

**Report of an Evaluation of the Peer Consultation Panel Pilot
to Review HPV Submissions**

Toxicology Excellence for Risk Assessment (*TERA*)
(<http://www.tera.org/peer/>)

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Executive Summary

The American Chemistry Council, the Physician's Committee for Responsible Medicine, and the U.S. Environmental Protection Agency (EPA) participated in a peer consultation pilot during 2008 to review test plans (TP) and robust study summaries (RSS) from the High Production Volume (HPV) Challenge and Extended HPV programs. The purpose of the pilot was to test whether stakeholder review might be improved by implementing a focused approach designed to emphasize stakeholder and expert involvement. The panel of experts and stakeholders met in two public meetings to review and discuss TPs and RSSs prepared by the primary producers for 22 HPV chemicals. The producers who prepared the TP and RSS submissions were invited to attend the meetings in-person or by conference call. Reports for each meeting summarized individual panel members' comments and areas of agreement and disagreement regarding recommendations of the expert committee.

Participants completed a written evaluation of the pilot. This report summarizes the evaluation process and results. In general, those responding to the survey were positive about the pilot and the results and recommended it over the original HPV process. For example, many respondents commented that the pilot was well-organized and the process was effective at expediting the HPV reviews. They saw the benefit of bringing together the three main HPV commenters for meaningful dialogue with the sponsors to identify missing information and resolve questions quickly. Furthermore, the pilot was able to clearly focus the review and provided for more conclusive results in many cases. More importantly, the panel meetings allowed participants to gain a better understanding of others' perspectives and the sponsors appreciated the opportunity to interact with the reviewers and present information and answer questions.

Participants also offered a number of suggestions for improving the process. For example, in the area of logistics, many thought the quality of the teleconference needed improvement and wireless internet access would be beneficial to be able to access important information during the meeting. Panel participants suggested that the process for selection of chemicals be improved and that the agenda be finalized earlier, so that they can better prepare for the meetings.

The sponsors also thought that more time to prepare for the meetings and for follow-up between meetings would be helpful, especially when sponsors were asked to bring additional information back to the panel. And, while sponsors appreciated receiving pre-meeting comments, they would have liked to receive these comments earlier. Sponsors also thought that a better understanding of their role at the meeting, and the ground rules for their participation during the meeting, were needed. Several sponsors also thought that some panel members needed a better understanding of what constitutes an acceptable test plan.

Finally, both sponsors and panelists thought that any next steps and resolution on individual chemicals need to be made clear to all participants at the meeting. Several panelists and sponsors also commented on the need for additional expertise on the panel, specifically, in ecological effects, structure activity relationships (SAR), and physical-chemical endpoints.

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Background

In the fall of 2008, the American Chemistry Council (ACC) (on behalf of a broad group of chemicals industry groups), the Physician's Committee for Responsible Medicine (PCRM), and the U.S. Environmental Protection Agency (EPA) conducted a peer consultation pilot to review test plans (TP) and robust study summaries (RSS) from the High Production Volume Challenge (HPV) and Extended HPV (EHPV) programs. The purpose of the pilot was to test whether stakeholder review and input on the TP and RSS might be improved by implementing a process and approach different from the one used during the HPV Challenge program. During the Challenge program, interested stakeholders, including EPA, would post comments on the test plans and robust study summaries to EPA's website during a 120-day comment period (which not infrequently extended longer than 120 days), and sponsors would then respond to those comments on the website.

During the pilot, stakeholders participated in two face-to-face panel meetings attended by sponsors whose test plans and robust study summaries were under review. The goal of these meetings was to improve the efficiency and effectiveness of the stakeholder review. For more details on the design of the peer consultation process, please see description of the pilot and approach, *Description of Peer Consultation Panel Pilot to Review HPV Submissions* (Attachment 1). More information can be found at <http://www.tera.org/Peer/HPV/index.html>. Twenty HPV or EHPV submissions, covering 23 chemicals, were reviewed by the panel in two meetings. A list of participants, chemical submissions, and sponsors is found in Attachment 2.

This report summarizes the major findings and recommendations from a participant evaluation of the pilot process.

Evaluation Questions

The evaluation form included nine questions and respondents were invited to provide narrative answers. The questions were designed by TERA (with input from ACC) to elicit comments on the positive attributes of the pilot process and results, identification of aspects that were not effective, and suggestions for future processes. A final question was included to capture any other important comments or suggestions that the other questions may not have prompted.

TERA distributed the evaluation by email to all registered attendees from the two meetings. Respondents were assured that their results would be kept confidential and results reported anonymously. This report is a summary of the results. A copy of this report will be sent to each evaluation participant.

Table 1. HPV Pilot Evaluation Questions. Nine questions sent to all participants in the November and December HPV Pilot peer consultation meetings.

HPV Pilot Evaluation Questions

- 1. Was the pilot process effective? Why or why not?*
- 2. What changes or improvements would you recommend to the pilot process if it were to continue?*
- 3. One goal of the pilot was to “expedite the review process.” Do you think it accomplished this (over the original HPV process)? Why or why not?*
- 4. Did the pilot provide participants with opportunities to discuss scientific and technical comments with one another? Was this important, and why?*
- 5. Was the interaction between panel members and sponsor representatives useful to identification (and perhaps resolution) of problems and issues?*
- 6. Please comment on whether this process is of value or benefit to your organization/company/consortia?*
- 7. Do you have any comments or suggestions regarding logistics (e.g., meeting room, location, conference call quality, agenda, distribution of materials, communications).*
- 8. What process would you recommend for future HPV submissions? The original process? The pilot process? Something different?*
- 9. Please provide any other comments or suggestions.*

Respondents

TERA emailed the evaluation form (see Attachment 3) to each person who registered to attend one of the two meetings. Thirty-eight people were sent the evaluation form; 29 were industry sponsors or those working with sponsor consortia, seven were panel members or those working with the panel, and two were observers. Fifteen questionnaires were returned from participants representing sponsor groups; at least one response was received from each of the 11 different sponsors/consortia for the 20 submissions (100% sponsor response rate). Six returns from panel members and others working with the panel were received (100% response rate for panel participants – EPA with two individual responses, PCRMM (combined response), the third panel

member, the Facilitator, and the Note Taker. The other participants (e.g., observers from ACC) did not submit comments for this evaluation. See Attachment 2 for a list of participants, sponsors, and chemicals reviewed.

Table 2. Number of Respondents by Role.

<i>HPV Pilot Evaluation Respondents</i>		
Role in the Pilot	Number of returns	
Company/Consortia Sponsors and Representatives	15	15 respondents represented all 11 submission sponsor groups. Most sponsor groups provided one response, a few sponsors provided 2 individual responses.
Panel members plus	6	EPA (2), PCR/M, panel member, the Facilitator, Note Taker.

Findings

Results from the questionnaires were compiled by question. Key points and a summary of responses for each question/topic are provided below. The responses from panel and sponsors are presented separately. Numbers of responses were too small to provide reasonable further breakdown of the groups.

Was the pilot process effective?

Question 1: Was the pilot process effective? Why or why not?

The vast majority of sponsors thought that the pilot process was effective. Participants generally felt that the real time exchange and feedback were beneficial in bringing clarity and aiding the resolution of issues in the test plan. One respondent noted, “By bringing together the three main commenters, the process was able to move forward.” Many commented that this face-to-face interaction provided the opportunity for sponsor companies and panel members to discuss the submissions, which facilitated a better exchange of ideas and also led to immediate clarification of misinterpretations, and avoided lengthy and potentially misunderstood written communications. Several respondents commented that the process was efficient and expeditious, without being a major effort. One commented that the third-party facilitation of discussions and review provided the opportunity for objective documentation and consensus.

A few participants felt they either could not evaluate the effectiveness of the process either because they had no experience with the old format, or the discussion on their submission was too minimal to form an opinion. One sponsor participant felt that the reviewers should have

reached consensus on the issues and their relative importance, and that not all the reviewers had a comparable understanding of what was an acceptable test plan.

Panel participants thought that the pilot was effective, citing a number of different reasons. The program allowed EPA, others, and sponsors to have meaningful dialogue about chemicals and generally addressed questions and concerns quickly to obtain a clearer focus and desired results about chemicals at the end of the session. One panel member noted that “in the original HPV program, sponsors rarely had the opportunity to discuss their cases with EPA, and EPA staff often needed questions answered that resulted in placing those questions/concerns on the website to be addressed.” The in-person format of the meeting allowed for efficiency by rapid clarification of minor and major issues from the sponsors and reduced the potential need for multiple rounds of written comments, leading to quicker resolution. One panelist noted that the process was effective because the discussion among the panel members resulted in greater appreciation of uses, potential exposures and risks than would have been the case if the submissions had been reviewed in isolation, as was done in the past. Another cited three reasons for effectiveness – the sponsors were able to answer quickly any clarifying questions, which clarified misconceptions and enhanced panel discussions; sponsors were able to ask clarifying questions of panelists, which resulted in greater understanding of panelists’ comments; and third, panelists were able to ask questions of each other, leading to better understanding of opinions and better decisions. This last point was emphasized by a panel member who noted that interaction with individuals having different expertise and perspectives frequently provided insight and appreciation of relevant facts that he would not have otherwise had.

One panel member thought a weakness of the pilot was that the experts were heavily weighted toward mammalian toxicology and that the physical-chemical SIDS endpoints could have received more attention. Likewise, a sponsor thought the panel needed an ecological effects person.

Did the pilot “expedite the review process?”

Question 3: One goal of the pilot was to “expedite the review process.” Do you think it accomplished this (over the original HPV process)? Why or why not?

The designers of the pilot sought to expedite the process for reviewing HPV submissions. Participants were asked whether the pilot succeeded at achieving this goal. Many thought it did, while a few others could not comment due to lack of experience with the original HPV review process.

Most of the sponsor respondents had previous experience with the HPV Challenge Program and almost all of them thought that the pilot did expedite the process. Several commented that this process was much faster and comments were transmitted in less than the 120 days of the original process. One also noted that receiving the comments via email eliminated the need for daily monitoring of the docket to determine if comments had been submitted. Several commented on improved efficiency because of the opportunity to seek clarification from panel members and that the discussions were more useful and productive than the written comments posted to the EPA website. One explained, “we accomplished in one one-hour meeting what would have

taken at least three email exchanges over several months to accomplish,” and another noted that in a very short period of time the questions and concerns of the panel were made clear.

One sponsor participant thought that the pilot process provided reviews for substances that might otherwise have languished for years going un-reviewed, but that the pace of HPV reviews (of those already submitted and future submissions) must be accelerated considerably for the process to be meaningful. Another responder anticipated that complicated cases may not move as swiftly as those in the pilot.

The panel members also agreed that the pilot process was quicker and more effective than the original HPV process. One thought the pilot provided more information in terms of getting questions and thoughts about a chemical (s) answered in a way that allowed for a more conclusive product than that presented in the original HPV program. Another noted that the review was streamlined with the pilot, but was not certain the pilot system is practical in the long-term, in that it relies heavily on a small group of individual panel members.

Discussions and Interactions

Questions 4 - Did the pilot provide participants with opportunities to discuss scientific and technical comments with one another? Was this important, and why?

Question 5 - Was the interaction between panel members and sponsor representatives useful to identification (and perhaps resolution) of problems and issues?

Sponsors appreciated the opportunity for interactions with the reviewers. They thought this important and felt that the interactions between panel and sponsors were beneficial. They noted a number of benefits. Real-time exchange of information enhanced efficiency, minimized miscommunications, provided a more robust picture of the chemical and its issues to panel members, provided opportunity to clarify the more difficult points, provided resolution to more simple issues, and allowed broader information exchange, in general. One noted that, “The review committee did appear to accept input from the sponsors and consider this information.” Another observed that the exchange of information between panel members was also beneficial as the panel members contributed comments and questions to one another as well as to the sponsors.

Several sponsor respondents could not fully answer the question because their submissions received very little discussion. Several sponsor respondents identified a concern with the panel and interactions. One thought that the reviewers did not seem to understand what was required to meet a minimum level of adequacy in regard to data acceptability and one commented that it seemed like all the reviewers had a need to make comments, whether value was added or not. Another thought that the panel lacked experience with the program and this was reflected in the comments and discussions that occurred. A third noted that in his/her company’s experience with the pilot, one panel member took a somewhat adversarial approach and at times was combative. The sponsor participant suggested the panel member be coached to avoid this behavior and to strive for a more harmonious approach. This same commenter thought that the

approach to running the meeting should be reexamined. The moderator, in the commenter's case, was too rigid and controlled the interaction between sponsor and panel members, sometimes cutting off the sponsor when the person wanted to respond to a statement (often times to correct a misperception).

Panel members likewise felt that the opportunity to discuss scientific and technical comments with one another and the sponsors to be very beneficial, and a key advantage of the pilot approach. Discussions among panelists were important because they provided opportunities for panelists with different expertise and perspectives to share knowledge and experience about chemical information and individual tests; leading the others to new insights and better individual opinions. One observed that, "on several occasions there were changes in opinions from initial pre-meeting comments that had been developed in isolation based on clarifications and discussions facilitated by the face-to-face meetings."

Panel members also thought that the exchange of information with sponsors led to quick clarification of questions arising from the test plans, as well as other important information that was, in some cases, absent from the test plans. One panel member noted that, "In the original HPV program, sponsors rarely had the opportunity to discuss their cases with EPA, and EPA staff..." In some cases they thought that recommendations for additional testing were received more favorably, because of the face-to-face discussions, than if the comments had been merely posted on the web. One panelist noted that the interactions with the sponsors were very helpful for identifying problems. He commended one sponsor in particular with numerous submissions in the first meeting who provided written responses to the large number of panel questions in time for consideration at the second meeting. This information resulted in resolution of many of the chemicals' initial issues.

Value and Benefit of the Pilot Process

Question 6: Please comment on whether this process is of value or benefit to your organization/company/consortia?

This question was directed to the sponsors. Almost all the sponsor respondents were positive about their participation in the pilot and felt that it was valuable and beneficial to their consortia or company. One respondent wrote, "We don't have many materials still in the HPV process, but I can see that it will benefit future submitters, mainly by providing timely response and dialog, rather than the black hole that previous submissions seemed to disappear into." Others noted that the pilot was efficient and improved communication, and that it provided guidance on regulatory authority requirements and level of detail desired in the dossiers. A few sponsors disagreed on the pilot's value or benefit, with one noting that, "If the sponsors were to be a part of the review, the value of the process would be improved."

Logistics

Question 7: Do you have any comments or suggestions regarding logistics (e.g., meeting room, location, conference call quality, agenda, distribution of materials, communications)

Generally the sponsor respondents thought the facilities and logistics adequate. Several sponsors and panel members commented that the pilot was well organized and the review coordinator was very responsive, organized and knowledgeable. They offered several suggestions for improvements. Many sponsors and observers commented that it was helpful (and more economical) to be able to access the meeting via teleconference, but the quality of the call seemed to vary for different participants; several mentioned that the quality of the telecommunications were not adequate, while another found the quality of the conference call good. Respondents thought the meeting facilities were adequate, but several suggested wireless internet access in the meeting room would be helpful to retrieve information during the meeting. One sponsor respondent recommended that the meeting be held in Cincinnati where hotels are cheaper and most of the people associated with the program were located.

Many sponsor respondents mentioned the value and importance of receiving pre-meeting comments from the panel members, but some suggested that all the reviewers' comments should be compiled before sending, and that comments need to be distributed to the sponsors earlier so that they can be better prepared and more substantive discussions may take place. Receiving comments in advance also allowed a sponsor to decide whether to attend in person or by phone.

The panel members were generally satisfied with the meeting logistics and the way the pilot was run, with one panel member noting that, "the process was run very professionally and allowed optimum results." Some panel participants however, thought the limited access to the meeting room and necessity to have EPA escorts in the building was inconvenient. One participant also suggested that webcasting would be an approach to increase external participation. Panel members also suggested that a more efficient manner of identifying chemicals for review needs to be developed and the agenda should be finalized earlier so that distribution of materials can be efficient and timely. In addition, a system for panelists and sponsors to access the same documents is needed to insure that all are working from the same copies or versions.

Recommendations for Changes and Improvements

Question 2: What changes or improvements would you recommend to the pilot process if it were to continue?

Some sponsor participants had individual suggestions to improve the process. Several commented on the timing of the process. One noted that the pilot seemed very rushed and there was not enough time between meetings for the company sponsor to prepare and follow-up on recommendations, while another mentioned the limited notification time for the sponsor participation. Several asked that questions and comments from the panel be provided further in advance of the meeting, so that they can better prepare for the meeting. Similarly, another suggested that it would be useful if there was an opportunity before the formal meeting to have informal clarification dialogue with the individual reviewers after receiving their pre-meeting comments. The respondent thought that these informal, advanced discussions might serve to promote greater constructive dialogue at the meeting and that a report of the conversations could be made during the formal meeting.

One sponsor mentioned that it took too long (two months) after the meeting to provide the draft reviewer comments for feedback. While the sponsor respondent thought that to some extent this is understandable given the holiday season, it must be remembered that their submission had been made over two years earlier, and the membership of the consortium changed or moved on to other endeavors. Because it is difficult to reconstitute consortia to respond to comments, the respondent suggested that any future reviews of already submitted HPV Challenge packages must be scheduled as soon as possible and in rapid succession. “The HPV work will continue to be ‘old news’ to many companies as they move forward with new obligations associated with REACH, ChAMP and possibly TSCA reform.”

Sponsor participants had several other suggestions. One wanted to see a single consensus opinion of all panel members on the adequacy of the test plan, rather than the individual opinions. Another suggested a better format for an action list at the end of the meeting. One sponsor participant noted that there was interest expressed during the meeting discussion for non-HPV endpoints, but since these are out of the scope of the program, providing this information should not be mandatory. Finally, one sponsor noted that (while not necessarily a pilot process improvement), it would be an improvement to have a small team from the sponsor company or panel participating in the call to make sure they have an expert for the different types of data and information available.

Panel members also had suggestions for improvements. They mentioned that finalization of the meeting agendas earlier would aid the sponsors and panel in being fully prepared for the meeting. In addition, a better understanding of the process was needed. One person commented on the facilitation of the meetings, noting that the Facilitator did a nice job of managing the interactions on a few occasions where it was clear that the sponsor representative disagreed with the panel member opinion. The panel member suggested, however, that the traditional approach of limiting sponsors to “clarifying questions” and limiting their ability to fully discuss issues, was awkward at times when the sponsors wanted to share opinions and comments, which in many cases the panel members found valuable. The panel member suggested that in the future that the ground rules for discussion be communicated clearly to the sponsor participants.

One member remarked that no resolution on a few of the cases in which panel members could not agree was problematic. There was uncertainty about how the outcomes were to be used and how responses to panel comments would be communicated and ultimately used by EPA, the process for “bringing assessments back” for additional review needed to be made clearer, as well as the process for communication of follow-up action items by panel members. In addition, one panel member thought there should be some type of closure or final position of the industry sponsor, and an understanding of where the final test plans will be housed. In some cases, it was unclear the degree to which potentially relevant background documents were to be reviewed by the panel, particularly for those with complex categories or prior TP reviews, and a common understanding of this by all panel members would be beneficial.

One panelist noted that if demand for reviews is large, a prescreening of submissions could be useful and meeting time could be reserved for those submissions with more complex issues that would benefit from discussion. A few panel members felt it would have been beneficial to

include additional expertise on the panel, specifically environmental fate, chemistry, and QSAR modeling. Another panel member would encourage sponsors to attend the meeting in person.

Recommendations for Future HPV Submissions

Question 8: What process would you recommend for future HPV submissions? The original process? The pilot process? Something different?

A majority of sponsors preferred the pilot process, and a few preferred the original process. Of those who preferred the pilot, some suggested improvements and enhancements as discussed above. Several respondents mentioned that the timeliness of the process is most important, with one noting that the original process was useful from a technical view, but that the response time from the reviewers needed improvement. Another agreed that the format of the process is not as important as the pace and that “the lapse time from original submission to review is critical to a substantive participatory process.” Another commented that companies must be given an opportunity to clarify and respond to any questions raised while they are still focused on the program and still engaged in consortia, “all of us live in an ever-changing-regulatory-world, and it is likely that the obligations of companies will continue to expand worldwide. Thus, efficiency is critical.” Finally, one thought that the pilot was a better process, but it requires additional resources and funding to be successful.

The individual panel members thought that the pilot process was a significant improvement over the original approach. One noted that the panel offered good advice on how to improve dossiers and that the premeeting comments were important for preparing for the meetings and facilitated discussions of differing opinions by the panel members. This panel member thought that the facilitator did an outstanding job. He questioned how many chemicals per year such a process could accommodate, as it depends primarily on three stakeholder panel members, and whatever resources they may have at their disposal.

One panel member noted that the original HPV process involved a number of scientists from many different disciplines (chemists, biologists, ecotoxicologists, and toxicologists), but the pilot involved fewer people, and the review was not as thorough as it could have been through the old process. This panel member attempted to address all endpoints within the available time and overall goal of the pilot, but the test plans did not get the rigorous or thorough reviews of original HPV test plans.

Additional Comments

One sponsor raised a question regarding how the pilot results will be communicated. The sponsor noted that the original plan for the HPV Challenge entailed posting all submissions and all comments on the HPV web site. If the pilot consultation reports are not posted with the individual chemicals, the chain is broken; interested parties will see a submission page but no follow up comments, and can easily assume nothing has been done. The participant felt that, “In my mind this negates the intent of the voluntary HPV program, which was to provide a

transparent review process for the sponsored HPV substances,” and highly recommend that the report be added to the HPV Challenge web pages for each substance.

Attachment 1 - Description of Peer Consultation Panel Pilot to Review HPV Submissions

Background

This pilot project will develop and test a process to review HPV Test Plan submissions. Currently, EPA's posts industry-developed Robust Study Summaries (RSS) and Test Plans (TP) on its website for 120 days to permit public comment. During that comment period, EPA also reviews and comments on the RSS/TPs. All comments are posted on EPA's website. Industry sponsors are free to accept or reject any particular comment, but must provide a written explanation or justification when rejecting comments. These industry responses are also posted on EPA's website. This procedure was employed for almost all of the HPV Challenge submissions; however, there is a small number of Challenge chemicals that have not yet undergone this review and comment process. Under the pilot, a number of those Challenge submissions in addition to a group of chemicals in the Extended HPV (EHPV) program¹ will be reviewed by panel members at one of two 2-day in-person meetings to be held before the end of 2008. Approximately 40 chemicals will be selected by ACC and EPA to undergo review in this pilot project.

Purpose of Pilot

The purpose of the pilot is to test a new approach to provide stakeholder and EPA input on the robust summaries and test plans. Panel meetings will be used to facilitate the exchange of expert opinions on the technical soundness of the RSS/TPs and to ensure full discussion of comments for sponsor consideration.

The goal of a revised program is to expedite the review process for both EPA and stakeholder comments, and present opportunities for different parties to discuss scientific and technical comments with one another.

Approach

- A panel of expert scientists will meet to discuss and comment on the adequacy of the test plans and robust study summaries submitted in the HPV Challenge or Extended HPV programs. The panel members will include expert scientists from two organizations that have provided public comments on test plans submitted in the past (i.e., the Physician's Committee for Responsible Medicine (PCRM) and EPA). A third expert, who authored many of the comments submitted by Environmental Defense Fund on the original HPV

¹ The original Challenge program involved chemicals reported to EPA on the 1990 Inventory Update Rule (IUR) as manufactured or imported in volumes greater than 1 million pounds per year. The EHPV program is industry's voluntary continuation of the Challenge program. Under the EHPV, companies committed to sponsor chemicals reported under the 2002 IUR as manufactured or imported at volumes of 1million pounds or more annually that had not been produced or imported in quantities sufficient to qualify as HPV under the Challenge program.

Challenge submissions, will also serve on the panel. A senior scientist from *TERA* will facilitate the panel meetings to ensure that all appropriate scientific issues are addressed.

- The meetings will be open to the public and held at the U.S. EPA facilities in the Washington DC metro area.
- Two 2-day meetings will occur before the end of 2008.
- Panelists will provide individual comments and discuss their opinions. Agreement or consensus is not required.
- A meeting report will summarize comments and panelists' opinions.
- The meeting reports will be made available to the public via a *TERA* webpage.

Roles and Responsibilities

Sponsors

- Sponsors will prepare and submit EHPV RSS/TPS to EPA. Sponsor representatives will be invited to attend the meetings at which their RSS/TPs are scheduled for discussion. They may participate in person or by conference call. The sponsors should be prepared to answer clarifying technical questions from the panel members. The sponsors will be permitted to ask panelists clarifying questions to ensure comprehension of panelists' comments.
- The sponsors will consider the panelists' comments and revise their test plans accordingly, and/or prepare an explanation for rejecting comments. The final test plan will be submitted to the EPA docket.

Panelists

- Each panel member will review the RSS/TPs prior to the meeting and come to the meeting prepared to discuss the adequacy of the RSS/TP for HPV.
- Panelists will be asked to send *TERA* initial comments or questions prior to the meeting so they may be distributed to the sponsors to aid them in their preparations for the meeting. *TERA* will send these initial comments (omitting attribution) to the appropriate sponsors. *TERA* will send initial comments (with attribution) to other panel members. Because these are panelists' initial thoughts, these comments will not be part of the official record and will not be distributed beyond the sponsors and panel members.
- Individual panelists are not precluded from contacting the industry sponsor directly to ask for additional information or clarification prior to the meeting. If a panelist does so, he or she will inform the other panelists (by email prior to the meeting), of the nature of the communication and describe or characterize the information obtained. Outside parties, including sponsors, should not contact panel members, except through the *TERA* coordinator. Consideration for such contact will be made on a case-by-case basis and any and all information gained from this contact will be shared at the meetings.
- Panelists are encouraged to prepare written comments that will be raised at the meeting and included in the meeting report.
- At the meetings, panel members will actively discuss the adequacy of the RSS/TP and address the charge questions:

- Does the information² provided address the SIDS endpoints?
- Is the information provided adequate to support the conclusions for each relevant SIDS endpoint?
- If a category is presented, is the rationale for the category reasonably appropriate, and is the use of read across scientifically defensible?
- Brief conclusion statements for each charge question will be drafted and reviewed by panelists prior to the meeting conclusion.

Public

- The public will be invited to participate and will be provided the opportunity to attend the meetings to observe, submit written comments on the test plans, and/or make brief technical comments at the meetings. Comments can be submitted to *TERA* through the *TERA* website and *TERA* will email the comments as they are received to the panel members and appropriate sponsors. *TERA* will make sure that the panel members also receive any public comments posted to the U.S.EPA docket.

ACC

- Secure funding for the peer consultation process.
- Participate in planning the pilot and evaluation of the pilot.
- Facilitate participation of sponsor companies and consortia in the pilot.

TERA

- The pilot will be administered by *TERA*, which will be responsible for:
 - Developing the pilot approach;
 - Organizing and conducting the meetings;
 - Announcing the meetings to interested persons;
 - Facilitating the meetings to ensure all agenda items are discussed and all panel members are fully heard;
 - Preparing a report that summarizes the comments and results of the discussions;
 - Posting the results;
 - Developing evaluation criteria for the pilot; and,
 - Conducting the evaluation.

Guidance to Panel

- In preparation for the first consultation meeting, *TERA* will convene a conference call with panelists and ACC to discuss:
 - The pilot process;
 - Roles and responsibilities of ACC, EPA, panel members and *TERA*;
 - Meeting structure;
 - Schedule of meetings; and,
 - Scope and guidance for panel comments and discussions (i.e., the charge).

² Note that exposure and use information that is part of the HPV or EHPV submissions is not subject to review in this Pilot; however, panelists may use this information to help inform their opinions regarding the screening level hazard needs.

- For the peer consultation meetings, panelists will be asked to comment on the adequacy of the RSS/TPs for the HPV program. The panelist comments should focus on the charge questions outlined above.

Communication with the Public

- An objective of the pilot is to design and implement a process that is transparent, allowing interested persons to be informed, as well as participate by way of submission of comments and observation of the meeting discussions. *TERA* will communicate with the public to inform them about the HPV Peer Consultation Pilot through the following means:
 - *TERA* will prepare and maintain a web page that will provide key information on the pilot project and each meeting.
 - The *TERA* web page will link to the appropriate EPA site to provide users with access to the RSS/TPs.
 - A description of the pilot process and schedule will be made available.
 - Interested persons will be invited to submit comments, and information on how to submit technical comments will be provided.
 - Reports from the panel meetings will be posted.
 - *TERA* will develop and maintain an email list to send announcements on meetings, requests for public comment, and other pilot activities.
 - Interested persons can sign up for this list via the *TERA* web page or by directly contacting *TERA*.
 - An initial email will be sent to *TERA*'s peer consultation mailing list to inform them of this new project and invite them to sign up for future notifications.
 - *TERA* will also encourage other stakeholders in the project to inform their constituents via press releases, email or list server notifications, or other means.

Meeting Reports

- A *TERA* senior scientist will take notes of the panel discussions and prepare a brief report in bulleted form of the panelists' conclusions concerning the charge questions. The report will append the individual panelist written comments, if available. The draft report will be reviewed and approved by the panel. The final report will be posted on the web page and a notification will be sent to the mailing list.

Meeting Logistics

- Meetings will be held at EPA offices in the Washington DC area.
- If sponsors cannot answer all questions or provide needed information at the meeting, the Facilitator will suggest that the remaining discussion be postponed until the information is available. This may be at a later time on the current meeting agenda or at the second meeting. If this is not possible, *TERA* will consider distributing the answer/information to the panel post meeting for their consideration and revision to individual comments.

Evaluation of the Pilot

- The pilot process and results will be evaluated by participants in early 2009.
- *TERA* will discuss evaluation criteria and process with ACC and EPA prior to the first meeting of the Panel and will conduct the evaluation.

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Attachment 2 –Submissions, Sponsors, Panel, Other Participants

Submissions, Sponsors, and Sponsor Representatives			
Submissions	Sponsor	Pilot Participants	Meeting Date
Benzenamine, N-phenyl-, (tripropenyl) derivatives	Lubrizol Corporation	<ul style="list-style-type: none"> • Dr. Steven Signs • Dr. Yafan Li 	November 18, 2008
Dithiophosphate Alkyl Ester Category	Lubrizol Corporation	<ul style="list-style-type: none"> • Dr. Steven Signs • Dr. Yafan Li 	November 18, 2008
Formaldehyde, reaction products with (1-methylhexyl) phenol, calcium salts	Lubrizol Corporation	<ul style="list-style-type: none"> • Dr. Steven Signs • Dr. Yafan Li 	November 18, 2008
Heptanoic acid, mixed esters with pentaerythritol and valeric acid	Lubrizol Corporation	<ul style="list-style-type: none"> • Dr. Steven Signs • Dr. Yafan Li 	November 18, 2008
Octanoic acid, 1,1'-(2,2-dimethyl-1,3-propanediyl) ester	Lubrizol Corporation	<ul style="list-style-type: none"> • Dr. Steven Signs • Dr. Yafan Li 	November 18, 2008
Soybean oil, sulfurized	Lubrizol Corporation	<ul style="list-style-type: none"> • Dr. Steven Signs • Dr. Yafan Li 	November 18, 2008
Zinc Dialkyldithiophosphate Category	Lubrizol Corporation	<ul style="list-style-type: none"> • Dr. Steven Signs • Dr. Yafan Li 	November 18, 2008
Acetonitrile, 2,2',2''-nitrilotris	Akzo Nobel Functional Chemicals LLC	<ul style="list-style-type: none"> • Mr. Edwin Bisinger, Jr. • Ms. Louette Rausch 	November 19, 2008
1,4-bis(pentabromophenoxy) tetrabromobenzene	Albermarle	<ul style="list-style-type: none"> • Mr. Todd Steddeford • Dr. Marcia L. Hardy 	November 19, 2008
Phenothiazine, 10H-	Cytec	<ul style="list-style-type: none"> • Dr. Randy Deskin (Cytec) • Mr. Bob Fensterheim (RegNet) • Mr. Andrew Jacques (RegNet) 	November 19, 2008
1,4 Cyclohexanedicarboxylic acid	Eastman Chemical Company	<ul style="list-style-type: none"> • Dr. James Deyo 	December 15, 2008
Trifluoromethane	DuPont	<ul style="list-style-type: none"> • Dr. Gary Jepson 	December 15, 2008
Residual oils, oxidized	Lubrizol	<ul style="list-style-type: none"> • Dr. Steven Signs 	December 15, 2008

Submissions, Sponsors, and Sponsor Representatives			
		<ul style="list-style-type: none"> • Dr. Yafan Li 	
C4-6 IRF Stream	Exxon Mobil	<ul style="list-style-type: none"> • Dr. Ammie Bachman • Ms. Susan Blevins • Mr. Rich Davi • Ms. Carol Fairbrother • Dr. Douglas Winkelmann 	December 15, 2008
C3-5 BIR Stream	Exxon Mobil	<ul style="list-style-type: none"> • Dr. Ammie Bachman • Ms. Susan Blevins • Mr. Rich Davi • Ms. Carol Fairbrother • Dr. Douglas Winkelmann 	December 15, 2008
1,3-Propanediol	ACC 1,3 Propanediol Panel	<ul style="list-style-type: none"> • Ms. Leigh Belcher (DuPont) • Ms. Kathy Kiibler (Shell) • Dr. Ralph Gingell (Shell) 	December 15, 2008
Quarternary TEA	Evonick Goldschmidt and Stepan Chemical	<ul style="list-style-type: none"> • Dr. Wendy Koch (Epona Associates, LLC) 	December 15, 2008
Na Cocoyl Isethionate (SCI)	Sodium Ethyl Sulfonates Coalition (SESC)	<ul style="list-style-type: none"> • Mr. David Mallon (Unilever) • Dr. Eliot Deag (Unilever) • Dr. David Kent (Keller and Heckmann LLP) 	December 16, 2008
Na Isethionate (SI)	Sodium Ethyl Sulfonates Coalition (SESC)	<ul style="list-style-type: none"> • Mr. David Mallon (Unilever) • Dr. Eliot Deag (Unilever) • Dr. David Kent (Keller and Heckmann LLP) 	December 16, 2008
p-Toluenesulfonic acid	para Toluenesulfonic Acid Coalition	<ul style="list-style-type: none"> • Dr. Jack Murray • Mr. Robert Foster (NOTOX, B.V.) 	December 16, 2008

Panel Participants	
Participant	Role
Dr. H.B. (Skip) Matthews Matthews Toxicology Consulting Company	Panel
Dr. Louis (Gino) Scarano U.S. Environmental Protection Agency	Panel, EPA
Mr. Larry Newsome U.S. Environmental Protection Agency	Panel, EPA
Dr. Chad B. Sandusky Physicians Committee for Responsible Medicine	Panel, PCRM
Dr. Nancy Beck Physicians Committee for Responsible Medicine	Panel, PCRM
Dr. Michael L. Dourson Toxicology Excellence for Risk Assessment (<i>TERA</i>)	Facilitator
Dr. Andrew Maier Toxicology Excellence for Risk Assessment (<i>TERA</i>)	Note-taker

Others in Attendance who did not participate in the evaluation

- Ms. Christina Franz, American Chemistry Council
- Dr. Richard Becker, American Chemistry Council
- Ms. Pat Rizzuto, BNA
- Ms. Jacqueline Patterson, *TERA*

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Attachment 3 – Evaluation Form

Evaluation of Peer Consultation Panel Pilot to Review HPV Submissions

Background

In the fall of 2008 the American Chemistry Council (ACC), the Physician’s Committee for Responsible Medicine (PCRM), and the U.S. Environmental Protection Agency (EPA) conducted a peer consultation pilot to review test plans (TP) and robust study summaries (RSS) from the High Production Volume Challenge (HPV) and Extended HPV (EHPV) programs. The purpose of the pilot was to test whether stakeholder review and input on the TP and RSS might be improved by implementing a process and approach different from the one used during the HPV Challenge program. During the Challenge program, interested stakeholders, including EPA, would post comments on the test plans and robust study summaries to EPA’s website and sponsors would respond by posting public comments.

During the pilot, stakeholders participated in two face-to-face panel meetings attended by sponsors whose test plans and robust study summaries were under review. The goal of these meetings was to improve the efficiency and effectiveness of the stakeholder review. For more details on the peer consultation process, please see the attached description of the pilot and approach, *Description of Peer Consultation Panel Pilot to Review HPV Submissions*.

This evaluation form seeks your comments and opinions on the pilot process. Your cooperation and participation is very important in order to determine whether this process is one that should continue in the future. Please complete the evaluation form, answering the questions to the best of your ability. Please feel free to provide additional comments and suggestions, and expand upon any of your answers.

Please enter your responses directly into this Word file and return a copy to me. If you have questions or concerns, please email or phone me.

Thank you,

Jacqueline Patterson
Toxicology Excellence for Risk Assessment

Information about you

Name:

Email:

Phone:

Company/Organization:

Did you participate in person or by teleconference?

Have you been involved in the HPV Challenge program in the past, and if so, how?

Your role in the pilot process:

- Sponsor company/consortia representative
- Panel Member
- Observer

Evaluation Questions

- 10. Was the pilot process effective? Why or why not?**

- 11. What changes or improvements would you recommend to the pilot process if it were to continue?**

- 12. One goal of the pilot was to “expedite the review process.” Do you think it accomplished this (over the original HPV process)? Why or why not?**

- 13. Did the pilot provide participants with opportunities to discuss scientific and technical comments with one another? Was this important, and why?**

- 14. Was the interaction between panel members and sponsor representatives useful to identification (and perhaps resolution) of problems and issues?**

- 15. Please comment on whether this process is of value or benefit to your organization/company/consortia?**

- 16. Do you have any comments or suggestions regarding logistics (e.g., meeting room, location, conference call quality, agenda, distribution of materials, communications)**

17. What process would you recommend for future HPV submissions? The original process? The pilot process? Something different?

18. Please provide any other comments or suggestions.

Thank you for your time. We will compile these results and provide a summary to all those who responded.