NANOTECHNOLOGY IN THE FOOD INDUSTRY- LEGAL ISSUES, REGULATION AND CHALLENGES.

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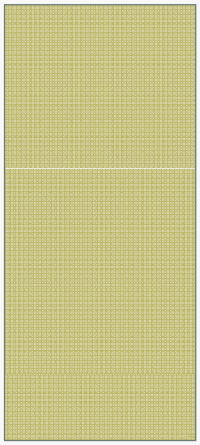

BACKGROUND

- Definition of Nanotechnology?
- Nano-technology is the act of manipulating matter on an atomic and molecular scale. Generally, nanotechnology deals with structures sized between 1 to 100 nanometre.

- Nanotechnology allows scientists to work on the scale of molecules to create, explore, and manipulate the biological and material worlds measured in nanometers, one-billionth of a meter thereby potentially being able to do more with less.
- To get a sense of the size in question it is worth knowing that a sheet of paper is about 100,000 nanometers thick; a human hair is about 80,000 nanometers wide.

NANOTECHNOLOGY IN THE FOOD INDUSTRY

- Nano technology has been used in the other industries for many years, however, more recently the technology has been making inroads into the food industry as well.
- Nanotechnology is already used in a number of food related consumer products including foods, supplements, pesticides, food packaging, and cookware.
- Presently, it appears nanotechnology in the food industry is used most in supplements, then in food packaging and cookware, and used the least frequently in actual food items. As a matter of fact, as of 2010, the only actual nanofood that was listed as sold in the United States was the Nanoceuticals™ Slim Shake Chocolate by RBC Life Sciences®, Inc. (The product claims to have "nanoclusters" mixed with tiny particles of cocoa that are designed to carry nutrients to the eater's cells).

CURRENT AND ANTICIPATED USES

- **Current Uses**
- • Samsung has fridges on the market in Asia and America that use nano-silver to kill bacteria.
- • Nano-engineered molecules, which lock onto contaminants simplify the process of cleaning drinking water - potentially hugely important for the developing world.
- Nano-coatings are being used to make the life span of manufactured food even longer.

- **Anticipated/Contemplated uses**
- • Teeth cleaning chewing gum
- • Self-cleaning cutlery
- • Programmable drinks
- Packaging that absorbs oxygen, making food last longer, is on its way.
- • Reductions in fats and salts in processed foods. Unilever believes it can reduce the fat content of ice cream from 15 per cent to one per cent.
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CONCERNS ABOUT THE USE OF NANO TECHNOLOGY IN FOOD

- The paramount issue of concern to regulators and opponents of nanofoods is how mysterious the whole process still is. Often, It is not known when nanofood is being ingested or if its ingestion is safe.
- Further, there is the concern of whether the FDA, which is responsible for regulating the food industry in the United States, and other similarly situated agencies around the world are sufficiently apt to regulating nanotechnology uses in food and/or if they will do so effectively. i.e. Keeping up with these fast paced technology.
- Another big concern for skeptics of nanofood is the insufficient record keeping of nano technology use in food.

FDA'S REGULATION OF NANOTECHNOLOGY PRODUCTS

- In the U.S., the regulation of food is charged to the Food and Drug Administration (FDA or USFDA).
- The FDA is an agency under the United States Department of Health and Human Services.
- The statutory authority for FDA oversight is the Federal Food, Drug, and Cosmetics Act (FFDCA).
- FDA's Mission - The mission of the Food and Drug Administration is, in part, to ensure that the products it regulates reach the marketplace safely and effectively.

FDA'S REGULATORY PROCEDURE(S)

- • **Premarket Approval** – in this method mandates that the before being put in the chain of commerce, new pharmaceuticals, high-risk medical devices, food additives, colors, and biologicals must be approved by FDA

- • **Premarket "Acceptance" --** In this general category are several similar authorities. For these products, FDA receives and reviews some form of notice that the products will be marketed. These products are often copies of similar products that were approved previously or are products prepared to approved specifications. For example, pharmaceuticals that are manufactured to existing USP Monographs

- • **Post Market Surveillance** -- In this third category, FDA manages the risks of products like foods, cosmetics, radiation emitting electronic products, and materials such as food additives and food packaging that are "generally recognized as safe" (GRAS). For these products, market entry and distribution are at the discretion of the manufacturer/producer.

FFCDA REQUIREMENTS FOR FOOD AND COSMETICS

- Generally speaking, the FFDCA does not require pre-market approval of food or cosmetics.
- it is the manufacturer's duty pursuant to FDA guidance, to determine if the products they produce are safe enough to be introduced into the market.
- Cosmetics and Food are regulated by the FDA only if they are adulterated or wrongly branded. Products deemed adulterated are mainly those that contain "any poisonous or deleterious substance" which may make them harmful to health. In most cases, the FDA only becomes involved if the product has been hazardous and/or caused harm to consumers.
- (Section 405 of FFDCA as amended)

FFDCA DIRECTIVE ON DRUGS

- Unlike food and cosmetics, pre-market approval is required prior to commercialization of a new drug in the United States, thus, the regulation of drugs under the FFDCA is substantially more stringent.
- To get approved, and for its product to be allowed to enter the stream of commerce, the applicant must provide information on the chemical parts and structure of the drug, it must give information on how the drug is produced and packaged,...and, most critically, demonstrate that the drug is safe and effective.

‘GRAS’ -FDA’S LOOP HOLE

- Also there is the ‘GRAS’ exemption…..
- Food additives like titanium oxide amongst others are classified by the FDA as GRAS “Generally Recognized As Safe”.
- With this label or classification said new additives can bypass the extensive and costly testing that it may otherwise have been subjected to.
- "Because GRAS notification is voluntary and companies are not required to identify nanomaterials in their GRAS substances, FDA has no way of knowing the full extent to which engineered nanomaterials have entered the U.S. food supply

OTHER STATUTES – "THE TOXIC SUBSTANCES CONTROL ACT"

- TSCA authorizes the EPA to regulate hazardous chemical substances where the "manufacture, processing, distribution, use, or disposal of the substance presents an unreasonable risk of injury to health or the environment.
- TSCA broadly defines "Chemical substance" and it generally would include engineered nanomaterials, but nanoparticles used in cosmetics, food, food additives, or as drugs are under the auspices of FDA because they have been excluded from TSCA regulation.

TSCA CONTINUED

- There must be pre-manufacture notification in order for a new chemical substance, or before a TSCA Inventory substance can be placed into a "significant new use". The notice, in these cases, must be presented to the EPA a minimum of 90 days before manufacture.

It is obvious that TSCA mandates a thorough and stringent regulatory process. It will be logical for the specific exclusion of cosmetics, food, food additives and drugs from TSCA regulation, to be done away with.

Given the degree of lack of knowledge about the effect(s) of the consumption and ingestion of nano food, it appears too much leeway has been handed to manufacturers of food products.

CWA

- The CWA like TSCA gives the EPA better oversight and supervisory powers .
- It gives EPA power to require that the operator or owner of a point source conduct monitoring and sampling and make available information that is essential for the EPA to carry out the purposes of the CWA.
- EPA also has the authority to inspect the facilities and the records of effluent sources.
- These kinds of statutory authority could be used as an information gathering technique and/or better oversight for nanotechnology regulation.

OTHER JURISDICTIONS

How is nanotechnology use in food regulated in other jurisdictions?

Food safety agencies in Canada and the European Union require all ingredients that use nanomaterials to be submitted to regulators before they can be put on the market.

Generally, In Europe, nanotech **must stay out** of food until it has been proven safe.

CONCLUSION

- It appears, the U.S. is lagging behind other developed nations in the regulation of the use of nanotechnology particularly in the food industry.
- Most countries in Europe; Australia and even neighbors Canada all seem to have more control over the use of nano technology in food (in their various jurisdictions) than the FDA does in the U.S.
- The FDA seems to have left too much in the hands of manufactures and sponsors of products. The fact that so little is known about the possible effects of the ingestion of nano technology coupled with the fact that the manufacturers usually have their bottom line to consider when making safety determinations (which may sometimes cloud their judgment), makes it is obvious that the current regulatory system of the FDA leaves much to be desired.

CONCLUSION

- Finally, the FDA should borrow a leaf from the regulatory process employed by the European Union; the EPA on toxic chemicals pursuant to TSCA; the EPA with its CWA's information gathering/compelling powers; or better yet the FDA can employ the regulatory method it uses pursuant to the FFDCA in regulation of drugs for food as well.
- These adjustments would undoubtedly put the FDA in a better stead and aid it in better and safer regulation of Nano technology use in food.