

Testimony of Christopher J Gintz on behalf of nanoTox Inc before the Select Committee on Science and Technology - the United Kingdom's House of Lords – Nanotechnologies and Food Subcommittee on June 24, 2009

By invitation from the British Government - British Embassy, Washington, DC

Biography of Mr. Christopher J. Gintz

Christopher J Gintz is a lifelong inventor involved in the formation of companies in the computer, information processing and science technology business. In 2003 he co-founded NanoHoldings LLC, a Company that raised \$30M for investment in the commercialization of nanotechnology from leading nanotech research centers such as Rice and Cambridge Universities. From 2005-2009 years he helped form and served as Chief Technology Officer for fourteen nano-specific technology companies spanning a wide range of civilian and military uses. Innovative technologies under development include materials with improved mechanical strengthening properties and replacements for earth metals that are increasingly depleted. In March 2009 he joined nanoTox Inc. as a strategic advisor for the advocacy of a private company- government partnership to study the toxicological properties of nanomaterials. He is the co-inventor of the notebook computer and has been responsible for the development of many electronics and energy technologies requiring complex understanding of the interaction between users and the environment. He holds a Bachelor of Arts degree in Sociology and Bachelor of Science Degree in Computer Science with advanced studies in statistics, chemistry and technology commercialization.

Introduction

The global economic crisis has significantly altered American national investment priorities. Science investment leading to accelerated technology commercialization is now a significant national priority. The size of this financial investment in American science is unprecedented. The country has not seen an equivalent commitment to the mobilization of scientific effort since the creation of the space program in the 1960's. Foremost on the administration's priority list dovetailing with its economic plans is the creation of an alternative energy policy that simultaneously reduces America's carbon footprint and increases its commitment to technology by creating high paying nanotech jobs. This agenda cannot advance without the successful commercialization of nanotech. The Economic Recovery Act is comprised of both a commitment to an investment in fundamental science and a renewed commitment to responsible regulation of technology making environmental, health and safety a national priority. Scientific investment and discovery in this area is global in scope with the American investment dwarfed by the financial commitments of America's trading partners in the United Kingdom, the European Community, Russia, China, Korea, Japan and Singapore.

This commitment is shown by the scope of the effort that is underway to study the complex interaction between these new technologies, people and the environment. Never before in mankind's history have we had the opportunity to study the potential health consequences of a material as it is being developed. Regulatory efforts heretofore have been reactive and usually after some debilitating health, safety or environmental problem emerged. This is not true for drug development however, where clinical trials assessing the potential health consequences are a major element of the regulatory environment. Stakeholders' interests in the nanotech debate are meant to be inclusive. There is a general agreement by all concerned stakeholders that the specific studies of nano/biological interactions are important.

The following list of American governmental agencies involved in this process is not meant to be exhaustive but is indicative of the range of scientific and regulatory frameworks in which American business operates. However, a host of Federal agencies including the National Science Foundation, the Department of Energy, the National Institute of Health, the Food and Drug Administration, the Environmental Protection Agency and the National Institute of Occupational Safety and Health all have a stake in the development of nanotechnology. They have convened working groups consisting of domain experts covering the spectrum of interested stake holders including science experts, academic researchers, industrial partners, consumers and regulators to study the complex interaction of these materials and their interface with macro systems.

For example, in May 2009 the United States Food and Drug Administration convened its Second National Workshop at the Greentech/Nanotech Conference in Houston, Texas to define and access reference nanoscale particulates by their chemical composition, surface characteristics, size, and electrical characteristics to determine their behavior when interacting with biological systems. Future health and safety studies contemplated include but are not limited to an evaluation of their potential toxicity when handled and processed by workers and their subsequent disposal at the end of their life cycle.

nanoTox Inc. business and technical personnel are involved in participating from the inception in these workshops acting as an advocate for the safe and responsible handling of materials through the entire scientific, business development and materials production supply chain. In addition, nanoTox' scientists are engaged with the emergence of food nanotechnology and during the last three years have published chapters in the most recent textbooks in the specialized area of gastrointestinal toxicology. Although it is funded by private investors it seeks to act in the role as a coordinating body bridging private industry concerns for factual scientific inquiry with the government's regulatory information requirements. It is formed out of the belief that all stakeholders are interested in verifiable scientific proof as a basis for responsible and balanced governmental regulation. nanoTox Inc. believes that periodic, on-going assessments are needed and that continuous monitoring of industrial processes is necessary to protect workers, consumers, and the environment. These assessments will help jump start the nanotech industry by creating a scientifically proven data base on which insurers can depend so that nanotech companies can accelerate product development in the marketplace thereby stimulating the economy.

nanoTox's initial deliverables include using both *in vivo* strategies (acute and subchronic toxicity studies focused on different exposure routes) and *in vitro* strategies (development of in vitro engineered human tissues, epidermis, bronchial and intestinal epitheliums.) These studies are intended to identify the potential impact of manufactured nano scale particles on human health.

Food Safety

Insuring the safety of the food supply is a global concern. People's concerns are well founded. During the past five years there have been significant health concerns about global pandemics with health scares involving the meat supply (mad cow's disease, swine flue, bird flu), bacterial outbreaks caused by improper inspection and handling of vegetables and peanuts, and deliberately tainted food stuffs such as the melanomin contamination in baby formula and milk supplies in China. Each health scare has been created by its own unique circumstances costing the world economy billions of dollars and created a general uneasiness among the populace about the safety of its food supply. As a result, the American agricultural industry has called for additional inspection and regulation to govern food safety. The *Wall Street Journal* reported on June 18, 2009 that the Congress has drafted legislation specifically for this purpose.

Since it is the Select Committee of the Science and Technology Committee of the House of Lords specific interest to investigate the specific use of nanotechnology in food, my comments will now specifically address the use of nanotechnologies and nanomaterials in food products, dietary supplements and food packaging. I will separate my comments between the food chain and the cosmetics chain.

Nano stakeholders have formed several mechanisms for the orderly dissemination of factual information about nanotechnology and both its interaction in the food chain and cosmetics. Two qualified sources of information are www.goodnanoguide.org/tiki-index.php and the International Risk Governance Council: "The Appropriate risk governance strategies for nanotechnology applications in food and cosmetics" see www.irgc.org/img/pdf/irgc_Pbnanofood_web.pdf.

Most experts agree that the negative implications for nanoscale materials in the food chain and cosmetics are **unlikely** but cannot be excluded, especially particles smaller than 20 nanometers.

According to the IRGC:

“...There are problems at all phases of risk governance in nanotechnology. These include accepted and approved definition of what does and does not constitute a nanomaterial. Almost no hard data regarding nanoparticles in the contents of materials in specific products and very little scientific knowledge of the risks associated with nano scale ingredients or the products that contain them. As a result, the general public with a limited knowledge of nanotechnology is being influenced by alarmists writing

communications, which are based on societal culture rather than any scientific basis. Consequently concerns about health issues and risks are growing even though there is no substantive evidence to justify these concerns.”

State of the Science

As proof of this assertion, a literature search on the Internet finds only three references to food products and nanoscale particles. *Science News* reported on May 27, 2007 that the number of consumer products including food and food packaging using nanotechnology has doubled from 212 to 475 since the *Project on Emerging Nanotechnologies* launched the world’s first online inventory of manufacturer-identified nanotech goods in March 2006. Clothing and cosmetics top the inventory” See <http://www.nanotechproject.org/consumerprodcuts>. One can conclude from this search that given the billions of dollars spent on groceries, the size of the market for nanoparticle foodstuffs at this point in time is nearly non-existent.

Active research agendas on nanotechnology food and food packaging are also limited. There is no coordinated research effort on the study or use of nanotechnologies in food and food packaging. Only two scientists have a published research agenda in the field of nanotechnology and food. Dr. Frans Kampers, a Dutch scientist at the Wageningen University and Research Center and Dr. Rod Hill at the University of Idaho were symposium presenters on the subject (See *Science News*, February 18, 2009 “Could Nanotechnology Make an Average Donut into Health Food?” www.ScienceDaily.com/releases/2009/02/090214162746.htm) at the American Association for the Advancement of Science annual meeting entitled “From Donuts to Drugs: Nano-Biotechnology Evolution or Revolution.” Dr. Kampers alleged “...that European food companies already use nanotechnology in consumer products but few volunteer the information to consumers.” Dr. Kampers research agenda focuses on applications, products, processes, and sensors useful in food safety, food quality monitoring and in packaging.”

Dr. Kampers stated “European food scientists use nanotechnology to create structures in food that can deliver nutrients to specific locations in the body for the most beneficial effects.” What are the nutrients and where is the scientific proof to back up these allegations? This is one investigator speculating in a symposium about what *may* happen not what is factually happening at this time. The main barriers to developing nanoscale nutrients are the cost and benefits associated with their development. We believe that those are anticipated developments are and not currently actively under development.

The nanotech packaging industry is in its infancy. There are nine references regarding nanoparticles and food storage in the *Products on Emerging Nanotechnologies* database. This is hardly an unmanageable group of products to access. They span the gamut from devices for actual food storage (plastic storage bags containing silver particles), beer bottles containing nanoparticles to keep gas from dissipating (nanoclays), plastic wrap (containing zinc oxide acting as an ultraviolet catalyst), baby bottles and salad bowls (silver nano particles to fight bacteria), aluminum foil (nanoscale carbon linings for better

heat adsorption) and nano starch (improved adhesion in sealing bags) and refrigeration solutions including (nanoparticles in insulation) and odor adsorption. If there were a gap in the nanotechnology regulatory environment, it would involve the packaging industry. This application area represents a potential regulatory gap and perhaps merits further scrutiny because the food stored in some methods comes in direct contact with nanoparticles that subsequently contact biological systems.

Specific examples of the debate about cosmetics usually encompass a discussion of TiO₂ (titanium dioxide) base sunscreens. These sunscreens contain engineered nanoparticles but there is no current mechanism to distinguish “nano forms” from “other forms” of titanium dioxide. Here is a case where TiO₂ sunscreens are considered existing materials not “new or novel” materials. This application area, like food packaging perhaps merits further scrutiny because nanoparticles are directly coming in contact directly with biological systems.

Answers to Specific Inquiries

- 1) Most of the specific research in America on food and packaging is conducted at leading academic research universities in the form of **non-Good** Laboratory Practices (GLP) studies with poor documentation/reproducibility. These researchers have problems getting the necessary funding.
- 2) The main barriers to developing these technologies are: a) fear of consumer rejection of nano products and b) the regulation of technology.

Health and Safety

The health and safety risks associated with nanoparticles in food and food packaging in the United States are unknown at this time. The two issues must be handled separately. The field is wide open since there has been no risk assessment performed in either area. Specific to the food supply we believe strongly that the United States Food and Drug Administration has the primary responsibility for monitoring all developments in food safety including food additives and nanotechnology. This is equivalent in Europe to the European Food Safety Authority (EFSA) and in the United Kingdom, the Food Safety Board. We would encourage the FDA’s participation in international rule making with its regulatory counterparts.

Nanotechnology is not genetically modified food. Risk management regarding the food supply should be approached from the perspective of balance and proportionality between the costs and benefits of regulation. The regulatory impact of mandatory versus “indirect” approaches versus an absence of regulation should be considered. “Food” is different from “dietary supplements.”

See *ScienceDaily* February 10, 2009 “Nanoparticles in Dietary Supplements Cause Health Concerns, Regulatory Challenges;” <http://www.sciencedaily.com/releases/2009/02/090909075633.htm>) In the United States there is limited regulatory control over the dietary supplements business. They have

limited distribution and are perceived to be a niche between the food business and the pharmaceutical business. Most products come with a disclaimer that these products are outside of the review of the Food and Drug Administration. Admittedly this is a regulatory gray area. Further assessment of the use of nanoscale nutrients that are used to boost nutrient adsorption and other alleged health benefits needs further study and assessment.

Answers to Specific Inquiries

- 1) The health and safety risks that present the highest risks in food and packaging are leachables from packaging. Testing has not been conducted at the nano scale but may have been tested in some form at the macro scale.
- 2) nanoTox assists companies in analyses, stability of the nanoformulation and toxicology testing. Additional research needs to be conducted comprehensively.
- 3) We cannot speak for the government. Industry plans to risk assess new food products through CFSAN on a case-by-case basis and nanotechnology will need to be retested. The food industry follows basic toxicology testing guidelines as set forth in the FDA Redbook (guidelines for testing Food Additives....Direct and Indirect)

Regulation

We believe that there are six key regulatory governance principles we wish to propose for consideration by all domestic and international nanotechnology regulators without regard to select topics. These are:

- 1) The regulatory response should be coordinated; coordination with international entities between states as well as inter-departmental and interagency levels.
- 2) Regulatory approaches to nanotech should be adaptive and flexible as we learn more factually about the technology.
- 3) Information gathering initiatives, a key first step in an additive regulatory system, should be designed with end points in mind, should offer incentives for participation and should involve industry and academic researchers.
- 4) Risk management approaches should strive to be comprehensive, by incorporating a lifecycle approach to govern the potential risks of nanotechnology and should be designed with the importance of scope and timing horizons in mind.
- 5) Risk management approaches should strive for balance and proportionality.
- 6) An understanding of the profile of the beneficiaries of nanotechnology and the risk bearers in concert with who is accountable ensuring the appropriate deployment of both technology and regulatory oversight. Stakeholders should be engaged appropriately and regulatory systems should be transparent.

The US Government through the Food and Drug Administration believes that it has the necessary expertise and scientific depth to coordinate the involvement of stakeholders in the process for defining nanomaterials and nanotechnologies as they apply to its

regulatory area, which includes the topic area. The primary statute applicable to the regulation of nanoproducts falling under the FDA's authority is the Food, Drug and Cosmetic Act (FDCA). For products subject to pre-market approval which includes pharmaceuticals, high risk medical devices, and biological products, existing regulatory requirements are expected to be a sufficiently stringent and flexible to accommodate the regulation of nanotechnology—However, the FDA does recognize that current data requirements, reporting and notification mechanisms do not contain specific information to allow for the assessment of nanomaterial safety.

Some products are subject to post—market surveillance requirements including cosmetics and food. This is perhaps an area that stakeholders may agree that there is a need for increased regulatory scrutiny of products containing nano materials. This is not a trivial matter since many standard scientific tests do not apply to nano and in most cases measurement techniques and instrumentation is not yet developed. This situation is further complicated by the lack of definition with associated materials being tested. For example, “is a flat platelet of nanometer dimensions equivalent to a round particle of the same material?”

A regulatory approach to developing policy options for nanotechnology including food and food packaging should include:

- 1) A formal statement of policy or preparation of a jurisdictional strategy.
- 2) An attempt to gain more knowledge of nanotechnology's risks especially in the context of its interaction with biological systems.
- 3) Commission a regulatory gap analysis.
- 4) Make use of existing current regulations to indirectly regulate nanotechnology.

Answers to Specific Inquiries:

- 1) The US Government today has no single definition of “nanomaterials” and “nanoparticles” but effort is underway by industry, government, academic researchers and consumer stakeholders to define them according to their composition, size, surface area, dimensions, and properties such as their electronic conductivity.
- 2) The US Government does not yet have a reporting mechanism for reporting nano-sized materials to the Food and Drug Administration.
- 3) The US Government intends through the efforts of the Environmental Protection Agency to monitor and regulate the use of pesticides and fertilizers that contain nanotech materials.
- 4) In terms of where nano will be used, CFSAN has no nano notifications as of this time.
- 5) The US Government coordinates its work on nanotechnologies through voluntary participation by interested stakeholders. Forums for the purpose have been held at Rice University (Houston, Texas), the Alliance for Nanohealth, Conferences, Workshops, and Conference Calls organized by agencies and Symposia.

Public information and consumer engagement

The American public obviously has a major stake in the acceptance of products that contain nanoparticles and avenues of debate about nanomaterials in food and food packaging must be developed. There are public and private groups that are instrumental in the conduct of this debate. For example, the US Government's Consumer Products Safety Commission has the primary responsibility for organizing stakeholder opinions on product safety. We believe that the Government and its regulating bodies have the following responsibilities when talking about nanotechnology:

- 1) The Government should be positive stating its intention to support nanotechnology research and development with the intent to capture future benefits.
- 2) Benefits of nanotechnology need to be balanced with statements about potential risks, the extent to which we do not yet fully understand from a scientific perspective.
- 3) Jurisdictions need to stress that until such time more information is available, existing regulatory frameworks are sufficient to ensure health and safety of stakeholders including consumers and the environment.
- 4) Jurisdictions need to note the current lack of data pertaining to new materials novel properties, the lack of measurement instruments, standards, and methods to deal with hazards, exposure evaluation and overall risk assessment.
- 5) Jurisdictions note the need to review the need for nanotechnology specific regulatory frameworks in the future and update existing regulatory frameworks as required.
- 6) Jurisdictions should aggressively work with a Company like nanoTox and research universities to speed the process for building and evaluating a fact track model of proposed nanotechnology regulations. It would greatly reduce business uncertainty, foster investment leading to jobs creation needed in the world economy today.

Answers to Specific Inquiries

- 1) We cannot ascertain any existing public perception in the United States about food nanotech and therefore we have seen little written or discussed about it in either the scientific or popular media. The United States tends to be much less formal about the regulation of new technology and the strategy is to have the competition in the marketplace define the features and benefits by the producers.
- 2) We have yet to see any difference in nano; it is uncertain whether it will have any impact since few products exist. We do not see the need to label something as different if there is no proven difference.