Nmo - EU

Search All Issues | Contents
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Page A-2

News

Toxic Substances
EU's REACH Framework Is Applicable To New Nanomaterials, Agency Head Says

HELSINKI--Manufactured nanomaterials are covered by the European Union's new REACH chemical regulatory framework, even if there are no specific provisions for the rapidly developing nanotechnology sector, the head of the European Chemicals Agency (ECHA) said Dec. 3.

"REACH does not contain provisions specific for nanomaterials, but that does not mean that nanomaterials are not covered by REACH," Geert Dancet, ECHA interim executive director, said during a presentation at the EuroNanOSH 2007 conference in Helsinki.

Dancet said the precautionary principle at the center of the REACH framework forces manufacturers, importers, and all other downstream users to ensure that chemicals introduced to the market pose no risk to human health or the environment.

"This principle applies to nanomaterials, in the same way it does to all other chemicals placed on the European market," Dancet told the conference, which runs through Dec. 5.

Nanoscale Uses Should Be Identified

Dancet said the key registration, evaluation, and authorization elements of the REACH framework will apply to nanomaterials.

Registration dossiers--which must be filed for all substances with more than one metric ton put on the market annually--should always contain information on the identified uses, including those at nanoscale levels, Dancet said.

Registration dossiers and chemical safety reports--required for all substances with at least 10 metric tons put on the market annually--should include all relevant physicochemical, toxicological, and ecotoxicological information, Dancet said.

"For nanomaterials, this would include the particle size of a substance, and in particular any available information on adverse effects caused by a substance used at the nanoscale level should be provided," Dancet said.

Under the REACH evaluation process, competent authorities in any of the 27 EU member states can require further information and additional testing, as seen fit, to address particular concerns, Dancet said.

This additional information may lead to calls for the establishment of communitywide risk management measures beyond those already implemented by manufacturers, importers, and downstream users, as well as calls for restrictions on use, such as "the establishment of occupational exposure limit values for nanoscale particles in the workplace," Dancet said.

Arguments Against REACH Coverage Debunked

Dancet discounted often-heard arguments that extremely low production levels for most nanomaterials should exclude them from the scope of REACH.

"As for any other substance below the tonnage level which triggers action under REACH, nanomaterials can ... be subject to any risk reduction measure foreseen under REACH, as long as there is convincing evidence that such an action is required," Dancet said.

Similarly, Dancet cautioned against the assumption that nanomaterials will always be considered to have the same properties as the substance from which it is derived.

He noted that titanium dioxide is produced and used at both the nanoscale and non-nanoscale level, and acknowledged that REACH treats both the bulk material and the nanosize material as the same substance. "However, that does not prevent the registrant from identifying dangerous properties of this substance depending on its size, ... and classifying the different types accordingly," Dancet said.

In addition, even after registration is complete, Dancet pointed out that registrants remain responsible for updating registration dossiers when new information becomes available.

Specifically, this will force manufacturers, importers, or users to report on new identified uses for nanomaterials or new knowledge on risks to human health or the environment, Dancet said.

Dancet argued that treating nanoscale derivatives as being similar to their parent substances will improve human health and environmental analysis under the REACH process. "The whole weight of the substance, at nanoscale or not, counts for the threshold above which a registration dossier has to be submitted," he said.

This makes it more likely that a nanoscale derivative of a certain substance is evaluated under REACH, Dancet said, whereas treating nanoscale derivatives as a new or different substance "would more likely lead to the situation that they do not reach the tonnage level needed to be under the scope of REACH."

Better Information Needed for Safety Assessment

Dancet told conference participants that full application of the REACH framework to nanomaterials will require a range of scientific advances, including:

- new work on potential harmful effects of nanoparticles, as compared with their parent substances;
- new work on test methods for calculating potential harmful effects;
- development of better measurement techniques and technical equipment, notably for monitoring nanomaterials in the workplace;
- determination as to whether existing risk assessment methodologies applied under REACH are appropriate to assess risks arising from nanomaterials; and
- investigation of new risk management measures that could or should be applied to nanomaterials.

"To decide for legislative purposes whether a nanoscale particle is dangerous to human

health requires not only adequate and internationally recognized test methods, but also internationally agreed criteria on which test results can be used to classify a substance as such," Dancet said.

Dancet recognized that these issues go beyond the capacity of the European Chemicals Agency. "There is consensus among the international community that hazard assessment has to be dealt with at the international, rather than the regional or national level," he said.

He suggested that new criteria for classifying nanoscale particles as dangerous to human health or the environment and new test methods for nanomaterials should be developed at the multilateral level, either by the 30 member countries of the Organization for Economic Cooperation and Development, or through channels operated by the United Nations.

By Lawrence J. Speer