

Nano Rising

Emerging technology presents serious regulatory hurdles and even greater possibilities for the flavor and fragrance industry

The Wilson Center's Project on Emerging Nanotechnologies has reported that products making nanotechnology claims have more than doubled, from 212 to 475, since March 2006. (The group launched its online inventory of nanotech goods at that time.) According to the Center, "nanotechnology was incorporated into more than \$50 billion in manufactured goods." And, "since fiscal year 2001, the US has invested over \$8 billion in nanotechnology research. In 2006 alone, over \$12 billion was spent worldwide on nanotechnology research and development by governments and industry." According to the group, the United States leads the nanotechnology pack, with 52% of the reported products. In second place was East Asia. The group maintains that the nanotech boom is just the beginning, and expects the number to grow rapidly over the next few years. To date, the flavor and fragrance industry has represented a tiny sliver of this boom.

Though definitions of what is—and is not—"nano" vary, the US Food and Drug Administration (US FDA) uses three criteria:^a

- "Research and technology development at the atomic, molecular or macromolecular levels, in the length scale of approximately 1–100 nanometer range." (Just a fraction of the width of a human hair.)
- "Creating and using structures, devices and systems that have novel properties and functions because of their small and/or intermediate size."
- "Ability to control or manipulate on the atomic scale."



Nanomaterials can be applied in a number of food applications—such as chewing gum—for controlled flavor release.

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Key nanomaterials include fullerenes, which are typically spherical, closed and hollow aromatic carbon compounds composed of twelve pentagonal and varying numbers of hexagonal faces, and nanotubes, which are typically carbon microscopic tubes measured in nanometers. These materials can be used for an almost endless array of effects, including controlled release of flavors and fragrances, masking of off-flavors, and protection of volatile flavor compounds in the service of enhanced shelf-life. But health worries abound.

In February of this year, the International Organization of the Flavor Industry (IOFI) issued an information letter (#1353) detailing the risks associated with nanomaterials:^b

"[N]anomaterials can cross physiological barriers such as olfactory mucosa, the blood-brain barrier, and penetrate the gastrointestinal tract. Nanomaterials frequently display reactivity that is different than larger structures of the same, chemically identical material.

"Due to their small size and unpredictable reactivity, they can present unique toxicity concerns. Therefore, the IOFI Science Board recommends that nanomaterials be used in flavors only after a complete and thorough assessment of their safety and toxicity."

Meanwhile, the US Environmental Protection Agency (US EPA), in its February 2007 white paper on the topic, initiated a voluntary premanufacture notice program, which applies to those companies manufacturing, importing or using nanomaterials.^c These notices are reviewed by the Agency's Office of Pollution Prevention and Toxics. According to the white paper, "The premanufacture review process serves as a gatekeeper to identify concerns and exercise appropriate regulatory

^bIOFI defines nanomaterials as "materials that are <100 nm in size in any one dimension."

^cIn the first phase of this program, the US EPA is not requesting that participants develop additional data, only that they submit existing data.

^aThe US FDA does not consider this a formal definition.

oversight. For example, use restrictions, occupational exposure limits/controls, limits on releases to the environment and limits on manufacture may be required until toxicity and fate data are developed to better inform a risk assessment of the chemical.”^d The notice, in other words, seeks to clarify whether certain nanomaterials qualify as new chemicals due to the inclusion of foreign atoms or other materials. These substances would be subject to a review under the Toxic Substances Act. Participants were invited to voluntarily report available information on the engineered nanoscale materials they manufacture, import, process or use. Furthermore, the designation of some materials as “new chemicals” at the nano scale could mean that some substances cease to be GRAS in nano applications. The burden is clearly falling on the industry.

Simultaneously, Friends of the Earth, an aggressive flavor and fragrance industry critic, has released a new report entitled “Out of the Laboratory and onto Our Plates: Nanotechnology in Food and Agriculture.” The publication, which specifically targets the development programs of Kraft, Nestle, Unilever and Heinz, was co-authored by Rye Senjen, who states, “Nanotechnology can be very dangerous when used in food. Early scientific evidence [*unspecified* –Ed.] indicates that some nanomaterials produce free radicals which destroy or mutate DNA and can cause damage to the liver and kidneys.”

In Europe, The European Food Safety Authority (EFSA) is working on behalf of the European Commission to

issue an opinion regarding the risks of nanoscience and technologies in food applications and its effects on the environment. A draft is due in July. Among the data EFSA has collected is:

- Data on the safety of nanomaterials used in food and feed
- Food and feed applications and products containing or consisting of nanomaterials or produced by nanotechnology
- Methods, procedures and performance criteria used to analyze nanomaterials in food and feed
- Use patterns and exposure to humans and the environment
- Risk assessments performed on nanomaterials used in food and feed
- Toxicological data on nanomaterials used in food and feed
- Environmental studies performed on nanotechnologies and nanomaterials used in food and feed
- Other data of relevance for risk assessment of nanotechnology and nanomaterials in food and feed

In addition, The European Union’s Scientific Committee on Consumer Products recently ruled that, for nanomaterials, “either new risk-assessment methods have to be developed or the existing ones have to be improved ... [A] detailed characterization of chemical and physical properties, e.g. particle size and number and surface characteristics, is needed in addition to the standard mass concentration. The SCCP considers that the risk assessment of nanoparticles in cosmetics should then be carried out on a case-by-case basis taking into account these specific properties.”

Dovetailing with health concerns by governmental and nongovernmental organizations is a consumer public that little understands nanotechnology—its risks and benefits. According to a forthcoming BfR study, 53% of surveyed respondents were in favor of using nanomaterials in cosmetics. Another 69% rejected the notion of nanoparticles in spices. Finally, 84% of respondents did not approve of foods “altered” by nanomaterials. A survey study in the journal *Appetite* published last year reinforces these results. “Public Acceptance of Nanotechnology Foods and Food Packaging” notes that “overall, participants were hesitant to buy nanotechnology foods or food with nanotechnology packaging.” The study concludes: “Results further suggest that social trust in the food industry is an important factor directly influencing the effect evoked by these new products Perceived benefit seems to be the most important predictor for willingness to buy.”

^dManufacturers that choose not to file premanufacture notices are encouraged to at least discuss with the US EPA whether such a notice is necessary.