evaluated and that the authors did not clearly define the severity of asthma in the study subjects."
The senators ask Jackson more than a dozen questions, including asking whether EPA has "a policy of consistently disregarding studies misinforms the public and leads to inflated and highly uncertain estimates of public health risks" and why EPA has failed to conduct a quantitative uncertainty analysis on PM2.5 exposure.
The senators ask for a reply by July 8. With EPA planning to release its revised ozone standard later this month and other NAAQS reviews pending, the senators say, "Given the timeframe with which we are dealing the need for your prompt response to these important questions of scientific integrity cannot be understated. The economy and many of our fellow Americans are suffering. To further perpetuate the problems of high unemployment and poverty without strong scientific and economic support for EPA's calculated efforts would be unwise."
Elsewhere in the letter, the senators also note that EPA has not yet replied to their May 10 letter asking how EPA has implemented recommendations from NAS to address concerns with the formaldehyde assessment. -- Victoria Finkle

Elizabeth Erwin
Communications Assistant
National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency
Office: (703) 347-0205
Fax: (703) 347-8699

{In Archive} RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

Woodruff, Tracey to: Kate Guyton, Sutton, Patrice 07/06/2011 11:55 PM

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Sent: Wednesday, July 06, 2011 11:31 AM
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Subject: Fw: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

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Industry group boosted political spending last year -- and it paid off

Jeremy P. Jacobs, E&E reporter

E&E Daily: Tuesday, February 7, 2012

The American Chemistry Council significantly ramped up its lobbying efforts in the fourth quarter of last year, spending more than double its total for any quarter in recent history.

ACC, the chief lobbying arm of the chemical manufacturing industry, spent $5.37 million in the fourth quarter. The total represents the fifth most of any lobbying operation on Capitol Hill during that period, outspending the perennially deep-pocketed efforts of General Electric Co. and the Pharmaceutical Research and Manufacturers of America, according to a Center for Responsive Politics analysis conducted for *E&E Daily* .

A review of ACC's lobbying disclosure report shows the group was involved in a host of issues, ranging from efforts to update chemical regulations, to U.S. EPA's air pollution rules for boilers and incinerators, to EPA's long-delayed health assessments of substances like bisphenol A (BPA) and formaldehyde. The group also successfully pushed for inserting language into the $1 trillion omnibus spending package passed at the end of the year and aired its first television ads of the election cycle.

The spending is significant because it shows ACC, which public health advocates view as public enemy No. 1, is having an ever-growing role on regulatory and legislative issues.

Anne Kolton, an ACC spokeswoman, said the lobbying shows the group has a renewed and sharper focus on Capitol Hill.

"The spending is a reflection of our increasingly aggressive approach to advocacy," Kolton said. "Policies that will support economic growth and job creation are very important for the future of our industry."

For all of 2011, ACC spent almost $10.3 million, significantly more than the $8.1 million it spent the year before. Last year's total trumps what was doled out by Dow Chemical Co., the industry's other major lobbying operation, which spent $7.3 million. The American Petroleum Institute, the largest trade association for the oil and gas industry, also spent far less than ACC in

2011 -- less than $6.3 million.

In some cases, the results of ACC's increased spending are crystal clear.

The group was most effective lobbying on the year-end omnibus spending package. Buried in the 1,200-page bill was language that requires EPA's Integrated Risk Information System (IRIS) to implement changes to its scientific methodologies outlined in a National Academy of Sciences review of the agency's formaldehyde risk assessment. It also requires EPA to submit a progress report to Congress by March and stipulates that EPA send three IRIS assessments to NAS for review next year.

ACC has long pushed for IRIS reforms, though critics argue that the group's goal is to delay the agency from finalizing assessments because they are the foundation of new, often stricter, regulations.

Notably, Democrats and some public health advocates touted the IRIS reforms in the omnibus as a compromise, implying that Republicans had sought stronger provisions to handcuff the IRIS program. Public health advocates have also noted that EPA is already in the process of implementing the NAS recommendations (*E&E Daily* , Dec. 20, 2011).

Kolton nevertheless called the language a "major victory."

"We saw a lot of success last year," she said. "It is a difficult environment, but we were able to move some key priorities."

The omnibus also contained $1 million to pay NAS for a scientific peer review of Department of Health and Human Services' "Report on Carcinogens." Last year, the document said styrene -- a common component of plastic food packaging -- is "reasonably anticipated" to cause cancer. The report also said formaldehyde, a common construction material, is a known carcinogen.

Industry has vocally criticized the report, and the styrene industry has sued HHS.

While ACC was clearly successful on the omnibus, the effects of its efforts were felt in other areas as well -- albeit less obviously.

The group criticized Sen. Frank Lautenberg's (D-N.J.) "Safe Chemicals Act" (S. 847), which would overhaul the 1976 Toxic Substances Control Act (TSCA) and require manufacturers to prove their substances are safe before they go on the market. Lautenberg's efforts appear to have stalled late last year after a hearing featuring ACC President Cal Dooley devolved into screaming when Democrats pressed Dooley, a former Democratic congressman, to submit legislative language (*Greenwire* , Nov. 17, 2011).

Similarly, ACC's disclosure forms show it lobbied EPA on its 27-year-old IRIS assessment of dioxin, a family of chemicals believed to cause cancer. EPA was supposed to finalize the non-cancer portion of its dioxin assessment in January but missed that deadline in the face of significant industry opposition. The agency has yet to explain what is causing the delay (

Greenwire , Feb. 1).

ACC has similarly pressed EPA on its formaldehyde assessment, which is also more than 20 years old and has been delayed indefinitely, and other controversial chemicals like hexavalent chromium and phthalates.

Those results have raised the ire of public health advocates.

"The greatest impediment to protecting the public from toxic chemicals in everyday products is the money spent by the chemical industry in Washington to block legislative action to reform TSCA, and to prevent government scientists from taking steps to better-inform the public," said Daniel Rosenberg of the Natural Resources Defense Council.

Jason Rano of the Environmental Working Group said that industry could have put those millions of dollars to better use.

"Clearly, it paid off to be a lobbyist for the chemical industry last year," he said. "Instead of spending its millions to block tougher public health protections of dangerous chemicals, the ACC could have used those resources to help build a safer generation of products we're all exposed to every day."

Wading into politics

ACC's lobbying total was also boosted because the group aired television and radio ads for the first time in recent history.

The group aired television spots that tout support for domestic energy production and small businesses in the districts of Republican Reps. John Shimkus of Illinois, Tim Murphy of Pennsylvania and Ed Whitfield of Kentucky, as well as Democratic Reps. Cedric Richmond of Louisiana and Gene Green of Texas. Whitfield and Shimkus are chairmen of House Energy and Commerce subpanels on issues relating to chemical manufacturing, and Green is a ranking member on one.

ACC aired similar ads for Republican Sens. Scott Brown in Massachusetts and John Barrasso in Wyoming.

Kolton said ACC intends to do more television ads this year but that it remains to be seen whether the group wades fully into election-year politics and backing specific candidates. "We are evaluating as we go," she said.

ACC's political action committee has been active so far this cycle as well. PAC dollars come from a different pot than lobbying funds and typically consist largely of employee contributions.

The PAC contributed nearly $78,500 to federal candidates through the end of 2011, according to the Center for Responsive Politics. That is significantly less than the $294,000 it gave to federal candidates last cycle, the most ACC's PAC has ever dished out. It is likely, though, that ACC's

campaign contributions will ramp up as the election approaches this year.

There has been a significant partisan shift in the contributions, however. The Center for Responsive Politics breakdown shows the ACC PAC has given nearly 70 percent of its contributions to Republicans. In the 2010 cycle, a narrow majority of its contributions -- 54 percent -- went to Democrats.

The shift may be partially explained by Republicans -- who are generally more sympathetic to ACC's agenda -- taking control of the House in 2010, giving them more control over the congressional agenda.

Some of the PAC's most notable contributions this cycle have been $6,000 to Whitfield as well as $5,000 to Shimkus, Barrasso and House Majority Leader Eric Cantor (R-Va.). On the Democratic side, the PAC has given $5,000 to Sens. Joe Manchin of West Virginia and Ben Nelson of Nebraska as well as $2,500 to House Minority Whip Steny Hoyer of Maryland.

E&ETV's OnPoint: ACC's Dooley discusses new advocacy campaign

With a politically charged climate in Congress, can meaningful policy on shale gas exploration, energy efficiency and energy regulations move in the near term? During today's OnPoint, Cal Dooley, president and CEO of the American Chemistry Council, exclusively discusses his organization's new advocacy and awareness campaign with E&ETV. The campaign, Chemistry to Energy, focuses on the chemistry industry's role in the United States' economic recovery. Dooley weighs in on the controversy surrounding shale gas exploration and the exportation of liquefied natural gas to Asian and European markets. Today's OnPoint will air at 10 a.m. EST.

{In Archive} RE: EPA, Key Adviser Oppose House Bid To Halt Chemical Risk Assessments - Inside EPA

Burke, Thomas to: Daniel Axelrad, woodrufft@obgyn.ucsf.edu, lzeise@oehha.ca.gov, Kate Guyton, Juleen Lam — 10/07/2011 10:59 AM

Archive: This message is being viewed in an archive.

Thanks for sending this Dan. Was a very interesting hearing to be part of.

Tom

-----Original Message-----
From: Axelrad.Daniel@epamail.epa.gov [mailto:Axelrad.Daniel@epamail.epa.gov]
Sent: Friday, October 07, 2011 10:23 AM
To: Burke, Thomas; woodrufft@obgyn.ucsf.edu; lzeise@oehha.ca.gov; Guyton.Kate@epamail.epa.gov
Subject: EPA, Key Adviser Oppose House Bid To Halt Chemical Risk Assessments - Inside EPA

EPA, Key Adviser Oppose House Bid To Halt Chemical Risk Assessments
Posted: October 6, 2011

Backed by a key scientist, EPA's research chief Paul Anastas is resisting language House lawmakers have included in the agency's pending spending bill that would halt the release of major chemical risk assessments until the National Academy of Sciences (NAS) has had a chance to review them and has backed recently announced program reforms.

At a House subcommittee hearing Oct. 6 to review EPA's Integrated Risk Information System (IRIS) program, Anastas drew strong support from Thomas Burke, an associate dean of The Johns Hopkins Bloomberg School of Public Health who also chaired a 2009 NAS panel that issued recommendations on ways to improve EPA risk assessments, with both men providing separate arguments to why the assessments shouldn't be delayed until the program is reformed.

A subsequent 2011 NAS panel that faulted EPA's draft assessment of formaldehyde reiterated some of the recommendations contained in the

2009 panel report, that Burke chaired. Many industry groups and GOP lawmakers are touting the formaldehyde report – and urging EPA to delay issuing new risk assessments until it has adopted the panel's suggestions.

To pressure the agency to adopt the NAS recommendations, House Republicans have also included language in EPA's fiscal year 2012 spending bill that would require the agency to implement the recommendations, have the NAS review any changes EPA makes to the IRIS program and have the NAS review several pending and future risk assessments, including the controversial assessment of arsenic. The House began considering the bill before the summer recess but lawmakers are scheduled to resume consideration later this year.

Sens. James Inhofe (R-OK) and David Vitter (R-LA) have also called on EPA Administrator Lisa Jackson to "suspend" issuance of controversial assessments until the reforms have been implemented and subjected to NAS review.

But at the Oct. 6 hearing of the House Energy and Commerce's energy and environment subcommittee to examine what subcommittee Chairman John Shimkus (R-IL) said is the "underlying bias present in the program and the impact of science manipulation on jobs and the economy" Anastas and Burke pushed back against efforts to halt the assessments until the NAS recommendations are adopted.

In written testimony at the hearing, Anasatas, assistant administrator of EPA's Office of Research and Development, reiterated that the agency is making changes to the program, but noted that NAS was clear that the program should continue to issue risk assessments despite the needed improvements.

“It is important to note that the NAS report viewed the implementation of their recommendations as a multi-year process,” he said. “For example, the NAS stated ‘it is not recommending that EPA delay the revision of the formaldehyde assessment to implement a new approach.”

Burke went even further, warning that language in the bill delaying the program would cause problems for public health programs that depend on the assessments to set standards to protect human health. “I think it would be a disservice to public health agencies throughout the country and even around the world” if we brought the IRIS program to a halt, Burke said in response to a question from Rep. Gene Greene (D-TX), the subcommittee's ranking Democrat.

Burke also clarified remarks he made last summer, first reported by Inside EPA, that EPA's IRIS program is in “crisis” and is in need of reform the program. At a June 30 meeting on the agency's new chemical safety research program, Burke warned EPA officials and other scientific advisers that “the sleeping giant is that EPA science is on the rocks . . . if you fail, you become irrelevant, and that is kind of a crisis.”

"You can't fail this time," Burke said.

In response to questions from Greene, Burke said that, “Obviously there is a lot of criticism and the credibility of science is really important,” Burke continued. “So why is EPA in crisis? Because of the incessant attacks on their credibility.”

“We owe it to the American public, we owe it to the scientific community” to have risk assessments based in sound science, Burke told the committee. “It would be better to do it right than destroy the credibility of the process.”

Focus On IRIS

The hearing was held to gather input on the IRIS program and its effects on regulations. IRIS has come under fire recently from industry and Republicans who argue that the assessments are overly conservative and not based in sound science, and who are pointing to the NAS' criticism of the program in chapter 7 of its review of the formaldehyde risk assessment as further need for improvement.

In the wake of such concerns, the agency in early July unveiled a series of reforms designed to strengthen the program and respond to the NAS concerns, including the development of a standing IRIS Advisory Committee at the Science Advisory Board (SAB) to address thorny scientific questions and review risk assessments that have provoked controversy among industry and other critics who fear they are too conservative.

EPA also announced a series of additional plans to clarify the information presented in IRIS assessments, provide better rationale for which studies EPA relies on in its assessments, streamline the documents and increase transparency, but industry groups viewed these plans as falling short of the necessary revision of a program they have long disliked.

EPA is moving forward with a host of IRIS assessments and has recently released several assessments, including one for trichloroethylene (TCE) -- a common groundwater contaminant -- and continues to defend the science behind the documents.

When Anastas issued the TCE assessment, he strongly touted the public health benefits of the program, saying the TCE assessment “underscores the importance of EPA's science and, in particular, the critical value

of the IRIS database for ensuring that government officials and the American people have the information they need to protect their health and the health of their children."

But the agency has so far issued only one assessment -- for acrylonitrile -- that Inhofe and Vitter have urged EPA to "suspend," leaving the agency with a series of major tests on upcoming future assessments, including one for hexavalent chromium, which environmentalists are pushing the agency to quickly issue.

Anastas told the Oct. 6 hearing that the agency is moving forward with applying the NAS' recommendations to assessments, but pointed out that "these improvements will have a greater impact on our new assessments as opposed to those already in the pipeline."

Anastas also defended the IRIS review process, noting that assessments "are held to the highest Agency standards," receiving considerable internal and external review and comment. "These standards are among the best in the federal government and the scientific community."

OMB Review

However, Rep. Bill Cassidy (R-LA) called for increased oversight of IRIS assessments from the White House Office of Management and Budget (OMB), and advocated reinstating the OMB-led review process that was in place during the Bush Administration.

EPA Administrator Lisa Jackson reversed the Bush review process shortly after taking office, putting EPA back in the lead after the Government Accountability Office (GAO) called the IRIS program a "high risk" program due to the lengthy delays inherent in the OMB-led review process.

But Cassidy called for reinstating the OMB-led process. IRIS assessments, while not regulatory by themselves, are used to inform policy, Cassidy said, adding that he is concerned that “policy is manipulating science to achieve advocacy as opposed to truth.”

“Why in the world are we basing decisions that affect a number of jobs” on questionable science, Cassidy said. “I'm struck how sometimes processes are used to manipulate the response to the finding.”

The congressman added that cost-benefit analyses should be conducted for IRIS assessments and “I'm thinking OMB needs to be involved.”

But GAO is is expected to reach the opposite conclusion in a soon-to-be-released review of the 2009 changes to IRIS. In testimony to the subcommittee, David Trimble, director of GAO's natural resources and the environment program, reiterated earlier comments that the Obama Administration's reforms “appeared to represent a significant improvement over the previous IRIS process and, if implemented effectively, with sustained management and oversight, could help EPA restore the credibility and increase the timeliness of this program.” The reforms, he said, streamlined the IRIS process, consolidating and eliminating unnecessary steps and reducing delay; established transparency; and restored control of the process to EPA, taking the management of reviews away from OMB to considerably speed up the release of assessments.

However, Trimble added, a lack of statutory deadline; ever changing science and methodologies; delays; challenges from industry, environmentalists and lawmakers; and what are becoming frequent changes to the IRIS process will continue to hamper the program. -- Jenny

{In Archive} Re: Fw: NEWS UPDATES: Group accuses industry of slowing EPA assessments (Greenwire)

Lauren Zeise to: Kate Guyton 07/08/2011 01:58 PM

Archive: This message is being viewed in an archive.

thanks Kate.

>>> Kate Guyton <Guyton.Kate@epamail.epa.gov>
7/8/2011 10:32 AM >>>

FYI...

----- Forwarded by Kate Guyton/DC/USEPA/US on
07/08/2011 01:30 PM -----

CHEMICALS: Group accuses industry of slowing EPA
assessments
(07/08/2011)
Jeremy P. Jacobs, E&E reporter

The chemical industry's recent call for an
independent review of U.S.
EPA's chemical toxicity assessments is a "thinly
veiled attempt" to
block new federal standards on dangerous substances,
a group promoting
chemical testing and regulation said today.

At issue, the Center for Progressive Reform (CPR)
says, is a letter sent
last month by the American Chemistry Council (ACC)
sent to the White
House that said a recent independent review of EPA's
Integrated Risk
Information System (IRIS) assessment of formaldehyde
revealed
significant scientific problems with the program
(Greenwire, June 23).

In their own letter to the White House Office of
Management and Budget,
CPR's Rena Steinzor and Wendy Wagner imply that the
ACC request that the
National Academy of Sciences review all IRIS
assessments is a bid to
stall regulations.

"ACC," the wrote, "aggressively extrapolates from the
review and argues
that NAS review should be required for all IRIS
assessments without any
regard for the disastrous effects such a requirement

would have on human
health and the environment."

A NAS review of every IRIS assessment, they go on, "would grind" the
assessment "process to a slow walk at the expense of the health and
safety of everyone in the United States."

In response, ACC emphasized that the NAS review showed that IRIS needs
significant improvements.

"We agree that IRIS is critical to protecting public health and the
environment, which is why it is so important to make sure the program is
effective," said ACC's Scott Jensen. "As the NAS stated in their latest
review, 'persistent problems' with IRIS will only continue to lead to
flawed risk assessments. Until EPA fixes these problems with IRIS, we
believe the NAS must ensure the quality of ongoing risks assessments."

The NAS report on IRIS's formaldehyde assessment did take several issues
with the scientific methodologies used by EPA. "Overall," the NAS panel
said, "the committee found that EPA's draft assessment was not prepared
in a logically consistent fashion, lacks clear links to an underlying
conceptual framework and does not sufficiently document methods and
criteria used to identify evidence for selecting and evaluating
studies" (Greenwire, April 8).

The IRIS program was also listed this year in the Government
Accountability Office's annual "high risk list" of troubled federal
programs (Greenwire, Feb. 16).

CPR cites cost of industry proposal

The CPR scholars argue that the current framework at EPA is set up to
address the concerns noted in the NAS and GAO reports. Currently, they
wrote, EPA is in charge of scientific assessments

while OMB reviews
draft regulations "with an eye to the budget, not the
scientific
underpinnings."

"[OIRA] employs just two scientists," CPR wrote, "and
hence is not
designed to conduct scientific peer review."

Further, they also argue that a NAS review for every
IRIS assessment
would cost thousands, "if not millions," of dollars
for each new IRIS
assessment.

ACC's Jensen countered that argument by insisting
that paying for NAS
reviews would be a good investment because funding
flawed IRIS reviews
are a waste of resources.

Steinzor and Wagner concluded by noting that
currently about nine new or
updated assessments are promulgated by IRIS each year
-- a mere drop in
the bucket of assessments that need to be done.

"IRIS work needs to be accelerated, not delayed,"
they wrote. "At this
rate, the work needed to develop profiles for
statutorily-identified
'hazardous air pollutants' and other chemicals that
Congress and the
agency have identified as needing more effective
controls is already
pushed back several decades in the future."

Click here to read the CPR letter.

Archive:

{In Archive} RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

Woodruff, Tracey to: Kate Guyton, Sutton, Patrice 07/07/2011 02:08 PM

This message is being viewed in an archive.

Yes - I think Lisa would be very in to this.

tw

-----Original Message-----
From: Kate Guyton [mailto:Guyton.Kate@epamail.epa.gov
]
Sent: Thursday, July 07, 2011 10:57 AM
To: Woodruff, Tracey; Sutton, Patrice
Subject: RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

Well I think some background on Cochrane reviews and GRADE would be a good starting place? And focus on a better way to navigate the evidence for IRIS purposes... not all the way to clinician recommendations?

Do you think Lisa would be game for this?

I'll email Vince ASAP.
Thanks,
Kate

Kate Z. Guyton, PhD DABT
Toxicologist, NCEA, ORD, US EPA
703-347-8562 | guyton.kate@epa.gov
Mailing Address: US EPA (8623-P), 1200 Pennsylvania Ave. NW, Washington DC 20460 FedEx and Ground Deliveries: Two Potomac Yard (North Building), 2733 S.
Crystal Drive, Arlington VA 22202

From: "Woodruff, Tracey" <WoodruffT@obgyn.ucsf.edu>
To: Kate Guyton/DC/USEPA/US@EPA
Cc: "Sutton, Patrice" <SuttonP@obgyn.ucsf.edu>
Date: 07/07/2011 01:43 PM
Subject: RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

I think that is ok.... but do GRADE first? I would suggest a Lisa/us combination

Ye s- email Vince - he must be involved in the response to Vitters

-----Original Message-----
From: Kate Guyton [mailto:Guyton.Kate@epamail.epa.gov]
Sent: Thursday, July 07, 2011 9:07 AM
To: Woodruff, Tracey
Cc: Sutton, Patrice
Subject: RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

YES. I think we need a GRADE overview as a start? Who would be best-- one of you, Lisa B, Holger, Kris? We can certainly link everyone in, but need someone to "teach" the principles and discuss how this can apply to evaluation of evidence mainly from animal studies. I can suggest this to Vince AND Mary Ross (NAAQS)? I am not certain it will reach Anastas, but...

Thanks,
Kate

From: "Woodruff, Tracey" <WoodruffT@obgyn.ucsf.edu>
To: Kate Guyton/DC/USEPA/US@EPA, "Sutton, Patrice" <SuttonP@obgyn.ucsf.edu>
Date: 07/06/2011 11:55 PM
Subject: RE: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

YES, or Navigating, it is a perfect win to have Paul write back and say
- YES, I have the tool that we are developing...

Do you have a way to engage with them on this? Of course the layers of bureaucracy do seem daunting - maybe you can talk with vince.

Would be good timing for a webinar.

tw

-----Original Message-----
From: Kate Guyton [mailto:Guyton.Kate@epamail.epa.gov]
Sent: Wednesday, July 06, 2011 11:31 AM
To: Woodruff, Tracey; Sutton, Patrice
Subject: Fw: NEWS UPDATES: GOP Senators Broaden EPA

Science Attacks To Criticize NAAQS Process (Risk Policy Report)

Could GRADE help...?

Here's the letter:
(See attached file: June 30 letter.pdf)

Thanks,
Kate

Kate Z. Guyton, PhD DABT
Toxicologist, NCEA, ORD, US EPA
703-347-8562 | guyton.kate@epa.gov
Mailing Address: US EPA (8623-P), 1200 Pennsylvania Ave. NW, Washington DC 20460 FedEx and Ground Deliveries: Two Potomac Yard (North Building), 2733 S.
Crystal Drive, Arlington VA 22202

----- Forwarded by Kate Guyton/DC/USEPA/US on 07/06/2011 02:30 PM -----

GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process
Posted: July 1, 2011
Two key GOP senators are stepping up their attacks on EPA science by criticizing "defects" in the scientific review process for EPA's national ambient air quality standards (NAAQS), drawing parallels between flaws in the NAAQS program and criticisms of scientific errors in EPA's risk assessment for the chemical formaldehyde.
Sens. James Inhofe (R-OK), ranking member on the Environment & Public Works Committee, and panel member David Vitter (R-LA) sent a June 30 letter to EPA Administrator Lisa Jackson asking more than a dozen "important questions of scientific integrity" targeting several aspects of the NAAQS process, including how EPA selects scientific studies for reviews of its standards, the weight of evidence methodology EPA uses, and uncertainties in the process.
Inhofe and other Republicans have long criticized the agency for pursuing stricter NAAQS, which regulate six criteria pollutants including ozone and fine particulate matter (PM2.5). States must craft air quality plans that outline the pollution cuts they will impose on industry to come into, or stay in, attainment with the standards.
Critics say that ever-tightening standards lead to increasingly expensive pollution controls that harm states' economies.
Industry, Republicans and others have, for example, criticized EPA's proposal to tighten the Bush EPA's 2008 ozone standard of 75 parts per billion (ppb) to

a range within 60 to 70 ppb as supported by its science advisers.

Under the Clean Air Act EPA is barred from considering costs when setting NAAQS, and must propose changes to its standards based on science on the risks of exposure to a criteria pollutant. But Vitter and Inhofe say there are "fundamental problems to assuring high-quality, unbiased scientific results" in the NAAQS process.

The letter signals the senators stepping are up their broad attacks on EPA data, after touting recent a National Academy of Sciences' (NAS) critique of EPA's risk assessment of formaldehyde, to raise broad questions about the validity of other agency science, such as the data that EPA uses to justify its air quality standards. For example, speaking at a June 8 hearing of several Senate Environment & Public Works subcommittees on the impacts of EPA's air quality rules, Vitter questioned the legitimacy of EPA air rules and the agency's actions in general based on the NAS' conclusions in its review of the Integrated Risk Information System assessment of formaldehyde.

The NAS review, released in April, found that EPA did not provide sufficient evidence to support its conclusions that human exposure to formaldehyde can cause leukemia or Hodgkin lymphoma, and raised additional concerns about the agency's process for reaching weight of evidence conclusions in its risk assessments.

Industry and Republicans have called on EPA to adopt NAS'
recommendations for the chemical risk assessment program, including putting pending assessments on hold until the changes have been made.

"The same scientific defects noted in the formaldehyde assessment are also present in EPA's evaluations of the science used to establish and revise" NAAQS, the senators write in their June 30 letter. Their critiques over the NAAQS process come despite the fact that NAS praised EPA's updated risk assessment practices for setting criteria pollutant standards. The letter is available on InsideEPA.com. (Doc ID: 2368871) The senators question the process EPA uses to decide which studies to cite when determining air quality standards, arguing that "Current methods for selecting studies appear to systematically exclude or discount well conducted, peer reviewed studies that show no adverse health effects from air pollution at or below current air quality standards."

They add that, "Current methods for weighing evidence allow EPA to discount multiple no-effect studies and rely instead on single studies showing an effect," and that "Current practices do not provide for a comprehensive analysis of uncertainty and variability as a way to make risk assessments more useful for decision makers."

The letter points to a number of specific examples where the senators charge that "EPA has discounted or ignored studies" that find no association between a

pollutant and a particular health outcome -- including between ozone and asthma, ozone and cardiovascular morbidity and PM2.5 and chronic mortality.

Vitter and Inhofe also raise concerns with use of a 2006 study that found asthma symptoms for nitrogen dioxide (NO2) but not for ozone. "In the NO2 NAAQS review, EPA states that this study provides strong evidence for the health effects of NO2 . . . whereas in the 2008 ozone NAAQS review and reconsideration, EPA notes many reasons why the results of the study should be ignored, including the fact that only 12 children per day were evaluated and that the authors did not clearly define the severity of asthma in the study subjects."

The senators ask Jackson more than a dozen questions, including asking whether EPA has "a policy of consistently disregarding studies misinforms the public and leads to inflated and highly uncertain estimates of public health risks" and why EPA has failed to conduct a quantitative uncertainty analysis on PM2.5 exposure.

The senators ask for a reply by July 8. With EPA planning to release its revised ozone standard later this month and other NAAQS reviews pending, the senators say, "Given the timeframe with which we are dealing the need for your prompt response to these important questions of scientific integrity cannot be understated. The economy and many of our fellow Americans are suffering. To further perpetuate the problems of high unemployment and poverty without strong scientific and economic support for EPA's calculated efforts would be unwise."

Elsewhere in the letter, the senators also note that EPA has not yet replied to their May 10 letter asking how EPA has implemented recommendations from NAS to address concerns with the formaldehyde assessment. -- Victoria Finkle

Elizabeth Erwin
Communications Assistant
National Center for Environmental Assessment Office of Research and Development U.S. Environmental Protection Agency
Office: (703) 347-0205
Fax: (703) 347-8699

{In Archive} Re: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

Daniel Axelrad to: Kate Guyton 12/16/2011 03:15 PM

Archive: This message is being viewed in an archive.

Hey -

no breathholding here...hmm, aren't you going to take tons of time off now?

I'll be here through Wednesday. Then denver Dec 22 - Jan 3.

We are wrapping up a new complete draft of the children's indicators report today. I'm hoping this draft will be going into interagency review sometime shortly...

Kate Guyton Hi Dan! We hear Paul A is holding time to speak... 12/16/2011 03:01:18 PM

From: Kate Guyton/DC/USEPA/US
To: Daniel Axelrad/DC/USEPA/US@EPA
Date: 12/16/2011 03:01 PM
Subject: Re: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

Hi Dan!

We hear Paul A is holding time to speak to reporters next Wednesday... so that may yet be the date! Subject to review/revision/etc. Don't hold your breath....

Are you off next week? I'm around and at work, if the government is open :)

-----Daniel Axelrad/DC/USEPA/US wrote: -----
To: Kate Guyton/DC/USEPA/US@EPA
From: Daniel Axelrad/DC/USEPA/US
Date: 12/16/2011 02:56PM
Subject: Re: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

hmmm. I don't see it yet :)

hope all is well!

Kate Guyton---12/13/2011 12:31:29 PM---Yup! We are slated for this Friday, but I just heard next week might be possible... not sure if tha

From: Kate Guyton/DC/USEPA/US
To: Daniel Axelrad/DC/USEPA/US@EPA
Date: 12/13/2011 12:31 PM
Subject: Re: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

Yup! We are slated for this Friday, but I just heard next week might be possible... not sure if that's because we are waiting for permission from on high or what... either way, it's a gift that just keeps on giving!!

Daniel Axelrad---12/13/2011 12:22:40 PM---meanwhile, I hear that you have yet another week to go with perc? the fun never stops? From: Kate G

From: Daniel Axelrad/DC/USEPA/US
To: Kate Guyton/DC/USEPA/US@EPA
Date: 12/13/2011 12:22 PM
Subject: Re: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

---

meanwhile, I hear that you have yet another week to go with perc? the fun never stops?

Kate Guyton---12/13/2011 11:38:34 AM---Top Official Vows More EPA Risk Reforms While Defending IRIS Program Posted: December 12, 2011

From: Kate Guyton/DC/USEPA/US
To: woodrufft@obgyn.ucsf.edu, Lauren Zeise <Lauren.Zeise@oehha.ca.gov>, Daniel Axelrad/DC/USEPA/US@EPA
Date: 12/13/2011 11:38 AM
Subject: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

Top Official Vows More EPA Risk Reforms While Defending IRIS Program

Posted: December 12, 2011

CHARLESTON, S.C. -- The head of EPA's Integrated Risk Information System (IRIS) program is vowing to make additional reforms to the controversial program while also defending the agency's approach to adopting recommendations from the National Academy of Sciences (NAS) to improve it.

Vincent Cogliano, the program's acting director, told attendees during a session of the Society for Risk Analysis annual meeting here Dec. 7, that the agency is seeking to address concerns with how IRIS assessments are drafted and peer-reviewed, as well as how agency assessors weigh the evidence of data as the documents are created.

But industry groups are calling for additional reforms beyond Cogliano's proposals.

The IRIS program is under fire from industry and congressional Republicans who charge that the agency is rushing to complete a host of assessments for major chemicals expected to result in strict new regulatory requirements, without adequate scientific backing.

The critics point especially to EPA's draft assessment of formaldehyde, which an NAS panel strongly criticized for not containing adequate justification for its finding that the chemical is a leukemogen. In the report's chapter seven, the panel urged EPA to revise its IRIS assessment process, noting that the agency had revised its process for assessing air quality risks in just two years. The way EPA revised its process for drafting Integrated Science Assessments for criteria air pollutants is an example of how the agency "was able to revise an entrenched process in a relatively short time," the NAS panel said.

Since the issuance of the NAS panel report last April, critics have raised concerns that EPA has yet to adopt the overall process recommendations included in the document. Some have been pushing EPA to delay issuing any new risk assessments until the agency adopts the NAS panel's recommended reforms.

Public health activists and environmentalists, however, regularly complain that the program moves too haltingly to stay up to date, or to begin to address the vast number of chemicals in the environment.

But Cogliano urged attendees to remember the uncertainty that existed before IRIS, when various EPA programs and states had different risk values that could be used as the basis for various regulations, and often disagreed over which should be used, when and how.

He also pushed back against calls for EPA to delay issuance of IRIS assessments until the reforms have been adopted, noting that the NAS report urges EPA to continue to operate the IRIS program, and envisions a multi-year effort to implement all of the recommendations. "They did not tell us to stop doing assessments and they envisioned a multi-year improvement process and they encouraged us to go forward as we implement these improvements," Cogliano said.

He also downplayed industry suggestions that most IRIS assessments result in more conservative risk values than current assessments. He said that in a recent review of 20 chemicals with updated assessments, nine were more stringent than the earlier estimates. But, eight were less strict and 23 included first-time estimates, Cogliano said.

Cogliano also touted the agency's completion in late September of its long-awaited assessment of trichloroethylene (TCE), which had been some 20 years in the making. He contrasted the agency's experience with the formaldehyde assessment with the TCE assessment, where, he noted, that not only did staff complete the long-running

TCE assessment, it also received positive reviews from its peer reviewers.

And he praised the IRIS review process that Administrator Lisa Jackson introduced shortly after her arrival at EPA. Cogliano noted that it contained far fewer steps that the process developed during the Bush administration. He also noted that the new process contains four separate periods for review and comment from other federal agencies, peer reviewers or the public. And Cogliano described the IRIS process as "one of the most transparent risk assessment processes ever."

Nevertheless, Cogliano detailed a series of new and ongoing reforms the agency is developing to further improve the process. He said the agency will hold a workshop in the first half of 2012 to consider various weight of evidence (WoE) approaches. IRIS staff will use public and stakeholder input at the workshop to select a WoE framework or approach to test in a pilot with a handful of upcoming IRIS assessments, he said.

Cogliano had earlier expressed interest in adopting a WoE framework for use in crafting IRIS assessments during a October listening session of the chemical n-butanol, though he also raised concern that doing so could cause delays in the program. Representatives of the American Chemistry Council (ACC), a chemical industry organization, had urged EPA to adopt such a tool at that meeting (*Risk Policy Report*, Nov. 1).

Cogliano also outlined plans to "create an earlier peer review step in the process to improve the [IRIS] documents so the peer review document is better," and described measures taken to improve the clarity of new IRIS documents. Cogliano said they will be significantly shorter than documents of the last few years have been, will include a short, introductory preamble and more tables and charts. "The first step in the IRIS assessment is draft development, we'll be seconding that with a peer review workshop . . . on focused issues involving that chemical early in the IRIS assessment so we can get the benefit of public comment, stakeholder input and expert scientific advice so we can improve the assessment so the peer review draft will be much better."

And Cogliano indicated the new standing committee of EPA's Science Advisory Board (SAB) will review more than just individual IRIS assessments. The new standing committee is one of the reforms to the IRIS process that EPA research chief Paul Anastas announced in a series of reforms to the IRIS process in July, following the NAS formaldehyde report's release last April (*Risk Policy Report*, July 19). SAB staff are currently seeking nominations for members for the new subcommittee, which are due Jan. 6 (*Risk Policy Report*, Nov. 22).

"We are forming a dedicated [SAB] committee," Cogliano said. "We'll be going to take some assessments to this committee, we'll also be able to use the committee to give us advice on our [IRIS] process and how we are implementing the NAS recommendations."

But stakeholders are questioning the agency's approach. Matt Shudtz of the Center for Progressive Reform, a think tank that favors strict environmental rules, urged the

agency to further simplify the process, arguing that having just one simultaneous comment period for all parties would enhance efficiency.

Cogliano, however, said, "We've streamlined already, reducing the [IRIS] process to a seven-step process," from the much longer process under the Bush administration.

And Jennifer Sass of the Natural Resources Defense Council also questioned the amount of time it has taken EPA to complete some of its more controversial IRIS assessments, including those of formaldehyde and TCE. She blamed industry for most of these delays, arguing that industry often uses new research programs as a way to delay ongoing assessments. She noted that the TCE assessment, for example, started in 1989. "I know some people think it's reasonable. But I think it's ridiculous," Sass said. "States and communities rely on those [assessments.]"

But the American Chemistry Council (ACC), the chemical industry trade association, called for further reforms than Cogliano outlined. Rick Becker, a senior toxicologist at ACC, acknowledged Cogliano's announcements, but argued that EPA has yet to address some major advice in the NAS formaldehyde report -- and urged the agency to do so.

Becker thanked Cogliano for his announcements of the WoE workshop and the earlier review step intended to improve the draft IRIS documents that undergo peer review. But he outlined a number of NAS recommendations that he argues EPA has yet to address, including standardized methods for literature reviews and selecting principal studies that are the basis for the risk estimates, use of a mode of action WoE framework and established protocols for analyzing major study types.

"Maintaining the status quo in IRIS is not tenable. I'm pleased to hear there are changes, but more needs to be done," Becker said. "We need to ask the right questions up front. Articulate the strategy to collect relevant information, and include an opportunity for stakeholder discussion at that early point. There may be some science that is needed to improve the assessment that can be done relatively quickly."

Becker adds that EPA explaining the purpose of the IRIS assessment and what possible regulations it is intended to support would also be helpful to stakeholders. Stepping through the assessment process, Becker continues, "if defaults are used, there should be a clear rationale [in the document]. Information gaps and uncertainty need to be disclosed. These recommendations will help the risk management stage." -- *Maria Hegstad*

{In Archive} Re: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

Kate Guyton to: Daniel Axelrad 12/16/2011 03:01 PM

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To: Kate Guyton/DC/USEPA/US@EPA
From: Daniel Axelrad/DC/USEPA/US
Date: 12/16/2011 02:56PM
Subject: Re: Fw: NEWS UPDATES: Top Official Vows More EPA Risk Reforms While Defending IRIS Program (Inside EPA)

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Public health activists and environmentalists, however, regularly complain that the program moves too haltingly to stay up to date, or to begin to address the vast number of chemicals in the environment.

But Cogliano urged attendees to remember the uncertainty that existed before IRIS, when various EPA programs and states had different risk values that could be used as the basis for various regulations, and often disagreed over which should be used, when and how.

He also pushed back against calls for EPA to delay issuance of IRIS assessments until the reforms have been adopted, noting that the NAS report urges EPA to continue to operate the IRIS program, and envisions a multi-year effort to implement all of the recommendations. "They did not tell us to stop doing assessments and they envisioned a multi-year improvement process and they encouraged us to go forward as we implement these improvements," Cogliano said.

He also downplayed industry suggestions that most IRIS assessments result in more conservative risk values than current assessments. He said that in a recent review of 20 chemicals with updated assessments, nine were more

stringent than the earlier estimates. But, eight were less strict and 23 included first-time estimates, Cogliano said.

Cogliano also touted the agency's completion in late September of its long-awaited assessment of trichloroethylene (TCE), which had been some 20 years in the making. He contrasted the agency's experience with the formaldehyde assessment with the TCE assessment, where, he noted, that not only did staff complete the long-running TCE assessment, it also received positive reviews from its peer reviewers.

And he praised the IRIS review process that Administrator Lisa Jackson introduced shortly after her arrival at EPA. Cogliano noted that it contained far fewer steps that the process developed during the Bush administration. He also noted that the new process contains four separate periods for review and comment from other federal agencies, peer reviewers or the public. And Cogliano described the IRIS process as "one of the most transparent risk assessment processes ever."

Nevertheless, Cogliano detailed a series of new and ongoing reforms the agency is developing to further improve the process. He said the agency will hold a workshop in the first half of 2012 to consider various weight of evidence (WoE) approaches. IRIS staff will use public and stakeholder input at the workshop to select a WoE framework or approach to test in a pilot with a handful of upcoming IRIS assessments, he said.

Cogliano had earlier expressed interest in adopting a WoE framework for use in crafting IRIS assessments during a October listening session of the chemical n-butanol, though he also raised concern that doing so could cause delays in the program. Representatives of the American Chemistry Council (ACC), a chemical industry organization, had urged EPA to adopt such a tool at that meeting (*Risk Policy Report* , Nov. 1).

Cogliano also outlined plans to "create an earlier peer review step in the process to improve the [IRIS] documents so the peer review document is better," and described measures taken to improve the clarity of new IRIS documents. Cogliano said they will be significantly shorter than documents of the last few years have been, will include a short, introductory preamble and more tables and charts.

"The first step in the IRIS assessment is draft development, we'll be seconding that with a peer review workshop . . . on focused issues involving that chemical early in the IRIS assessment so we can get the benefit of public comment, stakeholder input and expert scientific advice so we can improve the assessment so the peer review draft will be much better."

And Cogliano indicated the new standing committee of EPA's Science Advisory Board (SAB) will review more than just individual IRIS assessments. The new standing committee is one of the reforms to the IRIS process that EPA research chief Paul Anastas announced in a series of reforms to the IRIS process in July, following the NAS formaldehyde report's release last April (*Risk Policy Report*, July 19). SAB staff are currently seeking nominations for members for the new subcommittee, which are due Jan. 6 (*Risk Policy Report*, Nov. 22).

"We are forming a dedicated [SAB] committee," Cogliano said. "We'll be going to take some assessments to this committee, we'll also be able to use the committee to give us advice on our [IRIS] process and how we are implementing the NAS recommendations."

But stakeholders are questioning the agency's approach. Matt Shudtz of the Center for Progressive Reform, a think tank that favors strict environmental rules, urged the agency to further simplify the process, arguing that having just one simultaneous comment period for all parties would enhance efficiency.

Cogliano, however, said, "We've streamlined already, reducing the [IRIS] process to a seven-step process," from the much longer process under the Bush administration.

And Jennifer Sass of the Natural Resources Defense Council also questioned the amount of time it has taken EPA to complete some of its more controversial IRIS assessments, including those of formaldehyde and TCE. She blamed industry for most of these delays, arguing that industry often uses new research programs as a way to delay ongoing assessments. She noted that the TCE assessment, for example, started in 1989. "I know some people think it's reasonable. But I think it's ridiculous," Sass said. "States and communities rely on those [assessments.]"

But the American Chemistry Council (ACC), the chemical industry trade association, called for further reforms than Cogliano outlined. Rick Becker, a senior toxicologist at ACC, acknowledged Cogliano's announcements, but argued that EPA has yet to address some major advice in the NAS formaldehyde report -- and urged the agency to do so.

Becker thanked Cogliano for his announcements of the WoE workshop and the earlier review step intended to improve the draft IRIS documents that undergo peer review. But he outlined a number of NAS recommendations that he argues EPA has yet to address, including standardized methods for literature reviews and selecting principal studies that are the basis for the risk estimates, use of a mode of action WoE framework and established protocols for analyzing major study types.

"Maintaining the status quo in IRIS is not tenable. I'm pleased to hear there are changes, but more needs to be done," Becker said. "We need to ask the right questions up front. Articulate the strategy to collect relevant information, and include an opportunity for stakeholder discussion at that early point. There may be some science that is needed to improve the assessment that can be done relatively quickly."

Becker adds that EPA explaining the purpose of the IRIS assessment and what possible regulations it is intended to support would also be helpful to stakeholders. Stepping through the assessment process, Becker continues, "if defaults are used, there should be a clear rationale [in the document]. Information gaps and uncertainty need to be disclosed. These recommendations will help the risk management stage." *-- Maria Hegstad*

{In Archive} RE: EPA, Key Adviser Oppose House Bid To Halt Chemical Risk Assessments - Inside EPA

Daniel Axelrad, Kate Guyton, Juleen Lam

Lauren Zeise to: , Thomas Burke, Tracey Woodruff 10/07/2011 02:11 PM

Archive: This message is being viewed in an archive.

Yes, thank heavens for Tom! Thanks Dan for sending.

>>> "Woodruff, Tracey" <WoodruffT@obgyn.ucsf.edu>
10/7/2011 8:04 AM
>>>
It was awesome that you were there - you can never
retire!

tw

-----Original Message-----
From: Burke, Thomas [mailto:tburke@jhsph.edu]
Sent: Friday, October 07, 2011 7:59 AM
To: Axelrad.Daniel@epamail.epa.gov; Woodruff, Tracey;
lzeise@oehha.ca.gov; Guyton.Kate@epamail.epa.gov;
Juleen Lam
Subject: RE: EPA, Key Adviser Oppose House Bid To
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From: Axelrad.Daniel@epamail.epa.gov
[mailto:Axelrad.Daniel@epamail.epa.gov]
Sent: Friday, October 07, 2011 10:23 AM
To: Burke, Thomas; woodrufft@obgyn.ucsf.edu;
lzeise@oehha.ca.gov;
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Subject: EPA, Key Adviser Oppose House Bid To Halt
Chemical Risk
Assessments - Inside EPA

EPA, Key Adviser Oppose House Bid To Halt Chemical
Risk Assessments
Posted: October 6, 2011

Backed by a key scientist, EPA's research chief Paul
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(NAS) has had a chance to review them and has backed recently announced program reforms.

At a House subcommittee hearing Oct. 6 to review EPA's Integrated Risk Information System (IRIS) program, Anastas drew strong support from Thomas Burke, an associate dean of The Johns Hopkins Bloomberg School of Public Health who also chaired a 2009 NAS panel that issued recommendations on ways to improve EPA risk assessments, with both men providing separate arguments to why the assessments shouldn't be delayed until the program is reformed.

A subsequent 2011 NAS panel that faulted EPA's draft assessment of formaldehyde reiterated some of the recommendations contained in the 2009 panel report, that Burke chaired. Many industry groups and GOP lawmakers are touting the formaldehyde report – and urging EPA to delay issuing new risk assessments until it has adopted the panel's suggestions.

To pressure the agency to adopt the NAS recommendations, House Republicans have also included language in EPA's fiscal year 2012 spending bill that would require the agency to implement the recommendations, have the NAS review any changes EPA makes to the IRIS program and have the NAS review several pending and future risk assessments, including the controversial assessment of arsenic. The House began considering the bill before the summer recess but lawmakers are scheduled to resume consideration later this year.

Sens. James Inhofe (R-OK) and David Vitter (R-LA) have also called on EPA Administrator Lisa Jackson to “suspend” issuance of

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But at the Oct. 6 hearing of the House Energy and
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Shimkus (R-IL) said is the “underlying bias present
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Burke pushed back against efforts to halt the
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In written testimony at the hearing, Anasatas,
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reiterated that the
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is making changes to the program, but noted that NAS
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“It is important to note that the NAS report viewed
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Burke went even further, warning that language in the
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Burke said in response to a question from Rep. Gene
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Burke also clarified remarks he made last summer,
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In response to questions from Greene, Burke said
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important,” Burke continued. “So why is EPA in
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“We owe it to the American public, we owe it to the
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community” to have risk assessments based in sound
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Focus On IRIS

The hearing was held to gather input on the IRIS
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Republicans who argue that the assessments are overly
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the NAS' criticism
of the program in chapter 7 of its review of the
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assessment as further need for improvement.

In the wake of such concerns, the agency in early July unveiled a series of reforms designed to strengthen the program and respond to the NAS concerns, including the development of a standing IRIS Advisory Committee at the Science Advisory Board (SAB) to address thorny scientific questions and review risk assessments that have provoked controversy among industry and other critics who fear they are too conservative.

EPA also announced a series of additional plans to clarify the information presented in IRIS assessments, provide better rationale for which studies EPA relies on in its assessments, streamline the documents and increase transparency, but industry groups viewed these plans as falling short of the necessary revision of a program they have long disliked.

EPA is moving forward with a host of IRIS assessments and has recently released several assessments, including one for trichloroethylene (TCE) -- a common groundwater contaminant -- and continues to defend the science behind the documents.

When Anastas issued the TCE assessment, he strongly touted the public health benefits of the program, saying the TCE assessment "underscores the importance of EPA's science and, in particular, the critical value of the IRIS database for ensuring that government officials and the American people have the information they need to protect their health and the health of their children."

But the agency has so far issued only one assessment -- for

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Anastas also defended the IRIS review process, noting that assessments "are held to the highest Agency standards," receiving considerable internal and external review and comment. "These standards are among the best in the federal government and the scientific community."

OMB Review

However, Rep. Bill Cassidy (R-LA) called for increased oversight of IRIS assessments from the White House Office of Management and Budget (OMB), and advocated reinstating the OMB-led review process that was in place during the Bush Administration.

EPA Administrator Lisa Jackson reversed the Bush review process shortly after taking office, putting EPA back in the lead after the Government Accountability Office (GAO) called the IRIS program a "high risk" program due to the lengthy delays inherent in the OMB-led review process.

But Cassidy called for reinstating the OMB-led process. IRIS

assessments, while not regulatory by themselves, are used to inform policy, Cassidy said, adding that he is concerned that “policy is manipulating science to achieve advocacy as opposed to truth.”

“Why in the world are we basing decisions that affect a number of jobs” on questionable science, Cassidy said. “I'm struck how sometimes processes are used to manipulate the response to the finding.”

The congressman added that cost-benefit analyses should be conducted for IRIS assessments and “I'm thinking OMB needs to be involved.”

But GAO is is expected to reach the opposite conclusion in a soon-to-be-released review of the 2009 changes to IRIS. In testimony to the subcommittee, David Trimble, director of GAO's natural resources and the environment program, reiterated earlier comments that the Obama Administration's reforms “appeared to represent a significant improvement over the previous IRIS process and, if implemented effectively, with sustained management and oversight, could help EPA restore the credibility and increase the timeliness of this program.”
The reforms, he said, streamlined the IRIS process, consolidating and eliminating unnecessary steps and reducing delay; established transparency; and restored control of the process to EPA, taking the management of reviews away from OMB to considerably speed up the release of assessments.

However, Trimble added, a lack of statutory deadline; ever changing science and methodologies; delays; challenges from industry, environmentalists and lawmakers; and what are

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Hopkinson

{In Archive} RE: EPA, Key Adviser Oppose House Bid To Halt Chemical Risk Assessments - Inside EPA

Woodruff, Tracey to: Burke, Thomas, Daniel Axelrad, lzeise@oehha.ca.gov, Kate Guyton, Juleen Lam 10/07/2011 11:04 AM

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From: Burke, Thomas [mailto:tburke@jhsph.edu]
Sent: Friday, October 07, 2011 7:59 AM
To: Axelrad.Daniel@epamail.epa.gov; Woodruff, Tracey; lzeise@oehha.ca.gov; Guyton.Kate@epamail.epa.gov; Juleen Lam
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To pressure the agency to adopt the NAS recommendations, House Republicans have also included language in EPA's fiscal year 2012 spending bill that would require the agency to implement the recommendations, have the NAS review any changes EPA makes to the IRIS program and have the NAS review several pending and future risk assessments, including the controversial assessment of arsenic. The House began considering the bill before the summer recess but lawmakers are scheduled to resume consideration later this year.

Sens. James Inhofe (R-OK) and David Vitter (R-LA) have also called on EPA Administrator Lisa Jackson to “suspend” issuance of controversial assessments until the reforms have been implemented and subjected to NAS review.

But at the Oct. 6 hearing of the House Energy and Commerce's energy and environment subcommittee to examine what subcommittee Chairman John Shimkus (R-IL) said is the “underlying bias present in the program and the impact of science manipulation on jobs and the economy” Anastas and Burke pushed back against efforts to halt the assessments until the NAS

recommendations are adopted.

In written testimony at the hearing, Anasatas, assistant administrator of EPA's Office of Research and Development, reiterated that the agency is making changes to the program, but noted that NAS was clear that the program should continue to issue risk assessments despite the needed improvements.

“It is important to note that the NAS report viewed the implementation of their recommendations as a multi-year process,” he said. “For example, the NAS stated ‘it is not recommending that EPA delay the revision of the formaldehyde assessment to implement a new approach.”

Burke went even further, warning that language in the bill delaying the program would cause problems for public health programs that depend on the assessments to set standards to protect human health. “I think it would be a disservice to public health agencies throughout the country and even around the world” if we brought the IRIS program to a halt, Burke said in response to a question from Rep. Gene Greene (D-TX), the subcommittee's ranking Democrat.

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The hearing was held to gather input on the IRIS program and its effects on regulations. IRIS has come under fire recently from industry and Republicans who argue that the assessments are overly conservative and not based in sound science, and who are pointing to the NAS' criticism of the program in chapter 7 of its review of the formaldehyde risk assessment as further need for improvement.

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{In Archive} RE: NEWS UPDATES: Omnibus Appropriations Bill Directs EPA To Adopt Recommended Changes to IRIS (BNA)

Kate Guyton to: Rusyn, Ivan I 12/19/2011 05:19 PM

Archive: This message is being viewed in an archive.

"up to three", that is...

"Rusyn, Ivan I" 3 is better than all... > -----Original Message----- 12/19/2011 05:05:47 PM

From: "Rusyn, Ivan I" <iir@unc.edu>
To: Kate Guyton/DC/USEPA/US@EPA
Date: 12/19/2011 05:05 PM
Subject: RE: NEWS UPDATES: Omnibus Appropriations Bill Directs EPA To Adopt Recommended Changes to IRIS (BNA)

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3 is better than all...

> -----Original Message-----
> From: Kate Guyton [mailto:Guyton.Kate@epamail.epa.gov]
> Sent: Monday, December 19, 2011 4:57 PM
> To: Rusyn, Ivan I
> Subject: Fw: NEWS UPDATES: Omnibus Appropriations Bill Directs EPA To
> Adopt Recommended Changes to IRIS (BNA)
>
>
> See page 34 (or search for "IRIS") at:
> http://rules.house.gov/Media/file/PDF_112_1/legislativetext/HR1540crSOM
> /psConference%20Div%20E%20-%20SOM%20OCR.pdf
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> Enjoy!
> Kate
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> The (Embedded image moved to file: pic06704.gif)previous
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> pic31818.gif)next hit directive is one of a number of policy riders in the
> (Embedded image
> moved to file: pic09232.gif)previous hitappropriations(Embedded image
> moved to file:
> pic00750.gif)next hit (Embedded image moved to file: pic25205.gif)previous
> hitbill(Embedded
> image moved to file: pic04975.gif)next hit. (See related story in this
issue.)
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>
> The (Embedded image moved to file: pic01539.gif)previous
> hitIRIS(Embedded image moved to file:
> pic00303.gif)next hit program has been assailed by congressional
> Republicans and industry
> advocates, who claim it lacks transparency, particularly when deciding on
> which studies
> (Embedded image moved to file: pic11422.gif)previous hitto(Embedded
> image moved to file:
> pic21098.gif)next hit consider when setting inhalation exposure limits
known
> as reference
> concentrations.
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> By March 1, 2012, (Embedded image moved to file: pic11247.gif)previous

> hitEPA(Embedded image
> moved to file: pic13584.gif)next hit must report (Embedded image moved to
> file: pic13648.gif)
> previous hitto(Embedded image moved to file: pic02971.gif)next hit
> Congress on its efforts
> (Embedded image moved to file: pic17864.gif)previous hitto(Embedded
> image moved to file:
> pic22913.gif)next hit make improvements (Embedded image moved to file:
> pic11075.gif)previous
> hitto(Embedded image moved to file: pic21545.gif)next hit (Embedded
> image moved to file:
> pic28712.gif)previous hitIRIS(Embedded image moved to file:
> pic17546.gif)next hit, and
> (Embedded image moved to file: pic18678.gif)previous hitto(Embedded
> image moved to file:
> pic01769.gif)next hit explain its reasoning if it has not incorporated any
> (Embedded image
> moved to file: pic15262.gif)previous hitrecommended(Embedded image
> moved to file: pic08519.gif)
> next hit (Embedded image moved to file: pic13985.gif)previous
> hitchanges(Embedded image moved
> to file: pic28289.gif)next hit. Within 18 months of the (Embedded image
> moved to file:
> pic15944.gif)previous hitomnibus(Embedded image moved to file:
> pic02865.gif)next hit bill's
> passage, (Embedded image moved to file: pic18540.gif)previous
> hitEPA(Embedded image moved to
> file: pic23245.gif)next hit is ordered (Embedded image moved to file:
> pic25508.gif)previous hit
> to(Embedded image moved to file: pic28318.gif)next hit set up a contract
> with the National
> Academies (Embedded image moved to file: pic27870.gif)previous
> hitto(Embedded image moved to
> file: pic09601.gif)next hit review up (Embedded image moved to file:
> pic28323.gif)previous hit
> to(Embedded image moved to file: pic21132.gif)next hit three (Embedded
> image moved to file:
> pic24472.gif)previous hitIRIS(Embedded image moved to file:
> pic27152.gif)next hit assessments
> (Embedded image moved to file: pic25087.gif)previous hitto(Embedded
> image moved to file:
> pic28570.gif)next hit determine whether they incorporate the NAS
> recommendations.
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> The managers' report also emphasized the need for (Embedded image
> moved to file: pic29763.gif)
> previous hitEPA(Embedded image moved to file: pic29901.gif)next hit
> (Embedded image moved to
> file: pic17103.gif)previous hitto(Embedded image moved to file:
> pic14423.gif)next hit use
> sound, objective, and peer-reviewed science in the (Embedded image
> moved to file: pic03527.gif)
> previous hitIRIS(Embedded image moved to file: pic11600.gif)next hit
> assessments.
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>
> One of the three (Embedded image moved to file: pic26969.gif)previous
> hitIRIS(Embedded image
> moved to file: pic14015.gif)next hit assessments the academies must review
> is EPA's assessment
> of the carcinogenic and non-carcinogenic hazards of inorganic arsenic.
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> NAS Recommendations
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>
> The NAS critique of the formaldehyde assessment generally faulted it for
> including long
> descriptions of individual studies, and said the descriptions should be
> replaced with concise
> statements of findings and tables presenting evidence. More detailed
> descriptions should be
> included in appendices, NAS said (69 DEN A-1, 4/11/11).
>
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>
> NAS also said the opening section should more fully describe the methods
> used in the
> assessment, in particular the explanations of the criteria for including or
> excluding certain
> studies and the explanations of the weight-of-evidence approaches used for
> non-cancer outcomes.
> These also should be expressed through concise statements and tables, NAS
> said.
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>
> Another recommendation was (Embedded image moved to file:
> pic05565.gif)previous hitto(Embedded
> image moved to file: pic00028.gif)next hit develop standardized evidence
for
> all health
> outcomes. Again, NAS said tables should replace long descriptions of
> findings. A standardized
> approach also is needed for evaluating critical studies, NAS said.
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>
> Rationales should be expanded, NAS said, for selecting the studies
> considered in setting
> reference concentrations (RfCs), which are inhalation levels that are

> expected (Embedded image
> moved to file: pic21543.gif)previous hitto(Embedded image moved to file:
> pic25347.gif)next hit
> have no health impacts over an individual's lifetime.
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> Finally, stronger, more integrative, and more transparent discussions of
the
> weight of evidence
> is needed in (Embedded image moved to file: pic02088.gif)previous
> hitIRIS(Embedded image moved
> to file: pic02943.gif)next hit assessments, NAS said.
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> The (Embedded image moved to file: pic12637.gif)previous hitbill(Embedded
> image moved to file:
> pic22409.gif)next hit also authorizes the (Embedded image moved to file:
> pic26463.gif)previous
> hitEPA(Embedded image moved to file: pic05049.gif)next hit administrator
> (Embedded image moved
> to file: pic04681.gif)previous hitto(Embedded image moved to file:
> pic01588.gif)next hit
> collect and obligate pesticide registration service fees in accordance with
the
> provisions of
> the Pesticide Registration Improvement Renewal Act (Pub. L. No. 110-94),
> which was enacted
> (Embedded image moved to file: pic11342.gif)previous hitto(Embedded
> image moved to file:
> pic00608.gif)next hit help reduce a backlog of (Embedded image moved to
> file: pic32060.gif)
> previous hitEPA(Embedded image moved to file: pic01758.gif)next hit
> pesticide registration
> decisions.
>
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>
> The full text of House Report 112-331 and the manager's reports are
> available at http://(Embedded
> image moved to file: pic29954.gif)previous hitappropriations(Embedded
> image moved to file:
> pic20888.gif)next
> hit.house.gov/News/DocumentSingle.aspx?DocumentID=272625
> The summary of the (Embedded image moved to file: pic14146.gif)previous
> hitomnibus(Embedded image
> moved to file: pic00690.gif)next hit spending (Embedded image moved to
> file: pic07949.gif)
> previous hitbill(Embedded image moved to file: pic12843.gif)next hit is
> available at http://
> (Embedded image moved to file: pic21430.gif)previous
> hitappropriations(Embedded image moved to

> file: pic25620.gif)next hit
>
> .house.gov/UploadedFiles/12.14.11_Final_FY_2012_Appropriations_Legislati
> on_-_Detailed_Summary.pdf
> .
> The text of Interior, Environment and Related Agencies (Embedded image
> moved to file:
> pic00748.gif)previous hitbill(Embedded image moved to file:
> pic27067.gif)next hit is available at
>
> http://rules.house.gov/Media/file/PDF_112_1/HR2055CRbill/pcConferenceD
> ivE-BillOCR.pdf.
>
>
>

{In Archive} RE: NEWS UPDATES: Omnibus Appropriations Bill Directs EPA To Adopt Recommended Changes to IRIS (BNA)

Rusyn, Ivan I to: Kate Guyton 12/19/2011 05:22 PM

Who's counting... :-(Letter additions attached. Feel
free to break my run-ons...

> -----Original Message-----
> From: Kate Guyton [
mailto:Guyton.Kate@epamail.epa.gov]
> Sent: Monday, December 19, 2011 5:20 PM
> To: Rusyn, Ivan I
> Subject: RE: NEWS UPDATES: Omnibus Appropriations
Bill Directs EPA To
> Adopt Recommended Changes to IRIS (BNA)
>
> "up to three", that is...
>
>
>
>
> From: "Rusyn, Ivan I" <iir@unc.edu>
> To: Kate Guyton/DC/USEPA/US@EPA
> Date: 12/19/2011 05:05 PM
> Subject: RE: NEWS UPDATES: Omnibus
Appropriations Bill Directs EPA
> To
> Adopt Recommended Changes to IRIS (BNA)
>
>
>
> 3 is better than all...
>
> > -----Original Message-----
> > From: Kate Guyton [
mailto:Guyton.Kate@epamail.epa.gov]
> > Sent: Monday, December 19, 2011 4:57 PM
> > To: Rusyn, Ivan I
> > Subject: Fw: NEWS UPDATES: Omnibus Appropriations
Bill Directs EPA To
> > Adopt Recommended Changes to IRIS (BNA)
> >
> >
> > See page 34 (or search for "IRIS") at:
> >
>
http://rules.house.gov/Media/file/PDF_112_1/legislati
vetext/HR1540crSOM
> > /psConference%20Div%20E%20-%20SOM%20OCR.pdf
> >
> > Enjoy!
> > Kate
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> >
> > (Embedded image moved to file:
pic11192.gif)previous
> > hitOmnibus(Embedded image moved to file:

> > pic07605.gif)next hit (Embedded image moved to
file:
> pic25264.gif)previous
> > hitAppropriations
> > (Embedded image moved to file: pic12181.gif)next
hit (Embedded image
> > moved to file:
> > pic28503.gif)previous hitBill(Embedded image
moved to file:
> > pic03829.gif)next hit (Embedded
> > image moved to file: pic23775.gif)previous
hitDirects(Embedded image
> > moved to file:
> > pic20608.gif)next hit (Embedded image moved to
file:
> pic29292.gif)previous
> > hitEPA(Embedded
> > image moved to file: pic05997.gif)next hit
To(Embedded image moved to
> > file: pic17549.gif)next
> > hit (Embedded image moved to file:
pic29556.gif)previous
> > hitAdopt(Embedded image moved to file:
> > pic25561.gif)next hit (Embedded image moved to
file:
> pic31627.gif)previous
> > hitRecommended
> > (Embedded image moved to file: pic06467.gif)next
hit (Embedded image
> > moved to file:
> > pic29541.gif)previous hitChanges(Embedded image
moved to file:
> > pic26129.gif)next hit (Embedded
> > image moved to file: pic31240.gif)previous
hitto(Embedded image moved
> to
> > file: pic27813.gif)
> > next hit (Embedded image moved to file:
pic29174.gif)previous
> > hitIRIS(Embedded image moved to
> > file: pic20601.gif)next hit
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> >
> >
> > By Amena H. Saiyid
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> >
> > The Environmental Protection Agency would have
(Embedded image
> moved
> > to file: pic06077.gif) previous hitto(Embedded
image moved to file:
> > pic20215.gif)next hit
> make

> > (Embedded image moved
> > to file: pic08683.gif)previous
hitchanges(Embedded image moved to
> file:
> > pic08213.gif)next hit
> > (Embedded image moved to file:
pic23992.gif)previous hitto(Embedded
> > image moved to file:
> > pic25824.gif)next hit its chemical risk
assessment program, using
> > recommendations by the National Academies, under
a congressional
> > directive as part of the
> fiscal 2012
> > spending
> > (Embedded image moved to file:
pic05601.gif)previous hitbill(Embedded
> > image moved to file:
> > pic23392.gif)next hit.
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> > The nine-(Embedded image moved to file:
pic15759.gif)previous
> > hitbill(Embedded image moved to
> > file: pic02670.gif)next hit (Embedded image
moved to file:
> > pic26428.gif)previous hitomnibus
> > (Embedded image moved to file: pic28027.gif)next
hit (Embedded image
> > moved to file:
> > pic04084.gif)previous hitappropriations(Embedded
image moved to file:
> > pic10075.gif)next hit
> > package (H.R. 2055) includes a manager's report
directing the agency
> > (Embedded image moved to
> > file: pic18786.gif)previous hitto(Embedded image
moved to file:
> > pic15498.gif)next hit (Embedded image moved to
file:
> pic24970.gif)previous
> > hitadopt(Embedded image moved to file:
pic06287.gif) next hit
> > (Embedded image moved to file:
pic23847.gif)previous
> > hitrecommended(Embedded image moved to file:
pic32604.gif)next hit
> > (Embedded image moved to file:
> > pic00503.gif)previous hit
> > changes(Embedded image moved to file:
pic21221.gif)next hit (Embedded
> > image moved to file:
> > pic22663.gif)previous hitto(Embedded image moved
to file:
> > pic05706.gif)next hit the Integrated
> > Risk Information System.
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> > In the manager's report, (Embedded image moved
to file:
> > pic02363.gif)previous hitEPA(Embedded
> > image moved to file: pic09010.gif)next hit is
directed (Embedded
> image
> > moved to file:
> > pic22171.gif)previous hitto(Embedded image moved
to file:
> > pic27489.gif)next hit incorporate, as
> > appropriate, recommendations (Embedded image
moved to file:
> > pic18240.gif)previous hitto
> > (Embedded image moved to file: pic12164.gif)next
hit improve
> (Embedded
> > image moved to file:
> > pic25542.gif)previous hitIRIS(Embedded image
moved to file:
> > pic07619.gif)next hit based on the
> > National Academies' National Research Council
April review of the
> > (Embedded image moved to
> > file: pic20913.gif)previous hitIRIS(Embedded
image moved to file:
> > pic07591.gif)next hit
> > assessment of formaldehyde.
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> >
> > The (Embedded image moved to file:
pic06704.gif)previous
> > hitIRIS(Embedded image moved to file:
> > pic31818.gif)next hit directive is one of a
number of policy riders
> in the
> > (Embedded image
> > moved to file: pic09232.gif)previous
hitappropriations(Embedded image
> > moved to file:
> > pic00750.gif)next hit (Embedded image moved to
file:
> pic25205.gif)previous
> > hitbill(Embedded
> > image moved to file: pic04975.gif)next hit. (See
related story in
> this issue.)
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> >
> > The (Embedded image moved to file:
pic01539.gif)previous

> > hitIRIS(Embedded image moved to file:
> > pic00303.gif)next hit program has been assailed
by congressional
> > Republicans and industry advocates, who claim it
lacks transparency,
> > particularly when
> deciding on
> > which studies
> > (Embedded image moved to file:
pic11422.gif)previous hitto(Embedded
> > image moved to file:
> > pic21098.gif)next hit consider when setting
inhalation exposure
> limits known
> > as reference
> > concentrations.
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> >
> > By March 1, 2012, (Embedded image moved to file:
> pic11247.gif)previous
> > hitEPA(Embedded image
> > moved to file: pic13584.gif)next hit must report
(Embedded image
> moved to
> > file: pic13648.gif)
> > previous hitto(Embedded image moved to file:
pic02971.gif)next hit
> > Congress on its efforts (Embedded image moved to
file:
> > pic17864.gif)previous hitto(Embedded image moved
to file:
> > pic22913.gif)next hit make improvements
(Embedded image moved to
> file:
> > pic11075.gif)previous
> > hitto(Embedded image moved to file:
pic21545.gif)next hit (Embedded
> > image moved to file:
> > pic28712.gif)previous hitIRIS(Embedded image
moved to file:
> > pic17546.gif)next hit, and
> > (Embedded image moved to file:
pic18678.gif)previous hitto(Embedded
> > image moved to file:
> > pic01769.gif)next hit explain its reasoning if
it has not
> incorporated any
> > (Embedded image
> > moved to file: pic15262.gif)previous
hitrecommended(Embedded image
> > moved to file: pic08519.gif) next hit (Embedded
image moved to file:
> > pic13985.gif)previous hitchanges(Embedded image
moved to file:
> > pic28289.gif)next hit. Within 18 months of the
(Embedded
> image

> > moved to file:
> > pic15944.gif)previous hitomnibus(Embedded image
moved to file:
> > pic02865.gif)next hit bill's
> > passage, (Embedded image moved to file:
pic18540.gif)previous
> > hitEPA(Embedded image moved to
> > file: pic23245.gif)next hit is ordered (Embedded
image moved to file:
> > pic25508.gif)previous hit
> > to(Embedded image moved to file:
pic28318.gif)next hit set up a
> contract
> > with the National
> > Academies (Embedded image moved to file:
pic27870.gif)previous
> > hitto(Embedded image moved to
> > file: pic09601.gif)next hit review up (Embedded
image moved to file:
> > pic28323.gif)previous hit
> > to(Embedded image moved to file:
pic21132.gif)next hit three
> (Embedded
> > image moved to file:
> > pic24472.gif)previous hitIRIS(Embedded image
moved to file:
> > pic27152.gif)next hit assessments
> > (Embedded image moved to file:
pic25087.gif)previous hitto(Embedded
> > image moved to file:
> > pic28570.gif)next hit determine whether they
incorporate the NAS
> > recommendations.
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> >
> > The managers' report also emphasized the need
for (Embedded image
> > moved to file: pic29763.gif) previous
hitEPA(Embedded image moved to
> > file: pic29901.gif)next hit (Embedded image moved
to
> > file: pic17103.gif)previous hitto(Embedded image
moved to file:
> > pic14423.gif)next hit use
> > sound, objective, and peer-reviewed science in
the (Embedded image
> > moved to file: pic03527.gif) previous
hitIRIS(Embedded image moved to
> > file: pic11600.gif)next hit assessments.
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> >
> > One of the three (Embedded image moved to file:
pic26969.gif)previous
> > hitIRIS(Embedded image moved to file:

pic14015.gif)next hit
> > assessments the academies must
> review
> > is EPA's assessment
> > of the carcinogenic and non-carcinogenic hazards
of inorganic
> arsenic.
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> > NAS Recommendations
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> > 4/11/11).
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> > non-cancer outcomes.
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> NAS
> > said.
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> >
> > Another recommendation was (Embedded image moved
to file:
> > pic05565.gif)previous hitto(Embedded

> > image moved to file: pic00028.gif)next hit
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> evidence for
> > all health
> > outcomes. Again, NAS said tables should replace
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> > findings. A standardized approach also is needed
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> > critical studies, NAS said.
> >
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> > Rationales should be expanded, NAS said, for
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> > considered in setting reference concentrations
(RfCs), which are
> > inhalation levels that are expected (Embedded
image moved to file:
> > pic21543.gif)previous hitto(Embedded image moved
to
> file:
> > pic25347.gif)next hit
> > have no health impacts over an individual's
lifetime.
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> >
> > Finally, stronger, more integrative, and more
transparent discussions
> of the
> > weight of evidence
> > is needed in (Embedded image moved to file:
pic02088.gif)previous
> > hitIRIS(Embedded image moved to file:
pic02943.gif)next hit
> > assessments, NAS said.
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> >
> > The (Embedded image moved to file:
pic12637.gif)previous hitbill
> (Embedded
> > image moved to file:
> > pic22409.gif)next hit also authorizes the
(Embedded image moved to
> file:
> > pic26463.gif)previous
> > hitEPA(Embedded image moved to file:
pic05049.gif)next hit
> administrator
> > (Embedded image moved
> > to file: pic04681.gif)previous hitto(Embedded
image moved to file:
> > pic01588.gif)next hit

> > collect and obligate pesticide registration
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> > (Embedded image moved to file:
pic11342.gif)previous hitto(Embedded
> > image moved to file:
> > pic00608.gif)next hit help reduce a backlog of
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> to
> > file: pic32060.gif)
> > previous hitEPA(Embedded image moved to file:
pic01758.gif)next hit
> > pesticide registration decisions.
> >
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> > The full text of House Report 112-331 and the
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> > available at http://(Embedded image moved to
file:
> > pic29954.gif)previous hitappropriations(Embedded
image moved to file:
> > pic20888.gif)next
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hit.house.gov/News/DocumentSingle.aspx?DocumentID=272
625
> > The summary of the (Embedded image moved to
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> pic14146.gif)previous
> > hitomnibus(Embedded image
> > moved to file: pic00690.gif)next hit spending
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> to
> > file: pic07949.gif)
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pic12843.gif)next hit
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pic21430.gif)previous
> > hitappropriations(Embedded image moved to
> > file: pic25620.gif)next hit
> >
> >
.house.gov/UploadedFiles/12.14.11_Final_FY_2012_Appro
priations_Legisla
> > ti
>
> > on_-_Detailed_Summary.pdf
> > .
> > The text of Interior, Environment and Related
Agencies (Embedded

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> > pic00748.gif)previous hitbill(Embedded image
moved to file:
> > pic27067.gif)next hit is available at
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>
http://rules.house.gov/Media/file/PDF_112_1/HR2055CRb
ill/pcConferenceD
> > ivE-BillOCR.pdf.
> >
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>
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letter 12-19-11 ir.docx

{In Archive} RE: NEWS UPDATES: Omnibus Appropriations Bill Directs EPA To Adopt Recommended Changes to IRIS (BNA)

Rusyn, Ivan I to: Kate Guyton 12/19/2011 05:05 PM

History: This message has been replied to.

Archive: This message is being viewed in an archive.

3 is better than all...

> -----Original Message-----
> From: Kate Guyton [
mailto:Guyton.Kate@epamail.epa.gov]
> Sent: Monday, December 19, 2011 4:57 PM
> To: Rusyn, Ivan I
> Subject: Fw: NEWS UPDATES: Omnibus Appropriations
Bill Directs EPA To
> Adopt Recommended Changes to IRIS (BNA)
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>
> See page 34 (or search for "IRIS") at:
>
http://rules.house.gov/Media/file/PDF_112_1/legislati
vetext/HR1540crSOM
> /psConference%20Div%20E%20-%20SOM%20OCR.pdf
>
> Enjoy!
> Kate
>
>
> (Embedded image moved to file:
pic11192.gif)previous
> hitOmnibus(Embedded image moved to file:
> pic07605.gif)next hit (Embedded image moved to
file: pic25264.gif)previous
> hitAppropriations
> (Embedded image moved to file: pic12181.gif)next
hit (Embedded image
> moved to file:
> pic28503.gif)previous hitBill(Embedded image moved
to file:
> pic03829.gif)next hit (Embedded
> image moved to file: pic23775.gif)previous
hitDirects(Embedded image
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> pic20608.gif)next hit (Embedded image moved to
file: pic29292.gif)previous
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> file: pic17549.gif)next
> hit (Embedded image moved to file:
pic29556.gif)previous
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> pic25561.gif)next hit (Embedded image moved to
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> hitRecommended
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> pic29541.gif)previous hitChanges(Embedded image
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> pic26129.gif)next hit (Embedded
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pic29174.gif)previous
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> By Amena H. Saiyid
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> The Environmental Protection Agency would have
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> to file: pic06077.gif)
> previous hitto(Embedded image moved to file:
pic20215.gif)next hit make
> (Embedded image moved
> to file: pic08683.gif)previous hitchanges(Embedded
image moved to file:
> pic08213.gif)next hit
> (Embedded image moved to file:
pic23992.gif)previous hitto(Embedded
> image moved to file:
> pic25824.gif)next hit its chemical risk assessment
program, using
> recommendations by the
> National Academies, under a congressional
directive as part of the fiscal 2012
> spending
> (Embedded image moved to file:
pic05601.gif)previous hitbill(Embedded
> image moved to file:
> pic23392.gif)next hit.
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> The nine-(Embedded image moved to file:
pic15759.gif)previous
> hitbill(Embedded image moved to
> file: pic02670.gif)next hit (Embedded image moved
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> pic26428.gif)previous hitomnibus
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hit (Embedded image
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> pic04084.gif)previous hitappropriations(Embedded

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> pic10075.gif)next hit
> package (H.R. 2055) includes a manager's report
directing the agency
> (Embedded image moved to
> file: pic18786.gif)previous hitto(Embedded image
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> pic15498.gif)next hit (Embedded image moved to
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pic06287.gif)
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pic23847.gif)previous
> hitrecommended(Embedded image
> moved to file: pic32604.gif)next hit (Embedded
image moved to file:
> pic00503.gif)previous hit
> changes(Embedded image moved to file:
pic21221.gif)next hit (Embedded
> image moved to file:
> pic22663.gif)previous hitto(Embedded image moved
to file:
> pic05706.gif)next hit the Integrated
> Risk Information System.
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> In the manager's report, (Embedded image moved to
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> pic02363.gif)previous hitEPA(Embedded
> image moved to file: pic09010.gif)next hit is
directed (Embedded image
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> pic22171.gif)previous hitto(Embedded image moved
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> pic27489.gif)next hit incorporate, as
> appropriate, recommendations (Embedded image moved
to file:
> pic18240.gif)previous hitto
> (Embedded image moved to file: pic12164.gif)next
hit improve (Embedded
> image moved to file:
> pic25542.gif)previous hitIRIS(Embedded image moved
to file:
> pic07619.gif)next hit based on the
> National Academies' National Research Council
April review of the
> (Embedded image moved to
> file: pic20913.gif)previous hitIRIS(Embedded image
moved to file:
> pic07591.gif)next hit
> assessment of formaldehyde.
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> The (Embedded image moved to file:

pic06704.gif)previous
> hitIRIS(Embedded image moved to file:
> pic31818.gif)next hit directive is one of a number
of policy riders in the
> (Embedded image
> moved to file: pic09232.gif)previous
hitappropriations(Embedded image
> moved to file:
> pic00750.gif)next hit (Embedded image moved to
file: pic25205.gif)previous
> hitbill(Embedded
> image moved to file: pic04975.gif)next hit. (See
related story in this issue.)
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> The (Embedded image moved to file:
pic01539.gif)previous
> hitIRIS(Embedded image moved to file:
> pic00303.gif)next hit program has been assailed by
congressional
> Republicans and industry
> advocates, who claim it lacks transparency,
particularly when deciding on
> which studies
> (Embedded image moved to file:
pic11422.gif)previous hitto(Embedded
> image moved to file:
> pic21098.gif)next hit consider when setting
inhalation exposure limits known
> as reference
> concentrations.
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> By March 1, 2012, (Embedded image moved to file:
pic11247.gif)previous
> hitEPA(Embedded image
> moved to file: pic13584.gif)next hit must report
(Embedded image moved to
> file: pic13648.gif)
> previous hitto(Embedded image moved to file:
pic02971.gif)next hit
> Congress on its efforts
> (Embedded image moved to file:
pic17864.gif)previous hitto(Embedded
> image moved to file:
> pic22913.gif)next hit make improvements (Embedded
image moved to file:
> pic11075.gif)previous
> hitto(Embedded image moved to file:
pic21545.gif)next hit (Embedded
> image moved to file:
> pic28712.gif)previous hitIRIS(Embedded image moved
to file:
> pic17546.gif)next hit, and

> (Embedded image moved to file:
pic18678.gif)previous hitto(Embedded
> image moved to file:
> pic01769.gif)next hit explain its reasoning if it
has not incorporated any
> (Embedded image
> moved to file: pic15262.gif)previous
hitrecommended(Embedded image
> moved to file: pic08519.gif)
> next hit (Embedded image moved to file:
pic13985.gif)previous
> hitchanges(Embedded image moved
> to file: pic28289.gif)next hit. Within 18 months
of the (Embedded image
> moved to file:
> pic15944.gif)previous hitomnibus(Embedded image
moved to file:
> pic02865.gif)next hit bill's
> passage, (Embedded image moved to file:
pic18540.gif)previous
> hitEPA(Embedded image moved to
> file: pic23245.gif)next hit is ordered (Embedded
image moved to file:
> pic25508.gif)previous hit
> to(Embedded image moved to file: pic28318.gif)next
hit set up a contract
> with the National
> Academies (Embedded image moved to file:
pic27870.gif)previous
> hitto(Embedded image moved to
> file: pic09601.gif)next hit review up (Embedded
image moved to file:
> pic28323.gif)previous hit
> to(Embedded image moved to file: pic21132.gif)next
hit three (Embedded
> image moved to file:
> pic24472.gif)previous hitIRIS(Embedded image moved
to file:
> pic27152.gif)next hit assessments
> (Embedded image moved to file:
pic25087.gif)previous hitto(Embedded
> image moved to file:
> pic28570.gif)next hit determine whether they
incorporate the NAS
> recommendations.
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> The managers' report also emphasized the need for
(Embedded image
> moved to file: pic29763.gif)
> previous hitEPA(Embedded image moved to file:
pic29901.gif)next hit
> (Embedded image moved to
> file: pic17103.gif)previous hitto(Embedded image
moved to file:
> pic14423.gif)next hit use
> sound, objective, and peer-reviewed science in the

(Embedded image
> moved to file: pic03527.gif)
> previous hitIRIS(Embedded image moved to file:
pic11600.gif)next hit
> assessments.
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> One of the three (Embedded image moved to file:
pic26969.gif)previous
> hitIRIS(Embedded image
> moved to file: pic14015.gif)next hit assessments
the academies must review
> is EPA's assessment
> of the carcinogenic and non-carcinogenic hazards
of inorganic arsenic.
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> NAS Recommendations
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> The NAS critique of the formaldehyde assessment
generally faulted it for
> including long
> descriptions of individual studies, and said the
descriptions should be
> replaced with concise
> statements of findings and tables presenting
evidence. More detailed
> descriptions should be
> included in appendices, NAS said (69 DEN A-1,
4/11/11).
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> NAS also said the opening section should more
fully describe the methods
> used in the
> assessment, in particular the explanations of the
criteria for including or
> excluding certain
> studies and the explanations of the
weight-of-evidence approaches used for
> non-cancer outcomes.
> These also should be expressed through concise
statements and tables, NAS
> said.
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> Another recommendation was (Embedded image moved
to file:
> pic05565.gif)previous hitto(Embedded
> image moved to file: pic00028.gif)next hit develop
standardized evidence for
> all health
> outcomes. Again, NAS said tables should replace
long descriptions of
> findings. A standardized
> approach also is needed for evaluating critical
studies, NAS said.
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> Rationales should be expanded, NAS said, for
selecting the studies
> considered in setting
> reference concentrations (RfCs), which are
inhalation levels that are
> expected (Embedded image
> moved to file: pic21543.gif)previous
hitto(Embedded image moved to file:
> pic25347.gif)next hit
> have no health impacts over an individual's
lifetime.
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> Finally, stronger, more integrative, and more
transparent discussions of the
> weight of evidence
> is needed in (Embedded image moved to file:
pic02088.gif)previous
> hitIRIS(Embedded image moved
> to file: pic02943.gif)next hit assessments, NAS
said.
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> The (Embedded image moved to file:
pic12637.gif)previous hitbill(Embedded
> image moved to file:
> pic22409.gif)next hit also authorizes the
(Embedded image moved to file:
> pic26463.gif)previous
> hitEPA(Embedded image moved to file:
pic05049.gif)next hit administrator
> (Embedded image moved
> to file: pic04681.gif)previous hitto(Embedded
image moved to file:
> pic01588.gif)next hit
> collect and obligate pesticide registration

service fees in accordance with the
> provisions of
> the Pesticide Registration Improvement Renewal Act
(Pub. L. No. 110-94),
> which was enacted
> (Embedded image moved to file:
pic11342.gif)previous hitto(Embedded
> image moved to file:
> pic00608.gif)next hit help reduce a backlog of
(Embedded image moved to
> file: pic32060.gif)
> previous hitEPA(Embedded image moved to file:
pic01758.gif)next hit
> pesticide registration
> decisions.
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> The full text of House Report 112-331 and the
manager's reports are
> available at http://(Embedded
> image moved to file: pic29954.gif)previous
hitappropriations(Embedded
> image moved to file:
> pic20888.gif)next
>
hit.house.gov/News/DocumentSingle.aspx?DocumentID=272
625
> The summary of the (Embedded image moved to file:
pic14146.gif)previous
> hitomnibus(Embedded image
> moved to file: pic00690.gif)next hit spending
(Embedded image moved to
> file: pic07949.gif)
> previous hitbill(Embedded image moved to file:
pic12843.gif)next hit is
> available at http://
> (Embedded image moved to file:
pic21430.gif)previous
> hitappropriations(Embedded image moved to
> file: pic25620.gif)next hit
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>
.house.gov/UploadedFiles/12.14.11_Final_FY_2012_Appro
priations_Legislati
> on_-_Detailed_Summary.pdf
> .
> The text of Interior, Environment and Related
Agencies (Embedded image
> moved to file:
> pic00748.gif)previous hitbill(Embedded image moved
to file:
> pic27067.gif)next hit is available at
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http://rules.house.gov/Media/file/PDF_112_1/HR2055CRb
ill/pcConferenceD

> ivE-BillOCR.pdf.
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{In Archive} IRIS Preamble: 2nd draft

Bob Sonawane to: Ghazi Dannan, Barbara Glenn, Danielle Devoney, Maureen Gwinn, Thomas Bateson, Sury Vulimiri, Nagu Keshava, Deborah Segal, 09/09/2011 09:49 PM

Cc: Kate Guyton, Weihsueh Chiu

Archive: This message is being viewed in an archive.

EICG Staff,

My apology for not forwarding the following email message from Vince Cogliano. Thanks to Kate and Weihsueh for bringing it to my attention.

Bob

Hello everyone -- Thank you for more than a dozen sets of comments on the first draft of the future IRIS Preamble. Your comments identified some areas I had missed and some places where I should've been more precise.

Attached is a second draft, in both redline and clean form. From the amount of "blood" in the redline version, I hope you'll appreciate that I took your comments seriously. If you missed the first round or have additional comments, please send them to me by Friday, Sept 9. I'll try to turn around another draft by the end of the following week, as I believe this is one of our many high priorities.

There's one major comment that would be difficult to address at this time: the evolution of thinking about evidence evaluation that has taken place outside of EPA's health assessment guidelines. The NRC report mentions several systematic reviews and explicitly cites the Cochrane Collaboration, which uses a much more formal system than ours and has separate rating systems for weight of evidence and quality of evidence. This Preamble shouldn't be the vehicle for developing new EPA guidelines (we'd be starting a dozen years behind the still-under-review Benchmark Dose Technical Guidance), but we should probably consider developing harmonized guidelines next year.

Thanks again for all your efforts to make IRIS better,
Vince


IRISpreamble-2draft-clean.docx


IRISpreamble-2draft-redline.docx

----- Forwarded by Vincent Cogliano/DC/USEPA/US on 08/29/2011 07:20 PM -----

From: Vincent Cogliano/DC/USEPA/US
To: Kathleen Deener/DC/USEPA/US@EPA, Amanda Persad/DC/USEPA/US@EPA, Annette Gatchett/CI/USEPA/US@EPA, Audrey Hoffer/DC/USEPA/US@EPA, Becki Clark/DC/USEPA/US@EPA, Belinda Hawkins/CI/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, Dan Petersen/CI/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Debra Walsh/RTP/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Jamie Strong/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Maureen Johnson/DC/USEPA/US@EPA, Michael Troyer/CI/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Paul White/DC/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Samantha Jones/DC/USEPA/US@EPA, Stan Barone/DC/USEPA/US@EPA, Stella Spyropoulos/DC/USEPA/US@EPA, Susan Rieth/DC/USEPA/US@EPA, Ted Berner/DC/USEPA/US@EPA

Date: 08/17/2011 04:43 PM
Subject: Draft introductory material for IRIS

Hello everyone -- Attached you will find draft introductory material that discusses criteria for selecting studies and evaluating evidence. This responds to an NRC recommendation that chapter 1 be expanded to describe the methods of the assessment.

I recommend moving it to the front matter as an indication that it is material that is constant from assessment to assessment, thus residing outside the numbered chapters. I recommend also that each assessment have a Preface that explains assessment-specific matters: why EPA is interested in the agent (is it a hazardous air pollutant, found at Superfund sites, etc) and other special facts (part of a group of 6 phthalates and a cumulative assessment, responding to an NRC recommendation, etc).

I'd like to have something close to final by the end of the month, so if you can get comments to me by Wednesday the 24th, I'll turn around another draft by the following Monday. Please don't recommend making this longer. A strategic goal of this section is to familiarize our peer reviewers with our methods. We know they don't read our guidelines, and they probably won't read anything longer than 10 pages, either. I hope this will give them a better feel for what we do and how we do it.

You may share this with others in NCEA, but please don't send it outside of NCEA at this time.

Thanks,
Vince

[attachment "IRISpreamble.docx" deleted by Vincent Cogliano/DC/USEPA/US]

Kathleen Deener Thanks to everyone for a very productive meetin... 08/11/2011 07:03:32 PM

From: Kathleen Deener/DC/USEPA/US
To: Amanda Persad/DC/USEPA/US@EPA, Annette Gatchett/CI/USEPA/US@EPA, Audrey Hoffer/DC/USEPA/US@EPA, Becki Clark/DC/USEPA/US@EPA, Belinda Hawkins/CI/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, Dan Petersen/CI/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Debra Walsh/RTP/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Jamie Strong/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Maureen Johnson/DC/USEPA/US@EPA, Michael Troyer/CI/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Paul White/DC/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Samantha Jones/DC/USEPA/US@EPA, Stan Barone/DC/USEPA/US@EPA, Stella Spyropoulos/DC/USEPA/US@EPA, Susan Rieth/DC/USEPA/US@EPA, Ted Berner/DC/USEPA/US@EPA, Vincent Cogliano/DC/USEPA/US@EPA
Date: 08/11/2011 07:03 PM
Subject: Re: Fw: NCEA Managers Meeting - August 11

Thanks to everyone for a very productive meeting today! As promised, here are the action items I jotted down in my notes. I've highlighted the responsible person in red (where I know who that is). Please let me know if I've forgotten something.

Status of implementing NAS recommendations :

- Circulate QFRs related to the July 14 IRIS hearing (see attached for most recent version)
- Circulate list of chemical and which "bin" they in (see attached)
- List of items/issues that need to be addressed:
  - framework/chapter 1 or introductory material (Vince has started drafting introductory material; David's group has been working on this as it related to the formaldehyde assessment)
  - consistency across NCEA in terms of page length, what's in the document, what's in an appendix

and what's in HERO (some examples exist -- urea, it sounds like John's group has made changes to the arsenic assessment, Vince has ideas)
    - tables (Paul expressed interest)
    - how to cite guidance in an IRIS assessment (link to document and page number in HERO?)
    - removing section 6 and replacing as an executive summary? (John has arsenic example)
    - should we talk to the programs and regions and find out what they actually need in the document?
- Pick a few chemicals that are in the earlier stages and use them as examples? Some chemicals that could work include: diethyl phthalate; t-butanol; cobalt; copper; ethyl benzene; ETBE
- Circulate draft introductory material that has been developed - Vince

My recollection with the items/issues list is that we would like to form a few small teams to work on some of these.

New peer consultation proposals :

- Lessons learned from dioxin peer consultation workshop - Belinda will circulate list
- Challenges, potential negatives - Paul will circulate list
- Schedule another meeting with the initial group talking about this - Lynn will schedule next meeting

Adding chemicals (table 2 or newly nominated) to the IRIS agenda :

- Revise program/regional input table to include information on Table 2 chemicals - Kacee (to be circulated soon)
- Develop criteria to add chemicals to the agenda (Kacee, Vince or Karen, Annette, David, John, James) - Kacee will schedule an initial meeting
- Vet the final process with Becki and Kevin, then run the list of chemicals (newly nominated and Table 2) through the criteria

Please let me know if I've missed anything or if I didn't get something quite right. Also, if you have an action item, please make sure you take care of it.

[attachment "Tiered approach to implementing NAS Recommendations_bins of chemicals.docx" deleted by Vincent Cogliano/DC/USEPA/US] [attachment "QFRs for 7.14.11 Hearing_NCEA Responses_August 11 2011.docx" deleted by Vincent Cogliano/DC/USEPA/US]

Kacee Deener, MPH

{In Archive} Fw: IRIS Preamble: 2nd draft

Kate Guyton to: Vincent Cogliano 09/09/2011 05:10 PM

Archive: This message is being viewed in an archive.

Hi Vince,

I just received this second version from Weihsueh. I would like to review it, but it won't be by the end of today. I'll send them as soon as I can.
Thanks,
Kate

Kate Z. Guyton, PhD DABT
Toxicologist, NCEA, ORD, US EPA
703-347-8562 | guyton.kate@epa.gov
Mailing Address: US EPA (8623-P), 1200 Pennsylvania Ave. NW, Washington DC 20460
FedEx and Ground Deliveries: Two Potomac Yard (North Building), 2733 S. Crystal Drive, Arlington VA 22202

----- Forwarded by Kate Guyton/DC/USEPA/US on 09/09/2011 05:03 PM -----

From: Weihsueh Chiu/DC/USEPA/US
To: Kate Guyton/DC/USEPA/US@EPA
Date: 09/09/2011 04:46 PM
Subject: Fw: IRIS Preamble: 2nd draft

Bob should have sent it to your group!

Weihsueh Chiu, PhD
Environmental Health Scientist
U.S. Environmental Protection Agency - 8623P
Washington, DC 20460
(703) 347-8607 (voice)
(703) 347-8692 (fax)
chiu.weihsueh@epa.gov

----- Forwarded by Weihsueh Chiu/DC/USEPA/US on 09/09/2011 04:46 PM -----

From: Vincent Cogliano/DC/USEPA/US
To: Kathleen Deener/DC/USEPA/US@EPA, Amanda Persad/DC/USEPA/US@EPA, Annette Gatchett/CI/USEPA/US@EPA, Audrey Hoffer/DC/USEPA/US@EPA, Becki Clark/DC/USEPA/US@EPA, Belinda Hawkins/CI/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, Dan Petersen/CI/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Debra Walsh/RTP/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Jamie Strong/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Maureen Johnson/DC/USEPA/US@EPA, Michael Troyer/CI/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Paul White/DC/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Samantha Jones/DC/USEPA/US@EPA, Stan Barone/DC/USEPA/US@EPA, Stella Spyropoulos/DC/USEPA/US@EPA, Susan Rieth/DC/USEPA/US@EPA, Ted Berner/DC/USEPA/US@EPA
Cc: Mary Ross/RTP/USEPA/US@EPA, Glenn Suter/CI/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Nagu Keshava/RTP/USEPA/US@EPA, Chon Shoaf/RTP/USEPA/US@EPA, Doug Johns/RTP/USEPA/US@EPA, Barbara Glenn/DC/USEPA/US@EPA, Karen Hogan/DC/USEPA/US@EPA, Amanda Persad/DC/USEPA/US@EPA, Paul

White/DC/USEPA/US@EPA, Cheryl Scott/DC/USEPA/US@EPA, John Fox/DC/USEPA/US@EPA, Krista Christensen/DC/USEPA/US@EPA, Leonid Kopylev/DC/USEPA/US@EPA, Jane Caldwell/DC/USEPA/US@EPA, Weihsueh Chiu/DC/USEPA/US@EPA, Jennifer Jinot/DC/USEPA/US@EPA, Jamie Strong/DC/USEPA/US@EPA, John Whalan/DC/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA
Date: 08/29/2011 07:55 PM
Subject: IRIS Preamble: 2nd draft

Hello everyone -- Thank you for more than a dozen sets of comments on the first draft of the future IRIS Preamble. Your comments identified some areas I had missed and some places where I should've been more precise.

Attached is a second draft, in both redline and clean form. From the amount of "blood" in the redline version, I hope you'll appreciate that I took your comments seriously. If you missed the first round or have additional comments, please send them to me by Friday, Sept 9. I'll try to turn around another draft by the end of the following week, as I believe this is one of our many high priorities.

There's one major comment that would be difficult to address at this time: the evolution of thinking about evidence evaluation that has taken place outside of EPA's health assessment guidelines. The NRC report mentions several systematic reviews and explicitly cites the Cochrane Collaboration, which uses a much more formal system than ours and has separate rating systems for weight of evidence and quality of evidence. This Preamble shouldn't be the vehicle for developing new EPA guidelines (we'd be starting a dozen years behind the still-under-review Benchmark Dose Technical Guidance), but we should probably consider developing harmonized guidelines next year.

Thanks again for all your efforts to make IRIS better,
Vince

IRISpreamble-2draft-clean.docx IRISpreamble-2draft-redline.docx

----- Forwarded by Vincent Cogliano/DC/USEPA/US on 08/29/2011 07:20 PM -----

From: Vincent Cogliano/DC/USEPA/US
To: Kathleen Deener/DC/USEPA/US@EPA, Amanda Persad/DC/USEPA/US@EPA, Annette Gatchett/CI/USEPA/US@EPA, Audrey Hoffer/DC/USEPA/US@EPA, Becki Clark/DC/USEPA/US@EPA, Belinda Hawkins/CI/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, Dan Petersen/CI/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Debra Walsh/RTP/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Jamie Strong/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Maureen Johnson/DC/USEPA/US@EPA, Michael Troyer/CI/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Paul White/DC/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Samantha Jones/DC/USEPA/US@EPA, Stan Barone/DC/USEPA/US@EPA, Stella Spyropoulos/DC/USEPA/US@EPA, Susan Rieth/DC/USEPA/US@EPA, Ted Berner/DC/USEPA/US@EPA
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Kate Guyton to: Bob Sonawane 09/09/2011 04:51 PM

Archive: This message is being viewed in an archive.

Hi Bob,

Did you share this with EICG?
Thanks,
Kate

Kate Z. Guyton, PhD DABT
Toxicologist, NCEA, ORD, US EPA
703-347-8562 | guyton.kate@epa.gov
Mailing Address: US EPA (8623-P), 1200 Pennsylvania Ave. NW, Washington DC 20460
FedEx and Ground Deliveries: Two Potomac Yard (North Building), 2733 S. Crystal Drive, Arlington VA 22202

----- Forwarded by Kate Guyton/DC/USEPA/US on 09/09/2011 04:50 PM -----

From: Weihsueh Chiu/DC/USEPA/US
To: Kate Guyton/DC/USEPA/US@EPA
Date: 09/09/2011 04:46 PM
Subject: Fw: IRIS Preamble: 2nd draft

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Environmental Health Scientist
U.S. Environmental Protection Agency - 8623P
Washington, DC 20460
(703) 347-8607 (voice)
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chiu.weihsueh@epa.gov

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My recollection with the items/issues list is that we would like to form a few small teams to work on some of these.

New peer consultation proposals :

- Lessons learned from dioxin peer consultation workshop - Belinda will circulate list
- Challenges, potential negatives - Paul will circulate list
- Schedule another meeting with the initial group talking about this - Lynn will schedule next meeting

Adding chemicals (table 2 or newly nominated) to the IRIS agenda :

- Revise program/regional input table to include information on Table 2 chemicals - Kacee (to be circulated soon)
- Develop criteria to add chemicals to the agenda (Kacee, Vince or Karen, Annette, David, John, James) - Kacee will schedule an initial meeting
- Vet the final process with Becki and Kevin, then run the list of chemicals (newly nominated and Table 2) through the criteria

Please let me know if I've missed anything or if I didn't get something quite right. Also, if you have an action item, please make sure you take care of it.

[attachment "Tiered approach to implementing NAS Recommendations_bins of chemicals.docx" deleted by Vincent Cogliano/DC/USEPA/US] [attachment "QFRs for 7.14.11 Hearing_NCEA Responses_August 11 2011.docx" deleted by Vincent Cogliano/DC/USEPA/US]

Kacee Deener, MPH

{In Archive} Fwd: Chapter 7

Rusyn, Ivan I to: Kate Guyton 01/24/2012 11:45 AM

History: This message has been replied to.

Archive: This message is being viewed in an archive.

Would this work for you?

Ivan Rusyn
Sent from Samsung Galaxy SII

-------- Original message --------
Subject: RE: Chapter 7
From: "Mantus, Ellen" <EMantus@nas.edu>
To: "Rusyn, Ivan I" <iir@unc.edu>
CC:

Hi Ivan,

I spoke with Jim Reisa, and I think that the primary advice is that since they have asked you to talk about the report (that is, represent the report and the Academies) is that you stay within the boundaries of the report and its message. Basically, stick to the report and be consistent with the report in what you say. I have attached the briefing slides that we used for Congress, which had a few more slides on Chapter 7 than the EPA presentation that we used (also attached).

Ellen

Ellen K. Mantus, Ph.D.


Formaldehyde_Congress.ppt


Formaldehyde_EPA_v4.ppt

{In Archive} Fw: IRIS Preamble: 3rd draft

Samantha Jones to: Kate Guyton 09/27/2011 05:32 PM

Archive: This message is being viewed in an archive.

Hi,

Heard you were interested in reviewing...enjoy!

----- Forwarded by Samantha Jones/DC/USEPA/US on 09/27/2011 05:32 PM -----

From: Vincent Cogliano/DC/USEPA/US
To: Kathleen Deener/DC/USEPA/US@EPA, Amanda Persad/DC/USEPA/US@EPA, Annette Gatchett/CI/USEPA/US@EPA, Audrey Hoffer/DC/USEPA/US@EPA, Barbara Glenn/DC/USEPA/US@EPA, Becki Clark/DC/USEPA/US@EPA, Belinda Hawkins/CI/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, Cheryl Scott/DC/USEPA/US@EPA, Chon Shoaf/RTP/USEPA/US@EPA, Dan Petersen/CI/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Debra Walsh/RTP/USEPA/US@EPA, Doug Johns/RTP/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Glenn Suter/CI/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA, Jamie Strong/DC/USEPA/US@EPA, Jane Caldwell/DC/USEPA/US@EPA, Jennifer Jinot/DC/USEPA/US@EPA, John Fox/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, John Whalan/DC/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Karen Hogan/DC/USEPA/US@EPA, Krista Christensen/DC/USEPA/US@EPA, Leonid Kopylev/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Mary Ross/RTP/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Maureen Johnson/DC/USEPA/US@EPA, Michael Troyer/CI/USEPA/US@EPA, Nagu Keshava/RTP/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Paul White/DC/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Samantha Jones/DC/USEPA/US@EPA, Stan Barone/DC/USEPA/US@EPA, Stella Spyropoulos/DC/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA, Susan Rieth/DC/USEPA/US@EPA, Ted Berner/DC/USEPA/US@EPA, Weihsueh Chiu/DC/USEPA/US@EPA, Cheryl Itkin/DC/USEPA/US@EPA, Joe DeSantis/DC/USEPA/US@EPA, Martin Gehlhaus/DC/USEPA/US@EPA
Date: 09/26/2011 03:40 PM
Subject: IRIS Preamble: 3rd draft

Hello everyone -- Thank you again for the second round of your comments on the new Preamble. I'm even happier with the attached third draft (again both clean and redline versions).

I think it's time for senior managers to decide how to roll out the Preamble to agency and interagency reviewers. I'd like to send a stand-alone Preamble to the peer reviewers of our next assessments about two weeks before their pre-meeting comments are due. That should help them know much more about our assessments and guidelines than they typically do.

Thanks again for all your efforts to strengthen IRIS,
Vince

IRISpreamble-3draft-clean.docx IRISpreamble-3draft-redline.docx

Vincent Cogliano Hello everyone -- Thank you for more than a doz... 08/29/2011 07:55:45 PM

From: Vincent Cogliano/DC/USEPA/US
To: Kathleen Deener/DC/USEPA/US@EPA, Amanda Persad/DC/USEPA/US@EPA, Annette

Gatchett/CI/USEPA/US@EPA, Audrey Hoffer/DC/USEPA/US@EPA, Becki Clark/DC/USEPA/US@EPA, Belinda Hawkins/CI/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, Dan Petersen/CI/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Debra Walsh/RTP/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Jamie Strong/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Maureen Gwinn/DC/USEPA/US@EPA, Maureen Johnson/DC/USEPA/US@EPA, Michael Troyer/CI/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Paul White/DC/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Samantha Jones/DC/USEPA/US@EPA, Stan Barone/DC/USEPA/US@EPA, Stella Spyropoulos/DC/USEPA/US@EPA, Susan Rieth/DC/USEPA/US@EPA, Ted Berner/DC/USEPA/US@EPA

Cc: Mary Ross/RTP/USEPA/US@EPA, Glenn Suter/CI/USEPA/US@EPA, Sury Vulimiri/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Nagu Keshava/RTP/USEPA/US@EPA, Chon Shoaf/RTP/USEPA/US@EPA, Doug Johns/RTP/USEPA/US@EPA, Barbara Glenn/DC/USEPA/US@EPA, Karen Hogan/DC/USEPA/US@EPA, Amanda Persad/DC/USEPA/US@EPA, Paul White/DC/USEPA/US@EPA, Cheryl Scott/DC/USEPA/US@EPA, John Fox/DC/USEPA/US@EPA, Krista Christensen/DC/USEPA/US@EPA, Leonid Kopylev/DC/USEPA/US@EPA, Jane Caldwell/DC/USEPA/US@EPA, Weihsueh Chiu/DC/USEPA/US@EPA, Jennifer Jinot/DC/USEPA/US@EPA, Jamie Strong/DC/USEPA/US@EPA, John Whalan/DC/USEPA/US@EPA, Glinda Cooper/DC/USEPA/US@EPA

Date: 08/29/2011 07:55 PM

Subject: IRIS Preamble: 2nd draft

Hello everyone -- Thank you for more than a dozen sets of comments on the first draft of the future IRIS Preamble. Your comments identified some areas I had missed and some places where I should've been more precise.

Attached is a second draft, in both redline and clean form. From the amount of "blood" in the redline version, I hope you'll appreciate that I took your comments seriously. If you missed the first round or have additional comments, please send them to me by Friday, Sept 9. I'll try to turn around another draft by the end of the following week, as I believe this is one of our many high priorities.

There's one major comment that would be difficult to address at this time: the evolution of thinking about evidence evaluation that has taken place outside of EPA's health assessment guidelines. The NRC report mentions several systematic reviews and explicitly cites the Cochrane Collaboration, which uses a much more formal system than ours and has separate rating systems for weight of evidence and quality of evidence. This Preamble shouldn't be the vehicle for developing new EPA guidelines (we'd be starting a dozen years behind the still-under-review Benchmark Dose Technical Guidance), but we should probably consider developing harmonized guidelines next year.

Thanks again for all your efforts to make IRIS better,
Vince

[attachment "IRISpreamble-2draft-clean.docx" deleted by Vincent Cogliano/DC/USEPA/US] [attachment "IRISpreamble-2draft-redline.docx" deleted by Vincent Cogliano/DC/USEPA/US]

----- Forwarded by Vincent Cogliano/DC/USEPA/US on 08/29/2011 07:20 PM -----

From: Vincent Cogliano/DC/USEPA/US

To: Kathleen Deener/DC/USEPA/US@EPA, Amanda Persad/DC/USEPA/US@EPA, Annette Gatchett/CI/USEPA/US@EPA, Audrey Hoffer/DC/USEPA/US@EPA, Becki Clark/DC/USEPA/US@EPA, Belinda Hawkins/CI/USEPA/US@EPA, Bob Sonawane/DC/USEPA/US@EPA, Dan Petersen/CI/USEPA/US@EPA, Darrell Winner/DC/USEPA/US@EPA, David Bussard/DC/USEPA/US@EPA, Debra Walsh/RTP/USEPA/US@EPA, Gina Perovich/DC/USEPA/US@EPA, Jamie Strong/DC/USEPA/US@EPA, John Vandenberg/RTP/USEPA/US@EPA, Karen Hammerstrom/DC/USEPA/US@EPA, Lynn Flowers/DC/USEPA/US@EPA, Maureen

Gwinn/DC/USEPA/US@EPA, Maureen Johnson/DC/USEPA/US@EPA, Michael Troyer/CI/USEPA/US@EPA, Norman Birchfield/DC/USEPA/US@EPA, Paul White/DC/USEPA/US@EPA, Reeder Sams/RTP/USEPA/US@EPA, Samantha Jones/DC/USEPA/US@EPA, Stan Barone/DC/USEPA/US@EPA, Stella Spyropoulos/DC/USEPA/US@EPA, Susan Rieth/DC/USEPA/US@EPA, Ted Berner/DC/USEPA/US@EPA

Date: 08/17/2011 04:43 PM

Subject: Draft introductory material for IRIS

Hello everyone -- Attached you will find draft introductory material that discusses criteria for selecting studies and evaluating evidence. This responds to an NRC recommendation that chapter 1 be expanded to describe the methods of the assessment.

I recommend moving it to the front matter as an indication that it is material that is constant from assessment to assessment, thus residing outside the numbered chapters. I recommend also that each assessment have a Preface that explains assessment-specific matters: why EPA is interested in the agent (is it a hazardous air pollutant, found at Superfund sites, etc) and other special facts (part of a group of 6 phthalates and a cumulative assessment, responding to an NRC recommendation, etc).

I'd like to have something close to final by the end of the month, so if you can get comments to me by Wednesday the 24th, I'll turn around another draft by the following Monday. Please don't recommend making this longer. A strategic goal of this section is to familiarize our peer reviewers with our methods. We know they don't read our guidelines, and they probably won't read anything longer than 10 pages, either. I hope this will give them a better feel for what we do and how we do it.

You may share this with others in NCEA, but please don't send it outside of NCEA at this time.

Thanks,
Vince

[attachment "IRISpreamble.docx" deleted by Vincent Cogliano/DC/USEPA/US]

Kathleen Deener	Thanks to everyone for a very productive meetin...	08/11/2011 07:03:32 PM

{In Archive} Fw: NEWS UPDATES: GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process (Risk Policy Report)

Kate Guyton to: woodrufft, Sutton, Patrice 07/06/2011 02:31 PM

Archive: This message is being viewed in an archive.

Could GRADE help...?

Here's the letter:

June 30 letter.pdf

Thanks,
Kate

Kate Z. Guyton, PhD DABT
Toxicologist, NCEA, ORD, US EPA
703-347-8562 | guyton.kate@epa.gov
Mailing Address: US EPA (8623-P), 1200 Pennsylvania Ave. NW, Washington DC 20460
FedEx and Ground Deliveries: Two Potomac Yard (North Building), 2733 S. Crystal Drive, Arlington VA 22202

----- Forwarded by Kate Guyton/DC/USEPA/US on 07/06/2011 02:30 PM -----

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GOP Senators Broaden EPA Science Attacks To Criticize NAAQS Process

Posted: July 1, 2011

Two key GOP senators are stepping up their attacks on EPA science by criticizing "defects" in the scientific review process for EPA's national ambient air quality standards (NAAQS), drawing parallels between flaws in the NAAQS program and criticisms of scientific errors in EPA's risk assessment for the chemical formaldehyde.

Sens. James Inhofe (R-OK), ranking member on the Environment & Public Works Committee, and panel member David Vitter (R-LA) sent a June 30 letter to EPA Administrator Lisa Jackson asking more than a dozen "important questions of scientific integrity" targeting several aspects of the NAAQS process, including how EPA selects scientific studies for reviews of its standards, the weight of evidence methodology EPA uses, and uncertainties in the process.

Inhofe and other Republicans have long criticized the agency for pursuing stricter NAAQS, which regulate six criteria pollutants including ozone and fine particulate matter (PM2.5). States must craft air quality plans that outline the pollution cuts they will impose on industry to come into, or stay in, attainment with the standards. Critics say that ever-tightening standards lead to increasingly expensive pollution controls that harm states' economies.

Industry, Republicans and others have, for example, criticized EPA's proposal to tighten the Bush EPA's 2008 ozone standard of 75 parts per billion (ppb) to a range within 60 to 70 ppb as supported by its science advisers.

Under the Clean Air Act EPA is barred from considering costs when setting NAAQS, and must propose changes to its standards based on science on the risks of exposure to a criteria pollutant. But Vitter and Inhofe say there are "fundamental problems to assuring high-quality, unbiased scientific results" in the NAAQS process.

The letter signals the senators stepping are up their broad attacks on EPA data, after touting recent a National Academy of Sciences' (NAS) critique of EPA's risk assessment of formaldehyde, to raise broad questions about the validity of other agency science, such as the data that EPA uses to justify its air quality standards. For example, speaking at a June 8 hearing of several Senate Environment & Public Works subcommittees on the impacts of EPA's air quality rules, Vitter questioned the legitimacy of EPA air rules and the agency's actions in general based on the NAS' conclusions in its review of the Integrated Risk Information System assessment of formaldehyde.

The NAS review, released in April, found that EPA did not provide sufficient evidence to support its conclusions that human exposure to formaldehyde can cause leukemia or Hodgkin lymphoma, and raised additional concerns about the agency's process for reaching weight of evidence conclusions in its risk assessments.

Industry and Republicans have called on EPA to adopt NAS' recommendations for the chemical risk assessment program, including putting pending assessments on hold until the changes have been made.

"The same scientific defects noted in the formaldehyde assessment are also present in EPA's evaluations of the science used to establish and revise" NAAQS, the senators write in their June 30 letter. Their critiques over the NAAQS process come despite the fact that NAS praised EPA's updated risk assessment practices for setting criteria pollutant standards. *The letter is available on InsideEPA.com.* (*Doc ID:* 2368871)

The senators question the process EPA uses to decide which studies to cite when determining air quality standards, arguing that "Current methods for selecting studies appear to systematically exclude or discount well conducted, peer reviewed studies that show no adverse health effects from air pollution at or below current air quality standards."

They add that, "Current methods for weighing evidence allow EPA to discount multiple no-effect studies and rely instead on single studies showing an effect," and that "Current practices do not provide for a comprehensive analysis of uncertainty and variability as a way to make risk assessments more useful for decision makers."

The letter points to a number of specific examples where the senators charge that "EPA has discounted or ignored studies" that find no association between a pollutant and a particular health outcome -- including between ozone and asthma, ozone and cardiovascular morbidity and PM2.5 and chronic mortality.

Vitter and Inhofe also raise concerns with use of a 2006 study that found asthma symptoms for nitrogen dioxide (NO_2) but not for ozone. "In the NO_2 NAAQS review, EPA states that this study provides strong evidence for the health effects of NO_2 . . . whereas in the 2008 ozone NAAQS review and reconsideration, EPA notes many reasons why the results of the study should be ignored, including the fact that only 12 children per day were evaluated and that the authors did not clearly define the severity of asthma in the study subjects."

The senators ask Jackson more than a dozen questions, including asking

whether EPA has "a policy of consistently disregarding studies misinforms the public and leads to inflated and highly uncertain estimates of public health risks" and why EPA has failed to conduct a quantitative uncertainty analysis on PM2.5 exposure.
The senators ask for a reply by July 8. With EPA planning to release its revised ozone standard later this month and other NAAQS reviews pending, the senators say, "Given the timeframe with which we are dealing the need for your prompt response to these important questions of scientific integrity cannot be understated. The economy and many of our fellow Americans are suffering. To further perpetuate the problems of high unemployment and poverty without strong scientific and economic support for EPA's calculated efforts would be unwise."
Elsewhere in the letter, the senators also note that EPA has not yet replied to their May 10 letter asking how EPA has implemented recommendations from NAS to address concerns with the formaldehyde assessment. -- *Victoria Finkle*

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