NanoRelease Food Additives First Steering Committee (SC) Call

Participants: Shaun Clancy, Abdul Afghan, Tom Neltner, Andrew Maynard, Annette McCarthy, Joe Scimeca, Andy Atkinson, Steve Roberts, Alessandro Chiodini, Don Forsyth, Mark Perry, Mehta Rekha, Bob Brackett, Francois Rossi, Michael Hansen, Carolyn Cairns, David Carlander, David Lefebvre, Tim Duncan, Rick Canady and Steve Froggett

Agenda:

- (1) Project Orientation
- a) A brief overview of the project's goals, scope, oversight, timeline and milestones was given to help orient the steering committee using the attached powerpoint slide set.
- b) Throughout this overview the SC members asked questions and offered suggestions related to scope and ways to ensure a successful outcome of the project. These comments were captured in a revised scope document (attached and available on Google Docs).
- c) (Discussion related to charge and to the decision matrix are included under those items below.)
- d) The SC will generally select the materials of focus, the methods to measure/characterize nanomaterials released into alimentary canal, and consider the routes by which the nanoparticles would enter food.
- e) Over the next two months, the SC will be asked to identify Task Groups to collect, analyze and draft White Papers on topics the SC also selects. The Task groups could for example include a review of important methods, nanomaterials types that may be found in foods and the routes of entry of the nanomaterials into foods.
- f) The White Papers would be developed over the next 4 months and would form the background for a State of the Science paper on to be drafted following a workshop in July and published in early 2013.
- g) In addition to these efforts, the SC members will be asked to identify labs and principle investigators to carry out the inter-laboratory testing of the methods. The inter-laboratory testing would be initiated in 2013.
- h) The group should plan to complete the above tasks this year (2012) in order to begin inter-lab testing and development of methods in 2013. Once the testing phase is complete, the project will seek to submit the methods to standards development organizations.

(2) Review Charge, Scope and Objective

A draft statement of the project scope, charge and objectives was provided to the SC members prior to the call, and presented during the orientation. SC members discussed several aspects of scope to clarifying the project. The following points were discussed and confirmed *(pending edits to these notes by the SC)*:

- a) Both indirect and direct food additives are within scope. Environmental contamination is also technically within scope but such food contamination by engineered nanomaterials seems unlikely at present.
- b) The focus is on methods development, not data generation. However, some release data will be collected in the process of developing methods, and that data will be made publically available. The scope of this project is to identify / develop release methods and to build the confidence in their utility.
- c) The project's focus will be on developing confidence in methods to measure interactions of nanoparticles along the alimentary canal resulting from oral exposure.
- d) It was noted that how the nanoparticle becomes incorporated in the food may influence how/if the nanoparticle is released from the food and what characteristics it may have. If these characteristics alter which methods can detect its release, then this topic (i.e. food nanoparticle incorporation) should be considered.
- e) The SC agreed that multiple definitions of "nanomaterials" exist and that the success of this project is not dependent on acceptance or use of any. The project's focus is on identifying / developing methods to characterize alimentary canal interactions with food particles.
- f) It was recognized that many regulatory agencies have and use definitions of nanomaterials, but they do not have a list of accepted / rugged methods to request to be used to generate data for submissions.
- g) It was recognized that considerations of risk will influence SC member's selection of materials and exposure scenarios to focus on during the methods testing phase. However, the project's scope does not include conducting risk assessments; rather to identify and develop the tools (methods) useful for such assessments.
- h) Exposure frequency (e.g. daily vs infrequent) should be considered and added as a column in the decision matrix.
- i) Initial drafting of the scope document used the generic term "gut". The SC agreed that this term should be changed to alimentary canal to consider ENM characterization prior to gut entry.
- j) The alimentary tract lining is generally the dividing line for considering methods. For example, systemic distribution and biological effect will generally not be considered.
- k) Overall project focus is on methods with the highest utility to characterizing particles with respect to their likelihood to cross the alimentary tract lining (plus considering alimentary tract cell uptake).
- (3) Review decision matrix
- a) The SC is asked to fill in the left column of the decision matrix with information on intentionally produced nanoparticles in foods. The SC is also asked to review and edit the selection criteria in the top row. The decision matrix, when complete, will be used to make decisions about which materials will be the initial focus of the methods development phase of the project.

- b) It was emphasized that the SC needs to feel that the matrix is comprehensive and thus a useful tool to help the group consider what is likely to be in foods, and prioritize consideration of methods to characterize nanomaterials in foods.
- c) The NanoRelease secretariat found a multi-voting process to be an effective tool to both select priorities and foster discussion about those selections. The group expects to use a similar approach with this matrix.
- d) The SC recommended adding focus on the underlying biology (e.g. the morphology of the mucosa, the types of cells and their role). The column(s) would help draw attention to "how the particles interact with the cells". Joe Scimeca indicated he would consider how to do this.
- (4) The Information Catalog
- a) The focus of the Information Catalog is on methods available to measure aggregation, dissolution, uptake for a range of particles that are exposed to the cell lining the alimentary canal. For the scope of the project and its goals, defining nanomaterials is not necessary and may be too limiting.
- b) It was requested that the detection limit of methods be indicated in the catalog.
- c) The SC agreed to cast a wide net for information collection, and consider at a later time if the scope needs to be readdressed.
- (5) Call schedule, face-to-face meeting and nominations for co-chairs
- a) The SC members were asked to respond to Doodle polls for the next two calls.
- b) A face to face/webinar meeting will be scheduled to facilitate drafting of the charges for the task groups.
- c) Based on the responses from these calls, the secretariat will attempt to identify a good day and time to schedule regular calls on a bi-weekly basis.

Next Steps:

- 1. David Carlander will check into an ongoing project that has been undertaken to review nanomaterials in foods, since this group could benefit from adding the information already collected by that project.
- 2. The SC members are encouraged to add information to the Information Catalog and the Decision Matrix via the google documents site, or send the info to the ILSI secretariat.
- 3. The SC members will be sending edits and/or comments to the draft project charge, scope and objectives. The SC will look to approve these during the next call.
- 4. SC members are requested to respond to the doodle polls to identify the next conference calls times.