FDA & Nanotechnology

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COSMETICS

For cosmetics, FDA recommends that the safety assessment by producers for cosmetic products using nanomaterial should address several important factors such as:

- The physico-chemical characteristics;
- Agglomeration and size distribution of nanomaterials at the toxicity testing conditions which should correspond to those of a final product;
- Impurities;
- Potential product exposure levels, and the potential for agglomeration of nanoparticles in the final product;
- Dosimetry for in vitro and in vivo toxicology studies;
- In vitro and in vivo toxicological data on ingredients and their impurities, dermal penetration, irritation (skin and eye) and sensitization studies, mutagenicity/ genotoxicity studies; and
- Clinical studies to test the ingredient, or finished product, in human volunteers under controlled conditions

SUBSTANCES GRAS FOR FOOD

Regarding the use of food substances that are affirmed or identified as GRAS, FDA recommends that, whenever there has been a significant change in manufacturing process for a food substance, which includes manipulating the GRAS at the nano scale, producers should:

- Determine what changes have been made to the identity of the food substance as a result of the change in manufacturing process, including its physicochemical structure and properties, purity, and impurities;
- Taking into account any impact of the change in identity of the food substance, conduct a safety assessment for the use of the food substance, including characteristic properties such as physicochemical structure and properties, purity, impurities, bioavailability, or toxicity;
- Consider whether the use of the substance is within the scope of a GRAS affirmation or identification as GRAS in 21 CFR. Relevant to such a determination are the identity of the food substance and its conditions of use described in the administrative record for a substance affirmed or identified as GRAS. For example, it would not be where:

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    - The identity of, manufacturing process for, or the conditions of use of the food substance are significantly different from those of the substance affirmed or identified as GRAS; or
    - The food substance is not of appropriate food grade as a result of impurities introduced into the food substance by the change in manufacturing process;
- Consult with FDA about your conclusions about the impact of the significant manufacturing change on the safety and regulatory status of use of the food substance; and
- Make an appropriate regulatory submission to FDA as circumstances warrant.
- As FDA explained in the final rule establishing the GRAS affirmation process,

  "A regulation affirming the GRAS status of an ingredient, must, under section 201(s) of the act, be restricted to the ingredient that has been in common use in food or that was the subject of scientific tests to determine its safety. The burden is on the manufacturer to demonstrate that the ingredient he is using is of the same composition as the ingredient that has been traditionally used or that has been investigated by researchers."

  Furthermore, if there is a question whether a food substance differs from the food substance identified in the regulation affirming the substance as GRAS because of a change in manufacturing process, "it is the obligation of the manufacturer to demonstrate whether the ingredient has been affirmed as, or is otherwise, GRAS."

Regarding the use of a food substance for which there is an existing determination that a use of a food substance is GRAS, FDA recommends that whenever there has been a significant change in manufacturing process for a food substance that is the subject of a GRAS determination, including procedures that utilize nanomaterials previously unused in the processes, producers should:

- Determine what changes have been made to the identity of the food substance as a result of the change in manufacturing process, including its physicochemical structure and properties, purity, and impurities;
- Taking into account any impact of the change in identity of the food substance, conduct a safety assessment for the use of the food substance, including characteristic properties such as physicochemical structure and properties, purity, impurities, bioavailability, or toxicity;
- Consider whether the GRAS status of the use of the food substance would be affected – for example, it would not be GRAS if:
    - The identity of, manufacturing process for, or the conditions of use of the food substance are significantly different from those described in a previous GRAS determination;

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    - The manufacturing changes are so novel as to preclude general recognition of safety; or
    - The food substance is no longer of appropriate food grade as a result of impurities introduced into the food substance by the change in manufacturing process;
- Consult with FDA about your conclusions about the impact of the significant manufacturing change on the safety and regulatory status of the use of the food substance; and
- Make an appropriate regulatory submission to FDA as circumstances warrant.

FOOD CONTACT SURFACES

Regarding the use of food contact substances for which there is an effective Food Contact Notification, FDA recommends that whenever there has been a significant change in manufacturing process for a food contact substance, including surfaces that utilize nanomaterials previously unused in the surfaces, producers should:

- Determine what changes have been made to the identity of the food contact substance as a result of the change in manufacturing process, including its physicochemical structure and properties, purity, and impurities;
- Taking into account any impact of the change in identity of the food contact substance, conduct a safety assessment for the use of the food contact substance, including characteristic properties such as physicochemical structure and properties, purity, impurities, bioavailability, or toxicity;
- Consider whether the substance would be within the scope of an effective FCN. For example, it would not be within the scope of an effective FCN if:
    - The identity of or the conditions of use of the food contact substance are significantly different from those described in a previously submitted notification; or
    - The food contact substance is no longer of appropriate food grade as a result of impurities introduced into the food contact substance by the change in manufacturing process;
- Consult with FDA about your conclusions about the impact of the significant manufacturing change on the safety and regulatory status of the use of the food contact substance; and
- Make an appropriate regulatory submission to FDA as circumstances warrant.
- Altering the manufacturing process of a notified food contact substance to either produce components in the nanometer scale or increase the proportion of nanometer scale components can sometimes be a significant manufacturing change that could result in a substantive change to the specifications and/or in the

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identity of the food contact substance or its impurities, and/or levels of impurities. In the event of such substantive change, FDA advises you to submit a new notification.

FOOD OR COLOR ADDITIVES

Regarding the use of food substances that are the subject of a food additive or color additive regulation FDA recommends that, whenever there has been a significant change in manufacturing process for the use of a food substance, including procedures that utilize nanomaterials previously unused in the processes, producers should:

- Determine what changes have been made to the identity of the food substance as a result of the change in manufacturing process, including its physicochemical structure and properties, purity, and impurities;
- Taking into account any impact of the change in identity of the food substance, conduct a safety assessment for the use of the food substance, including characteristic properties such as physicochemical structure and properties, purity, impurities, bioavailability, or toxicity;
- Consider whether the use of the food substance is authorized under a food additive or color additive regulation. Relevant to such a determination are the identity of the food substance and its conditions of use described in the administrative record for a substance subject to a food additive or color additive regulation. For example, the food substance would not be within the scope of a regulation where:
    - The identity of, manufacturing process for, or the conditions of use of the food substance do not comply with a regulation; or
    - The food substance is not of appropriate food grade as a result of impurities introduced into the food substance by the change in manufacturing process;
- Consult with FDA about your conclusions about the impact of the significant manufacturing change on the safety and regulatory status of the use of the food substance; and
- Make an appropriate regulatory submission to FDA as circumstances warrant.

Questions? Need Help?

Contact us now if you need help with FDA regulation or compliance.

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