

EPA Regulation of Pesticides Containing Nanoscale Materials

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Presentation Overview

- Why important
- Nano-Pesticides
- OPP's Draft Policy
 - Reporting obligations for registrants
 - Classification of ingredients
- Regulatory Activities



Why Important?

- Nanomaterials behave differently
 - Size and unique properties such as shape can influence exposure and toxicity
 - Potential Human Health Concerns:
 - Dermal absorption (so small they may pass through cell membranes)
 - Inhalation (go to the deep lung and may translocate to the brain i.e, could cross the blood brain barrier)
 - Potential Environmental Concerns:
 - High durability or reactivity of some nanomaterials raises issues on the fate in environment
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Nano-Pesticides: Nanosilver Petition

- International Center for Technology Assessment (CTA) and 13 other organizations (2008)
 - Asks EPA to use its authority under FIFRA to regulate an estimated 600 unregistered nanosilver products marketed in US
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Nano-Pesticides: Nanosilver Petition (continued)

- **Products include** (Not all subject to EPA FIFRA regulation):
 - air and water purifiers and filters
 - cleaning sprays and wipes
 - children's toys, baby bottles and infant products
 - food storage containers, cutlery, cutting boards
 - clothing
 - soaps, personal care and hair products
 - refrigerators, washing machines, computer hardware
- **Example claims of antimicrobial properties**
 - Antibacterial, Antibiotic effect
 - Eliminates 99.9% of bacteria, fungi and hundreds of other disease causing microorganism
 - Renders material "permanently anti-microbial and anti-fungal"
 - Sterilizes bacteria of over 650 species
 - Control air free from bacteria, virus germs, fungus or even avian influenza



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Nano-Pesticides: Registration

- Pre-application meetings & pending applications
 - Several contain nanosilver
 - Use as material preservatives/additives for textiles, polymers, coatings, and/or plastics to protect the treated products from microbial degradation –similar to registered silver products
- Several currently registered pesticides claim to contain nanoscale materials
 - Registered without EPA's knowledge of nanoscale materials in the products



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Nano-Pesticides: 2009 SAP Consultation

- Advice on how to assess risks of products containing nanoscale silver:
 - Nanoscale materials may differ from macroscale materials of the same substance and differ from each other
 - More data are needed in all disciplines to have adequate information to assess the risks of nanosilver
 - OPP should determine data needs for nanosilver products on a case-by- case basis
 - Life Cycle Analyses (LCA) can be adopted for nanoproducts
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Draft Policy: Reporting Obligation

- Under FIFRA section 6(a)(2) registrants and applicants must report to EPA information on the presence nanoscale material in products
 - An active or inert ingredient and any component parts thereof intentionally produced to have at least one dimension that measures between 1 and 100 nanometers.
 - Only existing information known to company
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Draft Policy: Classification

- An active or inert ingredient will be considered “new” if the pesticide contains a nanoscale material (FIFRA and PRIA)
 - Would apply even when a non-nanoscale form of that same active or inert is already in a registered product
 - Example: Nanosilver would be considered new even though silver is a registered pesticide



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Regulatory Activities: Proposed Nanosilver Registration

- Proposed decision to conditionally register a nanosilver textile preservative product
 - 4 years
 - Tiered data requirements: product chemistry, toxicology, exposure, and environmental data
- Public comment period
 - 35 comments
 - Citizens, industry, NGOs, state, CA POTWs

(August 2010)



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Regulatory Activities: Data Call-Ins

- Currently registered products containing nanoscale materials
- Evaluate data needs on a case-by-case basis according to the composition of the product and its intended use.
- FY11



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Regulatory Activities: Labeling

- Nano-Products will be labeled the in the same way as other pesticide products.
- Ingredients: listed as "nano-X"
- Claims will be evaluated on a case-by-case basis.



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