ACA Advisory Committee Meeting Agenda
January 9, 2001

Evaluation Framework for Screening-Level Evaluations of Human Exposure to HPV Chemicals:
Presentation and update – Rob Shimp

The presentation went through the framework as described in the Sept. 25, 2000 paper, focusing on tracking through Figure 2 – **Description of Generic Screening Level Human Exposure and Hazard Evaluation Framework for HPV Chemicals.** Much of the subsequent discussion took this figure as its reference point, for both sets of questions:

- Those dealing with the assessment of the utility of the framework, needs for clarity or change, and key considerations to categorize HPV chemicals needing more information

  1. *Do you agree that the screening level exposure evaluation process that ACA has suggested can be used with hazard data to help characterize and categorize HPV chemicals?*
     - *Why?*
     - *Why not?*

  2. *Is there anything missing, or unclear, in the screening level exposure evaluation process that ACA has suggested, or the document describing it? If so, how would you recommend the process be changed, or better explained?*

  3. *In your judgment, what are the key considerations that should be used to categorize HPV chemicals, differentiating those that can be set aside (or designated lower priority for action) for now from those needing more information or management action?*

And

- Those dealing with what information are most useful in communicating with the general public on chemicals, and the key technical elements of evaluation of HPV chemicals useful for public communications.

  1. *In your experience, what kinds of information have you found to be most useful in communications with non-specialists (e.g., the general public) about chemicals, and generally, how do they respond to such information.*

  2. *What do you believe are the key technical elements of a screening level evaluation for an HPV chemical that should be highlighted in communications to the public (i.e., selected from a body of information collected on hazards, uses, and/or exposures)?*

Questions or suggestions, along with discussion evoked, are set out below. First those clarifying the framework, as part of the presentation.

Q: What do we mean by available screening-level model and/or data?
A: By that we mean existing information and techniques that are useful to understand exposure and hazard – material that is available now to use, rather than requiring new research or newly designed analytic structures.

Observation: Identifying occupational and community and product exposures is neat, descriptive, but a little artificial. We need to find a way to communicate that worker exposures may exist whether it happens in the course of manufacturing or in formulating products. Similarly, community exposures could occur in either situation as well. (I.e., Box 14 can include both occupational and community exposures.)

Q: Is ACA creating this evaluation framework for others to use, as they choose to do so?
A: Yes.

Then will the information all be available in one database, accessible to all? That may be a recommendation. Today we will deal with **what information** should be communicated. And **how best to communicate** the data to the public is the subject of the Feb. 16 meeting.

Observation: The conclusion (at Box 17) that a chemical currently has limited exposure potential and/or is a low level hazard is intended to derive from any or all of Boxes 8, 9, 10, and 11. The figure might be clarified so that the arrows from these boxes clearly feed into the route to Box 17, as well as to the boxes that estimate exposures (Boxes 12, 13, 14, 15.).

Further the exposures deriving from one chemical could vary and/or be the subject of multiple evaluations, as a result of different products and uses. (For example, a silica might be fused into a kitchen counter as well as used as an abrasive cleaner.)

Observation: Product related exposures are very complex, varied, multiple, and occur in many product uses and situations. PVC pipe exposed to sunlight deteriorates and lead (used as a stabilizer) then becomes an exposure risk, potentially for children, an occurrence not related to the intended use of the pipe.

Generic question for ACA consideration: You need to define how hard you look for exposure. What will you recommend to manufacturers and formulators as to the intensity and extent of scrutiny?

Q: Where do we deal with product breakdown or destruction? Exposure may happen, yet there this is in quite a different way than in manufacture. **A:** We intend to deal with that in the (yet-to-be completed) ecological exposure framework.

Observation: At boxes 5 and 11, dispersal or release exposure consequences will occur, and in different ways. E.g., use of a de-icer may have direct human/worker exposure results at Box 10, while the runoff or dispersal or release from its use will be identified in Boxes 5 and 11.

Observation: While Box 16 covers aggregate exposures, from multiple sources, you need to also account for cumulative exposure, resulting from multiple scenarios of exposure. This is either a refinement of the analysis at Box 16, or another possibility for which guidance is needed.
Q: The diagram describes "approaches, but seems to emphasize modeling. To what extent will monitoring information be included? **A:** The Exposure Analysis Resources will include a "Library of Existing Exposures Estimation Approaches". This will include screening level approaches –both for monitoring and models. So, while the evaluation framework focuses on modeling exposures, we will provide monitoring guidance as well, and recognize that available monitoring information may be useful. Additionally, the Library will include higher tier approaches, intended for more precision than initial screening, for either monitoring or modeling.

Q: What will be the specificity, and level of detail, for exposure and safety in different industrial uses? There is conflicting data on TLVs in different contexts. **A**: That is a sponsor responsibility to decide how far to go, (But the intent is that the sponsor choices will be transparent and reported).

Q. How much raw data will be publicly available? **A**. The data-sharing group is now working to to find ways that competitors can report data without violating or compromising CBI concerns.

Observation: Some of that depends on reporting in ranges, which do not always work. Worst-case scenarios may help in some instances, to exclude chemicals even under a worst case exposure situation, based on low hazard. But more specificity will be needed for specific analyses. If 20% of the uses are unknown (i.e., no data is reported), we have a problem, and knowing anything about the degree of risk is impossible. **Observation**: Peer pressure, and better ways to share data, may be the best answer we currently have. Missing chunks of data and information on uses, and therefore exposure, may be a major issue in the beneficial impact of this ACA screening level evaluation framework.

Observation: Be sure to include the human factors information available from CPSC, which helps understand how consumers relate to and react with various products. This should be included in the Resources Library.

Now the questions and comments focused on the utility of the process, what changes or clarifications are needed, and key considerations to categorize HPV chemicals for more information.

1. **Yes, the process is basically useful to characterize and categorize HPV chemicals**. Given that, there are a number of questions and suggestions for ACA to consider.

2. **At Boxes 8, 9 and 10, should not look only for the "most likely" exposures**. That is worrisome; we should be after all hazard concerns, so the question is not which occupational or community or product exposures are most likely, but which are most hazardous.

   We need to **be especially mindful of susceptible sub-populations**, e.g., children and pregnant women. If there is a hazard, we will want to evaluate any exposure, and our ability to do toxicity analysis will get more sophisticated, responding to such needs.

3. **Occupational exposures need to account for wide variances, and include the maintenance, clean-up, repair and emergency response people**, who may not be exposed as part of normal manufacturing or formulating. The same is true for community exposures, and this analytic need should be explained for the potential HPV sponsor users.

4. **How will you deal with positive mutagens**? Are we doing dose/response analysis? Most HPV chemicals will not have endocrine effects data, however.

5. **There seems a presumption that the screening process will drop some chemicals "off the map." That is not likely, rather it will yield priority rankings**, where we can decide to address the chemical likely to adversely affect 10,000 before the one that risks 10.

   Having moved from "most likely" exposures, we need to identify those that will be most significant. We are looking for human exposure potential and identifying the most sensitive products and processes. Those will include those that threaten susceptible sub-populations, those where internal ingestion is likely, anything involved with drinking water treatment or transport, food containers or additives, likely inhalants in the course of normal use.

Later in the meeting, a draft of questions that are intended to help sponsors and users of the process think about exposure and hazard were shared with the group. The "questions to think by" specify use, normal and misuse, dilution and concentration, and a number of other factors that related to this general area of discussion.

Boxes 12, 13, and 14 all use "available screening level approaches" to do priority setting. The specific approaches used, that form the base for a management decision should be identified (revealed) by the user of the process.

Products that may be safe in normal, prescribed uses, may become dangerous in their impact on humans at higher concentrations or well-intended overuses. (I.e., "if a 5% solution cleans, then a 50% solution will do it better".) How can we get analysis of reasonably expected overuse or misuse?

6. **Remember, the "perfect is the enemy of the good",** as the adage goes. We need to define the process to achieve "the good" and not be overly concerned that it cannot achieve "the perfect" and address all uses and possibilities for exposure.

   We are mainly dealing here with "risk characterization" not with "risk assessment", until we get to sponsors' decisions and actions, at or after Box 19.

   There are some criteria to keep in mind: First, do no harm. That is, don't assure the consumer that the product is safe, because there is some risk in all. Second, design the process so that it gets better over time; aim for ongoing and continuing improvement.

7. **The sponsors of the HPV chemical testing are the ones making the decisions,** as to whether the chemical has limited or no exposure potential or is a low level hazard, or whether further evaluation or action is needed. All the screening process can do is to provide and help assure that a consistent process is followed to identify exposure, on the basis of which process it is possible to make quality decisions.

   The trick is to assess the right scenarios, since otherwise the data is useless or irrelevant.

   And **the real criterion is for "low current concern", in a process that is iterative, and in which we expect to continue to improve exposure and hazard information.** The targets of the decision support information and process are the sponsors, not primarily the agencies (EPA, CPSC).

8. **Two key issues for ACA: Be sure to deal with the analysis of exposure for susceptible sub-populations, and communicate that the process is not perfect.** It is not at all clear that the process will get to Boxes 12, 13 & 14 with an exposure estimate that has dose/response analysis characteristics.

   Therefore, start with the greatest hazards, not with the chemicals. The degree of hazard is one of the key drivers; dioxin demands much more information about use and exposure than a far less toxic substance. Similarly, uses in food or products that are ingested demand much more information.

   Do a good job on the use analysis – Boxes 8, 9, 10, and look past intermediate products to things that are ingested or inhaled. Put another way, try to "find the worst first" (as EPA is doing with a

pending rule that goes somewhat beyond HPV chemicals in analyzing producer use information and production data).

These evaluation process questions may improve the downstream communications, from formulators to users, and stimulate better awareness and communication of new information on exposure and hazard.

9. **Is the definition of benefits a worthy addition here?** Data on hazards may move toward banning or ceasing to use a substance. Data on exposure may help with a decision based about the types of uses or limiting harm. Does not data on benefits help resolve those instances where no clear decision is indicated from the hazard and exposure analyses? Are we not moving to a risk/benefit analysis?

   While there was general agreement on the value of benefits information, the consensus was that it was properly dealt with in another forum. Trying to integrate it into this screening level for human exposure simply adds complications and is too time consuming for our present purposes.

   It is true that as companies make decisions on what to do with exposure and hazard information, they will consider both the availability of lower risk substitutes and the benefits of continued use of a particular chemical. Therefore, Box 19 might well require asking not just whether more evaluation is needed, but whether, or how, the sponsor company continues to use the chemical. This is a part of risk management.

   One danger is misplaced confidence, on either the positive or negative aspects of the data. There is danger in citing benefits being seen as *de facto* propaganda rather than clear analysis. Thus, perhaps, rather than 'benefits' per se, the process might recognize the legitimacy of 'exceptions' for continued use. E.g., tamoxifin now is known to be a potential carcinogen, but it is still useful in treating breast cancer, and therapy should not be discontinued solely because of this new awareness.

   Further, the reason for using the chemical in a particular application may be key. Is it a surfactant or a fragrance? Point of view may be important – the company is driven in part by economic value; the individual may be driven by consequences of personal use.

10. **Other key considerations in the categorization of HPV chemicals may be persistence and bioaccumulation**, recognized in Boxes 5 & 11, which will be accounted for in the ecological exposure framework, still under development. Persistence and bioaccumulation potential are factors that would be likely to shift a conclusion towards "needs further work."

    An important consideration is to define how and where to deal with product breakdown, and disposal. A benign product that breaks down into toxic elements needs to be so identified, for appropriate action.

    Likewise, monitoring should be included as part of the evaluation framework process.

11. **Factors for decision should be clear**, and this even raises the question of the value of retaining Box 19 as part of this framework, or a separate outcome and decision stage. The adequacy of exposure assessment does not, in itself, assure an appropriate decision by the sponsor. Thus the basis for the decision should be explicit, especially where different decisions may be made based on (or with knowledge of) the same data. The 'margin of exposure' used should be cited.

Somewhere in the process, the synergistic effects of multiple exposures, cumulative effect, additive scenarios of exposure should be captured, although this may be the subject not of screening evaluation but a 'higher-tier' evaluation.

Box 19 is included, so that the 'so what' question is raised and recorded. It recognizes that the evaluation framework is intended to lead to a decision, and that the factors involved should be part of the transparent analytic and decision process. Choices will result, and there is a public 'right-to-know' aspect captured by Box 19. It should also be clear that the purpose of communicating ("marketing") this evaluation of HPV data is to reach sound decisions.

Given these considerations, the factors identified at Box 19b are not mutually exclusive, and should be linked with "and/or" conjunctions rather than "or".

ACA should be clear that the product risk management dimensions that may follow a decision at Box 19 are beyond the exposure analysis, and the quality of the specific decision is not guaranteed simply because sound exposure analysis had been done.

As a result, the framework needs to clearly separate the exposure analysis (objective) steps in the process from the "decision making" (subjective) parts of the process. It should also be clear that the decision making conclusion is a point of view by the sponsor, not necessarily consensus.

12. **Further, the language and alternatives should be modified. Use the OECD language, as to "low priority for future work" rather than "sufficiently studied and managed" at Box 19a. Then, Box 19b becomes "high priority for future work". And a Box 19c should be added to record whether the company continues to use the chemical. In sum, Box 19 is most useful if the decision process is fully transparent, both as to the basis for the management decision, and the specifics of the decision.**

13. **Other specific suggestions for the narrative explanation of the process:**

- Do not assume that only companies bear responsibility for exposure. So also may individuals, regulators, and assumptions of proper use.
- Key routes to exposure should include "disposal of the chemical".
- Precise evaluation of exposure may need some mention of "dose potency".
- Occupational and community exposures now exclude accidents. Reconsider, especially for chemicals whose uses and characteristics may make them particularly likely to be involved, or to be dangerous in an accident.
- Also, add some explicit consideration of industrial wastewater and downstream exposures.

Finally, suggestions were made as to what information is most useful in communicating with the general public on chemicals, and the key technical elements of evaluation of HPV chemicals useful for public communications.

1. **Consider defining the audiences** – consumers, workers, media, others? Identify the top 10 points that each wants to know about HPV chemicals and test results.

2. **There is danger in trying to translate technical information into simpler form for the audiences**, since it raises a question of whether they should trust the translation and the translators. The question is how to find the right level of detail and specificity.

3. **The best answer, particularly given the facility with which this can be done on the Web, is to provide information in layers, at successively greater and more technical levels of detail.** Start with an abstract or summary, add FAQs, include reference to and explanation of specific terms.

4. **Don't limit information distribution to the Web,** however. Many still do not have regular, easy, comfortable access to the Internet. Also use print, handouts in plant communities, 800-numbers for consumers to call. Use the federal and state agencies to help identify information needs and effective ways to deliver it.

5. **What does the public want to know?** At least the following:

- Is this chemical safe for me, my kids, my pets?
- What are the specifics? In what uses and concentrations is it safe or dangerous?
- Give us the toxicity data. And the exposure data.
- Tell me what I need to know as a user of the product.
- Tell me what I need to know as a resident of the community where the chemical is manufactured.

1. **Survey and interview to find out what the audience wants to know.** A sample of 30 random interviews will yield a lot of information, and a very good start at defining information needs.

   Understand the "mental model" of the audience. This may be trickier, but there are existing protocols (among them from Carnegie-Mellon). Start with "tell us what you know about chemicals, or HPV chemicals".

2. **The public must know the information is there, available accessible.** Do not hold anything back. Let them determine how much is enough, and when they have enough detail and data.

   Use the media to let the public know the information is available and how to get it. Learn from the Environmental Defense "Scorecard".

   Communicate carefully and accurately; therefore, say, "This is based on examination and testing of these products in the following uses."

3. **Anticipate what the public will need, and want, in advance of release of the SIDS data.** It may be the "next hot topic". Be ready to deliver, not to promise, "information is coming soon."

   Also communicate to special populations, such as Community Advisory Panels.

4. **Extend the research** about what the public needs/wants to know, by adding specific samples, e.g., on income levels, by ethnicity, urban versus rural populations, as you suspect needs differ.

5. **Aim to get good results,** that is, to shift the public away from "chemicals are dangerous" to "the companies are paying attention, and assuring the safety of their customers."

   If the public recognizes that the companies know what to do to enhance safety, they can feel better about the testing data and its communication. (For starters, see about getting the 3 or 4 questions ED asked about perceptions of chemical safety several years ago.)

Finally, a quick summary presentation was done of "20 questions to think on", the first-cut of specific priority related inquiries for sponsors to develop on their HPV chemicals. This will go out to the panel for comment, prior to the next meeting.

Also to be distributed in about two weeks, for use at the February 16, Communications meeting:

- Communications Resource Document (AKA tool kit) – with a 9-step planning process.
- Technical Reporting Guidance (AKA "templates") – version 10.
- Guidance for Communicating with Non-technical Audiences.

Overall, the meeting seemed productive, high-energy, fairly focused, and concentrated on defining a productive screening evaluation process.