FDA draft guidance for use of nanotechnology in foods

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The FDA recently issued two documents focusing on nanotechnology: one for use in foods and one for use in cosmetics.

The food draft guidance (*Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives*) describes the factors manufacturers should consider when determining whether changes in manufacturing processes, including those involving nanotechnology, create a significant change that may:

- affect the identity of the food substance;
- affect the safety of the use of the food substance;
- affect the regulatory status of the use of the food substance; or
- warrant a regulatory submission to the FDA.

Both guidances encourage manufacturers to consult with the agency before taking their products to market. Such consultation can help FDA experts address questions related to the safety or other attributes of nanotechnology products, or answer questions about their regulatory status.

Strong science is critical to the FDA's ongoing review of the products it regulates. The FDA is investing in an FDA-wide nanotechnology regulatory science programme to further enhance the FDA's scientific capabilities, including developing necessary data and tools to identify properties of nanomaterials and assess the impact they may have on products.

"Understanding nanotechnology remains a top FDA priority. FDA is strengthening the scientific tools and methods for evaluating food products, cosmetics, drugs and medical devices," said FDA Commissioner *Margaret A. Hamburg*. "We are taking a prudent scientific approach to assess each product on its own merits and to not make broad, general assumptions about the safety of nanotechnology products."

In particular, the draft guidance states that the application of nanotechnology may result in product attributes that differ from those of conventionally manufactured products, and thus may merit examination. As with any other manufacturing technologies applied to food, nanotechnology and other emerging technologies may introduce issues that warrant additional or different evaluation during a safety assessment of a food sub-

stance. For example, so-called nano-engineered food substances can have significantly altered bioavailability and may, therefore, raise new safety issues that have not been seen in their traditionally manufactured counterparts. Where nano-engineered food substances have new properties, additional or different testing methods may be necessary to determine the safety of the food substance. For example, particle size, surface area, aggregation/agglomeration or shape may impact absorption, distribution, metabolism and excretion (ADME) and potentially the safety of the nano-engineered food substance.

The variation in biological activity that may result from engineering food substances in the nanometre range may raise questions about the applicability of traditional safety tests for these materials. Thus, as with any studies to support the safety of food substances, studies to establish the safety of food substances manufactured using nanotechnology should have been appropriately validated for these materials.

As to the use of nanotechnology in dietary supplement, the FDA listed nanotechnology "that results in new or altered chemical properties of the ingredient" as an example of a new dietary ingredient (NDI) requiring notification (*Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues*).

The NDI draft guidance states: a change in the manufacturing process for a NDI intended to produce particles in the 1–100 nm (approximate) nanoscale range may alter the chemical properties of the NDI. If so, the resulting ingredient with different chemical properties would likely not be covered under an existing notification for a related substance manufactured without using nanotechnology and, therefore, would likely require a NDI notification. Manufacturers planning a manufacturing change are encouraged to consult with FDA on any questions as to whether such a change would be viewed as having created a different NDI.

The FDA's current thinking concerning nanomaterials for food and cosmetics uses, explained in the two guidance documents, is not intended to provide guidance to manufacturers about the use of nanomaterials in other products, such as drugs or medical devices, regulated by the FDA.

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