Comment to the Food and Drug Administration
Docket Number and Title: 2006N-0107
FDA Regulated Products Containing Nanotechnology Materials
September 28, 2006

The Institute for Agriculture and Trade Policy (IATP) welcomes the invitation of the Food and Drug Administration to submit a comment to this docket. IATP is a non-profit, non-governmental organization based in Minneapolis, MN, with an office in Geneva, Switzerland. IATP promotes resilient family farms, rural communities and ecosystems around the world through research and education, science and technology, and advocacy. Ensuring the production of healthy and safe food and is part of fulfilling IATP's mission.

IATP is interested not only in nanotechnology applications to foods and food additives regulated by the FDA, and how they will impact food quality and public health, but also in the context of a broader public dialogue about the social and economic effects of nanotechnologies' myriad proposed uses. Nanotechnologies can potentially cause harm at the cellular level, are largely unregulated, and are being introduced into commerce largely without safety testing. Moreover, the broad commercial uses being proposed inevitably will result in nanoparticulate contamination of the human environment. FDA and other agencies have yet to design and implement a pre-market safety testing program for products with nanomaterial components. To do so would be consonant with the recommendation of the National Research Council regarding the "responsible development of nanotechnology."[1]

Detailed comments

Federal, to say nothing of private, investment in nanotechnology product development is far outpacing investment in research into the safety of nanomaterials and nanotechnology processes. According to a recent database study, the U.S. government alone has about 160 projects to develop agricultural and food processing nanotechnology applications.[2] Whereas the 2006 Fiscal Year budget of the agencies under the umbrella of the National Nanotechnology Initiative is about $1.3 billion, the Project for Emerging Nanotechnologies (PEN) has estimated the

[1] Committee to Review the National Nanotechnology Initiative, *A Matter of Size: Triennial Review of the National Nanotechnology Initiative*, National Research Council, pre-publication executive summary (September 25, 2006) at http://newton.nap.edu/execsumm_pdf/11752
[2] Jennifer Kuzma and Peter VerHage, "Analysis of Early State Agrifood Nanotechnology Research and Development," Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars (September 2006), 4.

budget for risk relevant research at a mere $11 million.[3] The FDA should lead the effort to increase by at least ten-fold the federal budget for relevant safety research.

Despite the too small federal investment in nanotechnology safety research, FDA should seek to benefit from what relevant research has been done by other agencies. There is some positive evidence of harm or potential harm from human exposure to carbon-based nanoparticles. For example, according to studies reviewed by National Institute for Occupational Safety and Health (NIOSH), inhalation of carbon nanotubes produced fibrosis in rats within a week.[4] There is much, much more about nanoparticle safety that remains unknown. The NIOSH reported last year, "very little is known about the safety risks presented by engineered nano-materials."[5] Given the Fortune 500 agribusiness and food processing firms that are applying nanotechnology platforms to product development (e.g. Kraft, DeGussa, Unilever, Nestlé etc.),[6] it is alarming that PEN's research has not found a single human hazard project that investigates the effects of nano-materials on the gastro-intestinal tract.[7]

Somehow, despite the lack of knowledge about risks to those working with nano-materials, at least 700 products with nano-materials have been commercialized, and commercialization applications are in the pipeline.[8] This broad trend of commercialization of molecular-sized particles without safety testing is not only dangerous, but flies in the face of what we should have learned from public health disasters involving other small particles, from the particles in environmental tobacco smoke to those from commercial asbestos applications. We therefore urge the FDA to accelerate its safety research on nanotechnologies, and to make approval of new nanotechnologies contingent on manufacturers providing public information that demonstrate their products to be safe to use. We believe that FDA's own safety research into possible human hazards of the effects of nanomaterials should prioritize studies concerning the gastro-intestinal and respiratory tracts.

Furthermore, FDA should work with other agencies to develop equipment to detect nanomaterials in products and in the environment, since without such equipment,

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[3] Andrew Maynard, "Nanotechnology: A Research Strategy for Addressing Risk," Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars (July 2006), 20.
[4] Jennifer Sass, "Nanotechnologies and Biology," National Resources Defense Council (2006), slide 16 at http://www.nrdc.org/health/science/nano.asp
[5] Cited in Charles Geraci, "Nanotechnology in the Workplace: Ensuring Occupational Safety Through Better Risk Management." NIOSH Nanotechnology Research Center, presentation to "Nanotechnology in Food and Agriculture," (June 6-7, 2006), slide 40.
[6] "Down on the Farm: The Impact of Nano-scale Technologies on Food and Agriculture," The ETC Group (November 2004), 39.
[7] *The Nanotechnology Consumer Products Inventory*, Project on Emerging Nanotechnologies, Woodrow Wilson International Center for Scholars (June 2006).
[8] The ETC Group, "The Potential Impacts of Nano-Scale Technologies on Commodity Markets: The Implications for Commodity Dependent Developing Countries," Trade-Related Agenda, Development and Equity Research Paper No. 4 (South Centre, November 2005), 13.

e.g. a less expensive version of an "atomic force" microscope, product inspection and regulatory enforcement will be impossible. Absent the adequate funding and implementation of such a research program, FDA should not continue to process applications for approval to commercialize products with nanomaterials.

A U.S. regulatory framework for nano-products should not make its primary objective to justify why new regulations are not "necessary" due to a purported "substantial equivalence" between nanomaterials and macro-materials. The regulatory framework should start with the peer-reviewed literature that shows nanomaterials to behave in biologically, chemically and/or physically distinct ways from macro-materials. One report summarizing this literature noted "[w]ith only a reduction in size, and no change in substance, properties related to electrical conductivity, elasticity, strength, colour and chemical reactivity can all change."[9] The interface of nanotechnologies with biotechnologies will change the properties of matter, ingested, inhaled or exposed to human beings, animals and the environment. Regulators must understand the effects of those changes on human, animal and environmental health in order to develop a regulatory framework and testing paradigms prior to processing applications for commercialization of nano-biotech products.

We agree with the May 2006 petition by the International Center for Technology Assessment (ICTA) et al requesting that the FDA enact new regulations in recognition of the scientifically demonstrated differences in the properties of nanomaterials. The ICTA petition asks that FDA require that "nanoparticles be treated as new substances; nanomaterials be subjected to nano-specific paradigms of health and safety testing; and that nanomaterials be labeled to delineate all nanoparticle ingredients."[10] We believe that this and other petitioner requests are well justified by science and law, and should be adopted as FDA elaborates its regulatory framework for nanomaterials and nanotechnology processes.

IATP hopes that agribusiness and food processing firms are conducting safety research, particularly on the effects of nanomaterials on the gastro-intestinal tract. But we suspect that such research data on safety and efficacy will be claimed as Confidential Business Information (CBI), given the extensive and interlocking patenting and confidentiality agreements on exchange of scientific information about the platform nanotechnologies. IATP suggests that FDA work with other federal agencies to develop data ownership protocols that would protect the public interest, as well as the interests of technology developers. We further recommend

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[9] "The Potential Impacts of Nano-Scale Technologies on Commodity Markets," 9.

[10] "Petition Requesting FDA Amend Its Regulations for Products Composed of Engineered Nanoparticles Generally and Sunscreen Drug Products Composed of Engineered Nanoparticles Specifically," The International Center for Technology Assessment et al. (May 2006), 3 at http://www.icta.org

that FDA work with other federal agencies to curb abuse of the CBI exemption of the Administrative Procedures Act that has lead to a near exclusion of health and safety data in commercialization applications from public review prior to and even after commercialization approval.

IATP is grateful for the opportunity to submit this comment at the outset of what may become a widespread commercialization of products with nanomaterials. We hope that FDA will prioritize safety research relevant to the products under its regulatory authority and to work with Congress, other agencies, industry and other interested parties to regulate for safety those nanotechnology applications that do not pertain to existing statutory authority.

Sincerely,

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