

**Comments of the Environmental Defense Fund to
EPA's SAB Chemical Assessment Advisory Committee (CAAC)
Briefing on the IRIS program and the Development of IRIS Toxicological Reviews**

April 3, 2013

Good morning. I am Dr. Richard Denison, senior scientist at the Environmental Defense Fund. In my comments today, I would like to address two issues: first, the matter of conflict of interest and bias, and second, the need to balance getting the science right with timeliness of IRIS assessments.

Conflict of interest and bias

I have noted with some concern the Science Advisory Board's (SAB) staff's indication that the members of the CAAC have not been screened for conflict of interest (COI) or appearance of impartiality, and instead that these screens will be done when subsets of the members are designated for specific Integrated Risk Information System (IRIS) reviews.

This has several implications. First, this committee needs to diligently refrain from providing advice or input to EPA in the absence of a COI and impartiality screen. While this meeting is being described as fact-finding, in my view some of the discussion has already come close to the line, with a number of members offering opinions and arguing for specific positions. Any future meetings of this committee as a whole would likewise need to avoid providing advice or input to EPA barring a COI and impartiality screen.

Second, I believe that this committee has a high likelihood of giving rise to COI. Let me just say at the outset that the issue of COI is difficult, and what I have to say is in no way intended to impugn anyone's integrity or question the relevance of their expertise. But several of this committee's members are chemical industry consultants who are employed by – indeed, are founders or principals¹ of – firms that work mostly or exclusively for, and

¹ Founders and principals of a company warrant special attention because they are likely to have a financial stake in the company that goes beyond just their employment and salary.

in some cases advocate on behalf of, companies that make or use chemicals directly relevant to IRIS, or trade associations that represent such companies.

It is often claimed that industry representatives or consultants should be included on such panels because “they know their chemicals best.” The mother of a young man accused of a crime may well know her son best – but that doesn’t mean we seat her on the jury.

COI can rise most obviously when a committee member works or has worked on a chemical subject to an IRIS review on behalf of an industry client. But the concern does not stop there. As we all know, methodological and related issues affecting IRIS assessments cut across many different chemicals. Individuals who have developed and received payment to advocate on behalf of the chemical industry for a position, say, that a mechanism of action must have been identified in order to conclude causality of a chemical and an adverse outcome, ought to be regarded as conflicted whenever that issue arises in any IRIS review.

Nor is the conflict necessarily limited to the direct activities of specific industry consultants on this committee. If other employees of the same firm have been paid by industry to work on chemicals, or on assessment-related methodological issues, that come up for IRIS reviews, this too must be regarded as a COI for the consultant on this committee, because of the potential for financial gain by the firm – and hence the individual – depending on the outcome of an IRIS assessment or a decision about a particular methodological approach. This concern is even more pronounced when the potential review is a founder or principal at the firm in question.

It is essential that any review of IRIS assessments or broader IRIS-related issues conducted under the auspices of this committee be, and be perceived as being, absolutely free of COI. The IRIS program’s peer review process has already been down this road, and it was not pretty.

Even where COI is deemed not to be a concern, I am concerned at the *severe lack of balance* with respect to bias on this committee. Again, several members have staked out very strong positions on specific chemicals and issues of direct relevance to IRIS – they are advocates for the industry positions on these matters. Those strong biases are in no way sufficiently counterbalanced through other members of the committee who come from academia or state government. Neither of these categories of experts are advocates in the same way that the industry consultants are, nor are they paid to take or develop evidence to support certain positions.

Case in point: I have kept rough track over the last day and a half, and well over half of all comments made by committee members were made the four industry consultants.

Balancing timeliness with getting the science right – it matters to real people

We heard calls yesterday, especially from industry consultants, that the IRIS process should slow down, that we can afford to wait while more data are developed; that we should add steps to the IRIS process, e.g., stop after the hazard characterization and have the committee review that before proceeding to the dose-response assessment; that the committee should play a role at the outset of every assessment; or that we should bring revised assessments back for another round of review. All of this before completing an IRIS review and allowing other decision-makers to act on such a review to address identified risk.

I would like to offer another perspective, as a public health and public interest scientist. All of these calls by industry would further delay [a process that is already far too slow and inefficient](#). I am afraid it is a bit too easy for industry scientists to argue for such delays: They aren't likely to live next to hazardous waste and Superfund sites or immediately downwind of facility smokestacks; they don't work 8 hours a day on a factory floor. People who do are desperate for the kind of information that IRIS provides and for the actions that follow to reduce the risks they face, especially people living in heavily impacted communities in this country, or subject to compounding risk factors such as poor nutrition, or higher disease rates due to more limited access to health care.

My point is this: the IRIS program is not an intellectual exercise. The chemicals in line for assessment are there for a reason: people are being exposed to them even as we sit here and debate the finer points of IRIS assessments. I am not suggesting these points aren't important, but it is essential that getting the science right is balanced with the need for timely assessments and decisions.

My greatest fear about this committee's IRIS reviews is that they become a quest for the perfect science or a call to delay action until we have near-absolute certainty about a chemical's adverse effects. Or that demands are placed on EPA that in an ideal world would be great, but in practice would make it harder, not easier, for EPA to do its job of protecting human health.

The chemical industry can afford to wait; indeed, under our system where a pending assessment means no action can be taken, ***all of the rewards of delay fall to one side – the (un)regulated industry – and all of the risks fall on the public.***

I'm not suggesting that you as scientists abandon the need to press EPA to get the science right – that's critically important. But I urge that you not lose sight of the equally important

need not to invite or demand further delay, because that will also delay or deny protection of public health.

I also ask that you recognize that the IRIS process can and should evolve and improve over time, incorporating further enhancements at a pace commensurate with resources and without slowing down progress toward completing ongoing assessments.

By all means, make your recommendations, but provide EPA with options that recognize that the IRIS process has to work in the real world and needs to provide for timely as well as scientifically credible decisions.

Thank you.



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