Message

From: Bahadori, Tina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7DA7967DCAFB4C5BBC39C666FEE31EC3-BAHADORI, TINA]
Sent: 12/6/2017 2:28:37 PM
To: Robert Kavlock [rkavlock@gmail.com]
Subject: RE: 2 IRIS stories from Inside EPA
Attachments: IRIS-Interagency Meeting 25SEP17.pdf; IRIS BEST 100617_2.pptx

We have it on slide 10 in the IRIS Interagency Workgroup Meeting. We also mentioned it a this NAS BEST meeting in the context of slide 8. If I find more, I'll send your way. Both slide decks are attached.
Tina

From: Robert Kavlock [mailto:rkavlock@gmail.com]
Sent: Wednesday, December 6, 2017 8:58 AM
To: Bahadori, Tina <Bahadori.Tina@epa.gov>
Subject: Re: 2 IRIS stories from Inside EPA

Ex. 5 - Deliberative Process

On Dec 6, 2017, at 7:26 AM, Bahadori, Tina <Bahadori.Tina@epa.gov> wrote:

Ex. 5 - Deliberative Process

Tina

From: D'Amico, Louis
Sent: Tuesday, December 5, 2017 11:18 AM
To: Thayer, Kris <thayer.kris@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Bahadori, Tina <Bahadori.Tina@epa.gov>
Subject: Fwd: 2 IRIS stories from Inside EPA

FYI.

(202) 564-4605 (o)
Ex. 6 - Personal Privacy

Sent from my iPhone
(Please pardon brevity and typos)

Begin forwarded message:

> **From:** "McGuinness, Moira" <McGuinness.Moira@epa.gov>
> **Date:** December 5, 2017 at 11:15:34 AM EST
> **To:** "D'Amico, Louis" <DAmico.Louis@epa.gov>, "Lehman, Rachel"

<lehman.rachel@epa.gov>
Cc: "Hubbard, Carolyn" <Hubbard.Carolyn@epa.gov>
Subject: 2 IRIS stories from Inside EPA

Industry Asks EPA To Consider Benefits, Endogenous Issue In IRIS Analysis

Industry is urging EPA to consider additional issues in its upcoming analysis of the human health risks of exposure to nitrate and nitrite, including conducting a risk-benefit analysis of nitrate's dietary benefits, setting a policy on endogenous chemicals before completing the assessment, and reviewing the existing assessment of perchlorate.

Any one of these requests would greatly complicate EPA's assessment of nitrate and nitrite, one of three new Integrated Risk Information System (IRIS) assessments that the program's new leaders announced in September with scoping documents for public comment.

While EPA's Chemical Assessment Advisory Committee (CAAC), a subpanel of its Science Advisory Board, has been generally supportive of the agency's plans for the upcoming IRIS assessments, PepsiCo and the Western Growers' Association are arguing that EPA's plans were too narrow in scope.

PepsiCo's comments, for example, reminded EPA of the dietary benefits of eating vegetables, often high in nitrates.

"[A] complete evaluation of nitrate/nitrite should use an established method for the evaluation of benefit-risk, such as the benefit-risk analysis for foods ("Brafo"). Further, it is difficult to understand why the Agency has elected not to consider benefits in the assessment, particularly when it is acknowledged that environmental exposures (i.e., those that will be regulated using output from the IRIS assessment) to nitrates are minor contributors relative to dietary sources (~80%)," according to the Oct. 23 comments from PepsiCo's consultant, ToxStrategies. *The comments are available on InsideEPA.com. (Doc. ID: 207435)*

"Without acknowledging benefits as part of a comprehensive evaluation, the potential for public confusion exists (e.g., should eating a healthy diet high in vegetable content be avoided because of the nitrate exposure?)."

ToxStrategies also urges EPA to consider risk-benefit assessments conducted by the European Food Safety Authority (EFSA) in addition to the 2017 assessment by the Agency for Toxic Substances and Disease Registry that EPA references in its scoping document for the analysis.

EFSA's 2008 assessment of nitrates in vegetables concluded that the estimated exposures from eating the vegetables are unlikely to result in appreciable health risks, and therefore the recognized beneficial effects of consumption of vegetables prevail, ToxStrategies says. This holds true even in circumstances in which exposure to nitrates via vegetables alone would exceed the acceptable daily intake by slightly more than two-fold, the comments add.

EPA and the Food and Drug Administration considered using risk-benefit analysis to assess methylmercury, which contaminates some seafood. But the updated fish consumption advisory for women of childbearing age and children, released at the end of the Obama administration, did not rely on risk-benefit analysis.

EPA last assessed nitrate/nitrite in 1991, and in scoping documents for the upcoming assessment, the agency explains that "Since 1987, a growing body of literature indicates potential associations between nitrate/nitrite exposure and other noncancer health effects. Some epidemiological studies also suggest an increased risk of cancer, especially gastric cancer, associated with dietary nitrite exposure" (*Risk Policy Report*, Sept. 26).

ToxStrategies also pushes EPA to develop a policy on assessing the human health risks of an endogenous substance -- one that exists naturally in the body, as well as being produced by commercial or industrial processes and potentially contaminating the environment, such as formaldehyde, methanol and nitrate.

As industry stakeholders argued with another endogenous chemical, methanol, ToxStrategies says EPA should develop such a policy before attempting the nitrate/nitrite assessment.

The American Chemistry Council (ACC) in 2013 urged EPA to hold a workshop on the endogenous issue, arguing that EPA should account for such endogenous levels or else the agency will set risk values at or below background levels, resulting in regulatory standards that will be difficult for industry to meet (*Risk Policy Report*, Oct. 22, 2013).

In its final 2013 assessment of methanol's non-cancer risks, EPA provided a novel analysis of how it differentiated between exogenous and endogenous exposures, but did not address the call for a broader endogenous policy (*Risk Policy Report*, Oct. 1, 2013).

ToxStrategies notes that EPA in its scoping document identifies "the role of endogenous and exogenous nitrate toxicity as a key scientific issue. Both endogenous and exogenous nitrate/nitrite are reduced to nitric oxide . . . essential for normal functioning of the brain, arteries, immune system, and others. The Agency has not routinely integrated endogenous/exogenous exposures into IRIS assessments, nor has the Agency developed guidance on how to do so. As such, the plan for differentiating exposures associated with normal physiological processes, such as maintenance of blood pressure, from exposures associated with potential adverse effects has not been

sufficiently addressed in the draft assessment plan. Further delineation and explanation of the plan for this complex topic is warranted -- including an opportunity for the public to comment on such."
Meanwhile, Western Growers, a trade group representing Arizona, California and Colorado fruit, nut and vegetable growers, is also urging EPA to expand its analyses, pressing the agency to reconsider its assessment of the rocket fuel perchlorate alongside the nitrate/nitrite assessment because they can have similar effects on the human thyroid hormone. EPA has been struggling for years to craft a health-based standard for perchlorate in drinking water, and is now operating under court-ordered deadlines to do so.
Western Growers remind EPA that perchlorate and nitrate/nitrite share the same health effect -- disruption of the thyroid -- and biological mode of action -- inhibiting the thyorid's ability to uptake iodine, which the thyorid needs to regulate properly.
"As USEPA proceeds with its IRIS nitrate/nitrite assessment, we believe it should also re-evaluate the inconsistency of a more conservative point of departure for perchlorate, especially in light of the fact that nitrate is known to account for much more of the [iodine uptake inhibition] burden at the thyroid than perchlorate. Moreover, re-evaluation of the perchlorate IRIS assessment should be a priority given that USEPA is currently considering the need for a National Primary Drinking Water Standard for perchlorate, and adoption of such standard could have widespread operational impacts on drinking water utilities and economic impacts on their customers. It could also undermine public confidence in the safety of foods containing low levels of perchlorate, leading to dietary changes that compromise public health."
The growers also urge EPA to consider an ongoing review of nitrate's health effects in drinking water by California's Office of Environmental Health Hazard Assessment (OEHHA).
California's draft document "specifically concludes that thyroid effects should not be used as the basis for a revised [public health goal] due to a lack of consistency in study results, lack of adjustment for iodine status, possible measurement bias, and limitations in ecologic assessments of exposure. OEHHA's interpretation recognizes that these studies are not sufficiently robust to support risk assessment or risk-based regulatory decision-making." -- *Maria Hegstad*

Industry Argues TSCA Program Obviates Need For Ethylbezene IRIS Analysis

An industry group is arguing that EPA's influential but controversial Integrated Risk Information System (IRIS) program should halt its plans to reassess ethlybenzene because the chemical is in line to be assessed by the new risk evaluation program required by the updated Toxic Substances Control Act (TSCA), and should be assessed by that program instead.
"The agency is required by statute to determine whether conditions of use for ethylbenzene present an unreasonable risk to human health or the environment based on a comprehensive, weight of the evidence review using the best available scientific information. An IRIS review is not a substitute for the TSCA Prioritization and Risk Evaluation processes," the Styrene Information and Research Council (SIRC) states in its Oct. 18 comments on draft scoping documents that EPA's IRIS program has prepared to update its 1991 assessment of ethylbenzene. *The comments are available on InsideEPA.com. (Doc. ID: 207439)*
The comments echo previous statements from industry stakeholders who questioned whether the IRIS program was relevant after Congress revised TSCA in the summer of 2016. Some longtime industry IRIS observers, many of whom have often criticized the IRIS program for producing what they consider to be overly strict risk analyses that they worry will lead to stringent regulations, argued that the new TSCA risk evaluation program will make the IRIS program redundant.
The Obama EPA intended to continue the IRIS program, with that administration's toxics chief, Jim Jones, telling *Inside EPA* that the toxics office would rely on IRIS in conducting TSCA analyses, where IRIS assessments existed, because of the toxics office's limited risk assessment experience.
But it is unclear how or whether the Trump EPA intends to incorporate the IRIS program. The president's fiscal year 2018 budget proposes greatly reducing its budget, while the Senate's proposed FY18 budget has language attached to it that would eliminate IRIS entirely.
SIRC notes that "the TSCA amendments implement strict deadlines to ensure EPA is accountable in completing each step of the chemical risk evaluation process expeditiously, and requires EPA to complete an aggressive workload within these time frames."
The statute gives EPA one year to determine whether a chemical is high or low priority, and three years to complete an assessment of a chemical deemed high priority. To keep the assessments on track, the statute also requires that EPA must have underway at least 20 high priority substances by Dec. 22, 2019.
The IRIS program, housed in EPA's research office, does not have any statutory requirements, and was crafted by IRIS staff in the 1980s to ensure consistency in risk estimates across EPA offices and programs. The IRIS program has long focused on existing chemicals -- those that were on the market when the original TSCA was enacted in 1976 and were largely grandfathered from regulation. These are the same group of chemicals -- number unknown but anticipated in the tens of thousands -- that the reformed TSCA directs EPA's chemicals office to assess.
But SIRC suggests that for "a pragmatic approach to chemical risk assessment, . . . the IRIS Program office defer to the Office of Chemical Safety and Pollution Prevention, and perhaps provide support to the staff implementing risk evaluations under TSCA. . . . SIRC recommends that

EPA cease an unnecessary IRIS assessment and support the TSCA program to not only save the IRIS program significant time and resources, but ensure chemical reviews are performed efficiently and consistent with the strict standards" in the revised TSCA.
SIRC further argues that IRIS should cease its assessment of ethylbenzene because ethylbenzene is already controlled by regulations based on the existing IRIS assessment, which is stricter than necessary, the group states. SIRC argues that "the necessity of an IRIS review disappears when those regulations are based on health values that are protective or overly protective," such as the IRIS reference concentration and reference dose values, "and when the agency has conducted risk reviews and found the regulations to be protective of human health and the environment."
SIRC in this case is citing a 2006 review of existing air regulations. EPA explains in its draft scoping document for ethylbenzene that the update was requested by several agency offices, including the Office of Land and Emergency Management (OLEM), multiple regional offices, Office of Air and Radiation (OAR), the water office and the toxics office, according to the recently released EPA documents.
IRIS staff conducted preliminary work to prepare for an ethylbenzene assessment in 2014. The IRIS program's new leaders, Kris Thayer and Tina Bahadori, stated in a September presentation that they confirmed with other agency offices that the chemical assessment is still a "current Agency need."
"As noted, measured human exposures of ethylbenzene in North America are low (generally <10 [parts per billion]), which is well below toxic effects of concern (750 [parts per million] tumors), and emissions of ethylbenzene have been declining. Industrial production of ethylbenzene accounts for less than 1% of exposure," SIRC says.
The group argues these figures plus conclusions in a 2015 publication and an earlier industry-backed assessment conducted through a voluntary Bush EPA program "demonstrate how the exposure, toxicology and risk information point to a single conclusion. EPA must indefinitely postpone, if not end, its IRIS review of ethylbenzene." – *Maria Hegstad*

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