Nanotechnology and the Food and Drug Administration: Science and Policy

Richard Canady, PhD DABT

Food and Drug Administration

First Annual Safety for Success Dialogue, European Commission

October 25, 2007

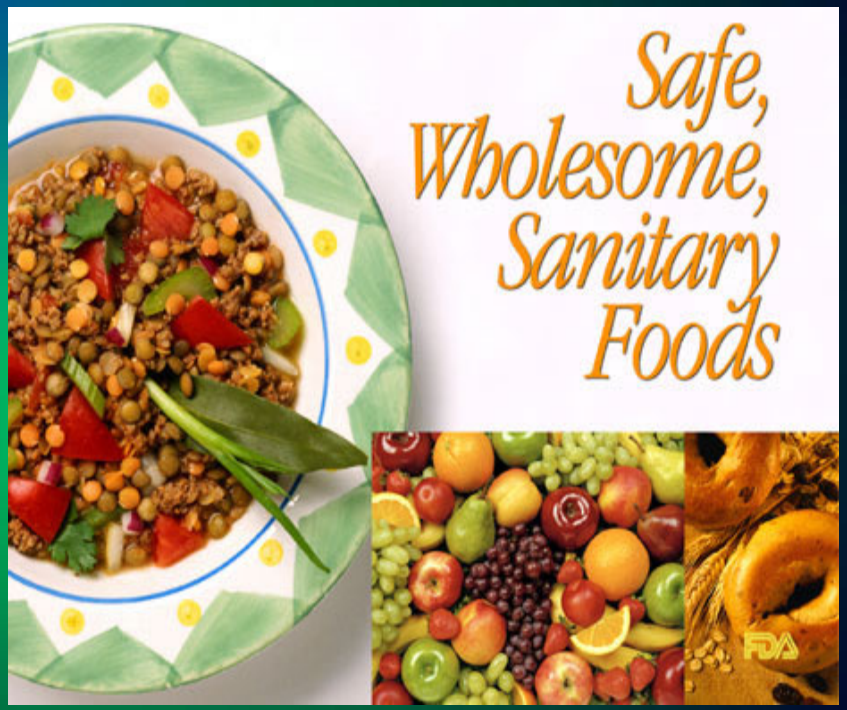
FDA MISSION

The FDA is responsible for ***protecting the public health*** by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

The FDA is also responsible for ***advancing the public health*** by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

FDA REGULATED PRODUCTS

- Animal feed
- Foods
  - Not meat or poultry
  - Bottled water
  - Wine (<7% alcohol)
  - Infant formula
- Food additives
  - Colors
  - Food containers
- Cosmetics
- Dietary Supplements



- Pharmaceuticals
  - Human
  - Animal
  - Tamper resistant packaging
- Medical devices
- Radiation emitting electronic products
- Vaccines
- Blood products
- Tissues
- Sterilants
- Counter-terrorism products

NANOSCALE MATERIALS FDA STATUS

- Regulation specific to product classes by statute
- Range of regulatory authorities
- Review of products, not technology
- Adaptable: new knowledge may lead to change

FDA NANOTECHNOLOGY TASK FORCE

- Encourage development of safe and effective products
- Address knowledge or policy gaps
- Guide science and technology
- Assess current state of science
- Strengthen collaboration with federal agencies

Nanotechnology Task Force Bottom Lines

1. Nanoscale materials could be used in most product types regulated by FDA.
2. Nanoscale materials present challenges similar to other emerging technologies.
3. The fact that safety and efficacy can vary with size can complicate the challenges.
4. Steps should be taken to better inform FDA reviewers and industry about what is known, needed, and expected.

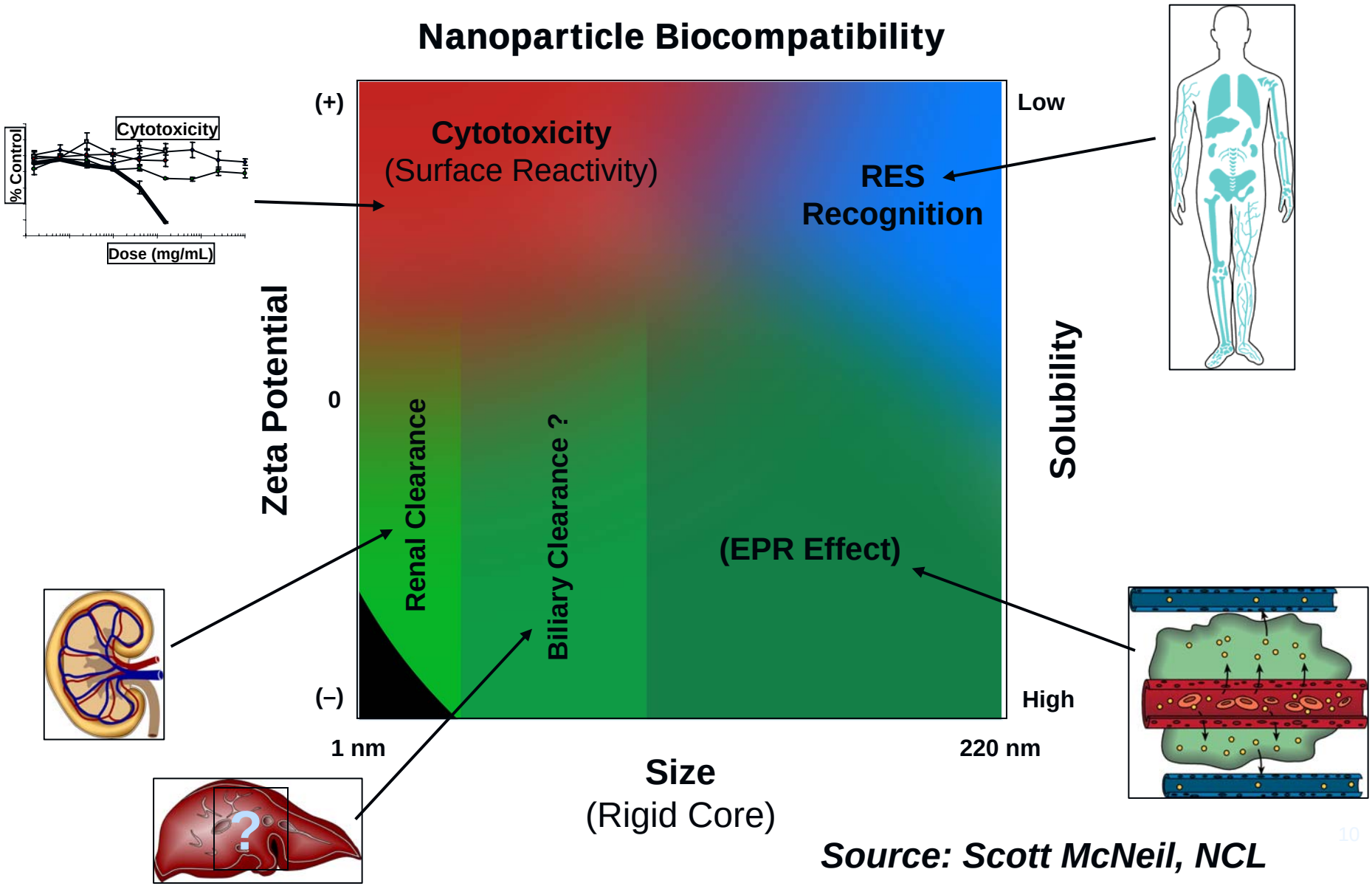
Size can complicate challenges

- Measurement
  - What to measure
  - How
- Product consistency
- Assays
  - Validity
  - Utility
- Definition of impurity

Definition issue

- No definition offered or used in FDA Task Force report
- Broad inclusive approach taken
- Continue to consider importance of material size and state of the science
- At some point it may be productive to tailor definitions to specific product areas

Trends: Biocompatibility



Source: Scott McNeil, NCL

State of the Science

Size and functionalization of particles can affect biological interaction

- but not always
- and not always in ways we think it will

State of the Science

If all nanoscale materials are compared to all non-nanoscale materials,

whether larger or smaller,

it is not apparent that the nanoscale materials as a group would have more inherent hazard.

SCIENCE RECOMMENDATIONS

Regarding understanding biological interactions

- Promote/participate in developing more knowledge about
  - biological interactions
  - detection and measurement
- Build in-house expertise and infrastructure to share and leverage knowledge
- Ensure Agency-wide regulatory-science coordination for nanoscale materials

SCIENCE RECOMMENDATIONS

Regarding adequacy of testing approaches

- Evaluate adequacy of testing approaches to assess safety, effectiveness, and quality of products with nanoscale materials
- Promote/participate in the development of
  - characterization methods and standards for nanoscale materials; and
  - models for the behavior of nanoscale particles in-vitro and in-vivo.

Regulatory Policy Issues Addressed by the FDA Task Force Report

- Ability to Identify Products that Contain Nanoscale Materials
- Authority Regarding Evaluation of Safety and Effectiveness
- Permissible and Mandatory Labeling
- National Environmental Policy Act

Identification of Products Containing Nanomaterials

FDA's authority to obtain information about particle size differs depending on whether products are subject to premarket authorization

- Comprehensive for products subject to premarket authorization
  - Prescription human and animal drugs, biologics, new dietary ingredients
- More limited for products not subject to premarket authorization
  - Conventional foods, cosmetics, dietary supplements
- Some products fall into both categories
  - Devices, OTC monograph drugs, GRAS food ingredients, food and color additives

Identification of Products Containing Nanomaterials

- Recommendations
  - Premarket Authorization
    - Issue guidance recommending that sponsors identify particle size of small particle materials in premarket submissions
  - No Premarket Authorization
    - When warranted, request data on particle size as part of rulemaking process used to establish or amend OTC drug monographs

Ensure Safety

FDA's authority to obtain information about safety and effectiveness differs depending on whether products are subject to premarket authorization

- Comprehensive for products subject to premarket authorization
- Cannot require submission of information when products are not subject to premarket authorization, but manufacturers are still responsible for ensuring the safety of their products
- Presence of nanoscale materials may change regulatory status

Ensure Safety

Recommendations

- Issue calls for safety data
- Issue guidance on
  - Manufacturing
  - GRAS food ingredients
  - Food and color additives
  - Devices
  - Cosmetics
  - Dietary supplements

Labeling

- Labeling of FDA-regulated products must be truthful and not misleading, and contain material information
- As with any product, we do not require the inclusion in labeling of information that is not material nor permit the inclusion of information that would make the labeling false or misleading
- Current state of the science does not indicate “all nanotech” safety concerns

Labeling

- Recommendation
  - Address on a product-by-product basis whether labeling must or may contain information on the use of nanomaterials

National Environmental Policy Act (NEPA)

- NEPA requires federal agencies to consider the environmental effects of proposed major actions
- Agencies can establish categorical exclusions for categories of actions that do not have a significant effect on the environment
- But procedures must be established to recognize extraordinary circumstances when a normally excluded action may have a significant environmental effect

NEPA

Recommendations

- Consider on a product-by-product basis whether an FDA-regulated product containing nanomaterials qualifies for an existing categorical exclusion or whether extraordinary circumstances exist
- Designate a lead to coordinate the agency's approach to its obligations under NEPA regarding nanotechnology

Research/data development

- FDA research database online soon
- National Toxicology Program
- Participation in White House National Science and Technology Council's research priorities effort
- Participation in Organization of Economic Cooperation and Development working parties data development
- Alliance for NanoHealth – FDA workshop on critical path issues

Bilateral Cooperation on Nanotechnology Issues

- FDA cooperates bilaterally with many international regulatory partners
  - see http://www.fda.gov/oia/default.htm
  - often supported by confidentiality arrangement allowing the sharing of non-public information
- FDA works together with DG-Enterprise, DG-SANCO, DG-Research, EFSA and EMEA
- Transatlantic Economic Cooperation agreement includes nanotechnology
  - focus is on communication and research

Multilateral Cooperation on Nanotechnology

- OECD
  - Working Party on Manufactured Nanomaterials
  - Working Party on Nanotechnology
- ISO TC229

CONCLUSIONS

- No new regulation proposed
- FDA regulates a range of potential nanoscale material products using range of authorities
- Premarket authority provides comprehensive approach to evaluating safety, effectiveness, quality of products
- Products not subject to premarket authority do not have the same level of information available to FDA

CONCLUSIONS (cont'd)

- Task force recommends issuance of guidances and requests for data with public input
- FDA will continue to review products on case-by-case basis
- FDA continues to stress the importance of early communication with industry
- FDA is seeking to increase data availability and expertise to facilitate review of products.

THANK YOU

richard.canady@fda.hhs.gov

This paper was produced for a meeting organized by Health & Consumer Protection DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.