General Comments at the IRIS December Bi-Monthly Meeting

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Importance of IRIS Enhancements

- As a former director of EPA's TSCA program (and senior manager in the air pollution and pesticides programs), I understand first hand the need for a strong IRIS program as key to public health protection and guiding and preserving consumer choice.
  - For the last several years all of my professional energies (both compensated and pro bono) have been focused on strengthening the IRIS program.
  - I am here today in my pro bono capacity.
- I believe the enhancements as announced in July, 2013 should improve both IRIS quality and timeliness.
- I will focus my remarks here on Step 1 Meetings

What I understand the purpose of these Step 1 meetings to be

- Not just an exercise in democracy
- NCEA staff want to change the IRIS:
  - Its output
  - The perceived or actual quality of the assessments
- Why are these changes needed?
  - Issues that EPA cannot ignore that are raised late in the process require resource- and time-intensive rework.
  - It is much easier to write an assessment if you know most of the issues you must address from the beginning so you can work the issues in parallel.

What did I expect of these Step 1 meetings based on EPA's July statements?

At the conclusion, both stakeholders and EPA would walk out with a clear understanding, for each chemical, of what are the:

- Problems the assessment is designed to address (e.g. Program office or states' current needs)
- Health and eco endpoints that will be the focus
- Most important studies, and their identified strengths and weaknesses
- Key scientific/science policy issues that must be addressed in the assessment (e.g. kidney tumors MOA)
- Research underway, data gaps that could be filled quickly, and how "stopping rules" will apply.

My conclusions

- I am very happy that this first meeting took place.
- But not one of my expectations was fulfilled.

What went wrong?

- Lack of engagement by stakeholders and EPA? No
- “Shape of the table”? No

Were these Step 1 meetings held too early in the process?

What does NCEA know about Step 1 chemicals and when does it know it?

(My previous list)

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IRIS Timeline (first steps)

- Nomination
- Problem Formulation
- Literature search & selection of pertinent studies
- Evidence tables
- Study evaluation
- Outline/plan the assessment
- Identification of difficult issues
- Draft the assessment

Current Schedule of Early Meetings

- Nomination
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A proposed Plan for Step 1 Meetings

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A proposed Plan for Step 1 Meeting

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= post on web

This plan does not require any change to the July 2013 enhancements

- In fact, it is more consistent with what many of us expected.
- The number of meetings with stakeholders remains the same.
- The meeting is still a “Step 1 meeting”
- The change is simply a change in timing to reflect when NCEA will be in a position to have a dialogue rather than just listen and ask questions.

Proposed Agenda for a Step 1 Meeting

- Three-fourths of the time to be devoted to sitting around a table discussing the difficult science issues in the forthcoming assessment
  - EPA proposes for discussion ones it has identified
  - Stakeholders add others, as necessary [It makes no sense for NCEA to plan the Step 1 meetings unilaterally]
- A quarter of the time is open to issues brought forward at the meeting by anyone.
- The issues are discussed IN DEPTH by both EPA and stakeholders. This is NOT a “listening session”

Proposed steps the Step 1 meeting

- Stakeholders have 30 days to submit additional material
- Chemical manager revises the plan for assessment to address these and other issues in robust & efficient fashion.
- NCEA management makes “go/no go” decision to do the assessment as planned and sets the delivery target date.
- The “clock” starts at this point and not before.

Keeping Evidence Tables Current

- Why is NCEA doing evidence tables?
  - Just to communicate with stakeholders?
  - Fundamental building block of a good assessment?
- Will NCEA be updating/correcting these tables?
- Why not post the updated/current evidence tables on the web?
  - Stakeholders (including those not here)
  - States and localities

"The unexamined life is not worth living"
(Socrates)

- A successful implementation requires concerted effort by both EPA and stakeholders.
- The implementation of these IRIS enhancements is **too important** to leave un-evaluated.
- We need a **docket** to house on-going evaluation of the performance by both EPA and stakeholders in this effort.