Consortium proposes consent agreement to test four types of nano carbon

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Several members of the NanoSafety Consortium for Carbon have submitted a proposed testing consent agreement for four types of nanomaterials, asking the agency "to expeditiously consider" the proposal and commence a public comment and negotiation process.

"We believe the joint approach to toxicity testing for nanoscale carbon materials outlined in our proposed agreement presents EPA, our members, and the public with a unique opportunity to address fundamental environmental, health, and safety issues not afforded by a traditional company-by-company, material-by-material approach," John Monica Jr., partner and head of the nanotechnology practice at Porter Wright, writes in an April 6 letter on behalf of the consortium to James Alwood, program manager in EPA's Chemical Control Division.

Monica tells Pesticide & Chemical Policy that the proposal was not prompted by impending EPA actions regarding nanomaterials — a proposed significant new use rule (SNUR) for new nanomaterials based on existing materials on the TSCA inventory; a proposed TSCA Section 8(a) reporting rule for nanomaterials based on existing chemicals already in commerce; and a TSCA Section 4 test rule for certain nanomaterials.

Instead, Monica says some consortium members have existing consent orders for toxicity testing for their materials, and while others currently operate under TSCA research and development exemptions, they eventually want to sell commercially and will have to get a consent order at some point. Given that many companies would have to do the same kind of testing, which is duplicative and expensive, the consortium is aiming to convince EPA to let the members pool their resources, he says.

According to the terms of the proposed agreement, 10 companies will sponsor testing of:

1) purified multi-walled carbon nanotubes 4-6 nanometers in diameter and less than 30 micrometers in length;

2) purified double-walled carbon nanotubes 1.5-4 nanometers in diameter and less than 5 micrometers in length;

3) purified single-walled carbon nanotubes 0.7-2 nanometers in diameter and less than 30 micrometers in length; and

4) purified graphene nanoplatelets in flake/sheet form, 0.5-100 nanometers thick.

Independent third parties approved by EPA will actually conduct the testing — a 90-day inhalation toxicity study in rats with a post exposure observation period of up to three months, or other testing as approved by EPA that will fulfill the testing agreement's "intent and purpose." Test data would be developed under standards based on TSCA and Organization for Economic Cooperation and Development test guidelines, or other appropriate methods.

Test guidelines would be altered — subject to EPA approval — to account for the materials' nanoscale properties. Testing progress reports would be submitted every 60 days after the agreement's effective date, and a final report would be provided to EPA within 120 day of the end of testing. Testing of each substance would be finished within two years after commencing.

Testing would be completed at least 14 weeks before the responsible party manufactures or imports a certain amount of the respective nanomaterial, or 14 weeks before a specific amount of time has passed since commercial manufacturing of the nanomaterial began — whichever comes first. These amounts will be determined during negotiations with EPA, Monica says.

EPA says it's reviewing the proposal and expects to begin a public process through a Federal Register notice to develop any testing consent agreement according to applicable regulations.