



# **NANOTECHNOLOGY**

**THE FUTURE OF EHS  
REGULATORY POLICY**

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## ***EPA's Regulation of Nano-Pesticides Under FIFRA***

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# Overview

- Definition of Nanotechnology
- FIFRA and Registration
- Nano-Pesticide Technologies
- OPP Authority and Challenges
- OPP Nanotechnology Work Group
- Market Place Claims
- Enforcement

# Definition – Three Parts

- **Size:** Approximately 1 –100 nm in any dimension
- **Properties:** Unique phenomena enabling novel applications
- **Control:** Deliberately engineered

# Registration Under FIFRA

- FIFRA Section 3(a)
  - Must Register a Pesticide Before Sale or Distribution
- Pre-Market Approval
- Registration is a License

# Registration under FIFRA

- **Pesticide**

- Defined as a substance intended to prevent, destroy, repel or mitigate any pest

- **Examples**

- **Antimicrobials:** mold, bacteria, viruses, algae

- **Rodenticides:** vermin

- **Herbicides:** lawn and garden, crop protection

- **Insecticides:** mosquitoes, beetles, *etc.*

# Nano-Pesticide Technologies

- Antimicrobial Apparel and Appliances
- Smart Coatings and Delivery Systems
  - Inert Coatings that open to deliver the AI when in contact with the pest
  - Active ingredients that are inert if discharged to water or inhaled by humans

# Nano-Pesticide Technologies

- To drive regulatory process, industry must create nano-products that
  - Significantly Reduce Pollution, Toxicity or Provide Disease Prevention
  - *Because:* Significant Regulatory Hurdles for OPP

# Nano-Pesticide Technologies

- FIFRA Incentives Beyond Patents
  - Data Compensation
  - Exclusive Use
  - Both Actives and Inerts

# Registration under FIFRA

- OPP: No Registered Nano-products
- Some Claimed but not Nano
- Discussions with Some but No Applications

# OPP Challenges

- Identifying Nanomaterials
- Risk Assessments: exposure, mammalian toxicity, environmental impact
- Are Current Testing Requirements and Methods Adequate?

# EPA Authority

- EPA White Paper
  - “Pesticides with nanomaterials subject to FIFRA review and registration”
- ABA Env. Section
  - EPA has adequate authority under FIFRA to regulate nanopesticides
  - “The Adequacy of FIFRA to regulate Nanotechnology-Based Pesticides” at [www.abanet.org/environ/nanotech/pdf/FIFRA/pdf](http://www.abanet.org/environ/nanotech/pdf/FIFRA/pdf)

# EPA Authority

- Registration Standard of “no unreasonable adverse effects”
- Risk Assessment Based on Submission of Data under Data Requirements
- Data Requirements (40 CFR 158)
- Not Static- EPA can Impose Additional Data Requirements (40 CFR 158.35(e))

# OPP Nanotechnology Work Group

- 2006: Charged to Develop Framework
- Co-Chairs: Betty Shackelford, Jack Housenger
- Reps from Most Divisions and OGC

# OPP Nanotechnology Work Group

- Two Significant Challenges
  - Nano-pesticide that Meets Definition
  - New Physical Form of Old Active
    - Silver
    - Zinc Oxide

# OPP Nanotechnology Work Group

- Risk Assessment = Hazard X Exposure
- New Data on Chemical Characteristics
- Toxicity
- Absorption, Metabolism, Excretion
- Environmental Fate and Ecological Effects

# OPP Nanotechnology Work Group

- New Data Requirements?
- New Testing Methodology?
- EPA Historical Response is Measured
  - SAP 1997 Treated Articles
  - P&G: Fit Product
  - Anthrax, Prions, Avian Flu

# OPP Nanotechnology Work Group

- New Physical Form- Nanoscale Version of Existing Active
  - Silver
  - Zinc oxide
- Product Chemistry- Manufacturing Process

# OPP Nanotechnology Work Group

- EPA May Say New Risk Assessment
- One Strategy: Demonstrate no exposure/tied in matrix and/or closed system
- Conditional registration, FIFRA section 3(c)(7)

# Marketplace Claims and Enforcement

- 40 CFR Section 156.10(a)(5)
- Is “Nano” False or Misleading?
- Heightened Efficacy Claim?
- Approved Company Names
  - Nanotechnologies, Nanosilva, Nanodynamics
  - Nanobio Corporation

# Marketplace Claims and Enforcement

- No Primary Brand Names w/ Nano
- Alternate Brand Names – some approved
- Treated Articles
- Devices

# Enforcement

- EPA Region 9 (SF, Cal.)
- \$208,000 Penalty Settlement
- Wireless Laser Mouse w/Nano-shield Coating (silver)
- Public Health Claims Outside Treated Article Exemption

# Conclusions

- Registration: Pre-market approval scheme
- OPP: Significant Challenges on Data Requirements and Methodologies
- OPP Commitment *but*
- Industry/Public must Drive the Need for a Scheme