The Toxicology of Nanoparticles

April 8, 2021
Welcoming Remarks

George Daston, PhD
President, Society of Toxicology
Procter & Gamble Company
Colloquium Series

- Partnership of US FDA Center for Food Safety and Applied Nutrition (CFSAN) and the Society of Toxicology (SOT)
- Sixth year of colloquia series, two this year, and this is the 25th event
- Stimulate dialogue among leading toxicology experts on future-oriented toxicological science relevant to food and food ingredient safety assessment
- Provide well-grounded foundation to inform the work of US FDA employees and others
- Not a forum for soliciting regulatory advice or discussing food or food ingredient regulatory issues
Colloquium Series

- These colloquia are open to the public via webcast at no cost
- Global audience from all employment sectors
- Recording and slides for all the colloquia are available at www.toxicology.org
Society of Toxicology Vision/Mission

To Create a Healthier and Safer World by Advancing the Science and Increasing the Impact of Toxicology

Among Strategic Objectives

- Promote Transdisciplinary Science and Cooperation with Other Disciplines
- Expand Global Outreach, Engagement, and Collaboration
- Provide Opportunities to Capitalize on Scientific Advancements
- Develop Communication Partnerships with Key Influencers
- Promote Use of Science in Decision Making
SOT FDA Colloquium Website

• Resource for 24/7 learning
• www.toxicology.org
SOT FDA Organizing Committee

- **Jia-Sheng Wang**, MD, PhD, Colloquium Committee Chair, University of Georgia, Athens, GA
- **Udayan Apte**, PhD, DABT, Colloquium Committee Co-chair, University of Kansas Medical Center, Kansas City, KS
- **Jason L. Aungst**, PhD, FDA Liaison, US FDA, College Park, MD
- **Omari Bandele**, PhD, US FDA, College Park, MD
- **Stephen W. Edwards**, PhD, RTI International, Chapel Hill, NC
- **Suzanne C. Fitzpatrick**, PhD, DABT, US FDA, College Park, MD
- **A. Wallace Hayes**, PhD, DABT, ERT, ATS, FRSB, FACFE, University of South Florida and Michigan State University, Temple Terrace, FL
- **Stephen M. Roberts**, PhD, University of Florida, Gainesville, FL
- **Mary Beth Genter**, PhD, SOT Council Contact, University of Cincinnati, Cincinnati, OH
Overview and Speaker Introductions

Richard Canady, PhD
NeutralScience LC3
<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
</tr>
</thead>
<tbody>
<tr>
<td>9:10 AM</td>
<td><strong>Lessons Learned from Nanomaterial Characterization: Critical Quality Attributes that Influence Biological Properties</strong></td>
</tr>
<tr>
<td></td>
<td>Anil Patri, NCTR, Jefferson, AK</td>
</tr>
<tr>
<td>9:45 AM</td>
<td><strong>Standard Dose Measurement for Nanomaterials: What to Include in Exposure and Toxicity so That We Can Bound Dose Estimates for Safety?</strong></td>
</tr>
<tr>
<td></td>
<td>Christie Sayes, Baylor University, Waco, TX</td>
</tr>
<tr>
<td>10:20 AM</td>
<td><strong>Break</strong></td>
</tr>
<tr>
<td>10:30 AM</td>
<td><strong>Dosing-Related Challenges in Toxicity Studies and Risk Assessment of Titanium Dioxide in Food</strong></td>
</tr>
<tr>
<td></td>
<td>Walter Brand, RIVM, Bilthoven, The Netherlands</td>
</tr>
<tr>
<td>11:05 AM</td>
<td><strong>Practical Application to Regulatory Toxicology: Issues Faced in Consideration of Developing Health Guideline Values</strong></td>
</tr>
<tr>
<td></td>
<td>Lynne Haber, University of Cincinnati Risk Science Center, Cincinnati, OH</td>
</tr>
<tr>
<td>11:40 AM</td>
<td><strong>Roundtable Discussion</strong>, Moderator: Rick Canady, all speakers and panelists Agnes Oomen, RIVM; and Timothy Duncan, US FDA.</td>
</tr>
<tr>
<td>12:40 PM</td>
<td><strong>Conclusion</strong></td>
</tr>
</tbody>
</table>
Panelist Questions

To stimulate discussion, Drs. Agnes Oomen of NL RIVM and Timothy Duncan of US FDA reviewed the slide sets and offer the following questions.

We ask that you consider these questions during the speaker presentations. Drs. Oomen and Duncan will initiate the panel discussion based on one or more of their questions.
1. Should well-dispersed nanomaterials be used for toxicity testing to cover worst case exposure situations?

2. How should we interpret toxicity studies in which there was some degree of agglomeration?

3. To which extent is information on toxicokinetics, e.g., internal exposure, needed to aid understanding the relationship between external exposure and hazard?
4. What are the key challenges that nano introduces to comparison of acceptable intake estimates to measured intake estimates?

5. What recommendations would you give for standardizing operational procedures to determine and report critical nano-toxicological and nano-exposure data?

6. Should the approach to safety assessment differ when a nanomaterial is intentionally added to a food vs. indirectly or unintentionally present?

7. Because key metrics like dose, identity, etc., are much more complicated for nanomaterials across concentrations and local conditions, should procedures be changed to ensure that allowable limits have enough of a safety margin?