

Regulatory Issues Concerning Food and Nutritional Products Containing Nanomaterials

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Key Regulatory Issues

- Whether FDA's statutory authorities provide sufficient tools to evaluate and regulate the safety of nanomaterials with novel properties when used in food, food packaging, and dietary supplements
- Whether FDA's existing procedures and systems are adequate to evaluate and regulate the safety of nanomaterials with novel properties when used in food, food packaging, and dietary supplements

Background Considerations Regarding FDA Regulation of Food “Safety”

- The food supply is complex and presents an array of safety issues:
 - natural toxins in food
 - physical contaminants
 - microbial contaminants
 - pesticide residues
 - ingredients: intentionally “added” substances

- The statutory scheme of the Federal Food, Drug, and Cosmetic Act (FDC Act) for regulating the safety of food reflects the complexity of the food supply
- As a result, the FDC Act contains a number of different “safety” standards
- These standards vary and focus on
 - the food itself
 - the use in food to which a substance may be put
 - the conditions under which the food is made and held
 - ingredients or substances migrating into the food.

The difference in rigor that accompanies the different “safety” standards in the FDC Act depends in large part upon whether pre-market approval requirements or post-market enforcement authorities apply.

Pre-Market Approval Systems: e.g., “Food Additives”

- The 1958 Food Additives Amendment (“FAA”) was designed to address the following public health scenario:
 - Potentially thousands of novel substances to be added to food
 - Only a few such substances specifically tested/reviewed for safety
 - Existing regulatory system hampered by limited resources
 - Public/private sector concerns about under/over regulation
- Sound familiar?

- Upshot: the FAA was designed and enacted to address safety issues like those presented by the use in food of nanomaterials with novel properties
- Tools for accomplishing the objectives of the FAA
 - Pre-market clearance with burden of proof on sponsor
 - A rigorous but non-absolute safety standard (“reasonable certainty of no harm”)
 - A broad, comprehensive definition of “food additive” coupled with reasonable exceptions, including one flexible, forward-looking exception for substances “generally recognized as safe” (“GRAS”)

- The GRAS concept
 - Central to implementing the food additive approval process and to prioritizing substances for review
 - Recent Applications:
 - Plant products of biotechnology consultation process
 - GRAS notification process
 - Not a shortcut or loophole:
 - GRAS status is based on publicly available data and information comparable to that needed to support food additive
 - Issue: whether a nanomaterial with novel properties can be GRAS for a given use?

Post-Market Enforcement Systems: e.g., for Dietary Supplements

- “Dietary ingredients” in dietary supplements are exempt from regulation as “food additives”
- General adulteration standard for supplements: “significant or unreasonable risk of illness or injury”
- “New Dietary Ingredient” (“NDI”): any dietary ingredient not marketed in the U.S. prior to October 15, 1994

Post-Market Enforcement Systems: e.g., for Dietary Supplements (cont.)

- For a New Dietary Ingredient, a pre-market “notification” must be filed with FDA 75 days before marketing providing the basis for manufacturer’s conclusion that a supplement containing an NDI is “reasonably expected to be safe”
 - failure to provide such information allows FDA to argue in enforcement action that an inadequate basis exists to determine whether the general adulteration standard is met

Nanomaterials with Novel Properties: Issues With Respect to Food and Color Additive and GRAS Rubrics

- What criteria will FDA apply for evaluating the safety of nanomaterials of
 - Substances already holding approved additive status?
 - Substances already considered by regulation or the notification process as GRAS?
- What criteria will FDA apply for approving nanomaterials of new or unapproved substances?

Nanomaterials with Novel Properties: Issues With Respect to Food and Color Additive and GRAS Rubrics (cont.)

- Are there circumstances under which nanomaterials will not be considered to present a safety concern
 - If yes, what factors need to be addressed to reach such a conclusion?
- What criteria will FDA consider applicable for establishing the GRAS status of nanomaterial substances with novel properties?

Nanomaterials with Novel Properties: Issues With Respect to the Dietary Supplement Post-Market System and the NDI Notification Process

- What criteria will FDA apply for assessing whether nanomaterials with novel properties are “new dietary ingredients”?
- What criteria will FDA apply in the “notification” process for assessing safety of nanomaterials with novel properties?

Conclusions

- FDA's statutory pre-market authorities provide a comprehensive regulatory framework for assuring the safety of nanomaterials with novel properties for use in food and food packaging; the framework for dietary supplements is not as comprehensive but provides a mechanism for evaluation by the agency
- FDA should author guidances with respect to the criteria to be followed in evaluating the safety of food, food packaging, and supplement uses of nanomaterials with novel properties

Conclusions (cont.)

- FDA should provide leadership, on both the domestic and international fronts, not only in developing guidance but in refining guidance as knowledge evolves
- Industry must conduct research and investigations to substantiate the propriety of the use in food of nanomaterials with novel properties

Post Script: Nanomaterial Regulatory Issues Beyond Food, Including:

- Drug, Cosmetic, and Medical Device Applications
- Workplace exposures
- Environmental exposures
- International harmonization efforts
 - current global status: the gamut, from laissez-faire to moratoria on research