

Nanotechnologies and FIFRA

By Lynn L. Bergeson

Nanotechnology regulatory mavens would agree that a good number of articles have been written about the Toxic Substances Control Act's (TSCA) adequacy in assessing the risks posed by existing and new engineered nanoscale materials. The United States Environmental Protection Agency's (EPA) Office of Pollution Prevention and Toxics is well along in tackling the tough issues that these emerging technologies pose in terms of risk assessment challenges and related matters, and EPA leadership is to be commended for its pioneering work in this regard. Less has been written about nanotechnologies and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which is curious since the regulatory hurdles and opportunities nanotechnologies pose for EPA's Office of Pesticide Programs (OPP), pesticide manufacturers, formulators, and other FIFRA stakeholders are every bit as challenging. This column explores applications of nanotechnologies in the agricultural sector, and a few of the issues OPP is now considering.

There are many promising agricultural applications of nanotechnologies. Nanosensors offer the promise of real-time pathogen detection/location reporting using nanotechnologies in micro electromechanical system (MEMS) technology. Increased biological efficiency could result in diminished amounts of pesticides being applied. Similarly, nanodevices used for "smart" treatment delivery systems hold promise. Smart field systems detect, locate, and report/apply, as needed, pesticide and fertilizers prior to the onset of symptoms. Nanopesticide delivery systems, including nanocapsules, nanocontainers, and nanocages, could replace conventional emulsifiable concentrates, thus reducing organic solvent content in agricultural formulations, and enhancing dispersity, wettability, and the penetration strength of the droplets. Enhanced use of smart systems could also diminish run off and avert unwanted movement of pesticides. These are only a few of the innovations nanotechnologies offer in the food and agriculture areas.

OPP is working with other EPA program offices to consider how best to address the growing number of issues engineered nanoscale materials pose. EPA's Science Policy Council Nanotechnology White Paper includes a brief discussion of FIFRA. EPA notes its expectation "that pesticide products containing nanomaterials will come under FIFRA review and registration." EPA also observes that nanotechnologies may produce "[m]ore-targeted fertilizers and pesticides that result in less agricultural and lawn/garden runoff of nitrogen, phosphorous, and toxic substances is potentially an important emerging application for nanotechnolog[ies] that can contribute to sustainability." Finally, EPA notes that until adequate nomenclature conventions are developed, it will be difficult to delineate in some instances "if reporting to EPA is required because the nanomaterials are not contained on the TSCA Inventory, or if use of a nanoscale material results in a change to a pesticide product already registered under FIFRA."

Key issues OPP can be expected to tackle include:

Registration Issues -- How will OPP review and approve a new nanopesticide, will OPP consider a nanoscale version of a conventional pesticide a new pesticide, what will inform OPP's registration decision logic, what are the data needs and how will they be satisfied given test protocols and/or methods do not in all cases exist, and where will the resources come from to undertake this work? The inclusion of nanoscale materials as inert ingredients in pesticide formulations also raises vexing issues. It is not clear what the review process will be for a new inert and/or nanoscale version of an existing inert ingredient, what data requirements might apply, and what process OPP will use to review these matters.

Label Claims -- How will EPA approach and monitor the growing number of claims being made by product manufacturers regarding the antimicrobial properties of certain engineered nanoscale substances (e.g., silver nanoparticles)?

Reporting Implications -- Will existing guidelines under FIFRA Section 6(a)(2) and the requirements set forth at 40 C.F.R. Sections 156.10 and 168.22 be adequate to inform the regulated community's understanding of what EPA believes is reportable under FIFRA with respect to engineered nanoscale materials?

New agricultural/antimicrobial products and application techniques are likely to revolutionize these markets, and there are many commercial opportunities to promote sustainable agricultural and pollution prevention through nanotechnologies. Industry stakeholders and others must engage with EPA and the United States Department of Agriculture early, openly, and regularly to ensure nanotechnologies fulfill their promise as pollution prevention and sustainable agricultural tools.

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