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US FDA FOOD INGREDIENT AND FOOD CONTACT NANOTECHNOLOGY GUIDANCE

On 20 April 2012, the US FDA published the draft "Guidance for Industry for Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies (Nanotechnology), on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives"[1].

This guidance reaffirms the mechanization of assessing the effects of a significant process change such as nanotechnology and obtaining an US FDA approval, if necessary, of a food substance (such as a food, food ingredient, color additive and food contact substances) that have been developed from this significant process change. Under US law food contact substances are considered indirect food additives.

According to section 402 of the Food Drug and Cosmetic Act, no food substances are allowed to be adulterated. All food additives must comply with the 1958 food additive amendment, the Food and Drug Administration Modernization Act of 1997 and all regulations from the amendment and act. All color additives must comply with the Color Additive Amendments of 1960 and regulations from the amendment.

For submission and approval by the US FDA a safety assessment must be performed of all food substances. This information must include the identity, technical effect, self-limiting levels of use, dietary exposure and safety studies and manufacturing processes including nanotechnology.

A company must assess whether a significant change in the manufacturing process, such as nanotechnology, can affect the identity, safety and regulatory status of a food substance. In this guidance the US FDA discusses what considerations and recommendations are applicable for this assessment by the company.

In Appendix 1 of the guidance document, the US FDA provides three examples of approved items that had significant changes in the manufacturing process but none of these changes involved nanotechnology. US FDA does note that "some food contact notifications (FCNs) (e.g. 716 and 818) have included information describing the use of a food contact substance with particle sizes in a nanometer range."

[1] Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food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

The US FDA states in Appendix 2 that there are five principal mechanisms for regulatory submission of food substances. These petition processes are:

- Premarket approval of a food additive
- Premarket notification program for a food contact substance
- "Threshold of Regulation" Program for a substance used is a food contact article
- Program to notify the US FDA of a determination that a use of the substance is generally recognized as safe (GRAS)
- Petition process for listing a color additive.

The FDA recommends that all comments from the public on this guidance document be submitted within 90 days of the publication date.

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