INSTITUTE FOR AGRICULTURE AND TRADE POLICY

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Good Morning. I am Steve Suppan, a senior policy analyst at the Institute for Agriculture and Trade Policy (IATP), where I have worked since 1994. IATP is a nonprofit, nongovernmental organization headquartered in Minneapolis with offices in Washington, DC and Geneva, Switzerland. IATP thanks the committee for this opportunity to share our views about some of the general regulatory and legislative challenges presented by nanotechnologies. Nanoscale science and technology manipulates matter at the level of 1–300 nanometers or billionths of a meter. A human hair measures 80,000 to 100,000 nanometers. Nanoscale materials have novel properties that make them potentially useful for a broad array of products. For example, nano-sized pieces of DNA are arranged to mimic more powerfully and quickly the process by which a termite digests wood to produce the sugars that could be used to manufacture cellulosic ethanol. Nano-sized carbon tubes are mixed into building materials to vastly strengthen them. According to the National Science Foundation, about $70 billion worth of products incorporating engineered nanomaterials were sold in the United States last year. Lux Research predicts a $3.1 trillion dollar global market for nanotechnology products by 2015.

Overview

The sum and substance of my testimony is this: nanotechnology products have been commercialized in the absence of nanotechnology specific U.S. federal regulation. These products continue to be put in the market place despite peer-reviewed scientific studies that show some nanomaterials have potential human health risks, often based on laboratory studies with test animals. Most of these studies have focused on the respiratory system, with remarkably few studies on the effect of nanomaterials on the gastro-intestinal system. I have brought with me copies for the Committee of a study on the potential for nanomaterials to cross the placental barrier and potentially affect fetal development.[1]

There is no official U.S. nanotechnology product registry. However, according to research by the Woodrow Wilson Center Project on Emerging Nanotechnologies, there are about a thousand consumer products incorporating nanomaterials currently on the market.[2] In my testimony, I will very briefly review the readiness of just two U.S. federal agencies, the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA), to regulate nanotechnologies. The National Nanotechnology Initiative (www.nano.gov) coordinates the activities of about two dozen federal agencies. For this committee and the legislature, understanding the extent of federal regulatory readiness will be helpful in determining what kinds of state oversight may be needed for nanotechnology product developers operating in Minnesota.

A snapshot of EPA and FDA capacity to regulate nanotechnology

Considering how many commercial products incorporate nanomaterials, it is remarkable how little information federal regulators have about those products and their related company product test data. They lack such information because there is no statute or rule requiring data submission for regulatory approval. Much of nanotechnology product test data is claimed as "Confidential Business Information" under the Administrative Procedures Act. It may be necessary to revise the APA to ensure that data required to ensure public health, the environment and workplace safety is not withheld from regulators under claim of CBI privilege.

EPA has acknowledged that its Voluntary Nanomaterials Stewardship Program has failed to elicit company cooperation and is considering development of a rule for mandatory submission with CBI protections. (The reluctance to regulate is not universal. The EPA's corresponding agency in Germany has called for a mandatory product registry and mandatory labeling of products with nanomaterials.[3]) In an October 6 speech, EPA administrator Lisa Jackson said that the EPA would review how nanoscale materials should be reported under the Toxic Substances Control Act.[4] The results of this review will presumably be communicated not only to nanotech product developers, but to all federal and state agencies with responsibilities for nanotechnology oversight.

Lacking nanotechnology product data, federal authorities have performed no pre-market safety assessments of products that incorporate nanomaterials, or claim to. In light of scientific evidence of potential risks of nanomaterials in commercial use, IATP joined a May 2008 petition to the Environmental Protection Agency to regulate nano-silver as a pesticide.[5] EPA action on the petition is still pending.

IATP remains concerned that the many promises of jobs and life-enhancing products made by a burgeoning nanotechnology industry may cause legislators and regulators to delay or dilute regulation in the mistaken belief that strong regulation and enforcement will impede product innovation. IATP believes, to the contrary, that to secure sustainable nanotechnology markets, there is an urgent need to authorize and implement pre-market safety assessments of products with novel materials that behave very differently from their macro-material counterparts.[6]

I will not knowingly eat silver, since it is toxic and indigestible. But if nano-silver becomes part of a vegetable or fruit coating to extend produce shelf life, shouldn't regulators have tested such a nano-coating for its health effects prior to allowing produce companies to use the nanocoating? Shouldn't such a nano-coated product, if approved by regulators, be labeled so consumers can choose whether or not they wish to consume such a product? Nanocoating of produce destined for the United States is not a hypothetical example. In a remarkable series of articles published March 24, Andrew Schneider, a Pulitizer Prize winning health reporter, reveals that Latin American produce destined for the United States has been nanocoated. Schneider cited an anonymous USDA researcher as saying, "We found no indication that the nanocoating, which is manufactured in Asia, has ever been tested for health effects."[7]

FDA is required to re-inspect the increasing volume of imported produce, to say nothing of drugs, medical devices and other products under its authority. What is FDA's capacity to inspect and test nanocoated import produce? Congressional testimony about FDA's port-of-entry resources is instructive for estimating its regulatory readiness, since some of these products are

or will be the subjects of nanotechnology applications. In November 2007, former FDA import product administrator Benjamin England testified that FDA had about 200 inspectors for about 300 U.S. ports of entry. To make up for this lack of port-of-entry capacity, FDA is negotiating bilateral agreements with major exporters to the United States that will allow FDA inspectors posted abroad to review the paperwork and conduct on-site audits to certify that export facilities follow U.S. safety standards.[8] Implementation and enforcement of these agreements with countries having weak regulatory capacity, such as China, a major nanotechnology manufacturer, will not be easy.

The FDA has a great deal of confidence that it will be able to manage risks associated with the food applications of nanotechnologies. According to Dr. Annette McCarthy, of FDA's food additive office, "For a lot of the nanotechnologies that are being designed at the moment, you would have a hard time today to come down to FDA and prove that it's generally recognized as safe [GRAS]. But two years down the line, it could be a slam dunk; it could be very simple [to prove GRAS]."[9] However, given the current de facto industry self-determination of what is GRAS, the General Accountability Office reported in February that nanomaterials could enter into commerce without FDA knowledge[10] which, to judge by Andrew Schneider's extensive reporting, is apparently the case.

U.S federal and state oversight of nanotechnologies: a short state of play

The Congressional Research Service has published an excellent overview of U.S. legislative and budgetary support for nanotechnologies.[11] The federal government has invested billions of dollars through the National Nanotechnology Initiative first launched by President Bill Clinton in 2001. In 2003, Congress enacted The 21st Century Nanotechnology Research and Development Act, which provides a statutory basis for nanotechnology research programs and budgets, and prioritizes research initiatives, particularly for military, energy and medical applications of nanotechnologies. Since its inception, the focus of the NNI has been product development, with miniscule investments, 1–2 percent of total research dollars, to determine potential environmental health and safety (EHS) risks of nanomaterials. In 2008, a National Research Council report joined many unofficial critiques of the NNI EHS risk research plan. Following reauthorization of the NNI in 2009, in January, Senators Mark Pryor (D-AR) and Benjamin Cardin (D-MD) introduced the Nanotechnology Safety Act of 2010, the first bill to require a dedicated EHS program, budgeting $25 million annually for the purpose.[12]

According to a Project on Emerging Nanotechnologies (PEN) study, "As of May 2007, 47 of 50 states and the District of Columbia contained at least one of the 637 companies, 138 university and government laboratories, and 45 other types of organizations working in nanotechnology."[13] By 2010 these numbers will have increased. Minnesota is among those states whose universities and companies are developing or have developed products with nanomaterials. For example, on May 19, Medtronic and other Minnesota companies will showcase a broad array of nanotechnology applications.[14]

I have not been able to survey state legislation on nanotechnology nor state investments in nanotechnology. The PEN study outlines some state and local oversight initiatives and scenarios in which state or local may be required. Oversight of manufacture and storage of nanomaterials, air quality concerning nano-particulates, manufacturing water discharged with nanomaterials, construction with nanomaterial products, and nano-manufacturing workplace

safety are just a few areas in which states or even local governments might wish to act, particularly if federal legislation and regulation are delayed or under-appropriated.

I do not know the extent to which the State of Minnesota has planned to regulate nanotechnology products or the extent to which the state and federal agencies communicate about such regulatory planning. The Minnesota Pollution Control Agency's strategic plan for 2008 includes: "A new goal to build on the state's capacity to address emerging environmental issues, such as endocrine disrupting compounds and nanotechnology."[15] It would be helpful to know what MPCA has done and how it is planning to build its capacity to monitor and enforce any statutes that the legislature may authorize for nanotechnology. However, MPCA's historical approach to targeting resources according to its inventory of pollutants, defined in terms of volume, will likely need to change to monitor nanotechnology. The quantity of nanomaterials that may cause environmental and/or public health harm will be much smaller in volume than what MPCA has traditionally inventoried. Prioritizing when and where to monitor pollutants will be a difficult task because potential risks of nanomaterials are not indicated simply by their size but also by their configuration and shape.

To the extent that the State of Minnesota and the FDA have cooperative programs on food and food facilities inspection, responsible state agencies will want to keep informed about gaps in federal nanotechnology oversight and shortfalls in regulatory capacity. State agencies should inform the legislature periodically about their cooperation with federal agencies on the broad range of products incorporating nanomaterials, particularly in the medical device industry in which Minnesota is a global leader.

Conclusion

While state agency reporting to this committee and others with responsibilities over the environment and workplace safety will aid the legislature in assessing oversight needs, I hope that the committee will not neglect to continue to request testimony from non-governmental representatives. Let me close with a few recommendations of the Transatlantic Consumer Dialogue for regulating nanotechnology.[16] IATP is a decade-old member of the TACD, which will meet with U.S. and EU officials to discuss these recommendations and others on April 27 in Washington, DC.

First, "establish mandatory reporting schemes to keep track of the introduction into the marketplace of manufactured nanomaterials." Without product data, no effective regulation is possible. Second, "develop and adapt regulatory frameworks to address the special characteristics of nanomaterials" and provide the statutory authority to do so. Third, "develop testing methodologies adapted to nanoparticles" and apply these methodologies throughout the life cycle of products with nanomaterials. Fourth, but by no means last, "establish commissions to study the social and economic consequences of existing industries and commodities by industries based in manufactured nanoparicles." If nanotechnology and other converging technologies are to launch a new Industrial Revolution, public discussion of the consequences of such a dramatic shift will help guide public investment in socially optimal applications of nanotechnologies.

IATP wishes to thank the committee for this opportunity to share some of our views on this critical public policy, technology and business development issue.

[1] Peter Wick et al., "Barrier Capacity of Human Placenta for Nanosized Materials," *Environmental Health Perspectives*, Vol. 118: 3, March 2010, http://www.ehponline.org/members/2009/0901200/0901200.pdf.

[2] http://www.nanotechproject.org/inventories/consumer/

[3] Martin Kotynek, "Winzlinge mit grossem Gefahrenpotential," October 20, 2009 at http://www.sueddeutsche.de/wissen/347/491711/text/.

[4] "Administrator Lisa P. Jackson, Remarks at the Conference on the Future of US Chemicals Policy," October 6, 2009, http://www.ustream.tv/recorded/2293176.

[5] http://www.nanoaction.org/nanoaction/doc/CTA_nano-silver%20petition__final_5_1_08.pdf

[6] E.g. Mike Stones, "Nanoscience to boost food safety, quality and shelf life," FoodProductionDaily.com, June 8, 2009.

[7] Andrew Scheider, "Regulated or Not, Nano-Foods Coming to a Store Near You," March 24, 2010, http://www.aolnews.com/nanotech.

[8] Steve Suppan, "Import Food Safety in the Twilight of the Bush Administration," Institute for Agriculture and Trade Policy, May 2008, http://www.tradeobservatory.org/library.cfm?refID=102785.

[9] Caroline Scott Thomas, "FDA: we can handle nanotech safety," June 8, 2009, FoodNavigator.com.

[10] "FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)," General Accountability Office, GAO-10-246, February 2010 at 26–32, http:www.gao.gov.

[11] John F. Sargent Jr., "The National Nanotechnology Initiative: Overview, Reauthorization, and Appropriations Issues," Congressional Research Service, May 6, 2009, http://www.crs.gov.

[12] http://thomas.loc.gov/cgi-bin/query/z?c111:S.2942

[13] Suellen Keiner, "Room at the Bottom?: Potential State and Local Strategies for Managing the Risks of Nanotechnology," Project on Emerging Nanotechnologies, March 2008 at 12, http://www.nanotechproject.org/process/assets/files/6112/pen11_keiner.pdf.

[14] To register go to http://www.lifesciencealley.org/programs_events/detail.aspx?id=492.

[15] http://www.pca.state.mn.us/publications/reports/strategicplan.html

[16] http://tacd.org/index.php?option=com_docman&task=cat_view&gid=75&Itemid=40