AGENDA

FIFRA SCIENTIFIC ADVISORY PANEL (SAP)
OPEN CONSULTATION MEETING

November 3 - 6, 2009

FIFRA SAP WEB SITE http://www.epa.gov/scipoly/sap/
OPP Docket Telephone: (703) 305-5805
Docket Number: EPA-HQ-OPP-2009-0683

U.S. Environmental Protection Agency
Conference Center - Lobby Level
One Potomac Yard (South Bldg.)
2777 S. Crystal Drive, Arlington, VA 22202

Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometal Pesticide Products

Please note that all times are approximate (see note at end of Agenda).

Tuesday, November 3, 2009

1:30 P.M. **Opening of Meeting and Administrative Procedures –** Joseph Bailey, Designated Federal Official, Office of Science Coordination and Policy, EPA

1:35 P.M. **Introduction and Identification of Panel Members –** Carey Pope, Ph.D., Session Chair, FIFRA Scientific Advisory Panel

1:40 P.M. **Welcome and Opening Remarks –** Steven Bradbury, Ph.D., Deputy Director, Office of Pesticide Programs, EPA

1:45 P.M. **Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometals –** Office of Pesticide Programs, EPA

- **Introduction -** William Jordan, Senior Advisor to the Office Director, Office of Pesticide Programs, EPA
- **Regulatory Framework** – Mr. Dennis Edwards, Chief, Regulatory Branch I, Antimicrobials Division
- **Product Chemistry** – Najm Shamim, Ph.D., Antimicrobials Divison
- **Human Toxicity from Silver and Nanosilver** –
  Melba S. Morrow, D.V.M., Antimicrobials Division;
  Jenny Tao, M.D., Antimicrobials Division;
  Jessica P. Ryman-Rasmussen, Ph.D., Health Effects Division
- **Nanosilver Exposure Pathways** – Tim Dole, C.I.H., Antimicrobials Division
- **Environmental Fate and Transport**– Najm Shamim, Ph.D., Antimicrobials Division
- **Ecotoxicity of Nanosilver** – Ed Odenkirchen, Ph.D., Ecological Fate and Effects Division
- **Summary** – William Jordan, Senior Advisor to the Office Director, Office of Pesticide Programs, EPA

3:30 P.M. **Break**

3:45 P.M. **EPA presentation (continued)**

5:30 P.M. **Adjourn**

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Wednesday, November 4, 2009

8:30 A.M. **Opening of Meeting and Administrative Procedures** – Joseph Bailey, Designated Federal Official, Office of Science Coordination and Policy, EPA
8:35 A.M. **Introduction and Identification of Panel Members** – Carey Pope, Ph.D., Session Chair, FIFRA Scientific Advisory Panel
8:45 A.M. **Public Comment**
10:00 A.M. **Break**
10:15 A.M. **Public Comment (continued)**
11:00 A.M. **Panel Discussion of Charge**

Charge Question 1. Potential Risks from Nanosilver Materials Issue: Whether pesticide products containing nanosilver as the active ingredient pose potential hazards and exposures to humans and the environment that are different from those associated with products containing conventional silver.

A. Available scientific literature indicates that nanosilver products may exert an antimicrobial effect by releasing silver ions, and that these ions may pose potential hazards to humans and the environment. The Agency is unaware on any information that would suggest exposures to silver ions released from nanosilver products differ from the hazards of silver ions released by non-nanosilver (hereafter referred to as silver) based products and, therefore, might present a different hazard profile. Is the Panel aware of any information inconsistent with this determination?

B. Available scientific literature also indicates that, in addition to any hazards resulting from the release of silver ions, nanosilver particles themselves may present hazards that differ from those of silver particles. What, if anything, does the existing scientific literature indicate about the potential for nanosilver materials with specific particle sizes in the range of 1 to 20 nm, 21 to 50 nm, and 51 to 100 nm to pose different hazards than those of larger-sized particles of the same material, particularly nanosilver vs. silver? What does the existing scientific literature indicate about the potential for particular physicochemical properties of nanosilver materials (e.g., shape, surface characteristics, composition, etc.) to pose hazards that are different from larger-sized particles of the same material? Does existing literature support “bridging” data? In other words, can

hazard or exposure data developed on 1 to 20 nm silver particles or silver composites be used to assess the risks for 51 to 100 nm silver particles or silver composites?

C. What, if anything, does the existing scientific literature indicate about the potential for nanosilver particles in the range of 100 nm – 1000 nm (or "agglomerated" nanosilver or nanometals/nanometal oxides) to pose hazards that are different from larger-sized particles of the same material?

D. If nanosilver particles present different hazards than either silver or agglomerated nanosilver, the potential risks to human health and the environment will depend on the extent of exposure. Several types of nanosilver pesticide products are described in the attached Background Paper, and other types seem possible in the near future (e.g., sanitizers and disinfectants; and chemicals used in or on industrial, commercial or residential systems, such as slimicides, preservatives, antifoulants, metal working fluids, etc.). What do available data on the release, fate, transport and transformation of nanosilver particles suggest regarding potential human or ecological systems exposure to nanosilver particles (individual or agglomerated) under realistic use scenarios?

E. The Agency would like the Panel's advice as to whether the models currently used by the Agency would be appropriate to predict potential environmental exposures to nanosilver and if not, what, if any, modifications would be necessary.

12:00 P.M. Lunch
1:15 P.M. Panel Discussion of Charge Question 1 (continued)
2:00 P.M. Panel Discussion of Charge

Charge Question 2. Data Requirements Issue: If the panel believes that nanosilver is different in terms of hazard/exposure what type of data (studies) would EPA need to adequately assess the potential risks associated with the use of an antimicrobial pesticide containing nanosilver particles, when the product is intended for use as an additive to various substrates (e.g., textiles, plastics, ceramics) to impart antimicrobial properties to the treated substrate? In liquid, spray form?

A. What types of data on the nanoscale material would be sufficient to adequately evaluate whether the hazard and exposure properties of the nanoscale material were comparable to that of a macroscale/bulk form of the same material? Could EPA rely on toxicity data for the bulk material to assess the risk of the nanoscale material?

B. What types of data would be sufficient to:

1) Evaluate whether the nanoscale material, once it has been applied to or incorporated within a substrate, remains associated with the substrate through the whole-life cycle of that substrate to such an extent that there would be essentially no human or environmental exposure to the nanoscale material or nanosized composite, and

2) Measure and characterize exposures to nanomaterials that may leach from treated materials?

C. Assuming appropriate studies could adequately show that nanosilver, which is applied to a substrate, would bind with that substrate to such an extent that there is essentially no exposure to the nanosilver, does the Panel think that other types of data (such as toxicity studies on the nanosilver particles or composite) would be needed? Similarly, if only silver ions are released from substrate containing nanosilver, would consideration of the potential risks associated with the silver ions be sufficient or would

additional data be needed to assess hazards and exposure to human health and the environment from nanosilver?

3:30 P.M. Break
3:45 P.M. Panel Discussion of Charge

Charge Question 3. Other Risk Assessment Issues.

A. Products developed using nanotechnology may contain a distribution of particle sizes. Please comment on how information concerning the percentage of the particles in a product falling within the nanoscale range (e.g., 1 - ~100 nm) could affect the risks of a product. Are particles at the lower end of the range (e.g., 1 nm) likely to behave like particles at the upper end of the range (e.g., 100 nm)?

B. Please comment on the extent to which the scientific literature indicates that data on one form of a nanosilver particle or other nanometal/nanometal oxide particle can be used to assess the potential hazards and exposures of another form of nanosilver that has different physicochemical properties (e.g., is a different size or shape or has different surface properties). For example, if nanosilver is reacted with a non-metal material to form a nanosilver complex or composite, to what extent could data developed for the nanosilver be used to predict the toxicity of the complex or composite?

C. Please comment on the extent to which the scientific literature indicates that nanosilver physicochemical properties change under different environmental or physiological conditions, what those conditions are, and how this variation could be best addressed.

5:00 P.M. ADJOURN

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Thursday, November 5, 2009

8:30 A.M. **Opening of Meeting and Administrative Procedures** – Joseph Bailey, Designated Federal Official, Office of Science Coordination and Policy, EPA
8:40 A.M. **Introduction and Identification of Panel Members –** Kenneth Portier, Ph.D., Session Chair, FIFRA Scientific Advisory Panel
8:50 A.M. **Panel Discussion of Charge**

Charge Question 4. Research Needs.

A. In the next year, what types of new information on individual products would be most useful to EPA for assessing potential risks of antimicrobial pesticides containing nanosilver or nanosilver composites, such as toxicity studies, exposure studies, etc.

B. What types of long term research would be most helpful for improving the assessment of the potential risks of antimicrobial pesticide products containing nanosilver or nanosilver composites?

10:00 A.M. **Break**
10:15 A.M. **Panel Discussion of Charge (continued as needed)**
12:00 P.M. **Lunch**
1:15 P.M. **Panel Discussion of Charge (continued as needed)**
2:45 P.M. **Break**
3:00 P.M. **Panel Discussion of Charge (continued as needed)**
5:00 P.M. **ADJOURN**

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Friday, November 6, 2009

8:30 A.M.	**Opening of Meeting and Administrative Procedures** – Joseph Bailey, Designated Federal Official, Office of Science Coordination and Policy, EPA
8:40 A.M.	**Introduction and Identification of Panel Members** – Kenneth Portier, Ph.D., Session Chair, FIFRA Scientific Advisory Panel
8:50 A.M.	**Panel Discussion of Charge (continued as needed)**
10:00 A.M.	**Break**
10:15 A.M.	**Panel Discussion of Charge (continued as needed)**
12:00 P.M.	**Lunch**
1:15 P.M.	**Panel Discussion of Charge (continued as needed)**
2:45 P.M.	**Break**
3:00 P.M.	**Panel Discussion of Charge (continued as needed)**
5:00 P.M.	**ADJOURN**

Please be advised that agenda times are approximate; when the discussion for one topic is completed, discussions for the next topic will begin. For further information, please contact the Designated Federal Official for this meeting, Joseph Bailey, via telephone: (202) 564-2045; fax: (202) 564-8382; or email: bailey.joseph@epa.gov