PPDC Update - Pesticides Containing Nanoscale Materials

Jennifer McLain, Ph.D.
Deputy Director, Antimicrobials Division

Office of Chemical Safety and Pollution Prevention (OCSPP)
Office of Pesticide Programs (OPP)

Nanotechnology

- Research and technology development at dimensions of roughly 1 to 10 nanometers.
- Creation and use of matter that have novel properties due to its small size

Nanoscale Materials and Applications

Nanoscale materials have many applications

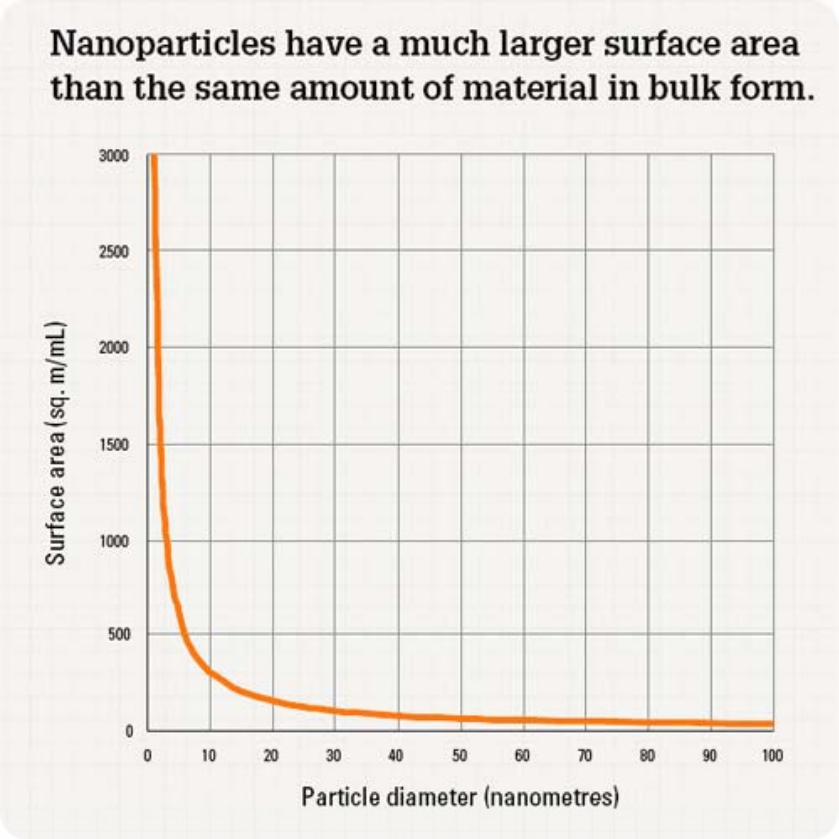
Examples include:

- Conductors and semi-conductors
- Medical devices
- Coatings
- Catalytic agents
- Pharmaceuticals
- Pesticides

The Scale of Things

Object	Size (nm)
Carbon nanotube(eng.)	2
Width of DNA	2.5
Virus	100
Dust	500,000
Width of Human Hair	75,000
Head of a pin	2 million
Shaquille O'Neal	2.1 billion

Size and Surface Area



- As size decreases, surface area increases
- Surface area related to reactivit,

Why is OPP Concerned?

- Unusual physical, chemical, and biological properties emerge at the nanoscale
- Properties may differ from those for bulk materials or molecules
- Size and surface area can influence exposure and toxicity

Why is OPP Concerned?

- 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 nanoscale materials raises issues on the fate in environment
- Uncertainty – many gaps in understanding

Pesticides & Nanotechnology: Actions

- Pending applications for registration
- Pre-application meetings
- Several currently registered pesticides claiming to contain nanoscale materials
- Unregistered products claiming both to use nanoscale materials and to provide pesticidal effects
- Petitions

Scientific Advisory Panel Consultation (11/2009)

- Advice on how to assess risks of pro ducts containing nanoscale silver:
  - Nanoscale materials mav differ from macroscale

    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

Draft Policy Proposal: Classification

- Presume an active or inert ingredient will be considered "new" if the pesticide contains a nanoscale material
  - 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

Draft Policy Proposal: 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

Regulatory Activities: Data Call-Ins

- Currently registered pesticides claiming to contain nanoscale materials
  - Registered without EPA's knowledge of the nanomaterials
- EPA anticipates further reporting of nano-products
- EPA will require additional data on all products with nanoscale materials (data call-in)
  - Evaluate data needs on a case-by-case basis according to the composition of the product and its intended use.
  - Plan to issue in 2011

Conditional Registration Proposed Aug 2010

- Product: HeiQ AGS -20
  - Textile preservative
  - Nanosilver-silica composite
    - 1 to 10 nm silver
    - 1,000 nm composite
- Conditions of registration [FIFRA §3(c)(7)(C)]
  - 4 year time limited registration
  - Tiered data requirements: product chemistry, toxicology, exposure, and environmental data
    - Tier 2 conducted with nanosilver if released during Tier 1
  - Label risk mitigation engineering controls and PPE

Proposed Conditional Registration Agency Findings [FIFRA §3(c)(7)(C)]

- No unreasonable adverse effects during period of conditional registration
  - Screening level risk assessment – risks to workers, consumers, and environment associated with use
- Insufficient time to generate data
- Public Interest
  - Potential environmental benefits: less use of silver
  - Potential consumer benefits: prolonged efficacy
  - Market equity & trade considerations: registered products
  - Promotes innovation

Summary

- EPA plans to inform existing registrants of their requirement to notify EPA if their products contain nanoscale materials
- EPA will be issuing Data Call-Ins on registered products that contain nanoscale materials
- EPA evaluating new applications and determining data requirements for products containing nanoscale materials on a case-by-case basis