REGULATORY FRAMEWORKS FOR NANOTECHNOLOGY APPLICATIONS IN FOOD: ARE THEY ADEQUATE?

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Center for Food Safety and Applied Nutrition (CFSAN)

- One of the five regulatory centers within the FDA (CDER, CDRH, CBER and CVM)
- CFSAN nanotechnology regulatory purview
  - Food contact substances and direct food and color additives, and generally recognized as safe (GRAS) substances (Office of Food Additive Safety)
  - Cosmetics (Office of Cosmetics and Colors)
  - Dietary Supplements (Office of Nutrition, Labeling and Dietary Supplements)

CURRENT STATE OF AFFAIRS

- A number of food-related products purportedly containing nanomaterials are already being marketed
  - Some are being marketed as containing substances previously approved in their macro form either as direct additives or food contact substances, or as GRAS.
  - Questions exist regarding the regulatory status of these products.

- Little or no knowledge of the oral safety of these marketed nanoproducts
  - Research on safety assessment methodologies for orally-administered nanomaterials still in its infancy

- Regulatory authority is considered to be sufficient for food-related nanoproducts that require pre-market approval (US and EU)

- Questions exist on the FDA's regulatory authority for GRAS and dietary supplements that incorporate nanomaterials.
  - Are substances previously affirmed as GRAS in their macro form still GRAS if nanosized?
  - Should nanoencapsulated dietary supplements still be considered as coming under DSHEA?

WHAT NEEDS TO BE DONE?

- Research on safety of orally available nanomaterials needs to be expanded.
- Guidance on safety assessment needs to be developed to inform stakeholders.
- Confirm the adequacy of regulatory authority for existing and future food-related nanoproducts.
- Continued interagency and international collaboration.

ONGOING

- Current safety research
  - FDA/NTP *in vivo* studies on nanosilver
  - FDA/NCTR research effort on developing protocols for *in vitro* safety assessment of nanomaterials.
  - OECD, "Project on Safety Testing of a Representative Set of Manufactured Nanomaterials"
  - European Framework Program 7 funding several nanomaterial research programs

- IFT/GMA/ILSI collaboration to identify research needs for food-related nanomaterials.

- Guidance development
  - FDA Nanotechnology Task Force report (July 2007) called for development of guidance for stakeholders.

http://www.fda.gov/nanotechnology/nano_tf.html

  - Guidance for food contact substances, food additives, and color additives
    - Chemistry
    - Toxicology

- Guidance for GRAS substances
  - Under development
- Guidance for dietary supplements
  - Call from private sector to increase FDA's regulatory authority for those supplements incorporating nanomaterials

CONCLUSIONS

- The present regulatory paradigm is sufficient for food-related nanomaterials required to undergo pre-market approval.
- The regulatory status of dietary supplements and GRAS substances that incorporate nanotechnology needs to be addressed.
- Nanomaterial safety research is critical to developing specific regulatory guidance.

The jury is still out on the overall safety of nanomaterial use in food-related products.

(nano)Tempest in a Teapot?

What, me worry? About nanotechnology?