INSTITUTE FOR **AGRICULTURE** AND **TRADE POLICY**

Racing Ahead

U.S. Agri-Nanotechnology in the Absence of Regulation

Executive Summary

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June 2011

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Author's note and acknowledgements: This paper owes a great deal to the contributions of the members of the NanoActivist listserv. Particular thanks are owed to Jaydee Hansen for correcting my draft errors and supplying yet more to read. The errors and failings of this paper are, of course, my own.

Published June 2011

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On June 9, the U.S. Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) separately released ground-breaking, albeit voluntary, draft guidance to industry, the first, long-overdue step toward regulating products that incorporate nanomaterials. The White House issued an executive memorandum the same day, on principles of regulation and oversight of nanotechnology and nanomaterials. The memo noted that, "[c]ompanies are already offering nanotechnology-enabled products with break-through capabilities in areas such as disease detection, lighter and stronger materials, and next-generation batteries."

But none of these products are regulated by U.S. federal agencies. Research and development for agricultural and food applications of nanotechnology has expanded rapidly in recent years, with over $50 billion in global public investment and at least as much in privately funded research. At least 1,300 products with Engineered Nanotechnology Materials (ENMs) have been commercialized, despite myriad uncertainties about the public health and environmental effects of ENMs.

These uncertainties result, in part, from novel physical, chemical and biological properties that are due to the extremely small size of these particles, which may range from 1 to 300 nanometers (the diameter of a human hair is about 80,000 nanometers). The exponentially greater surface-to-mass ratio of nanoscale materials results in different properties and uses than what is possible for the macro-scale counterparts of those materials. It is not yet clear what human health hazards may be created when nano-particles are ingested, or the extent to which ENMs might migrate from food packaging to the food and hence through the entire human body.

Several steps are needed to arrive at an operative and mandatory regulatory structure for nanotechnology products and processes. There is no agreed legal definition of what constitutes an ENM. Regulators do not have an official registry needed to regulate products already in the market nor an inventory of products in development. As of March 2011, the nongovernmental Project on Emerging Nanotechnologies (PEN) had registered more than 1,300 products whose manufacturers claim to include ENMs, and estimates that the number could grow to 3,400 by 2020.

The lack of definition is not just a technical issue, but also a political challenge. The decision to commit to binding legal definitions would be predicated on related decisions to regulate and a commitment to ensure the human, technical and financial resources to implement and enforce regulations. Even if, after the June EPA guidance on submitting ENMs for EPA review, definitions could be determined, and adequate resources provided, it will be difficult to require product data from commercialization applicants. A research project to estimate ENM production levels found that most companies surveyed regarded production levels as confidential business information (CBI) that they refused to disclose, even after the researchers guaranteed company confidentiality.

There are EHS risks that regulators could begin to assess, if they had nanotech product data, on the basis of current peer-reviewed scientific literature. Chinese researchers, for example, have discovered in animal testing that absorption of nano-silver may interfere with the replication of DNA molecules and can reroute molecular networks that could create genetic mutations. Nano-silver, among myriad other uses, is incorporated into food packaging materials to kill pathogenic bacteria and thereby extend a food's shelf life.

Estimates of the global cost of testing even just the toxicological effects of known ENMs range from $265 million to $1.8 billion. In the United States, the government bears the legal burden of collecting and analyzing data for risk assessments, but there is strong congressional opposition to providing the budget necessary to carry out that legal mandate. A report from the first (and thus far only) expert consultation on agri-nanotechnology under the auspices of the World Health Organization (WHO) and the United Nations Food and Agriculture Organization (FAO) suggests a "tiered approach" to ENM risk assessments. Such a tiered approach is characteristic of the European Union's "Registration, Evaluation, Authorization and Restriction of Chemicals" (REACH) legislation for regulation of chemical substances, products and wastes. Where the scientific literature indicates higher likely risks to public, worker and environmental health, regulators informed by such literature should obtain product data and perform risk assessments, leaving low-risk applications further down the priority list.

The range of food and agricultural nanotechnology applications includes making toxins more bio-available in pesticides, targeting nutrients in smaller doses, improving the texture of ice cream and detecting bacteria in packaged foods. Under current rules, companies have the discretion to determine whether a macro-substance already considered by the company to be safe and therefore not reportable to the FDA, deemed to be likewise safe and hence non-reportable in its nano-scale form. In addition, the exponentially larger surface-to-mass ratio of ENMs, compared to that of macro-versions of the "same" materials, will make the determination of Acceptable Daily Intakes impossible if companies are not required to submit data to regulators for their independent assessment.

In 2008, the Project on Emerging Nanotechnologies (PEN) and the Grocery Manufacturer's Association (GMA) brought together industry representatives, government regulators and NGOs to consider how EPA and FDA might regulate generic and hypothetical food packaging incorporating ENMs. The project revealed challenges to FDA's present regulatory process for food packaging materials, including: 1.) validating methodologies to characterize ENM properties to determine whether ENMs might migrate into food; 2.) validating migration study protocols that would determine consumer exposure to ENMs; 3.) evaluating whether current FDA set dietary concentration triggers for toxicity testing are adequate for ENMs; and 4.) determining whether toxicological data for the macro-scale counterparts of ENMs have any utility for predictive toxicology and safety assessment.

But these challenges are not just theoretical. The Pulitzer Prize–winning journalist Andrew Schneider has reported that some fruits and vegetables exported from Latin America are coated with nano-particles to extend their shelf life. Based on a review of patent filings, regulators have some knowledge of the ingredients of food nano-coatings. These ingredients include nano-silver and nano-zinc oxide as anti-microbials to combat bacteria; nano-silica to prevent water content loss and to ensure the film's transparency; and nano-titanium dioxide to prevent deterioration due to ultraviolet rays. The macro forms of these ingredients are permitted food additives, but testing has not yet been done to assess their safety at nano-scale. Administrative, technical and resources constraints create enormous hurdles to effective import inspection of food nano-coatings and food packaging using ENMs.

Because of, or perhaps despite, the scientific, budgetary and infrastructural difficulties of developing methods to simply and reliably measure the presence of ENMs in food, feed and food packaging materials, the Codex Alimentarius Commission, the international food standards body, may consider in July whether or not to include nanotechnology in its strategic plan for 2013–2018. Codex standards are presumed to be authoritative by the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures for the purpose of trade facilitation. There are many reasons why the commission should undertake work on agri-nanotechnology, not the least of which is that such products are already being traded without regulation or risk assessment on which to base regulations. At the same time, Codex standards require the scientific advice of FAO/WHO expert meetings and/or standing committees, such as the Joint FAO/WHO Committee on Food Additives. However, FAO and WHO member governments have not made the funding of such scientific advice a Codex priority. There is a risk, however, that if standards are developed before member countries have effective rules and resources to do mandatory pre-market safety assessments and post-market surveillance of foods with ENMs, Codex standards would only facilitate greater trade without adequate regulatory enforcement capacity.

There is a serious imbalance between optimistic public assessment of potential benefits and the potential risks of nanotechnology applications. Efforts to determine appropriate safety regulations should begin with a framework of comparative technology assessment to assess whether a nanotechnology application is the optimal means for achieving a specific technological or public interest goal. It appears that investors hope that products will become ubiquitous and "accepted" before risk research reveals harms so prevalent and/or severe as to force withdrawal of the product from commerce.

The June 9 announcement by EPA and FDA of their intent to issue voluntary guidance to industry on nanotechnology products under their respective authority is a small, but encouraging first step toward regulation. Minimizing the budgets and mandate for environmental, health and safety research into agri-nanotechnology and trusting that agri-nanotechnology hazards, if they appear as public health and environmental harms, will be untraceable and beyond the reach of liability plaintiffs, is not a viable technology or commercialization policy. Surely, a policy that relies on non-regulation and paltry investments in risk research cannot enable the so-called "New Industrial Revolution" for the 21st century that nanotechnology promoters promise.