

**Written Statement of Charles (Chuck) Elkins
before the Chemical Assessment Advisory Committee
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Introduction

I am happy to see the formation of the Chemical Assessment Advisory Committee and anticipate that the Committee will make very positive contributions to the Agency's IRIS program. I want to suggest a number of questions for the Committee to consider as it begins its work. I also have suggestions for how the Committee might answer them. I hope that the Committee will spend some time talking about these and similar questions regarding its mission and procedures. I was disappointed, however, that the draft agenda for this first meeting of the Committee did not allocate time to discuss these kinds of subjects which I believe should be discussed and decided by the Committee before it reviews its first IRIS assessment.

Let me give you a brief sense of where the ideas contained in this statement come from. I worked for EPA for 25 years in various senior positions including as the Director of the Toxic Substances Program and in the course of my career had direct senior management responsibility at one time or the other over every one of the Agency's subject-matter programs (air, radiation, waste, pesticides, etc.) with the exception of water. I therefore directed staffs that have both developed health assessments comparable to IRIS assessments and used IRIS assessments for decision making. For the past 18 years I have worked as an environmental consultant for trade associations, specializing during the past several years on the IRIS program and the National Toxicology Program's Report on Carcinogens. This statement is based on both my EPA experience and my experience as a consultant to industry. It expresses my own opinions and is not presented on behalf of any clients.

Questions for the Committee's Consideration

1. What should be the mission of this Committee?

My Suggested Answer:

Obviously, the core mission of the CAAC is to peer review some of the IRIS assessments produced by the National Center for Environmental Assessment (NCEA). This is an important task. However, if the mission of the Committee were restricted to just this function, the Committee would fall short of what is really needed.

In addition to reviewing discrete individual assessments, this Committee, I believe, should take on some responsibility for the overview of the entire IRIS program. As an example, a number of IRIS assessments are likely to be peer reviewed under contract rather than by this Committee. In the past, these contracted peer reviews have been criticized for being of a lesser quality both

scientifically and procedurally from SAB committee reviews. I believe that this Committee should provide some oversight of the quality of these peer reviews so that the entire IRIS program can be quality assured, and not just the assessments that are reviewed by this Committee.

In addition, as you are well aware, the National Research Council (NRC), in Chapter 7 of its review of the IRIS Formaldehyde Assessment, identified a number of cross-cutting issues in the IRIS program. Currently, the NRC is conducting a more comprehensive review of the IRIS program and may address some of the procedural and scientific issues facing the IRIS program, but certainly not all of them. More importantly, the NRC review is a snapshot in time, while the CAAC will be a continuing long-term presence. How the Committee identifies the scientific and procedural issues that plague the IRIS program is important. I believe it is noteworthy that the NRC did not solicit from users or stakeholders in the IRIS program their views of the shortcomings of the IRIS program and the perceived needs for improvement.

I recommend that the CAAC reach out to the other program offices in EPA, the other Federal agencies, state and local agencies, the NGO community, industry, and other stakeholders and ask for their help in identifying the most important issues and needs for the IRIS program. This will assist the Committee in its understanding of where the CAAC could be most useful in assisting EPA improve the program. As an example, if you were to ask me what some of the cross-cutting issues are that need attention based on my experience with the program, I would identify such science issues as the following:

- How should NCEA deal with calculated reference values that fall below background levels in the United States?
- How should NCEA deal with substances that naturally occur in the human body and also are involved in exogenous exposures?

The Committee may want to undertake some independent studies of these and similar topics just as Science Advisory Board committees have undertaken studies of cross-cutting issues in the past.

On the process side, I would identify such issues as:

- How can data gaps for upcoming assessments be identified early enough so that there is an opportunity for EPA or stakeholders to fill some of those data gaps in order to reduce significantly the uncertainties in the resulting assessment?

But I am only one of many people who use and work with the IRIS program. As the CAAC begins its work, I strongly recommend that the Committee seek out the views of users and other stakeholders on the needed improvements in the IRIS program and thereby identify areas where the Committee can help EPA make these improvements. Serious consideration should be given to repeating this solicitation of input from these users and other stakeholders on a periodic basis.

In short, the Committee should see as its mission helping to fix the problems that the IRIS faces now so with the goal that, in the future, the NRC will not have the need to send back an IRIS assessment for a major redo. This program needs to start getting more “A’s” instead of “D’s” or “F’s”. Whether or not five years from now we can declare that the IRIS program has been greatly improved will depend significantly on how this Committee performs its oversight role.

2. What does the Committee need to do in order to perform its role effectively?

My Suggested Answer:

It is obviously important that the Committee hear from EPA about its current plans for improving its IRIS assessments, particularly in line with the recommendations of the NRC panel reviewing the formaldehyde IRIS assessment. It is also important to learn what the current NRC panel on IRIS plans to cover. However, much of this information is about plans and objectives and not about current performance of the IRIS program. With a couple of exceptions, there are not actual draft assessments that reflect these important changes in the IRIS program. More importantly, these recommendation from NRC as well as NCEA’s announced plans do not address all of the problems that have been identified in the current IRIS program, partially because the NRC never solicited comments from anyone outside of EPA about what those problems are. I believe it is important that the Committee acquaint itself with the criticisms of the current IRIS program, looking beyond the Committee members’ personal experiences, if it is to play an effective role in helping EPA make sufficient improvements in the program.

NCEA, of course, is not the most appropriate source for this information. The Committee should seek out input from EPA’s program offices that use IRIS, from other Federal agencies, from state and local agencies, from NGOs, from industry, and from academia about the IRIS program and how it can be improved. This will almost certainly add to the list of reforms already generated by the NRC that are needed to make the IRIS program a high quality program that meets the needs of its users in a timely fashion.

3. To whom should the Committee be Responsible?

My Suggested Answer:

Of course, technically Committee members' expenses are paid by EPA. You will no doubt also establish a relationship with Dr. Olden and his staff, although this should be an arms-length relationship in order to maintain the independence of the Committee. However, I urge you not to let these relationships blur your understanding of the mission of this Committee which I believe should be to help insure the scientific quality of IRIS assessments. Your responsibility is to yourselves as independent reviewers of the IRIS program and also to the entire scientific community, the public health community, stakeholders, participants in the market place, and the general public who depend on IRIS assessments to help them make sound decisions about chemical use. These groups will be less visible to you than EPA as you proceed in your work, but they should always be seen as the real clients for your work.

Perhaps a good analogy would be to your being asked to write a letter of recommendation for a PhD student at your institution to support his or her application for a job in your field. You may really want to help this individual be successful, but you also have your responsibility to your professional colleagues not to recommend someone who is not well qualified and who may fail, to your ultimate discredit. You would not be doing the candidate, and certainly not your professional credibility, any favor if you were to give him a glowing recommendation when he does not deserve it. By analogy, this Committee's giving a "passing grade" to an inadequate IRIS assessment does EPA no favors—in fact, it would be a big disfavor to EPA—as well as to the rest of the community that is depending on you to help EPA publish only high-quality assessments on a timely basis on which they can depend for their decisions. EPA is not your client and deserves no more deference than any other party of interest as you perform your independent reviews of these assessments and the IRIS program in general.

4. What happens if the Committee makes a mistake?

My Suggested Answer:

You may find this question a little strange. After all, EPA authors the IRIS assessments, not this Committee. But you should realize that there is only one truly independent review of the scientific quality of an IRIS assessment provided for in the IRIS process—and that is the one conducted by this Committee (or alternatively, by a contract peer review panel). All the other reviews provided for by the IRIS process are conducted by either EPA itself or by other Federal agencies which do not profess to have in-house the range of technical credentials comparable

to those found on this committee or to comment independently of their agencies' interests. This Committee is in a unique position to assure the quality of IRIS assessments, and the consequences of failure to do so are very serious.

IRIS assessments are a fundamental building block for a host of decisions made by a multitude of organizations and persons:

- IRIS assessments are used in numerous risk assessments, decisions, and regulations produced by EPA program offices and the rest of the Federal government and comparable state, local, and even international governments.
- The general public views IRIS assessments as authoritative sources of hazard information that they can use to make their personal exposure decisions.
- Private companies use IRIS assessments to determine what levels of chemicals their workers, customers, and neighbors should be exposed to.
- Insurance companies use these same assessments to determine whether to insure companies, that use these chemicals, and at what price.
- Customers, workers, and neighbors of companies use IRIS assessments as an independent check on their exposure.
- Private companies, even in the absence of regulations, use these assessments to de-select these chemicals from use in their products and services.
- IRIS assessments play a role in tort suits that seek relief for consequences arguably tied to exposure to these chemicals.

Because of all these decisions dependent upon IRIS assessments, the public's health is obviously threatened by an IRIS assessment that is not stringent enough. Not so obvious is the fact that the public's health can also be threatened by an IRIS assessment that is too stringent! I realize that some believe that a highly precautionary approach to chemicals is a desirable public policy (that is, choosing to declare a chemical is hazardous when there exists even a modicum of doubt about a chemical's safety). However, as the former Director of the EPA's Toxic Substances Program that administers the Toxic Substances Control Act (TSCA), I reached a different conclusion. Unless the use of a chemical that is declared hazardous is so trivial that the use is discontinued completely, we can be assured that as a chemical's use is reduced in the market, other materials, probably chemicals, will be substituted in its place. Working in the TSCA program, I was constantly reminded that we often know far less about chemicals that are likely to be substituted for an IRIS review chemical than we do about the IRIS chemical. The

chemicals that are reviewed by the IRIS program tend to be those for which there are substantial data—otherwise, it would be impossible to conduct a full IRIS assessment. For these relatively well-studied chemicals, when we reduce its use in the marketplace, we should recognize the possibility that the risk from being exposed to the substitute chemicals could be greater than the risks of the chemical whose use we are reducing.

If the IRIS assessment is sound—just like Goldilocks’ porridge, not too lenient and not too stringent, but just right—then the IRIS program can successfully pass on to other decision makers the best possible estimate of the hazard of that chemical, and if the subsequent risk assessments are done well, informed decisions can then be made about the relative risks of using substitute chemicals. On the other hand, a too stringent or too lenient assessment of hazard can do a great disservice to the downstream decision makers and put public health in jeopardy. All of these downstream decisions that depend so heavily on the quality of the IRIS assessment highlight the importance of high quality IRIS assessments and the role of this Committee to protect the public health by assuring that only high quality assessments go out the door while at the same time helping EPA find ways to make more assessments more quickly available to these downstream decision makers.

This is a heavy responsibility to put on the shoulders of this Committee, and it will take leadership and assertiveness on the part of the Committee to fulfill this function well. The stakes are high. EPA does not need a “lapdog” advisory committee; it needs a German Shepherd or Great Dane “guard dog” that is absolutely committed to helping EPA produce timely high quality assessments and not allowing poor assessments out the door.

5. Who should draft the charge questions for the Committee?

My Suggested Answer:

In the past, SAB committees which have reviewed IRIS assessments have organized their work around a set of charge questions, which, if answered, in their totality are theoretically designed to cover the critical issues associated with the assessment under review. This approach is sound, in principle, but the practice has suffered in the past from the fact that usually all the IRIS charge questions have been drafted by the same people who drafted the assessment that is to be reviewed. In addition, these charge questions for the SAB committees have usually been drafted BEFORE anyone outside the Federal government, including stakeholders, has even seen the draft assessment for the first time and had a chance to identify scientific issues in the assessment. The charge questions have only rarely been changed after stakeholders have identified such significant scientific issues in their public comments on the draft assessment.

As some of you may know, the former NCEA management actively discouraged (to put it mildly) any dialogue between NCEA staff and stakeholders both before and while the assessments were being drafted. This is one of the principal reasons why the NCEA authors of the assessment are often the last to really know what is controversial about their draft document. Therefore, it is not surprising that the assessments as well as the charge questions have often not addressed some of the key scientific issues that are identified for the first time once someone outside the Federal government finally has a chance to read the draft assessment.

It is an obvious point that if one asks the wrong questions, one is likely to get the wrong answers. Therefore, because the charge questions are so important to the work of any peer review committee, I urge the Committee to assure itself that the key scientific issues raised by persons other than NCEA staff are either forthrightly identified and addressed in the assessment itself for your review or are flagged as issues in the Committee's charge questions. For these flagged issues that are not addressed in the assessment, I urge the Committee to ask that the NCEA staff provide the Committee and the public with their considered response to the identified issue so that the Committee will be better informed of the Agency's reasoning as it reaches its own independent view of the matter. In addition, once this Committee has provided its review of an IRIS Assessment to NCEA, the Committee should be provided with the Agency's response to the Committee's recommendations. While the Committee should not have a veto over the ultimate decisions of the Agency, senior Agency management should be informed if Committee members believe that the Agency has either not understood the Committee's recommendation or has chosen, without adequate justification, to reject the recommendation.

I am encouraged that the current director of NCEA, Dr. Ken Olden, has committed to exactly this course of action—namely, addressing the scientific issues raised by stakeholders by revising the assessment as appropriate and/or identifying them in the charge questions for the peer review process. This provides a basis for an agreement between this Committee and NCEA that this Committee will have the opportunity to address, as it sees fit, the most important scientific issues raised by either the staff or the public. I suggest that the Committee formalize this arrangement in an agreement between NCEA and the Committee. The Committee has a strong institutional interest in seeing this kind of procedure followed even if a future director of NCEA wishes to return to the old policy of not addressing stakeholders' scientific concerns in the Agency's IRIS assessments.

6. How Will the Committee obtain the knowledge to address the major issues in an assessment?

My Suggested Answer:

It is likely that this Committee will be asked to review IRIS assessments dealing with some of the most controversial data-rich chemicals being assessed, while IRIS assessments of chemicals with less data and with fewer controversies will probably be sent to peer reviews panels organized by an outside contractor. These assessments are complex and various interpretations of key studies and the totality of the data are likely to abound. Obviously, this Committee has a large array of talent, and the Committee will be augmented with subject-specific experts, but you are likely to find yourselves in need of all the help you can get to do your own independent review of such assessments.

If you have not participated in the review of one or more of these major data-rich IRIS assessments in the past, you may not be fully aware that for many of these chemicals, there are scientists employed or funded by industry and some environmental or public health interest groups who have specialized in these chemicals for much of their careers. Some of these scientists may actually work directly for a consulting firm or a university or other academic institution, but they likely get their funding from either the government or from industry or NGOs. Taken as a whole, they can represent a sizeable pool of talent to identify scientific issues and point the Committee to little-known facts about key studies that should be considered in their evaluation. Most of them will not be members of your Committee or be added as subject-matter experts when your Committee is augmented to review a particular chemical assessment.

It is this pool of talent that I believe the Committee should seek out, through public comment and through appointment as subject-matter experts to the augmented panels, as appropriate, in order to supplement the Committee's skills and knowledge.

7. Can you trust what you are told?

My Suggested Answer:

If, as I argue, you should seek out the input from stakeholders to help you identify critical scientific issues and facts related to a particular assessment, it is natural to worry about whether you can trust what they tell you. By the same token, the Agency itself is not without its own biases that the Committee needs to be aware of, especially if the Agency is already

heavily engaged in regulating as hazardous the chemical being assessed, which is often the case. Yet, you need the input of all these parties.

I want to suggest that the answer to this dilemma lies in the implementation of one of President Reagan's favorite mottos: "Trust, but verify." If you take the input from this pool of experts or the Agency as a source of potentially valuable information about, say the substitute of historical controls from a laboratory other than from the one where the study was conducted, thereby bringing the use of the results of the study in the assessment into question, or if you learn from them that the exposure calculations for an epidemiological study were arrived at by a less-reliable manner than understood earlier, there is no need for Committee members to take these statements at face value.¹ By asking for the source of these scientists' or the Agency's information, Committee members can verify the information themselves independently. The value of these inputs is that the Committee might not learn of these otherwise hidden facts if not alerted to them in this manner.

In the future, more careful attention by EPA to the objective evaluation of key studies based on their study design and the care taken in implementation and interpretation of these studies, subject to comment at that stage by outside scientists, should eliminate some of the need for scientific issues of interpretation and use of studies to be identified late in the assessment process. Ideally, the assessment itself should accurately describe the key studies and identify the scientific issues and reduce the surprises that now characterize the public's review of the draft assessments, often years after the assessment was begun.

8. How should the Committee interact with outside experts?

My Suggested Answer:

This committee needs to find an effective, arms-length way to tap into the pool of talent outside of EPA. In the past SAB Committees reviewing IRIS Assessments have asked for written comments from the public and then allowed each commenter only 5 minutes to make an oral presentation to the committee. Often, there was no interaction between the committee and the public presenter. In contrast, the committee usually allowed an almost unlimited amount of time not just for presentations by the Agency but also for dialogue between the committee and the assessment's authors from NCEA. A case in point is the draft agenda for this meeting, both in the time allotted and in the description of the interaction. The interaction with the Agency is described as a "dialogue", and the interaction with the public is described as "public

¹ These examples are true examples taken from an assessment conducted by another Federal agency, not EPA.

comments.” Hopefully, these words do not describe what the actual interaction between the Committee and the public will be on the day of the meeting.

In short I would contend that a more equal balance and a similar mode of interaction among those who are allowed to provide input to the Committee would better serve the Committee’s needs. The Committee is correct in encouraging the public to submit thorough written documents ahead of time so that the Committee can study them in detail before the meeting. This is comparable to requiring the Agency to submit a carefully structured assessment document that is itself self-explanatory. However, just as there are issues that the Committee will want to discuss orally with the assessment’s authors, there will often be issues raised by the public commenters that are worthy of oral discussion. In addition, public participants can provide the most help to the Committee if they are encouraged to make oral comments at the beginning of the meeting to help the Committee decide what issues it wants to spend its time on, but also near the end of the meeting in order to provide input on what has been said during the meeting.

Limiting presenters to 5 or even 7 minutes makes no sense, unless the Committee views public comment as only an exercise in democracy that allows the Committee to check the box to affirm that it allowed the public to have its say. Rather, in my view, public comments should be viewed as an essential part of the scientific process in which the Committee is engaged, and should be designed as such. Speakers should be given an appropriate time to present their facts and interpretations of the data, and the Committee should engage with them in order to make sure that the facts and interpretations are well understood by Committee members.

Recently, my colleagues and I invited an outside scientist to come to Washington to make a presentation on his study to a National Research Council committee. We would have paid his travel because we felt the NRC should hear in detail about the results of his study. We had to inform him, however, that this particular NRC committee would allow public presenters to speak for only 5 minutes. He indicated that he did not travel anywhere to make a 5 minute speech. I don’t blame him. Would any of you travel to a distant city to make a 5 minute speech? Have you tried to present any complex scientific information in just 5 minutes?

This approach by SAB review committees in the past of limiting the public to 5 minute presentations has had the effect of cutting off the committee’s nose to spite its face. If your Committee really wants to tap into the knowledge and skills of outside scientists, then you need to send a signal different from your predecessor committees. Throw out the arbitrary minute rule and allocate different amounts of time to various public speakers based on the depth and uniqueness of their written comments that would benefit from discussion between the speaker and the Committee. One size does not fit all. You are not bound by law or policy to give each

speaker the same amount of time. Certainly if dialogue with the EPA scientists is valuable to the Committee, so will be dialogue with some of the external scientists who come to present.

There is no substantive reason why the Agency staff should be given great deference and accommodation by the Committee compared to outside scientists. An assessment written over a period of years should be written, as the NRC has indicated, in a way that it is self-explanatory. Public comments, written by necessity over a period of a few weeks, at best, are more likely to need some oral explanation in order for the Committee to benefit fully from the external scientist's expertise and knowledge. If anything, the Committee should accommodate the difficult circumstances of a public presenter than an Agency that has had a longer time to prepare its views of the science. In other non-EPA committees, we have seen recognized experts in the audience invited to the table by the reviewing committee to interact with the committee, not as a member of the committee, but as a resource person. This Committee, faced as it will be with complex and controversial scientific issues, should exercise the flexibility and initiative necessary to carry out its task, which, in many regards is significantly different from the tasks assigned to many of the other SAB committees. By reviewing a public presenter's written comments, the Committee should be able to make an informed judgment about how much time is needed by each individual speaker in order for the Committee to obtain the full benefit of his skills and experience.

Conclusion

Thank you for your attention to this set of comments. I hope that my proposed answers to these important questions about the mission and procedures of this new Committee will stimulate each of the members and the Committee as a whole to fashion their own answers to these questions, and that you find some of my past experience as expressed in these comments helpful in your deliberations.