U. S. FDA’s Regulatory Approach to Nanotechnology In Food Contact Substances

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Nanotechnology and Food Contact Substances

• New food contact substance (FCS) must be the subject of a food contact notification (FCN).
• FDA focuses on particle size
  – when it is important for the identity of the food contact substance
  – when it impacts the functionality of the food substance
  – when it impacts the intended technical effect
Guidance for Approval of New Food Contact Substances

• Currently, no specific recommendations for nanotechnology
• Particle size must be considered if particle size affects functionality or toxicity
• Guidance currently under preparation
• Interim specific points to consider, as follows
Chemistry Considerations

• Identity
  – Particle size and distribution
  – Shape, surface area, surface charge
  – Morphology, aggregation

• Specifications for purity

• Intended technical effect and use
  – Functionality as related to size
Safety of the Food Contact Substance

- Is the uptake, absorption and bioavailability of the modified product different than the conventional product?
- Any new impurities created?
- Any new toxicology issues identified?
- *In vivo* toxicology issues for nanomaterials not completely known.
- Experimental parameters must be carefully considered.
Impact of Nanotechnology on Regulatory Status

• For currently approved *direct and indirect food additives*:
  – If a size change fundamentally alters properties of the material, it is no longer in compliance with regulations.

• For *food contact substances*:
  – Notifications are specific for manufacturer and material. Changing to nanosize material would require a new notification.
Impact of Nanotechnology on Regulatory Status

• For substances *generally recognized as safe*:
  – Obligation of the manufacturer to demonstrate whether the ingredient has been affirmed as, or is otherwise, GRAS.
  – FDA will review and comment under the GRAS Notification Program parameters.
Responsibility of the Manufacturer or User

• It is the manufacturer’s responsibility to ensure that the foods and food components that they bring to market are safe and lawful.

• Manufacturer or user has an obligation to take all appropriate steps to ensure that the substance as manufactured is safe and lawful under the conditions of its intended use.

• FDA encourages food manufacturers to conduct a thorough safety assessment of all manufacturing changes.