Response to Stakeholder Comments on ChAMP Prioritizations

Prior to and throughout the development of ChAMP, a variety of stakeholders have provided valuable and insightful comments on both draft and early process documents prepared by EPA for use in the program. Following review and careful consideration of the input received from these stakeholders, EPA has incorporated many of the changes suggested into both the development process for ChAMP Prioritizations and the individual documents themselves. The substance of the comments on each type of document appears below in italics, with notes where necessary to explain where or how EPA has addressed each issue.

These comments were presented on multiple documents from 2007 through 2008. Prior to the initiation of ChAMP, to begin to use the data gathered under the High Production Volume (HPV) Challenge Program, EPA developed a process for creating Hazard Characterizations (HC) for HPV chemicals. In June 2007, EPA shared a number of draft HC documents with a variety of stakeholders and asked for their input. When ChAMP was initiated in late 2007, EPA expanded the hazard characterization effort to include use of Inventory Update Reporting (IUR) data to develop exposure characterizations (EC) and to integrate these HCs and ECs into risk characterizations (RC). Using this supporting information, EPA developed Risk-Based Prioritizations (RBPs) for high production volume (HPV) chemicals. In December 2007, EPA shared a number of draft RBPs, including the supporting RCs, HCs, and ECs, with stakeholders and asked for their comments. In 2008, EPA also began developing initial evaluations of medium production volume (MPV) chemicals. The evaluation of the initial set of these chemicals consisted of hazard characterizations based on existing data and structure-activity relationship estimates. In June 2008, EPA shared several MPV chemical HCs with stakeholders and asked for their comments. In addition, OPPT senior managers met on two occasions to discuss ChAMP with a number of senior level representatives from academia, non-governmental organizations and industry. Engagement of these stakeholders was not intended to provide collective group advice or consensus views but rather individual input and advice on EPA's assessment and management program for existing chemicals in the U.S. A list of the participating stakeholders throughout this process is provided in the Appendix.

Risk-Based Prioritizations and Supporting Documents (EC, HC, RC)

Hazard Characterizations

In 2007 and 2008 EPA developed stand-alone "interim HC" documents as a first step in using HPV Challenge data to characterize HPV chemicals, and invited stakeholder comment on these documents. EPA ceased development and posting of these stand-alone interim HC documents in September 2008 as the process evolved. The input received on the original documents was used to redesign the process for developing HCs in general, and is realized in the HC portion of the integrated RBP documents EPA is currently developing.

- *Conducting a public literature search for any new hazard data made available since the date of the final HPV submission (or OECD SIAR/SIAP publication).* This step has been added to the process of developing an HC. A list of the search engines and databases that EPA routinely searches when preparing the HC is included in the document, *Methodology for Risk-Based Prioritization Under ChAMP*.

- *Clarifying the purpose and scope of the HC as a screening-level document that will be used in combination with IUR reporting data to develop a screening-level risk characterization for the purpose of informing EPA on the need for further work on individual chemicals or categories.* This information was added to the Background page of the Interim HC. To further address stakeholder comments regarding redundancy among the HC, EC and RC, as the process and document development evolved, this information has been removed from individual documents and is currently included in the document, *Methodology for Risk-Based Prioritization Under ChAMP* and on the ChAMP website.

- *Listing all the chemicals used in the HC, whether sponsored HPV chemicals or supporting chemicals.* All chemicals subject to a prioritization are listed on the first page of the integrated RBP document. EPA anticipates it will occasionally be difficult to list all chemicals on the first page, e.g., when very large categories are encountered. In these cases, EPA will provide the complete list of chemicals (and CAS Nos.) on subsequent pages or in an appendix.

- *Clearly indicating which chemicals discussed in the HC are sponsored HPV chemicals and which are supporting chemicals.* Sponsored and Supporting chemicals are indicated on the first page of the integrated RBP document. In addition, in the *Introduction* section of the HC, under *Justification for Supporting Chemicals*, the endpoint(s) for which a supporting chemical is used are provided. Finally, study summaries for supporting chemicals are clearly labeled as such.

- *Providing a link to the U.S. HPV Challenge website for each HPV Chemical/Category to provide quick access to the underlying robust summaries.* This link is provided in the first paragraph of the *Introduction* section of the HC (i.e., in Appendix A of the integrated RBP document).

- *Identifying whether public comments were received and posted to the U.S. HPV Challenge website.* Acknowledgement of the receipt of public comments is provided in the first

paragraph of the *Introduction* section of the HC (i.e., in Appendix A of the integrated RBP document).

- *Providing structures for all chemicals, both sponsored and supporting, within the HC.* This information is now provided at the end of each HC (i.e., in Appendix A of the integrated RBP document).

- *Identifying when EPA does not agree with sponsors' assumptions, statements or conclusions.* The HCs are EPA documents, as identified on the front cover. Therefore, EPA's approach is to include/modify sponsors' statements where EPA agrees with them, i.e., they become EPA statements by their inclusion in the HC. When EPA does not agree, this has been stated and EPA's interpretation and rationale is provided (examples can be found in *Category/Supporting Justifications* and in some study summaries/conclusions).

- *Clearly identifying data in summary tables as measured or estimated.* EPA has adopted the practice of indicating measured data in bold font and estimated data is presented in normal font and flagged with an '(e)' or a footnote. For a chemical/endpoint without test data, "No Data" is provided in the data matrix and if data is 'read-across' from an analog it is designated with '(RA)'.

- *Incorporating the Fate Characterization into the Hazard Characterization document.* EPA has adopted this practice, thus providing a more robust characterization of all SIDS (Screening Information Data Set) elements together and reducing redundancy.

- *Providing a clear indication of potential for persistence and bioaccumulation.* This has been implemented as part of the incorporation of the Fate Characterization into the HC.

- *Including a summary table of ecotoxicity data in HCs for categories.* This was originally only done for pchem/fate and health data, but has now been expanded to ecotoxicity data.

- *Expansion and reorganization of the Human Health Section.* This has been implemented, including:
  - moving the Acute Toxicity study summaries to beginning of the section;
  - including summaries of studies for non-SIDS endpoints that are provided by sponsors in their Robust Summaries and/or identified by EPA in their search of the sources listed in the document, *Methodology for Risk-Based Prioritization Under ChAMP*.

- *Providing a clear statement as to EPA's views for each endpoint category.* This has been incorporated by:
  - summarizing at the end of each hazard section (e.g. pchem/fate, ecotoxicity and human health toxicity) the conclusion for that category of endpoints.
  - summarizing in the **Hazard Characterization Summary** section of the integrated RBP document the salient findings and conclusions for pchem/fate, ecotoxicity, and human health toxicity.

- *Providing prominent conclusions.* This has been addressed by:

- providing a conclusion in bold-face type for each study summary; and
- providing a *Conclusions* section at the end of each hazard section (e.g. pchem/fate, ecotoxicity and human health toxicity).
- For stand-alone, interim HCs, EPA provided a summary and conclusions in a highlighted box at the beginning of the document; however, to address comments received regarding redundancy among documents, the overall hazard summary and conclusions have been integrated into the RBP document.
- The overall conclusions regarding hazards are summarized under the heading "**Hazard Characterization Summary",** in the integrated RBP document.

- *Providing clear determinations that data gaps do or do not exist under the HPV Challenge Program.* EPA's evaluation and reasoning regarding whether an endpoint has been fulfilled under the HPV Challenge Program is discussed within the appropriate section of the HC. Data gaps identified under the HPV Challenge Program are identified in the HC (i.e., in Appendix A of the integrated RBP document).

- EPA has *not* incorporated the suggestion to apply conclusions and data gaps identified with respect to an entire category specifically to each chemical within the category because this would not be consistent with international practice.
  - Delineating specific data gaps identified based on weight of evidence of a category to each individual chemical is inconsistent with the concept, rationale and benefits of using a category approach, in which "not every chemical needs to be tested for every endpoint. Rather, the overall data for that category must prove adequate to support a hazard assessment." (OECD Guidance for Grouping of Chemicals, 2007).
  - A category analysis is based on a weight of evidence, and therefore conclusions apply to the whole category. It is the data from the whole category that makes the case. Extrapolations of data across chemicals is often not a simple one-to-one extrapolation, but based on a weight of evidence.
  - To specifically 'extrapolate' the category conclusion based on a weight of evidence to each individual chemical is inconsistent with the concept, rationale and benefits of using a category approach. Furthermore, it implies there is a level of certainty that is typically not characteristic of a category analysis nor necessary for a screening-level hazard analysis.
  - Likewise, in the HC, **data gaps** for categories are identified on the basis of the category, not individual chemicals.
  - Therefore, in the HC, hazard characterizations and data gaps for categories are identified on the basis of the category, not individual chemicals.
  - EPA's practice is consistent with that of the OECD HPV Chemicals Programme[1].

[1]From OECD Manual for the Investigation of Existing Chemicals, Chapter 5: "When presenting conclusions, each chemical should be considered independently of the others.
There should be a separate paragraph for individual chemicals as well as for subcategories of chemicals. It is recognized, however, that one or more chemicals in a category may have limited data. Therefore any conclusions drawn for such chemicals will be derived from data available from the other category members. A final paragraph should be provided which makes an overall conclusion and recommendation regarding the whole category."

Exposure Characterizations

- *Expanding the public sources routinely searched for information.* EPA has identified a standard set of public sources now being consulted. That list is provided in the document, *Methodology for Risk-Based Prioritization Under ChAMP*.

- *Substantially revising the format and content of the EC generally and specifically*. Newer ECs have a substantially different appearance and organizational structure than the early ones, taking more advantages of tables and incorporating more non-CBI information from the IUR.

- *Reducing repetitiveness in Category ECs.* Newer ECs are more streamlined and repetition has been reduced, for example, by handling categories with chemicals having all the same uses and exposure concerns as a single exposure characterization and using individual tables summarizing the information that is specific to each category member.

- *Replacing the combined 'commercial worker and consumers' population with 'consumer'*. It should be noted that the IUR submission form combines reporting of potential commercial worker exposure and potential consumer exposure into one section. However, in the revised EC structure, EPA has included a separate section for potential exposure to consumers. The potential exposure to commercial workers is now incorporated in the potential worker exposure section.

- *More specifically indicating when and what information in the IUR was reported as 'Not Readily Available' (NRO) or was claimed as CBI*. EPA has provided indication that there may be additional IUR information that was reported as 'Not Readily Available' (NRO) or was claimed as CBI. This practice has been adopted in formulating new ECs. The transparency and completeness statistics in the ECs will help communicate to readers about the extent to which CBI information was factored into a specific prioritization decisions and reveal in a transparent manner the full accounting of production volume related to processing and use information provided by the reporting companies.

Risk Characterizations

- *Providing Risk Characterization Summaries for a consistent set of populations.* EPA has adopted a format that has a discrete risk statement for the following five populations: Aquatic Organisms, General Population, Workers, Consumers and Children.

- *Treating the combined 'commercial worker and consumers' population groups separately.* EPA has replaced the combined 'commercial worker and consumers' population with 'consumer', as described above.

- *Providing separate hazard characterization and risk characterizations for aquatic organisms (environment) and human health.* This suggestion has been incorporated.

- *Moved the "Data Needs" section from the RC to discussion in the Prioritization Decision section of the RBP.* The RBP reflects EPA's assessment of potential risks with the information currently available. If additional data is deemed necessary, this would be discussed as part of the prioritization decision.

- *Eliminate redundancy among documents and provide greater transparency about the rationale for the Risk-Based Prioritization.* EPA has incorporated the RC into the integrated Risk-Based Prioritization (RBP) document rather than being retained as independent document in order to eliminate duplication and to increase the transparency of the RBP rationale.

- EPA has *not* provided additional information, such a toxicity values, as part of the risk summary in the integrated RBP, because this information is provided in the accompanying, more detailed HC appendix to the integrated RBP document; this approach is supported by comments received regarding the need to decrease redundancy among the various components of the overall package of information.

Risk-Based Prioritizations

- *Provide Exposure Characterization and Risk Characterization Summaries for a consistent set of populations*. EPA has adopted a format that has risk statements for the following five populations: Aquatic Organisms, General Population, Workers, Consumers, and Children.

- *Provide additional discussion of "Data Needs"*. EPA is including data needs for use, exposure or hazard information in the *Prioritization Decision* section of the integrated RC/RBP document. EPA is being explicit concerning the extent to which decisions are being based on assumptions made in the absence of data and how conclusions might be affected by the receipt of data.

- EPA has received, and anticipates we will continue to receive, comments on specific chemical/category RBPs. In some instances the comments include voluntary commitments to provide additional data that the Agency had indicated were lacking; for example to help resolve questions concerning potential exposures and releases. Comments can be submitted to the ChAMP website (www.epa.gov/ChAMP). Additional information, such as data and CBI information, may also be submitted to EPA through the docket indicated on the ChAMP website. Such information (other than CBI) will be posted to the ChAMP website. The Agency will give highest priority to resolving issues on High Priority chemicals.

- EPA is *not* repeating in the integrated RBP such details as toxicity values or data supporting the conclusions on persistence or bioaccumulation because that information is already available in the more detailed supporting documents. The purpose of the RBP is to describe briefly and directly the rationale for and the specifics of the Agency's prioritization decision. Accordingly, the RBP simply summarizes the salient conclusions from the underlying support documents to provide the context for the Agency's decision. The HC and EC remain

available for consultation by anyone desiring the specific information underlying those conclusions, and are provided as appendices to the integrated RBP document.

Hazard-Based Prioritizations and Supporting Information

While generally supportive of grouping of chemicals for conducting hazard-based prioritizations, some concern was expressed about the 'structure-only' basis for the clustering. EPA recognizes the limitations associated with using a structure-based approach for grouping chemicals. It is this understanding that has led us to use the clustering approach only as an initial step in the process; one that provides a way to organize the subsequent work of gathering existing data and model estimates for chemicals subject to an HBP. Following the initial clustering, conducted by computerized algorithm, EPA experts experienced in evaluating new chemicals and identifying appropriate analogs evaluate each cluster with the aim of identifying chemicals which are know to behave differently from others in the cluster. Potential differences in physical-chemical properties, fate, metabolism, modes or mechanisms of toxic action are all considered. It should be clarified that a wide spread in a physical-chemical, fate or biological property across a cluster is not considered a "difference" per se if there is a distinguishable trend in the property or toxicity. In fact, the ability to identify trends and "break points" in properties or toxicity that is facilitated by evaluating chemicals in groups can provide valuable insights into what property or toxicity can be expected for a chemical among the group for which measured data is lacking. Likewise, when extrapolating or 'reading across' data to a chemical for which measured data is unavailable, use of a chemical grouping approach provides a larger 'weight of evidence' for making the extrapolation and understanding the uncertainties associated with it, i.e. a many-to-one extrapolation is more robust than a 'one-to-one' extrapolation. Additional discussion of the benefits of assessing chemicals in groups is provided in the OECD's Guidance on Grouping of Chemicals.

EPA is *not* abandoning the cluster approach in the HBP process. Grouping of chemicals for assessment is a long-standing EPA practice and one that is also applied in international chemical assessment programs. For example, EPA has a structure-based 'alert' system (i.e., New Chemicals Categories in the assessment of new chemicals subject to TSCA Pre-Manufacture Notice (PMN) for over thirty years. Likewise, the use of chemical categories for assessing HPV chemicals is an approach that is encouraged both in the US and internationally (i.e. U.S. HPV Challenge Program; OECD HPV Programme).

APPENDIX

Prior to and throughout the development of ChAMP, a variety of stakeholders have provided valuable and insightful comments on both draft and early process documents prepared by EPA for use in the program. Engagement of these stakeholders was not intended to provide collective group advice or consensus views but rather individual input and advice on EPA's assessment and management program for existing chemicals in the U.S.

Individual Stakeholders that Provided Comments on the Development of Risk- and Hazard Based Prioritization Documents

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