Message

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Sent: 1/23/2014 7:30:26 PM
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Subject: FW: With Burke Pending At ORD, EPA Steps Up Push To Adopt Key NAS Advice

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From: McGartland, Al
Sent: Thursday, January 23, 2014 2:29 PM
To: Bender, Michael
Subject: Fw: With Burke Pending At ORD, EPA Steps Up Push To Adopt Key NAS Advice

Composed on blackberry. Please excuse typos and brevity

From: Axelrad, Daniel
Sent: Wednesday, January 22, 2014 1:09:30 PM
To: McGartland, Al; Ohanian, Edward; Chiu, Weihsueh; Dockins, Chris
Subject: With Burke Pending At ORD, EPA Steps Up Push To Adopt Key NAS Advice

This starts out discussing the STPC workgroup, but then goes into quite a bit of detail on Weihsueh's presentation at SRA.

Risk Policy Report - 01/21/2014

With Burke Pending At ORD, EPA Steps Up Push To Adopt Key NAS Advice

Posted: January 17, 2014

Top EPA science officials are considering a series of responses to a key National Academy of Sciences (NAS) report on how to improve the agency's risk assessment practices, an effort that officials have long struggled to adopt but is now gaining ground as the report's lead author, Johns Hopkins University Associate Dean Thomas Burke, is awaiting Senate confirmation to lead EPA's research office.

EPA's Science Technology and Policy Council (STPC), a group of science policy makers chaired by the agency's Science Advisor, Glenn Paulson, is reviewing a lengthy list of efforts the agency could undertake to implement various recommendations in the NAS' 2009 report, "Science and Decisions: Advancing Risk Assessment," agency sources say.

One source says that with Burke set to become the research office's chief, the recommendations in the report and how to implement them have taken on greater urgency and meaning. "I'm sure he'll be sympathetic to the initiative to push it through, and will also have some opinions of his own" on which projects should be prioritized, the source says.

The most recent STPC meeting, held last month, largely centered around discussing the potential response projects, sources say. "People in the agency have until the end of the month to provide comments on activities we might initiate," the source says. Once those activities are selected, "the next job is to come up with implementation plans and resources."

Until now, agency officials have struggled with how to implement advice in "Science And Decisions," as well as a series of other NAS studies issued around the same time, including the 2007 publication "Toxicity Testing in the Twenty-first Century: A Vision and a Strategy" and a third NAS report, "Phthalates and Cumulative Risk Assessment: The Task Ahead," issued in 2008. All of the reports are considered influential, though the advice in "Science and Decisions" and the phthalates report, if adopted, is likely to be controversial as some of the recommendations could make risk assessments more conservative.

The phthalates report urged the agency to produce an assessment of the risk of the group of chemicals rather than assessing individual phthalates, which are commonly found in plastics, as well as in other applications. Its authors also broadened its recommendations to suggest that EPA step away from performing individual risk assessments and perform cumulative assessments on chemicals that target the same organ or health effect.

"Science and Decisions" has a broader focus, and suggests improvements to EPA risk assessment ranging from better scoping an assessment's goals and potential solutions before beginning the assessment to technical issues such as unifying how assessments of cancer and non-cancer risks are conducted.

In an interview with *Risk Policy Report* shortly after the report's release, Burke described it as an effort to break logjams that often occur in risk assessment as the agency and others seek more and more information to reduce uncertainties in the analyses, but also delay decisionmaking (*Risk Policy Report*, Dec. 9, 2008).

Environmentalists have urged EPA to adopt NAS' advice, focusing particularly on the "Science and Decisions" report, calls that put pressure on the agency to make their risk assessments more protective. But advocates are at odds with industry groups, who are urging EPA to adopt a narrower set of risk assessment reforms drawn from "Science and Decisions" as well as recommendations detailed in chapter of a 2011 NAS report criticizing the agency's draft assessment of formaldehyde.

EPA's first response to the Science and Decisions recommendations, a framework for human health risk assessment to inform decision making, is expected to be released soon. A draft was peer reviewed in 2012.

The document responds to "Science and Decisions" recommendations that EPA seek to improve the utility of its assessments by scoping its risk assessments at their outset, and even consider what risk management options are available before starting an assessment so that an assessment is most relevant to the questions and risk management decisions at issue. The finalized document is estimated for release in early 2014, according to a presentation at the Society for Risk Analysis annual meeting in Baltimore Dec. 10 by EPA's Julie Fitzpatrick.

Agency risk assessors and economists have also embarked on a project credited to recommendations in "Science and Decisions": an effort to better link risk assessment and the economic analysis required for many rulemakings, according to a presentation from EPA's Weishueh Chiu also at the Society for Risk Analysis' annual meeting Dec. 10.

Chiu said that agency toxicologists and economists have created a working group called the morbidity group, which has held an internal workshop and a series of meetings to tackle the particularly difficult challenge of monetizing non-cancer risk estimates.

In his remarks, Chiu explained that the workgroup was initiated "partly in response to 'Science and Decisions' and these sort of urgent needs for more quantified benefits..."

Chiu explains that "One of the key drivers here is that for major regulatory decisions, regulatory benefit cost analysis is a significant part of the decision-making process. It's required by statue for many regulations." Chiu adds that "One of the ... key missing links" for doing so "is that particularly for non-cancer benefits," where risk assessments such as the agency's influential Integrated Risk Information System (IRIS) assessments that Chiu oversees result in non-cancer risk estimates like reference doses (RfDs), acceptable daily intakes, or hazard quotients, "there's really no way to monetize the benefits of either going down to RfD or above or below the RfD what the benefits of those different types of decisions might be."

In contrast, EPA's cancer risk assessments result in risk estimates that can be set at various risk levels, often 1 in 10,000 or 1 in 1 million excess cancer cases. These numbers can be monetized, in part because it is possible to weigh the costs of a standard set at 1 in 10,000 excess cases of cancer with a standard set to protect against 1 in 1 million excess cancer cases. Additionally, there is

economic research into the costs of cancer treatment and individuals' willingness to pay to avoid developing cancer, research that is not available for many other effects seen in toxicology studies that are often the basis for non-cancer assessments.

Chiu explained that "the usual risk assessments like we do in IRIS, are really aimed at ... ensuring or predicting the absence of effects. The RFD is defined as, essentially, we want to ensure with a reasonable level of confidence there aren't deleterious effects in the population... And that can be used for policy decisions in a number of contexts. But if you want to go through economic analysis to inform policy, then you actually have to predict the occurrence of effects, because to make a regulatory change . . . you're changing the occurrence of effects and then you can monetize them."

Chiu outlined several challenges to applying economic analysis to non-cancer risk assessments that agency toxicologists and economists discussed at their internal workshop. Chiu noted the importance of establishing a causal relationship between an environmental exposure and an effect, and detailing a complete dose-response relationship.

"One of the questions is for noncancer effects, we don't have . . . a set of weight of evidence descriptors outside of the criteria pollutants for doing this," Chiu said. EPA's IRIS program has taken some criticism from industry groups for not providing these kinds of descriptors for non-cancer effects, which are routinely applied in cancer assessments. "We're certainly working on developing weight of evidence approaches."

On his presentation slides, Chiu noted that "It may be useful to have Guidance on whether and how to include health effects in benefits analysis based on weight of evidence."

A second issue Chiu outlined is that "in many cases noncancer effects are reported as markers or precursors and not necessarily the ultimate monetizable [health] effect. So this means the data we have doesn't inform something that is ultimately monetizable." Chiu gave examples such as organ weight changes in toxicology studies, which are frequent findings used for non-cancer risk estimates. "But that is not something that economists can [develop] willingness to pay for or some sort of diagnosable disease... This might require then sort of taking what we know from toxicology and using other data to make these linkages to known human effects."

Chiu outlined the extensive steps that would be necessary to perform such an analysis, starting with the importance of a fully described dose-response function. "In order to be able to translate this animal exposure data into something we can potentially monetize, we actually probably need the entire dose-response function. And then we would extrapolate this dose-response into what would the typical human's dose-response function would be," Chiu said. This information might be insufficient for economic analysis, Chiu added, if the effect of concern in the animal studies is not "something that we could establish a cost for. So then you need a subsequent step to translate that effect ... into something we can monetize."

Additionally, the process would call for increased uncertainty analysis, a long-controversial issue within EPA risk assessors. The practice was a major focus of Bush administration research chief George Gray, but he met with significant pushback to implementing the practice within the IRIS program. But Chiu noted that "now we want not just conservative end [risk estimates] . . . but actually the whole uncertainty distribution... So uncertainty analysis in each step."

In response to questions after his remarks, Chiu acknowledged the complexity of the process. He noted that during the internal workshop, staff discussed how to screen and select chemicals to undergo such intensive analyses, which would provide the most "bang for the buck" for undergoing the effort. -- *Maria Hegstad*