

**Steering Committee (SC) Call 8 Minutes
NanoRelease Food Additive**

August 15, 2012

Participants: Steve Roberts, Annette McCarthy, Joe Scimeca, Tom Neltner, Stefan Weigel, David Carlander, Mark Perry, David Lefebvre, Neil Buck, Richard Canady, Libby Tsytsikova

Call Agenda

(1) Approval of last call minutes

- SC members are asked to voice any objections on the call and are given one week from today to voice any further edits.
- SC member suggests minor wording changes to the minutes regarding statements on silicon dioxide, changes are applied without objection from the rest of the Steering Committee. Further edits, comments, or additions are requested with one week deadline.

(2) General project updates

- The Informational Handout is a summarizing document on the project which provides a general background, update on progress, and member lists. It is to be broadly distributed on the website and in emails/invitations. SC members are asked to send any comments on the content or wording as this document is to be sent out on behalf of the Steering Committee. Several SC members voice their appreciation and approval for the document, noting that the size is great for reading quickly to get a general gist of the project progress.
- SC member requests adding a date or version number to this document since newer versions will occur in the future as the project progresses. SC members discuss the option of creating a quarterly newsletter based on this document, and editing this handout to be the first issued newsletter. SC members agree that a project newsletter is a good idea, and that periodic update based on project progress is better rather than specific quarter times for releasing issues of the newsletter.

(3) SC Consensus (revised)

- On the last call, suggestions were made for changes to the SC Consensus. The revision is shown in blue text in the attachment, addressing the notion that decision making is not done at a discrete time point, but rather over a period of time, and this affects the idea of a quorum. SC members are asked if they have any opposition to the text. SC members agree that the additional text now properly reflects the ideas of the SC and clears up the quorum. SC approves this document as final, but can be revisited if any SC member wishes to in the future of the project. The document will be posted on the public website.

(4) Outcomes of the Decision Matrix (revised)

- This document was also considerably discussed on last call and new revisions have been made according to suggestions from last time and through email follow-up. The major change is a change in the flow of information – the outcomes have been more clearly stated earlier in the

document and the detailed process can be found later in the document. SC members agree that this document is now clearer.

- In this document, SC member requests the removal of the statement: “See cosmetics/inhalation regulatory definitions of solubility”. How would that be relevant for middle solubility in the alimentary canal?”
 - o SC members agree that it is neither the SC’s responsibility nor intent to determine a cut off for solubility. Identifying a definition of “solubility” and thus identifying which nanomaterials are soluble or insoluble is not a focus of the NanoRelease project (in determining the cut off for solubility for the risk assessment point of view). NR is rather focused on bioavailability, detection, and characterization, rather than the solubility aspect and defining solubility. SC members suggest that the issue of identifying solubility may or may not be addressed by Task Group 1 (TG1) or Task Group 4 (TG4), and it is up to the experts in those groups to determine the need for identifying a definition for solubility at all. It is likely that this discussion will evolve over time in the project and may begin in TG4 and carry through to development to testing next year.
 - o Therefore, in the Outcomes document, the purpose of the middle solubility item is to say that we need a range of solubility (low, middle, high), rather than to say that we have to define solubility.
 - o Defining solubility is difficult because it depends on the exact conditions (such as pH, food matrix, etc.) surrounding the material. Identifying a precise cutoff will likely not benefit the whole project and may slow the project down, thus TGs may not need to address this definition at all.
 - o SC members agree to remove this statement “See cosmetics/inhalation regulatory definitions of solubility”. How would that be relevant for middle solubility in the alimentary canal?”
- In the document, SC member points out the misleading wording of “specific time point of release”, and requests wording to be changed to “specific point of release in the alimentary canal”. In the document, SC members request all subsequent wording to be fixed according to this change, including at the following lines with changes indicated in italics: “Encapsulated materials that serve to deliver nutrients: (dissolve at *a later point in the alimentary canal*)” and “Encapsulated materials that serve to deliver flavor (dissolve at *an earlier point in the alimentary canal*).” All other SC members agree to these changes.
- A revised version of this document with the above changes will be shared on the next call for approval by the Steering Committee.

(5) Task Group Updates

- Task Group 1 (presented by Neil Buck) – TG1 had a Co-Chairs call to clarify the project plan recently and had a couple of actions coming out of that. TG1 had a full group call and will be scheduling another soon to address further planning and action items.

- Task Group 2 (presented by David Carlander) – TG2 had their first group call last week for which the Co-Chairs had circulated a draft outline of the white paper, with indicated project timeline. Co-Chairs will have a call on Friday to discuss the revised outline, with a second TG2 call next Friday on the 24th on which the draft outline workloads will be distributed. Membership is in good shape, but on Call 2, Co-Chairs will assess if there are any gaps in specific expertise on the task group.

Note: Andrew Bartholomaeus (invited to SOST) has shared a very TG2 relevant, extensive document analyzing the pharmacology of nanoparticles with regard to data studies (collection of information). This may help with providing framework for TG2 and potentially other TGs. Co-Chairs and the secretariat will bring this to the attention of Task Group members.

- Task Group 3 (presented by Rekha Mehta) - TG3 had first call in the last few weeks and the second call is coming up this Friday to discuss how to divide up the work for the white paper. So far, the membership looks great but Co-Chairs will get a better idea after the call on Friday.
- Task Group 4 (presented by David Carlander and Tim Duncan) – the first TG4 call is today. Co-Chairs have started to work on a draft outline for the white paper and will likely have more feedback after today's meeting.

(6) State of the Science Team (SOST)

- SC members were asked to submit their votes for their top choices of experts to invite to the State of the Science Team, to serve as a guideline for order of invitations to go out to experts.
- The list was compiled based on SC member input and research by the secretariat. Comments, objections, and additions to the list were due July 27. On the last SC call, the secretariat was asked to move forward with invitations, but due to the addition of a number of new names from SC member suggestions, the list became extensive and the secretariat needed more guidance. Therefore, the secretariat requested a vote to help order the choices, as a plan for how to recruit additional members.
- To date, the secretariat has had some indication of interest to be an author from Andrew Bartholomaeus, Steve Roberts, Andrew Maynard (or potentially Martin Philbert), and John Milner (formerly at NCI, now at USDA). Djen Liem of EFSA has also been invited. SC members are asked whether we can accept Andrew Bartholomaeus, Steve Roberts, Andrew Maynard, and John Milner as the first four confirmed SOST authors. SC members voice no objections.
- Optimal number of authors can range from 3 - 10 authors. It may be a better, easier process with 3 authors, but a better stakeholder balance can be fostered with more authors. Too many authors will create a situation in which some do not contribute much to the content of the report. We would like a high level document of what we know and need to know for the issue at hand. SC members agree that 6 or 7 authors would be best. We are more so aiming for a group of authors with depth of understanding, connections with current research or related efforts and organizations, and experience with policy issues. This is the primary objective, in addition to the stakeholder balance, so that the final document is a fair representation of the state of the science and in no way seen as leaning in a direction of certain stakeholder views over others.

(Sep 5, 2012)

- For balance of academia, industry, government, and NGOs, we need to further address the NGO/public interest perspectives. SC members are asked for NGO representative suggestions for SOST authors. It is possible that Pew could fund an NGO author for their time to some extent if this is an issue that comes up in the future.
- Paul Westerhoff, who is well respected amongst many NGO participants, is not technically affiliated with an NGO but may be a good contact to invite to the SOST or at least give ideas for NGO contacts. We have also reached out to Sue Davies of the Which? organization and other European public interest contacts that we are generally contacting to participate in the project.
- SC members suggest Friends of Earth in Europe and Samantha Dozier of Pet. SC requests that the secretariat send the next invitation round as an NGO invitation in order to achieve better balance of the SOST.
- ACTION ITEM: the secretariat will pull together a list of NGO candidates as an action item to send to the SC in the next two days.

(7) Project Timeline

- Revised timeline is attached including original target dates and new target dates. The TG cochairs webinar was originally scheduled for late July and is not for late September. We are now scheduling
- Sept. TG/SOS Webinar
 - o The purpose of organizing this webinar is that there is substantial overlap between TG charges, therefore getting together early and communicating is very important for the best project outcomes. Another major benefit is that setting a deadline is important in order for work to start going forward.
 - o The SC would like to make this as simple to participate in as we can for members through webinar or in person. The SC is not expecting TGs to have full text to share at this point, but rather the webinar is for sharing full outlines, writing assignments, and collaborative interests (overlapping or closely related sections of outlines – it is important to have these connections established early).
 - o Sept 17/18 is better than 10/11 at this point due to time for TGs. The exact dates will be confirmed within the next few weeks.
- The dates for the November 2012 Workshop need to be confirmed as soon as possible to be put on participants' calendars. The TG findings will be presented at this workshop and the SOST will be informed to begin their report.

(8) Final Comments

- No further comments or questions are voiced by the call participants. The next SC call is September 12th.