INSTITUTE FOR AGRICULTURE AND TRADE POLICY

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Comment to the Federal Register on U.S. Federal Organic Agriculture Standards and Nanotechnology: The National Organic Standards Board Materials Committee Guidance Document—Engineered Nanomaterials in Organic Production, Processing and Packaging

Institute for Agriculture and Trade Policy

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The Institute for Agriculture and Trade Policy (IATP) is a nonprofit, 501.c3 nongovernmental organization, headquartered in Minneapolis, MN with offices in Washington, D.C. and Geneva, Switzerland. Our mission states, "The Institute for Agriculture and Trade Policy works locally and globally at the intersection of policy and practice to ensure fair and sustainable food, farm and trade systems." To carry out this mission concerning organic agricultural production, IATP participates in the U.S. regulatory process, as well as in international forums, such as the Codex Alimentarius Commission.

IATP is pleased to submit this comment concerning the application of a technological platform in which the U.S. Department of Agriculture, in cooperation with agribusiness and food retailing firms, is heavily invested. IATP's former president and founder, Mark Ritchie, was a member of the Organic Growers and Buyers Association and IATP participated in the development of the USDA's national organic standard. IATP's Rural Communities and Local Foods programs work with many organic agriculture producers, buyers and retail establishments. IATP is the sole shareholder of Peace Coffee, a for-profit 100-percent organically grown and fair trade coffee company.[1] Hence IATP is invested in upholding the integrity of the organic standard and organic production and marketing practices.

General Comment

The National Organic Standards Board (NOSB) Materials Committee's Guidance Document notes, "Public comment overwhelmingly agrees that nanotechnology in organic production and processing be prohibited at this time." Rather than evaluate the basis in the comments and the literature cited therein for a prohibition, the Materials Committee requests USDA's National Organic Program to hold a symposium to help determine whether any restrictions on the use of nanotechnology in organic production are "possible, practical and legal." Given the refusal of industry to submit food and agri-nanotechnology product data for risk assessment and regulatory review, it is difficult to imagine how the symposium could determine what is "possible, practical and legal." Instead, lacking specific product data, as well as a symposium designed to discuss what has been published about the environmental, safety and health effects of Engineered Nanomaterials (ENMs), the symposium would do little except to debate the Materials Committee's working definition of nanotechnology, which will have no force of law within or outside the context of the organic standard's force of law. Such a symposium would do nothing to support U.S. government research into the environmental,

health and safety (EHS) consequences of ENMs, judged by the National Research Council, to be woefully deficient.[2]

The proposed design of the symposium is not oriented toward reviewing EHS literature on agri-nanotechnology, much less towards discussing how to require industry to submit EHS data to demonstrate that its nanotechnology products are safe and wholesome for human consumption.[3] Indeed, when the United Kingdom's House of Lords proposed such a requirement, industry warned that any requirement to submit product data to regulatory review would cause nanotechnology product developers to leave the United Kingdom for more laissez-faire regulatory jurisdictions.[4] Instead of reviewing EHS research on ENMs that would justify a prohibition on ENMs in organic production, particularly in light of the ongoing industry's regulatory data submission boycott, the Materials Committee's proposed symposium would review the 20-year debate over definitional issues in nanotechnology. The symposium would ponder whether USDA has right to restrict or even prohibit use of a technology, despite industry's refusal to submit product data, even when a nanotechnology application is the result of taxpayer funding. It is not clear what such a symposium would achieve except to sow doubt over the definition and value of the federal organic standard. Does USDA wish to endanger, again, the value of the organic standard for producers, processors and consumers by letting them know that the USDA will take several years to determine whether food and agri-nanotechnology applications are legally compatible with the organic standard?

On the basis of industry's refusal to submit nanotechnology product data for regulatory review, a cynic would argue that a symposium (or 2 or 3) would only buy more time for nanotechnology promoters to figure out how to capture a share of the lucrative organic market without having to submit their products or processes to stringent risk assessment, based on a putative "substantial equivalence" between natural nanomaterials and Engineered Nanomaterials (ENMs). The General Accountability Office's review of industry self-determination of what is Generally Recognized As Safe (GRAS) under delegated Food and Drug Administration authority suggested that ENMS could enter into commerce as GRAS with no pre-market safety testing. Industry determinations of GRAS between macro and nano versions of the "same" material are but one pathway for commercialization of ENMS without regulation to continue.[5]

IATP participated in Nano-Agri 2010, a June 2010 conference co-sponsored by the United Nations Food and Agriculture Organization and the Brazilian government's agribusiness research corporation, EMBRAPA, with which USDA carries out cooperative projects in food and agri-nanotechnology.[6] Allen Reilly, chief executive officer of the Food Safety Authority of Ireland, gave a presentation that is illustrative of the many regulatory hurdles that food and agri-nanotechnology would pose to maintaining the organic standard, if ENMs were incorporated into organic foods and food ingredients. First, Reilly said that a pre-market safety assessment should be required of all foods and food packaging materials that incorporate ENMs. But assuming that such a pre-market safety assessment could be designed and made part of the regulatory review required for commercialization approval, how would relevant regulatory authorities verify that post-approval nano-food products adhered to the safety assessment requirements?

In response to Reilly's question, a Dutch government participant said that testing for the presence of ENMs in food would be difficult, to judge by the experience of a Dutch testing lab. Lab technicians had mixed ENMs in a food substance and were surprised that they could not find the just-incorporated ENMs using the electronic tunneling microscope commonly used to visualize ENMs. One participant suggested that the technicians lacked sufficient training with the microscope. Another said that the angle of the ENMs after mixing might have made it impossible for them to be visualized. In any event, verifying that the ENMS had been incorporated, to say nothing of testing

for EHS effects or claimed product benefits, is proving far more difficult than officials had expected. In view of this and other difficulties in obtaining sufficient data to do a pre-market safety assessment, the NOSB Materials Committee should consider reposing the question about whether it is "possible, practical and legal" to restrict ENMs in food to whether one of it is "possible, practical and legal" to allow them in food, whether organic or conventional.

Conclusion and recommendation

Food processing and agribusiness firms engaged in nanotechnology research, sometimes in cooperation with USDA's Agricultural Research Service, have not submitted to regulatory authorities the food and agri-nanotechnology data required to carrying out risk assessment to develop standards. It is exceedingly difficult to imagine that the proposed symposium would prompt invited company representatives to talk in detail about ENMs in food and food packaging materials, much less to prompt them to begin to submit the necessary verifiable data. Nevertheless, at an agri-nanotechnology conference in 2009, a Food and Drug Administration official confidently asserted that the FDA was capable of regulating foods and food ingredients with ENMs under current legislative authority.[7]

USDA's National Organic Program, rather than joining FDA in assuming that food and agri-nanotechnology can be regulated under current authority, should adopt a presumptive prohibition on ENMs in products that meet the organic standard. The prohibition would be maintained until and unless industry has consistently submitted sufficient peer-reviewed EHS data to enable pre-market safety assessments of the foods, food packaging materials, food ingredients and food contact surfaces incorporating ENMs. This prohibition would remain in place unless and until U.S. federal food inspection and testing laboratories verified that the requirements of pre-market safety assessments were fulfilled in commercially approved organic foods and otherwise complied with the requirements of organic standards legislation and regulation.

Finally, we are puzzled as to why the NOSB would ignore a year's worth of comments from consumers, producers and processors that "overwhelmingly" oppose allowing the incorporation of ENMs in organics. Even if industry began to submit data for risk assessments and U.S. agencies finally began to require pre-market safety testing and labeling of products with ENMs, the NOSB should consider that a food or agri-nanotechnology application that met regulatory requirements would be an organic market killer. Consider one of the USDA's joint research projects with the McDonald's Corporation: develop a biopolymer with ENMs that will allow sliced apples wrapped in the nano-biopolymer to appear to be "fresh" even after 30 days. Why would the NOSB defy "overwhelming" public comment and support the use of such a nano-biopolymer for organic products? For industrialized food, "freshness" is a technically manipulated marketing trait. For organic foods, adverse publicity about nano-enabled "freshness" would be a market killer, and all the more so since there are no published studies about whether ENMs migrate from the biopolymer into the wrapped food. Rather than serve the nanotechnology industry, the NOSB and the NOP can best serve the organic standard by affirming the reasons for banning ENMs from organic products, rather than holding a symposium to search for reasons to show that such a ban is technically or legally impossible.

IATP wishes to thank the National Organic Standards Board for the opportunity to submit this comment.

[i] http://www.iatp.org/peacecoffee.cfm

[2] "Review of Federal Strategy for Nanotechnology-Related Environmental, Health and Safety Research," National Research Council, February 2009, 44. Available at http://www.nap.edu/catalog/12559.html.

[3] It is not clear from the Materials Committee report whether it has consulted the literature that reviews studies of food and agri-nanotechnology applications, in order to frame the terms of a symposium. For example, see Maria Powell and Mathilde Colin, "Nanotechnology and food safety: potential benefits, possible risks?" CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition and Natural Resources, 2008, 3, No. 38. Available at http://www.cababstractsplus.org/cabreviews.

[4] Rory Harrington, "A measure forcing food and packaging companies to submit details of nanotechnology research to a national database could trigger an R&D exodus from the UK, the Government has warned," *Food Production Daily*, March 31, 2010.

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

[6] "Food Safety at the NanoAgri 2010 Conference," *Global Food Safety Monitor*, August 3, 2010. Abailable at at http://open.iatp.org/phplist/globalFoodSafetyMonitor.php#nanoagri.

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