

**U.S. Environmental Protection Agency (EPA)
Board of Scientific Counselors (BOSC) Subcommittee for
Chemical Safety for Sustainability (CSS) / Human Health Risk Assessment (HHRA)**

Conference Call Meeting Minutes

November 10, 2015

DRAFT

Date and Time: November 10, 2015, 12:00 p.m. to 2:00 p.m.

Location: Conference call

Meeting Minutes

Provided below is a list of the discussions that took place during the teleconference with hyperlinked page numbers. The minutes follow. The agenda is provided in Appendix A, and the participants are listed in Appendix B.

Convene Meeting	2
Welcome and Review of Teleconference Purpose.....	3
Public Comments	3
Review, Discussion, and Approval of Responses to Charge Questions	3
Charge Question 4	3
Charge Question 3	8
Charge Question 5	10
Charge Question 1	10
Charge Question 2	13
Charge Question 6	13
National Research Program Directors' Comments	13
Final Discussion	14
Wrap-Up, Next Steps, and Adjourn	15
Appendix A: Agenda	A-1
Appendix B: Participants	B-1

The teleconference generally followed the issues and timing as presented in the agenda attached to this meeting summary.

DRAFT

Convene Meeting

Ms. Megan Fleming, Designated Federal Officer

Ms. Fleming welcomed everyone to the teleconference. She introduced herself as the designated federal officer (DFO) and said the meeting was the Board of Scientific Counselors (BOSC) Chemical Safety for Sustainability (CSS) and Human Health Risk Assessment (HHRA) combined subcommittee. She described these as a federal advisory committee and as the DFO, she is responsible for ensuring all BOSC meetings comply with the Federal Advisory Committee Act (FACA). Because the teleconference was public, Ms. Fleming started with a background on the subcommittees. The U.S. Environmental Protection Agency (EPA) re-chartered the BOSC executive subcommittee in 2014 to provide advice, information and recommendations to EPA's Office of Research and Development (ORD) on all aspects, both technical and management of its research programs. CSS and HHRA were established to provide program-specific advice to EPA's CSS research program and a smaller portion of the HHRA research program. The CSS and HHRA research programs plan to engage this subcommittee in the following years to obtain advice and recommendations on the program's portfolio and to assess progress in addressing EPA's needs.

Ms. Fleming mentioned this teleconference was a follow-up of the face-to-face meeting held October 6–8, 2015. During that meeting, the subcommittee became familiar with the CSS and HHRA research programs and discussed responses to six charge questions. The subcommittee was now tasked with delivering a report to the BOSC executive committee that showed consensus responses to the charge questions. At this teleconference, Ms. Fleming explained the task during the teleconference would be discussing a preliminary draft of that report. She noted the meeting was subject to FACA and the role of the BOSC DFO is ensuring that all FACA meetings are open to the public, retaining records of deliberations, etc. Everything would be available to the public. Ms. Fleming explained minutes of the teleconference would be taken by ICF International and would be available on the website after they had been certified by the chair of the subcommittee. She mentioned there were currently no comments from the public and no one had requested time to speak; however, if any member of the public wished to register a comment, Ms. Fleming encouraged them to speak up when she asked for those during the "Public Comments" section of the agenda.

Regarding logistics, Ms. Fleming clarified the chair, Dr. Ponisseril Somasundaran would run the meeting. She asked anyone who wished to speak to state their name beforehand and that they should be recognized by the chair. Ms. Fleming took the roll call. Dr. Somasundaran, Dr. Gina Solomon, Dr. Dale Johnson, Dr. Rebecca Klaper, Dr. Clifford Weisel, Dr. Donna Vorhees, Dr. Katrina Waters, Dr. Mark Weisner, and Dr. Kyle Kolaja all stated they were present. Dr. Jerzy Leszczynski and Dr. Chris Gennings were not yet on the line at that time. Ms. Fleming noted Dr. Jim Stevens was unable to make the call.

Ms. Fleming recognized there was time in the agenda for brief comments from the National Program Directors, Dr. Tina Bahadori and Dr. John Vandenberg.

She thanked everyone for attending the teleconference and proceeded to turn the meeting over to the Chair, Dr. Somasundaran, and the Vice Chair, Dr. Solomon.

DRAFT

Welcome and Review of Teleconference Purpose

Dr. Ponisseril Somasundaran, Chair & Dr. Gina Solomon, Vice-Chair

Dr. Somasundaran was pleased to welcome everyone to the teleconference. He thanked Ms. Fleming for incorporating their comments well and Dr. Solomon for editing. There were many comments he strived to incorporate and thanked the subcommittee for those. He mentioned the hectic agenda and motioned to get started. When discussing the agenda, Dr. Somasundaran, Dr. Solomon, and Ms. Fleming decided to go through each charge question. They thought some charge questions (i.e., 4, 3, and 5) were more important and that those should be covered first. An agenda was sent by Ms. Fleming to the subcommittee members which described that they would cover charge question 4 for 35 minutes, charge question 3 for 10 minutes, charge question 5 for 10 minutes, charge question 1 for 10 minutes, charge question 2 for 10 minutes, and finally charge question 6 for 10 minutes. They had all received the draft report with the comments. Many of the comments provided earlier had already been incorporated and those received that morning were forwarded by Ms. Fleming. Dr. Somasundaran motioned to begin with charge question 4 if there were no public comments.

Public Comments

Ms. Fleming noted there was time on the agenda to recognize any general comments from the public. Hearing none, she allowed Dr. Somasundaran to proceed.

Review, Discussion, and Approval of Responses to Charge Questions

Subcommittee

Charge Question 4

Dr. Somasundaran began with charge question 4 and mentioned they would discuss the entire report later. He asked for any additional comments or any comments on the comments that they saw on the right-hand side of the report. Otherwise, he wanted to recognize a comment on charge question 4 that mentioned the uncertainty of what was meant by hazard identification or traditional and new tools including information to assess risk. He noted there was an answer below the comment and both would be able to be incorporated.

Dr. McPartland expressed her thoughts on those two comments. She originally wrote the comment to move beyond hazard identification and suggested it was toxicological approaches. The comments were suggesting that perhaps “hazard identification” wasn’t the appropriate term there and that “toxicological approaches” would be better. In thinking through it, she mentioned they spend much time at the face-to-face meeting talking about ToxCast as well as some of the medium throughput technology platforms CSS was pursuing but CSS also has programs like ExpoCast within its portfolio as well, which was supposed to be focused on high throughput exposure modeling. She wondered if they were trying to describe the CSS program as a whole, if in fact “toxicological approaches” may be a better term to encompass the whole suite of approaches CSS contains, in addition to the high throughput screening. Dr. McPartland didn’t have a strong position on the matter, but she wanted to extend that to the subcommittee. A decision needed to be made about which term would work better.

Dr. Solomon had raised the comment and her concern was that the section were talking about hazard identification and systems-based risk assessment and yet the comment was based

DRAFT

specifically on CSS, not HHRA. Her understanding of the roles of the two programs was that CSS was working to move some of the more basic science tools forward that would generate data. In terms of making changes in the risk assessment process, that was focused more on HHRA than CSS. Dr. Solomon noted she didn't know what "systems-based risk assessment" was intended to mean. She suggested that perhaps the person who wrote that section could explain further. As an introduction sentence, it seemed to conflict the roles of CSS and HHRA and portray the CSS program as a risk assessment entity, which she didn't believe to be true.

Dr. Waters explained she, Dr. Stevens, Dr. Klaper, and Dr. Johnson had together written that sentence. The goal of the sentence was to convey that CSS was moving beyond traditional hazard assessment in order to be able to influence risk assessment, enabling more predictions of risk and humans. That being said, she believed the point that they may be conflating the roles of CSS and HHRA in the way it was currently written. She believed if they just said "moving beyond traditional toxicology approaches to systems-based approaches," it would just focus on the approach versus the goal. She expressed it was important with charge question 4 to convey the growth of the goal of the CSS program beyond hazard identification and enable risk assessment more broadly. Dr. Waters thought maybe they could compromise with rewriting the sentence to read "to move beyond traditional hazard identification and to enable science-based risk assessment using systems-based approaches."

Dr. Solomon said she would have a problem with that as well because it implied current risk assessment wasn't science based. There was a negative connotation in the document about animal toxicological testing and she would disagree with that because a lot of those new methods were new and had not been proven yet. Implying they would significantly improve risk assessment would be facts not in evidence at that point.

Dr. McPartland suggested alternative wording "the CSS research program is uniquely positioned to help the agency advance its toxicological approaches to enable a more systems-based..." but stopped because she realized that wording wouldn't work either. She mentioned she was trying to accomplish two things. One was to talk about the CSS program as helping the Agency in its conduct of risk assessments, but it wouldn't necessarily be the primary work area of CSS, which she believed addressed the first point Dr. Solomon had raised. If they do that (i.e., suggest research program products are helping the Agency), she noted it might be okay to attain the systems-based risk assessment phrasing at the end of the sentence.

Dr. Solomon proposed they use the word "prediction" that Dr. Waters mentioned to say "the CSS research program is uniquely positioned to help the Agency advance the science of exposure and toxicology prediction to enable a more systems-based approach to risk assessment in the future." She believed that to be a true statement. If they do help the Agency, it would work with where the risk assessors live.

Dr. Somasundaran suggested that based on those comments, maybe Dr. Solomon would like to incorporate those. He asked Ms. Fleming if there was still an opportunity to send the document around for further comments. Ms. Fleming mentioned the next steps following the teleconference would be discussed at the end of the call. After the teleconference, the subcommittee members would have the opportunity to send last and final comments to Dr. Solomon and she would consolidate and send them back for one final pass. To answer his question, the members would have the opportunity to send in some final edits.

DRAFT

Dr. Weisel mentioned that what Dr. Solomon said was critical in his mind when she used the word “risk assessment” to include exposure and not just toxicology. If that is not done, there is no risk assessment. Dr. Waters agreed with Dr. Solomon’s suggestions for that revision and Dr. Somasundaran proposed Dr. Solomon rewrite that section. Dr. Solomon agreed.

Dr. Somasundaran moved to the next comment on charge question 4. The section was still in bullet form, and Dr. Solomon attempted to rewrite it in text form. He mentioned he also contributed to that as well. He didn’t think that would raise any comments, but maybe subcommittee members would have comments on page 7 pertaining to the section on lifecycle analytics. He asked if there were any further comments. Ms. Fleming said Dr. Stevens was unable to join the call but had sent in his comments.

Continuing the discussion, Dr. Somasundaran asked for any further comments on the lifecycle analytics section. Hearing none, he moved on to the chemical evaluation section on pages 8 and 9 of the draft report. The main comment read that it “seemed ToxCast data would feed into/serve such an exposure-based prediction tool/modeling system rather than be the exposure-based prediction model itself.” The second comment asked “how does this differ from the current 15-point concentration approach? Or is what is meant here, ‘over multiple doses at different time points?’”

Dr. McPartland said those were her comments, and she wanted to explain her intentions further. Right under chemical evaluation, the paragraph is focusing heavily on the ToxCast program, which is the high-throughput screening “arm” of what CSS is doing, which is just one of their data development generation tools. She was wondering that given the beginning sentence from “moving from concentration-based single time point biochemical data to exposure-based prediction models,” whether or not that was a potential application of the data that is being generated from ToxCast rather than what ToxCast itself is supposed to do. For example, ToxCast is generating a lot of high throughput screening data and ToxPi is an example of a model that is developed to use that data for prediction of toxicity. Another example she gave was the estrogen receptor expert model they heard about at the face-to-face meeting. This was an estrogen receptor activity tool in which ToxCast data was the input. She wanted to distinguish between the purpose of what ToxCast was versus how the data of ToxCast generates itself may be then taken into higher levels of interpretation or prediction modeling.

Dr. Somasundaran said in many cases, the systems get exposure several times, not just in one dose. That is what he meant. Dr. Waters explained she and Dr. Stevens also had the comment that if the ToxCast program wanted to be able to generate data for assays that would be input to the adverse outcome pathways (AOPs) so that AOPs could be a framework for prediction, the data needed to be collected in a time dependent manner, not just in a dose-dependent manner. She said he was correct in that some of the assays have a 15-point concentration range, but many of them do not. The point that she and Dr. Stevens were trying to make was that if the program would like to be able to do the prediction later, they would need to generate both dynamic and concentration-dependent data. She noted an example of how this could be done was presented at the face-to-face meeting—the high-content imaging data provided some great preliminary results.

Dr. McPartland replied that she was hearing the point but was still slightly uncertain because the sentence was representing the ToxCast program, specifically and singularly, the high-content work that Dr. Waters mentioned would again be part of the CSS portfolio but not the ToxCast

DRAFT

program itself, which is purely the high-throughput screening assays. When Dr. Waters mentioned the first bullet did not include the word “ToxCast,” Dr. McPartland said the preceding paragraph lead into the first bullet, and they had been discussing ToxCast in the paragraph prior. As she transitioned to reading the first bullet, she understood it to still refer to ToxCast.

Dr. Johnson commented that the chemical evaluation section was talking about ToxCast and the success of that screening program. Again, it identifies challenges based on that program what still has to happen. Basically, in the first bullet, they do not know that ToxCast was very successful in identifying potential hazards that interact with the biochemical parameter, but it gets into something that relates more into a systems approach or even a toxicological approach. There must be an exposure based prediction part of it that connects it to ToxCast. Dr. McPartland added that the part could be something that ToxCast plugs into. Dr. Johnson said ToxCast is there, but there was another thing that has to move in and deal with exposure-based parts of it. Dr. McPartland said she thought programs like ExpoCast were trying to do that but that wasn’t ToxCast. The sentence before read “There are several challenges the subcommittee identified that need to be addressed with this initiative.” Based on what she had read up to that sentence, the only initiative that had been referred to happened to be ToxCast.

Dr. Solomon agreed that they should change the transition sentence. She suggested it read “As the CSS program broadens its efforts beyond ToxCast, there are several challenges” or “there are several challenges the subcommittee identified to be addressed with the CSS program.” She thought that if they just said that, it would confuse people and that Dr. McPartland was correct. They need to discuss other aspects of CSS. Dr. Somasundaran suggested the way to move forward would be to transition by saying what she suggested and list challenges.

Dr. Weisel asked if someone was actually saying that the first bullet was not related to ToxCast. He said in his mind, what needed to be done was that because ToxCast, ExpoCast, and others were all unique and separate programs, they needed an overarching mechanism to pull them together to address risk assessment. He noted ToxCast is just looking at toxicology and the first bullet was referring to that as well. Dr. Solomon said that was a good question. In the first bullet, she asked if it was referring primarily to the dynamics of some of the other assays such as the neurite growth assay and the zebra fish assay or was it referring to the cell based ToxCast assays and suggesting incorporation of a time dynamic into those. She thought that it was unclear.

Dr. Waters stated her understanding was that ToxCast was moving beyond cell based and biochemistry based high-throughput assays to more medium throughput high-content assays to be more relevant and representative of the biological space of toxicology. She believed all of those are part of the ToxCast screening program. Dr. Somasundaran asked Dr. Bahadori for her input on what was meant. Dr. Bahadori said the point Dr. Waters made was correct and that was what was described in the Strategic Plan (StRAP). The original set of assays that constituted the initial ToxCast program by design and intention was now evolving to include other assays. The goal of the FY 2016–2019 StRAP was to incorporate other types of assays (e.g., metabolism, medium-throughput assays, high-content, targeted more environmentally-relevant assays). She said Dr. Waters had described it precisely.

Dr. Solomon suggested they keep the first sentence that discussed the background on the ToxCast program successes and inserted a transitional sentence that reads “as the CSS program broadens to incorporate a broader array of assays, new opportunities will appear and there are several challenges the subcommittee identified that would need to be addressed as the program

DRAFT

moves forward.” In the bullet on the dynamics, she proposed they discuss the medium-throughput assays there specifically. She asked the group if that would help to clarify. Dr. Somasundaran and Dr. Johnson both agreed that would be the best way to transition.

Before continuing forward, Dr. Weisel said that his question pertains to using ToxCast in risk decisions without giving the overarching need to say that is only one component. Chemical evaluations do need to be exposure-based and there needed to be more about that. Dr. Somasundaran said he thought they were talking about more than one component. He asked Dr. Solomon if she had everything they needed and moved forward.

On page 9 of the draft report, Dr. Somasundaran read a comment that stated “I don’t recall this in the original text. It does point out added complexity, but I am not sure if there is any specific recommendation to be made other than to point out added areas complexity. The overall goal of this section was to focus them, not to added additional, although relevant, breadth. I recommend this be shortened and focused to a specific point.” He stated he understood the last part: the point itself that was complex. He believed that part could be deleted and the section could be condensed to say “the point about the system is complex with many components and fractions over time.” His expressed the importance of that. He asked who wrote the comment below that one. Ms. Fleming said that was Dr. Steven’s comment. Dr. Waters stated she agreed with Dr. Steven’s comment, but she didn’t think it belonged in that paragraph because that paragraph was speaking more to metabolism and the incorporation of metabolism. She suggested maybe they could break it out as a separate bullet. Dr. McPartland and Dr. Somasundaran agreed with that idea.

Dr. Somasundaran read the next comment, stating “I support computational chemistry approaches, but this seems like an opinion regarding what the future should look like more than a specific recommendation. I also don’t necessarily agree that a pure QSAR-based computational chemistry approach (how I read this sentence), although necessary and integral, is the desired and practical outcome.” He was confused as to what Dr. Steven’s comment was referring to. Dr. McPartland stated she had a very similar comment on charge question 3 where there was an indication or suggestion that the ultimate goal of the CSS research program would be to predict toxicology or risk from a computational chemistry approach. She didn’t know if she agreed with that idea, as similar to what Dr. Stevens had said. She believed it was out of bounds for the subcommittee to suggest that. She wanted to discuss. Dr. Solomon agreed and said she didn’t see them going to a pure computational approach in a foreseeable future. Dr. Somasundaran asked Dr. Solomon if she knew how to rewrite it and Dr. Solomon answered perhaps. She thought there were ideas within those paragraphs and she could make edits to address that one concern.

The last comment for charge 4 question Dr. Somasundaran deemed important was “I don’t recall the intention here and would delete. I think the point of this concluding statement may be to look back at what has been learned from ambitious programs in the past and keep those lessons in mind looking toward new technologies and applications. That is in line with our overarching recommendation to focus on specific deliverables within the large goals.” Dr. Somasundaran believed the statement was not accomplishing much and they could delete it. Dr. Johnson agreed they could delete that. He said it was probably a note on something which would eventually be expanded. It should be deleted because the rest of the document discussed existing resources. Dr. Somasundaran asked if there were any objections to deleting it, and there were none.

DRAFT

Charge Question 3

Dr. Somasundaran moved to charge question 3 on page 4, where he mentioned a general comment about who the partners were. He thought this included the EPA program and regional pieces at other places also. Dr. McPartland stated she had made that comment, but someone else had the same comment about who they meant when they said “partners.” In most of the charge questions, they talked about the program and regional offices, but for charge question 5, “partners” was actually broader and included stakeholders. They all knew that because they were at the face-to-face meeting, but wouldn’t be clear to other readers. She explained it should be a quick fix. Dr. Solomon said it was already done.

Dr. Somasundaran said the next comment was on the fourth line from the bottom about the CSS program making enormous progress becoming a leader and then another member said that was too strong a word. The suggestion was that it could be written that CSS had allowed significant progress. He stated that was a good comment, especially since sometimes when reports are submitted, strong words become less effective. He asked what others thought. Dr. Solomon agreed. Also in that sentence, the “enormous progress” seemed to be applying to the Office of Chemical Safety and Pollution Prevention (OCSPP), not to CSS itself, and then attributed that success to the CSS program. On many levels, she said it was quite an overstatement. She thought the other programs, including OCSPP, were just starting to use some CSS generated data but she didn’t think they could contribute international leadership to that yet. She mentioned she would not only think about deleting “enormous” but tone down the sentence overall.

Dr. Beamer explained they were trying to find a concrete example of how they were responsive to their partners and that phrasing reflected the wording of that office’s feedback. They could tone it down for the report if that was what the subcommittee preferred. Dr. Solomon mentioned the Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) program, for example, and that there was definitely leadership in Europe on chemical safety issues. It is tough, given what they are doing there, to say that CSS are the leaders on chemical safety with their old version of the Toxic Substances Control Act (TSCA). She said maybe she would soften it but indicate that OCSPP did feel that the CSS tools have enabled them to make significant progress. She asked if that would work. Dr. Johnson said they could say “CSS programs have supported the progress made by the offices in chemical safety.” Dr. Beamer agreed that would be a good way of toning it down, and Dr. McPartland also agreed with the change.

Dr. Somasundaran moved to the next comment following the agreement made from the subcommittee members. The comment read “TSCA does not have any requirements related to nanomaterials, so I deleted this reference.” He noted it was important, however, if TSCA did not have any requirements, it was okay to delete it. He asked Dr. Bahadori if it was true that there were no requirement related to nanomaterials. Dr. Bahadori answered TSCA did not specifically call out nanomaterials, but the OCSPP managed nanomaterials and biotechnology like they do any emerging chemical materials and technology. If it was a new material, they put it through the chemicals program. The regulation does not call out nanomaterials, but the OCSPP does treat it as a new chemical if it isn’t. Dr. McPartland believed the sentence achieved what it needed to without specifically referring to TSCA with the included edits. EPA does have some proposed rules about collecting more information on nanomaterials through TSCA, but she didn’t think they needed to get into that for this particular context. She didn’t know what the value was. Dr.

DRAFT

Somasundaran said it was important to have that in the back of their minds, even though the danger of nanomaterials is not clear. If it was there, at least it would stay in their minds, but maybe that was not their charge. Dr. Solomon asked if the rewritten sentence was okay with everyone, and Dr. Somasundaran agreed it was. Dr. McPartland said it was fine, but she was just referring to the TSCA reference. She thought it got the point across without mentioning the actual law, but rather the issue of new and emerging materials like nanomaterials and the scientific challenges around those.

Dr. Somasundaran said the next question was on the following page and recommended case studies and measures of success in multiple places (i.e., in response to charge questions 1, 2, and 3). The comment asked if they should consolidate those into one place or allow repetition. He thought it would be a good idea to consolidate and not repeat it. He asked what others thought. Dr. Solomon said she wrote the comment and it referred mostly to a sentence below the one she flagged about “what remains unclear is exactly how case study success will be evaluated and how the proposed research overall will directly or indirectly support each of EPA’s various regulatory programs. How will EPA judge whether case studies achieve pre-specified goals?” That whole section she thought was good. She had flagged it because there was discussion in charge questions 1, 2, and 3 on the general issue of measures of success and case studies to evaluate and measure success. It came up multiple times in their report. Dr. Solomon said it was okay to have repetition, and she didn’t attempt to consolidate it, but she wanted to ask and see if it was okay to repeat or if they should put that information into one charge question, and if so, which one.

Dr. Weisel mentioned one of the comments he made was he thought the entire document could use a short overview, highlighting things like Dr. Solomon had just brought up, because that went across many issues and information technology (IT) went across many issues. He said maybe that was one way to do it and then keep it there to reemphasize specifics.

Dr. Beamer asked how the document was going to be used and if it was going to be broken up into different parts and not read in full. Dr. Somasundaran referred to Ms. Fleming to answer. Ms. Fleming explained that would be at the discretion of the BOSC Executive Committee. Because the chair and co-chair are part of that, they might be able to offer insight on how the Executive Committee might use the report the subcommittee had produced. Dr. Solomon said she knew this subcommittee report would be folded into a larger report with the reports from other subcommittees. What she expected was that there would be some kind of executive summary or introductory section that would span the different subcommittee reports and they would want to think, as a subcommittee, about what key points they want to make sure they push forward into the executive summary they insert at the beginning. She noted she and Dr. Somasundaran welcomed input on that. From their discussions, she had a sense of some of the issues the subcommittee thought were important, so they might want to flag those as they go through so they could bring those to the bigger group.

Dr. Somasundaran mentioned the last comment was an easy fix. The question read “do we want to suggest that activity/toxicity prediction based on structure should be the ultimate goal of CSS research?” He believed it was easy to fix because it became too strong to suggest that predictions were just from the information on its chemical structure and co-actors. He acknowledged it was

DRAFT

too strong of a statement and they should just say that in the future, predictions to be based on information about the chemical structure. It didn't mean exclusively from chemical structure. Dr. Vorhees stated she read that sentence and it seemed like it went beyond what the charge question was asking, not the substance of the sentence. Dr. Solomon also mentioned she had some concerns because it was very similar to the point Dr. Stevens raised about doing purely computational QSAR type predictions in the future. She wasn't sure they wanted to go there. Dr. Johnson agreed he wouldn't go there either because there were many more complex things that were taking place just in that approach. Dr. Somasundaran proposed they delete it and move forward to charge question 5 on page 10 of the report.

Charge Question 5

For charge question 5, Dr. Somasundaran mentioned there were many additions but only one or two major comments there. The comment stated "Also in question 1 response, and mentioned in a few other places. Consolidate?" The mention of IT was mentioned in many places and the question was if it should be consolidated. Dr. Johnson thought it was important to mention IT in different sections because each might need a different type of IT approach. They identified that very clearly with concern that should be thought about very significantly in the future. He expressed he thought it was good to incorporate the IT part in different parts of it. Dr. McPartland agreed with Dr. Johnson, as a general matter, she didn't see the harm in being repetitive because they couldn't be sure about how the report would eventually be read by different audiences and individuals. It was a more conservative approach. She explained they needed to make sure some of the things weren't repetitive and, like Dr. Solomon had said, the repetitive things should appear in the executive summary. Dr. Solomon said that was fine. She wanted to discuss it with the subcommittee whether they should consolidate or go ahead and allow some repetition. At that point, she also wasn't sure if their draft was too long. Ms. Fleming had reassured them that she didn't think it was too long that they would need to cut. Dr. Somasundaran noted Ms. Fleming should check with someone and let them know if the report was too long. He thought it was okay. Ms. Fleming answered there were a few reports already and there was no standardized format or length at that point. The Executive Committee planned to meet in December and they would discuss formatting and maybe next time the subcommittee met, there would be a standardized format. Dr. Somasundaran asked for any more comments on charge 5 and there were none.

Charge Question 1

Dr. Somasundaran moved on to charge question 1 comments and that they would then move to charge question 2. On the first page, the comment read "Is the sentiment conveyed in this sentence in agreement with the previous sentiment with regard to how much can be accomplished against Agency objectives over the 2016–2019 time frame? On further thought, it is likely fine as written. Retaining this comment in case others flag this." Dr. McPartland said that was her comment, and she wanted to reconcile it, but she wasn't sure if she was forcing herself to do that. She acknowledged Dr. Stevens had commented as well to suggest they articulate the point that the goals and objectives of CSS are quite ambitious and would be challenging to accomplish in the stated time frame, but even if they were not fully accomplished, it seemed the CSS program will make some significant progress. She thought, with Dr. Steven's suggested edits, it reconciled the sentences in a way that was accurate. Dr. Somasundaran said

DRAFT

she was referring to the comment that read “these two sentences seemed to indicate both a constructive criticism that they were too ambitious but then suggests they will get there regardless. I added modifications to the second sentence to reflect a slightly different tone. It may be better to leave this for the specific comments.” Dr. McPartland asked Dr. Solomon for her input, and Dr. Solomon replied that she liked Dr. Steven’s edits.

Dr. Johnson referred to the sentence that mentioned the next few years and said it was difficult to tell if that was 2019 or past that. Dr. Solomon asked if they should say “by 2019.” Dr. Johnson said if that was what they meant, they should say that. Dr. Solomon said she would hate to be pinned down with a certain date, but she thought they could say that.

Dr. Somasundaran moved to the fourth sentence on the following page highlighted the words “cost-effective manner” and asked for the basis of the statement because they were not asked to evaluate anything beyond science planning. Dr. Vorhees mentioned she had made the comment, and it was more procedural. However, it seemed like they had done some kind of cost-benefit analysis. She said it was a cost-effective program, and she didn’t think they did that. She didn’t suggest ultimate wording, but maybe what the author meant was the research program was targeted toward useful ends and described and planned efficiently, but it was the word “cost-effective” and she didn’t think they examined that. Dr. Solomon noted she had put together the response and she wasn’t sure where they got it, but after looking at it, she agreed. She thought they should remove it and place a period after “uncertainty” and delete the rest of the sentence. Dr. Johnson and Dr. Somasundaran agreed.

Dr. Somasundaran moved forward to the next comment under “areas of improvement.” The sentence read “... both research programs are related to a lack of sufficient resources to take the enormity of the research problems and objectives.” Instead of “objectives,” the comment read “challenges?” Dr. Solomon believed the word “challenges” should replace the word “problems” which was fine with her. She made the change.

Dr. Somasundaran read the next comment which said “We all cannot help being aware of what’s happened to EPA’s budget in recent years. But I think we should quantify some of this text...maybe start the first sentence with ‘EPA staff described the major challenges...?’” Dr. Vorhees mentioned that was also her comment and it was related to the cost-effective comment. She asked who was making the assertion that there were many budget constraints. She believed they were all aware of them, but this was giving information that was described to them and she thought they should present it that way.

Dr. Solomon noted they should be careful not to imply that EPA was complaining to the subcommittee about their budget and working at a government agency, she knew management could be sensitive to that. She understands Dr. Vorhee’s point, but they did not do an independent assessment of EPA’s budget. Dr. Weisel also noted they were told a lot of people had been hired. Dr. Solomon asked for clarification from Dr. Bahadori or Dr. Vandenberg for the language there. Their goal was to acknowledge some of the resource limitations and identify those as a potential challenge, but because they did not independently review them, she wasn’t sure how much they could speak about the issue. Dr. Somasundaran said even if EPA had told them, it was also known from the publications that there was a reduction in budget. As a subcommittee, they didn’t substantiate it, but it is known that the budget has been decreasing. Dr. Vorhees stated she didn’t understand the value of the paragraph. They were not asked to look at the economics, but rather how sound the scientific plan is and comment on it. She felt it was

DRAFT

beyond what they were supposed to be doing.

Dr. Bahadori seconded Dr. Vorhees' statement. She said if she had done her job right as a director, she had a program designed to deliver on what she knows of her budget at the time and what she could predict its undulations will be within the realm of reason. If she had three times the money, she would definitely do more, but she felt they had designed a program that was consistent with the present guidance. Dr. Solomon proposed they remove the paragraph and Dr. Johnson agreed because it was saying something that they actually didn't look at because like Dr. Bahadori stated, that is what she does. She looks at budget resources. Dr. Somasundaran asked for objections to the deletion of the paragraph and there were none.

The next comment pertained to "EPA partners" and read "should we just define and use this term consistently throughout as EPA did?" Dr. Solomon stated she would delete one or more of them later. Dr. Johnson then suggested they could also define and identify what it means. Dr. McPartland said her understanding was that the key stakeholders referenced in charge question 5 did not include the general public. She asked Dr. Bahadori if that was correct. Dr. Bahadori confirmed that the stakeholder did not include the general public, because CSS feels like they don't have the expertise to work with the general public. This is not a community they have counted among their stakeholders. Dr. McPartland stated whether there could be growth or more investment. She agreed with Dr. Beamer's comment.

Dr. Somasundaran continued to the next comment, reading "Is this a hurdle? What about rewriting – something like 'The Agency is required to present information in plain English, which is useful so that a non-technical audience understands EPA's scientific word. However, EPA has multiple audiences...' " ... Dr. Beamer suggested they needed more people who had expertise in that area. Dr. Vorhees proposed rewording "another hurdle" or read what Dr. Beamer had suggested in the comment. Dr. Solomon noted this science could not be communicated in simple language. If they turned it around the way Dr. Vorhees suggests, it implies they are supporting the conversion to lay language because it would be useful. This was very soft and indirect and people might not understand what they were saying there and that information might not be able to be communicated in lay language.

Dr. Weisel suggested the first sentence should not be first and it should begin with "EPA..." Dr. Somasundaran was concerned the public was unaware of the program and that point was very important. Dr. Beamer stated she understood the concerns, but perhaps what she was trying to say was that even the complicated stuff should be available to the public and lay person. Obviously, not everything should be written in plain English. Dr. Solomon mentioned she was attempting to use Dr. Weisel's suggestion to reword and rework to remove the word "hurdle" because she agreed it was too strong. Dr. Beamer proposed they cut the word "hurdle" and say "cannot only be communicated in simple language." She didn't want to imply that they ignored it. Dr. Somasundaran believed they had enough comments mentioned to work on it and asked Dr. Solomon for assurance. Dr. Solomon said she thought so. She would cut the first sentence and insert something about the difficulty of communicating scientific information.

Dr. Somasundaran moved to the next comment, which read "What exactly are we asking them to do? What are the important 'theories of organizational change' and how should these theories shape their approach?" Dr. Stevens had responded "this is a strong paragraph that should remain intact. No comments, just enthusiastic support." Dr. Vorhees stated that was her comment and Dr. Steven's language so maybe they would need his further input there. Dr. Somasundaran

DRAFT

suggested she speak with Dr. Stevens and resolve the comment. Dr. Vorhees noted if she was receiving that guidance, she wouldn't think it was enough guidance for her. Dr. Beamer stated she thought it was coming from more formal efforts, involving other skill sets. She didn't know where he was going with this statement. It might not have been a specific enough example by itself. Dr. Vorhees agreed a simple question to Dr. Stevens would help.

Charge Question 2

Dr. Somasundaran moved to charge question 2 regarding EPA partners. The last question on charge question 2 was "Is this recommendation to CSS..." He asked Dr. Solomon if she was requesting clarification from Dr. Bahadori or Dr. Vandenberg. Dr. Solomon said their committee couldn't make recommendations for program offices to other EPA offices. It looked as though that recommendation was directed towards others outside the CSS program. If that was true, she advocated deleting it. If it was directed towards CSS or HHRA, she recommended rewording it.

Dr. Beamer said perhaps they could use that language. It seemed it would be great to have some budget for some of those problem formulations. Dr. Weisel mentioned the other thing he heard was to get their input. Dr. Beamer noted the reason they wrote that section was based on what they heard from partners and how they were strapped for time, but engagement at problem formulation could be beneficial. She asked if there were a way to encourage that through their interaction. Dr. Beamer said it was in the preceding paragraph; he suggested that maybe it was beyond what they should recommend and should consider deleting it. Dr. Solomon explained in charge question 3 where Dr. Beamer had flagged the language there, she could add problem formulation there and try to examine and make sure all of those come through clearly and then delete that one sentence.

Charge Question 6

Moving to charge question 6, Dr. Somasundaran acknowledged there were not many comments. The only main comment was one he made at the end before the "areas of improvement" section and he needed clarification. They thought the challenge was related to the third bullet point in the areas of improvement section. Dr. Somasundaran asked the group if that sentence was removed, would the problem be solved. Dr. Johnson suggested either removing it or replacing it with something that lead to the web-based tools that were being developed. Dr. Solomon proposed that they left it out there because it was slightly out of the scope of the HHRA program and that charge question was focused solely on HHRA. It seemed off-target.

Dr. Somasundaran agreed on the removal and noted there were no further comments on charge question 6. He acknowledged they had covered all of the comments on every charge question and had fifteen minutes remaining for discussion. He asked Dr. Solomon if there was anything they should ask the subcommittee.

National Research Program Directors' Comments

Dr. Tina Bahadori, CSS & Dr. John Vandenberg, HHRA

Dr. Solomon said it would be great to hear from Dr. Bahadori and Dr. Vandenberg on their views. Dr. Bahadori responded that she was impressed by the caliber of the discussion and the draft report. She was grateful they took the time to read the materials and have the conversations with the scientists among themselves. She noted even the draft report was extremely helpful, as

DRAFT

well as the discussion of the comments, especially the comment relating to the issues of resources. She was unsure of what the Executive Committee would do, but she knew CSS would take the report and put it to good use.

Dr. Vandenberg echoed Dr. Bahadori's comments. He recognized that a lot is put into the reviews, and it pays off. He was impressed by the thoughtfulness. Already, they had begun to change some things in response to the face-to-face meeting itself. They have every reason to strengthen their collaboration. He thanked the subcommittee for their time and commitment and he was looking forward to the full report. Dr. Somasundaran told Dr. Bahadori and Dr. Vandenberg that the strength was really the teamwork.

Final Discussion

Dr. Solomon suggested they have a last check of anyone from the subcommittee having any additional questions or overarching comments that were left out of the report or not addressed on the call. Dr. Weisel mentioned that after looking one more time on charge question 5 where they discuss chemical evaluation; it was almost all on ToxCast. He asked if they should expand it beyond ToxCast. Dr. Somasundaran proposed he send some suggestions in and they would see how they fit into the report. Dr. Weisel mentioned his busy schedule, stating he would try, but he could not guarantee anything.

Dr. Solomon noted it was a good point; she was looking through the chemical evaluation section and bullet one mentioned exposure-based predictions, but it was more focused on the time point issue rather than the dose and exposure issue. Exposure should be mentioned there as being important. She asked if she should attempt to include a bullet there and then proceed to circulate it to the subcommittee. Dr. McPartland agreed that was a good idea. She suggested Dr. Solomon try to distinguish that from what CSS was doing from ToxCast because she was concerned ToxCast would be presumed to be something that does everything.

Dr. Solomon asked the subcommittee if there was anything else she should reflect in a bullet on exposure in addition to the point that exposure should not be neglected as the toxicological evaluations move forward. Dr. Weisel stated part of the reasoning—nothing against what was presented to them—but everything CSS does cannot be presented. He suggested the subcommittee could state they recognize there are other programs besides ToxCast that address exposure that they didn't have time to review, and they were looking forward to reviewing that at the next meeting. Dr. Bahadori mentioned the exposure component of the program, including the "low-hanging fruit" of the ExpoCast that is in chemical evaluation. There are also efforts on lifecycle human exposure modeling and a lot of ecological exposure evaluation. She thought they were making a good point that there was not a lot of time to delve into that information. The beauty was that it was also the beginning of a deep emphasis on exposure. A part of that recommendation to come back to a future meeting with that focus would be greatly appreciated.

Dr. Solomon noted there were also rounds of grant making to institutions outside of EPA with a focus on exposure science. She believed that to also be an extramural piece that would be important. They should mention there were a number of exposure-related elements. She proposed she put a sentence in that the exposure-related elements were also important and they had not fully reviewed those to date but look forward to reviewing them in more detail in the future. Dr. Johnson said the question was if they thought there was a sign exposure-based type of analysis occurring or likely to occur in the 2019 time frame. Dr. Weisel stated ExpoCast was a

DRAFT

major effort brought by EPA to numerous conferences. Dr. Somasundaran wrapped up this portion of the agenda by asking Ms. Fleming for the next steps.

Wrap-Up, Next Steps, and Adjourn

Dr. Ponisseril Somasundaran, Chair & Dr. Gina Solomon, Vice-Chair

Ms. Fleming explained she would discuss the next steps of the process. During the call, Dr. Solomon had been making changes to the document itself. Her understanding was that Dr. Solomon would send the document to Dr. Somasundaran and CC herself when she had refined it to her satisfaction. Dr. Solomon had the report in her hands and would distribute it to the subcommittee and request any final feedback before finalizing the report. Her understanding was that they were aiming to receive feedback by the Friday following the teleconference. She asked Dr. Solomon if that sounded reasonable to her. Dr. Solomon said she and Dr. Somasundaran should receive something that night or early the following morning. She noted when comments had been addressed, she deleted the comment bubble, but left the revisions in track changes, so when it was distributed to the members, it would show the changes, but the comments would be removed. Dr. Somasundaran said the following morning would be best for him.

Ms. Fleming then mentioned she would be going out of the country and would not be able to redistribute the report to the subcommittee. When it comes to redistributing the report, it would come from Dr. Somasundaran or Dr. Solomon. The ultimate goal was to turn the report around by Monday, November 16, 2015. The report would go to Ms. Fleming after approval and then would be sent to the executive committee. She asked if it would be helpful to pull the key points out and put them into the report. Dr. Somasundaran agreed and Dr. Solomon said others could comment as they came. Dr. Weisel asked if four to five main points would be reasonable and Dr. Solomon replied with two to three. If there were more, they would need to prioritize them.

Ms. Fleming reiterated that she should be copied on any transmittals and to remember not to reply to all participants. Dr. Solomon and Dr. Somasundaran were said to be the points of contact that week. Dr. Somasundaran asked for any further questions. Hearing none, he and Dr. Solomon thanked everyone for what they had done and ended the call.

Appendix A: Agenda

United States Environmental Protection Agency Board of Scientific Counselors (BOSC)
Chemical Safety for Sustainability (CSS)/Human Health Risk Assessment (HHRA)
Subcommittee

Teleconference Agenda – November 10, 2015, 12:00-2:00 PM EST

Call-in: 866-299-3188
Code: 202-564-6604

TIME	TOPIC	PRESENTER
Tuesday, November 10, 2015		
12:00 – 12:05	Convene Meeting	Megan Fleming, Designated Federal Officer
12:05 – 12:15	Welcome and Review of Teleconference Purpose	Ponisseril Somasundaran, Chair Gina Solomon, Vice Chair
12:15 – 12:20	Public Comments (if any)	
12:20 – 1:40	Review, Discussion, and Approval of Responses to Charge Questions	Subcommittee
1:40 – 1:50	National Research Program Directors Comments	Tina Bahadori, CSS John Vandenberg, HHRA
1:50 – 2:00	Wrap-up, Next Steps, and Adjourn	Ponisseril Somasundaran, Chair Gina Solomon, Vice Chair

Appendix B: Participants

BOSC CSS Subcommittee Members:

Ponisseril Somasundran, *Chair*
Gina M. Solomon, *Vice Chair*
Paloma Beamer
Chris Gennings*
Dale Johnson
Rebecca Klaper
Kyle Kolaja
Jerzy Leszczynski*
Jennifer McPartland
James Stevens*
Donna Vorhees
Katrina Waters
Clifford Weisel
Mark Wiesner

* Unable to attend

EPA Designated Federal Officer (DFO): Megan Fleming, *Office of Science Policy, ORD*

Other EPA Attendees:

Tina Bahadori
Sundara Bhandaram
John Cowden
Intaek Hahn
Daniel Hicks
Michael Loughran
Joseph Manuppello
John Vandenberg

Other Participants:

Sundara Bhandaram
Joseph Manuppello

Contractor Support:

Camden Byrd, ICF International