

Legal Lookout: EPA Now Talking Nano

Pollution Engineering, April 2010

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Agency's advisory panel releases report on nanosilver and other nanometal pesticide products.

EPA's Scientific Advisory Panel (SAP) released in January the minutes of its November 2009 meeting regarding evaluation of nanosilver and other nanometal pesticide products. The report is available at www.epa.gov/scipoly/sap/meetings/2009/november/110309ameetingminutes.pdf. For prospective nanosilver Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registrants, the news is not encouraging.

SAP results

The panel's five key recommendations and conclusions are extensive and a must-read for nanopesticide stakeholders. First, the final recommendations address nanosilver almost entirely, and little or no mention is made of "nanometal pesticide products."

Second, the panel stated that existing models "are not appropriate" for use with silver nanomaterials and "will not accurately predict nanosilver exposure scenarios." The panel thus argued that new models implementing novel approaches to predict environmental exposures to nanoparticles should be created. The panel reiterated some of the existing data that suggest differences in toxicokinetics and toxicodynamics for nanoscale materials.

Third, SAP agreed that pesticide products should be tested on a "case-by-case basis." EPA should use a meta-analysis on the products to understand better trends in life cycle analyses, and "close attention" should be given to products that claim a non-ionic mode of action as an antimicrobial agent.

SAP indicated that "current data requirements for antimicrobial pesticide products are a starting point, but the general use patterns and test guidelines require adjusting to accommodate the novel properties and novel uses that will likely evolve through the application of nanotechnology."

The panel discussed the need for studies that provide information about the degradation of substrates containing nanomaterials; metabolism and the transformation of dislodged nanomaterials; and fate information related to leaching, dissipation and bioaccumulation. They recommended that a system of metrics for environmental exposures be developed, including mass, particle number, and surface area concentrations. According to SAP, a life cycle analysis is needed to determine stability of nanosilver products over time.

Fourth, the panel outlined detailed research needs that EPA should consider, both near term and longer term. The outline will discourage even the most optimistic potential FIFRA registrant for a nanopesticide as the research needs are extensive and likely costly. The panel also identified the "most useful short-term information needs," of which stakeholders should be aware.

Finally, the panel stated that a "critical issue" that "must be clarified is the use of [the] terminology 'nano,'" and that for standardization, "the unique property for nanosilver should be established."

Discussion

As some may be aware, EPA is reportedly poised to announce soon that it is adopting a policy to require any pesticide registrant that is aware that some constituent of a registered pesticide product is nanosized (i.e. presumably that has particles or structures with a diameter less than 100 nm) to submit the information to EPA pursuant to FIFRA Section 6(a)(2). EPA is expected to announce this new interpretation of Section 6(a)(2) reporting requirements in a Federal Register notice, either in the form of a pesticide registration notice or as a formal policy statement or regulatory interpretation. In addition, this notice is expected to confirm EPA's view that substitution of a nanoscale active or inert ingredient for a conventionally-sized active or inert ingredient in a product currently registered under FIFRA requires that the registrant submit an application to amend that registration. In light of the conclusions and recommendations of the panel, EPA's soon-to-be-announced policy under Section 6(a)(2) can be expected to be all the more difficult to oppose. PE

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