Nanomaterials in Food Packaging:
The U.S. Regulatory Process and Key Issues

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Overview

- Background on the project and its goals
- Key elements of U.S. packaging regulation
- Broad conclusions on nanotech packaging
- Specific scientific issues
  - Chemistry
  - Toxicology
- Discussion

PEN-GMA Project

- Motivation of the project sponsors
- Project goals
  - Foster dialogue
  - Identify issues
  - Educate participants and public
- Process and participants
  - Government, industry, and consumer experts
  - Three working groups as basis for dialogue
  - Independent author

U.S. Regulatory System for Food Packaging: Key Elements

- Premarket notification for food contact substances, with some exceptions
- FDA premarket scientific review, based on detailed chemistry and toxicology guidance
  - What migrates and at what level?
  - Is it safe?
  - Burden of proof on sponsor
- Streamlined review process but clearances are company- and application-specific
- EPA review of anti-microbial packaging materials

Broad Conclusions on Application of the System to Nanomaterials

- Novel properties demand careful case-by-case scientific assessment
- Current FDA scientific guidance provides sound foundation, but some materials may require modified or new tests
- FDA policy guidance on application of current system to nanotech products would be useful
- Industry ultimately responsible for demonstrating safety using methods that satisfy FDA reviewers

Chemistry Issues

- Characterization of the ENMs identity and properties, such as
  - Particle size and morphology
  - Surface chemistry and reactivity
  - Aggregation/agglomeration potential
  - Potential for binding with protein
- Defining and describing ENM impurities
- Migration study methodology and validation

FDA Toxicology Issues

- Appropriateness of current exposure triggers for toxicity testing
- Toxicological data requirements and testing protocols
- Utility of data on conventional scale versions of ENMs

Conclusion

- Consumers in a satisfactory position regarding system's ability to keep unproven products off the market
- Industry has considerable work to do to answer scientific questions
- FDA also under pressure to provide leadership in preparing agency for nanotech