

NanoRelease Food Additives**May 15, 2012****Steering Committee Conference Call/Webinar**

Participants: Andrew Atkinson, Carolyn Cairns, Rick Canady, David Carlander, Tim Duncan, Shaun Clancy, Don Forsyth, Michael Hansen, Agnieska Kinsner, Andrew Maynard, Annette McCarthy, Kelly McVearry, Nancy Rachman, Steve Roberts, Joe Scimeca, Libby Tsytsikova

Agenda:**(1) SC CO-CHAIRS**

- Steve Roberts has agreed to serve as a SC Co-Chair. Annette McCarthy has tentatively agreed pending final approval from FDA. The group agreed to accept Steve and Annette as provisional Co-Chairs for this call.
- Steve chaired the discussion of the remaining agenda items.

Action item: SC will be asked to email approval of the co-chairs following the call.

Note: After the call Annette confirmed that she will serve as SC Co-Chair.

(2) APPROVAL OF APRIL 2nd MEETING MINUTES

- The intent is to make the minutes of the meetings public eventually as a record of the group's deliberations. The SC was asked to weigh in on any concerns they might have with the minutes from that perspective.
- On p. 4, "MARINA" is incorrect and will be replaced by "NanoSafety Cluster Report."

Action item: SC to provide comments to Rick and/or Libby on the April 2 meeting minutes by Friday, May 18 (rcanady@ilsil.org, Itsytsikova@ilsil.org)

(3) DECISION MATRIX

- **Draft "Statement of Purpose"** intended to accompany the Matrix. This was generated because ILSI had been asked where the list came from and recognized such a statement was needed. The statement is envisioned to be on the public website accompanying the Matrix. Unlike other NanoRelease projects, NR FA is unlikely to come up with a list of materials that are known to be "in foods." In the discussion that followed, SC members raised clarifying points that need to be conveyed in the "Statement of Purpose," including the fact that the list is not intended to represent materials in commerce. The idea is not to select materials for inclusion that are *in food*, but to select materials that are important because they: (1) *could theoretically be used in food*; (2) have potential for high impact/concern if found in food; (3) exhibit a range of the characteristics of importance for analytical methods development; and (4) overlap with materials that are the focus of other, related projects (e.g., NanoLyse) in order for NR FA to efficiently and successfully reach the goal. That goal is developing methods that may be applicable to the most important NMs that may find use in food. There perhaps is more nuance necessary in the "Statement" than can be captured in only 4 bullets; however, the statement needs to be kept as brief as possible. The SC was asked to provide input.

- **Further Matrix refinements –**
 - Staff asked the SC to advise whether the original version of the Matrix should be retained on the project’s public website for transparency reasons.
 - The Information Catalogue was made available last week. It had been agreed at the April 2 meeting that the Information Catalogue would be made available prior to the next round of voting so SC members could decide if anything was missing from the Matrix.
 - 2 edits were made in the Matrix in response to comments received: nanoclays and aluminosilicates (Row 8) have been combined; “ease of use” has been incorporated for consideration (last column on the right).
 - There was also a comment received about titanium dioxide. An SC member had relayed that the marketing of a high concentration of nanotitania in a food additive would not be likely on functional grounds. Titania are used for white color, and the presence of high concentration NPs would render the food translucent or transparent, thus defeating the purpose. However, a publication by researchers in AZ reported that an existing food grade titanium dioxide, which is GRAS and already used in food, contains about 37% of NPs ≤ 100 nm. Thus, existing additives might contain a high percentage of NPs regardless of whether or not their presence is intended to achieve a particular technical effect. The project’s intent is to develop methods that would be applicable to NPs getting into food regardless of how/why they got there. The group agreed that this is properly a characterization issue because of the possibility for exposure. While a “high- concentration nano” ingredient is unlikely to be marketed, there still may be unintentional exposure.

Action Items:

- *Staff will distribute a revised draft of the “Statement of Purpose” for SC review and comment.*
- *SC members to advise whether the original Matrix as well as the final should be on the project’s public website.*
- *Further comments on the Matrix list should be sent to Rick asap (rcanady@ilsj.org). The next round of voting on the Matrix is due within the next 2-3 weeks.*
- *If you have already voted and wish to reconsider in light of today’s discussion, contact Nancy (nrachman@ilsj.org).*

(4) INFORMATION CATALOGUE (on Sharepoint)

- The Information Catalogue is a collection of background articles relevant to the project. The purpose & focus of the Information Catalogue is to support the selection of materials on the Matrix, help decide Task Group membership, and to assist the T Gs to refine and implement their Charges. The Catalogue Categories were created with this in mind. The SC was asked to scan the Catalogue and the papers so any additions/changes to the Matrix can be made quickly and the next round of voting can occur within 2-3 weeks.
- Libby demonstrated how to access the Catalogue, link to files it contains and upload missing/additional files. ILSI staff will sort through newly uploaded files and assign them to

the appropriate folder(s). ILSI RF is grateful to Tim Duncan for making so many of these references available. Missing documents are in red font. If SC members can provide any of the missing files please do so. As a reminder, ILSI RF has blanket copyright license to share them within the project.

- Scanning titles and papers for what others have said is in food can help complete the Matrix for the next round of voting. It is important for the SC to review and provide input on the Catalogue asap in order for the next round of voting on the Matrix to be completed within the next 2-3 weeks.

Action Item: SC to scan review the IC, provide missing files and think of TG experts. Contact Libby for assistance with accessing the Catalogue on Sharepoint (tsytsikova@ilsi.org).

(5) TASK GROUPS

- **Revisions to TG names and charges** - based on comments received, staff realized clarifications to the groups and charges were needed: the focus of the work is on *development of analytical methods*. Also, it was suggested that it is advisable to include consideration of materials coming from packaging. (We are not suggesting that the project take on development of methods for materials getting into food from packaging. The intent is to provide analytical methods to support source attribution for NPs that may show up in food.) Migration studies using simulants are relied upon to predict potential for substances to move from packaging into food, so it is important to consider methods for detecting and characterizing NPs in these systems. A focus on packaging enables the project to draw upon work done by the ILSI Europe project as appropriate.
- **Process issues** - The current descriptions and charges are a starting point for the TGs. Once co-chairs are selected and the TGs are populated with experts, it is envisioned that each TG will clarify/modify its own charge as it sees fit. The SC voted to accept the current TG descriptions and charges as provisional, pending their finalization by the TG Co-Chairs.
- **TG experts and Co-chairs** –
 - In other projects, a successful approach has been to have 2 Co-Chairs for each TG, one from the SC and one from academia. The SC was asked to volunteer to be TG co-chairs, and to nominate experts. The initial list of experts staff circulated was generated from the Information Catalogue. In addition, we have already received some volunteers from ILSI NA and FDA.
 - Steve requested that staff prepare a list of Co-chair responsibilities to provide to volunteers.
 - The nano- industry association alliance will be asked to recommend TG experts.
 - The SC discussed whether it is of interest to bring in bioinformatics expertise (e.g., Martin Leach of the Broad Institute) to the TGs at this juncture. Staff suggested that such expertise will be essential as the analytical methods reach the “report out” stage to help ensure that data generated will be useful for toxicity, exposure and risk assessment and for identifying further research needs. The SC should discuss further when to add this expertise to the project; adding another TG may be advisable later on.

- SC members were urged to put out the call for TG Co-Chairs and experts asap. The TGs will need to complete their work over the summer in order for the project to meet its timelines, so time is of the essence.

Action Items:

-SC to send nominations for co-chairs and experts to Rick or Libby. It is very helpful to provide background for each nominee including some indication if he/she is willing to serve.

-Staff to draft TG co-chair responsibilities.

(6) UPDATES FROM RELEVANT PROJECTS (presentations will be available on the Sharepoint site)

- **NanoLyse** (*Stefan Weigel*) – EU Framework Project has received a 9-month extension to Sept 2013. It is looking at presence, identity and concentration of NPs; developing and validating methods for NPs in food matrix. It includes a conventional material that contains NPs such as the SC discussed (see above). Expected main outcomes are reference materials, methods for Ag and SiO₂ in food matrices, and screening and confirmatory methods.
www.nanolyse.eu.

Action Item: *Stefan will review our Matrix and add to it based on the review done for the NanoLyse project.*

- **OECD Task Force on Novel Foods and Feeds** (*Mar Gonzalez, joined by Bertrand Dagallier*) – the main focus has been on tools to help risk assessors with genetically modified crops, e.g., the range of composition of foods and feeds. Nano is not currently an important focus, but may be in near future. OECD bodies are currently defining their 2013-16 program of work. Although no projects have yet been defined, it is clear from responses of many delegates that the Novel Foods Task Force will have to act as the resource for evaluation of the safety of new technologies, e.g., synbio, nano.
- **ILSI Europe Novel Foods & Nanotech** (*Alessandro Chiodini*) – FAO/WHO wants to update their 2009 report on the use of nano in food and packaging. They have a particular interest in the developing country perspective, and the potential of nano to address problems of water quality and waste. The ILSI Europe nano risk assessment publication is on the SharePoint site. The focus of a recent workshop in Lisbon was a tiered approach to developing information on NMs. A manuscript has been submitted to J Food Chem Tox; an ILSI Report will also be issued. The manuscript is in the Information Catalogue. The tiered approach it describes could be a useful model for the NR FA to consider. Also, many experts from this workshop could be good candidates to serve on NR FA TGs. A new activity is reviewing the feasibility and efficacy of existing and new methods for generating safety data for novel foods.
- **ILSI Europe Packaging Materials** (*Massimo Ambrosio*)- This project focuses on evaluating lifecycle issues for food packaging. There was a February 2012 workshop in Brussels. EC and FDA participated. Issues identified included: 1) The possibility of different regulatory

schemes in member states can be a hurdle to the promise of the technology; 2) the EU definition of NM must be improved. Four Workgroups are operating: 1) Applicability of NMs to packaging (NMs will be acceptable only when clear advantages are seen); 2) end-of-life risks; 3) measurement techniques; 4) safety assessment (critical to acceptance). Lack of uniformity in regulatory approaches to nanomaterials in member countries and definitional issues for nanomaterials have been identified as problems. A manuscript is in preparation and publication is anticipated in early summer 2012.

(7) NEXT STEPS

- Since finding TG experts is a crucial starting point in the project, the Co-Chair suggested that the SC hold regular biweekly calls until the TGs are up and running. Monthly calls will resume thereafter.

Action item: staff will poll SC for a fixed day/time for biweekly calls

(8) ACTION ITEMS - SUMMARY

Prior to adjourning the call, Co-Chair and staff recapped the major areas of action items:

- Vote on Co-chairs
- Review Info Catalogue - consider how much revision needed to the Matrix before next vote; provide nominations for TG Co-Chairs and experts
- Additions/edits to call minutes