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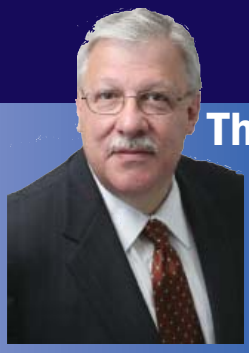
Weekly in-depth coverage of food regulations, additives, microbiology, contaminants and feed



This Week's On the Front Burner Contributors George Misko & Mitzi Ng Clark

On the Front Burner

Feeling a bit farsighted trying to catch up on the latest in regulations pertaining to nanomaterials in food packaging? Squint no more! Just take a look through the magnifying glass provided below by our two esteemed experts from Keller and Heckman.

Thinking Small: The Regulation of Nanomaterials in Food Packaging

By George Misko and Mitzi Ng Clark

Antibacterial water bottles. Plastic wrap that sterilizes food upon use. Food containers equipped with nano-sensors to detect spoilage and contamination.

While these products might seem commonplace in the world of science fiction, they represent only a few examples of the use of nanotechnology in food packaging today. In fact, the topic of nanotechnology has received considerable attention in recent years, as it is a field that is quickly developing, not only in the food packaging arena, but in the food, drug, cosmetic, medical and industrial sectors as well.

Along with these developments, questions have arisen as to how best to regulate nanotechnology. Here in the U.S., the Food and Drug Administration (FDA) has acknowledged the need for guidelines on the use of nanotechnology in food packaging materials, but has yet to issue any formal regulation or guidance on the matter. The European Union (EU) has taken a more active stance on the oversight of nanotechnology, as is clear from recent regulatory developments in the area.

What is nanotechnology?

So, what exactly is nanotechnology? The question seems simple enough to answer, but currently, there is no set, uniform definition of nanotechnology. The National Nanotechnology Initiative, a program established in 2001 to coordinate federal nanotechnology research and development, defines nanotechnology as "the understanding and control of matter at dimensions between approximately 1 and 100 nanometers," where unique "size-dependent properties" enable novel applications.

FDA and the European Commission have endorsed similarly broad definitions of nanotechnology, which emphasize the manipulation of materials on a small scale, and the unique properties of these materials, when compared to their larger counterparts.

Any discussion of nanotechnology necessarily begs the question of the meaning of nanomaterial, but this, too, has been subject of avid debate. Generally speaking, nanomaterials fall into three basic categories:

- naturally occurring nanomaterials, such as mineral composites that exist ubiquitously in the environment;
- incidental nanomaterials, such as those produced as by-products of industrial processes; and
- engineered nanomaterials, that is, those which are intentionally created or produced to a nano-scale to achieve a specific function or effect.

But even across these categories, questions have arisen on the appropriate size range with which to categorize nanomaterials, and whether other characteristics should come into play in their definition. For instance, while a vast majority of working definitions refer to "nanoscale" as having at least one dimension with a length scale ranging from 1 to 100 nanometers (nm), there are some definitions that suggest a lower or higher scale. In addition, there has been discussion as to whether the definition of nanomaterial should be based solely on size, or whether other nanoscale properties should be considered, such as size distribution, surface area and other physico-chemical characteristics.

These are just some of the questions currently being considered by government bodies confronting the task of defining nanomaterial for regulatory purposes.

Regulatory status of nanomaterials in the U.S.

FDA established the Nanotechnology Task Force in 2006 to address possible approaches to FDA-regulated products containing nanomaterials. The Task Force published a report of its recommendations in 2007. Importantly, the report focuses attention on engineered nanoscale materials (ENMs), rather than natural or incidental nanomaterials. Moreover, the report emphasizes the utility of a case-by-case assessment of ENMs, and discourages the adoption of a precise definition of nanoscale materials in light of the evolving state of the science.

Finally, the Task Force urges FDA to consider the following objectives:

- To promote the understanding of biological interactions and long-term health effects of nanoscale materials;
- To further the understanding of novel properties of nanomaterials that might contribute to toxicity, such as surface area or surface charge;

- To further the understanding of measurement and detection methods for nanomaterials;
- To build infrastructure to share and leverage knowledge; and
- To ensure consistent transfer and application of relevant knowledge.

While the FDA has indicated that guidance on nanomaterials is forthcoming, no such guidance has been issued to date regarding the status of ENMs in food packaging. Thus, as it stands now, the agency is evaluating ENMs in food packaging on a case-by-case basis, using traditional evaluation methods and "nano-specific" considerations.

Currently, Food Contact Notification (FCN) No. 818, which clears the use of titanium nitride in some polymers, appears to represent the only instance where FDA has cleared a nanomaterial for use in food packaging.

. . . And in the EU

On the EU side, regulatory activity in the area of nanotechnology has been somewhat more rigorous, particularly with regard to developing a comprehensive science-based definition of the term "nanomaterial." These efforts stem, in part, from an April, 2009 resolution issued by the European Parliament, which called for the inclusion of a definition of nanomaterials as part of nano-specific amendments to relevant legislation.

Prompted by this resolution, the European Commission invited the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) to provide scientific guidance on the factors to consider when defining "nanomaterial." These considerations were summarized in a pre-consultation opinion, which proposed a length scale of 1-100 nm for the size range of nanomaterials. The opinion also recommended that other factors be considered in the definition. In particular, the opinion states that size, size distribution, specific surface area, and physico-chemical characteristics should be accounted for in developing the term nanomaterials. In addition, the opinion noted that whether a material is manufactured or natural, and whether it is a nanocomposite and persistent should be encompassed in the definition.

Lastly, the SCENIHR opinion established a threshold approach to performing nano-specific risk assessments.

Based on part of this input from SCENIHR, the European Commission published, on October 25, 2010, a draft recommendation on the term "nanomaterial." The recommendation proposes that, to be classified as a nanomaterial, one of the following three criteria must be met:

(1) It consists of particles, with one or more external dimensions in the size range 1 nm to 100 nm for more than 1 per cent of their number size distribution;
(2) It has internal or surface structures in one or more dimensions in the size range of 1 nm to 100 nm; or
(3) It has a specific surface area by volume greater than 60 m^2/cm^3, excluding materials consisting of particles with a size lower than 1 nm.

Though the status of the draft recommendation is currently pending, the European Food Safety Authority's Scientific Committee issued draft guidance on February 25, 2011 setting out recommendations on the risk assessment of nanomaterials in food and feed, including food additives, enzymes, flavorings, food contact materials, novel food and feed additives and pesticides. Importantly, and unlike the European Commission's draft recommendation, the guidance makes clear that the recommendations would apply solely to engineered nanomaterials. The guidance also emphasizes that no formal definition of ENM is being proposed, though it does makes reference to the definitions proposed in the European Commission recommendation and the proposed novel foods regulation, EC No 258/97.

Nanotechnology also has impacted EU legislation with respect to food-contact materials. In particular, the Plastics Implementing Measure (PIM), which consolidates all of the current directives and regulations on plastic food-contact materials and goes into effect in May 2011, specifically excludes nanoform materials from automatic clearance based on the listing for their non-nanoform counterparts.

In addition, nanoform substances are not eligible for exemption under the "functional barrier" principle; this principle allows certain non-listed substances to be used in plastic food contact articles if they are separated from food from a functional barrier layer. These changes are in line with the spirit of other legislation in the EU concerning food and cosmetics, which impose separate clearance and/or labeling requirements for nanomaterials.

Nanotechnology is quickly becoming a part of our reality and, as this occurs, regulatory bodies will continue to be confronted with how best to define and regulate nanomaterials, when necessary. It is clear that nanomaterials are not a homogenous class, and that any regulation of nanomaterials very well might be a moving target as the technology continues to develop.

ABOUT OUR AUTHORS

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