



THE CENTER FOR
FOOD SAFETY



CENTER FOR FOOD SAFETY & INTERNATIONAL CENTER FOR TECHNOLOGY ASSESSMENT
660 PENNSYLVANIA AVE., SE, SUITE 302, WASHINGTON, DC 20003
(202) 547-9359 * fax (202) 547-9429
2601 MISSION STREET, SUITE 803, SAN FRANCISCO, CA 94110
(415) 826-2770 * fax (415) 826-0507
WWW.CENTERFORFOODSAFETY.ORG | WWW.ICTA.ORG

October 12, 2010

Ms. Lisa Ahramjian
Executive Director
National Organic Standards Board
USDA-AMS-TMP-NOP
1400 Independence Avenue, SW
Room 2646–So., Ag Stop 0268
Washington, DC 20250-0268

Comment on Docket: AMS–NOP–10–0068; NOP–10–08.
CC: Submitted via www.regulations.gov

**Comments on National Organic Standards Board (NOSB)
Materials Committee**

**Proposal from Materials Committee to the NOSB on Nanotechnology and
Nanomaterials for discussion October 25-28, 2010**

Introduction

We appreciate the opportunity to comment for the fourth time on an NOSB Guidance Document that considers the exclusion of nanotechnology and nanomaterials from organic. We will also present verbal testimony at the October 25-28 NOSB meeting and welcome any clarifying questions or feedback from NOSB before then to help move the Board towards recommending a final decision on the issue.

The Center for Food Safety (CFS) is a non-profit, membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and other forms of sustainable agriculture. CFS represents members throughout the country who support organic agriculture and regularly purchase organic products.¹ We have submitted 8,320 individual comments from our members who are concerned about allowing nanotechnology and nanomaterials in organic, under separate cover.

With regard to nanotechnology, CFS and its sister non-profit, the International Center for Technology Assessment (ICTA), have both worked on this issue for some time. ICTA is dedicated to providing the public with full assessments and analyses of technological impacts on society. ICTA has a specific project on nanotechnology, *NanoAction*,ⁱⁱ through which we coordinate campaigns and represent our members. ICTA has filed two ground-breaking legal petitions on the human health and environmental risks of nanotechnology on behalf of a coalition of public interest organizations, one with FDA in 2006 and one with EPA in 2008.ⁱⁱⁱ These petitions request that those agencies use their existing authorities to address the issues created by the rapid commercialization of nanomaterials in various sectors under their respective jurisdictions. These documents and their supporting administrative records provide a wealth of information on this topic that NOSB might find helpful in its process. We are heartened by some of the suggestions from the Materials Committee, but let us start with the most problematic.

I. THE PROPOSED SYMPOSIUM ON NANOTECHNOLOGY IS AN UNNECESSARY AND DANGEROUS DELAY IN PROTECTING ORGANIC INTEGRITY. EVEN IF A NANOTECHNOLOGY SYMPOSIUM IS HELD IN THE FUTURE, AN IMMEDIATE DECISION MUST BE MADE TO PROHIBIT NANOTECHNOLOGY AND NANOMATERIALS AS A CLASS.

The National Organic Standards Board (NOSB) Materials Committee recommendation on nanotechnology is, in effect, a proposal for the NOSB to impose a moratorium on making any concrete decisions with respect to the use of nanotechnologies in organic. It seems contradictory to, again, delay voting on nano, particularly given the Committees' direct acknowledgement of "overwhelming agreement within the organic industry to prohibit nanotechnology in organic production and processing," in the introductory paragraph of its Guidance Document – *Engineered Nanotechnology in Organic Production, Processing and Packaging*.

CFS disagrees with the Material's Committee recommendation to delay making a decision to prohibit nanotechnologies and nanomaterials in organic despite clear evidence that nanotech contravenes the principles of organic. This failure to act threatens the integrity of the organic standard and undermines consumer confidence in organic and the USDA organic seal. Moreover, CFS and others in the organic community believe NOSB has received more than enough scientific, policy and public input to prohibit nanotechnology now, and to not put off making a decision until an undetermined future time, when a different and less informed Board will then assume responsibility.

As is the case with genetic engineering, irradiation and sewage sludge, the public has spoken loud and clear that it does not support the use of nanotechnologies or nanomaterials in organic. CFS believes that precautionary action must be taken on nanomaterials and nanotechnologies due to the known risks to human health and environmental systems. These risks include the potential of nanoparticles to cross biological membranes, cell, tissues, and organs more readily than larger particles. Some nanomaterials may penetrate intact skin and gain access to systemic circulation. When ingested, nanomaterials may pass through the gut wall and into the blood

circulation and when inhaled, they can go from the lungs into the blood system. Once in the blood stream, nanomaterials can circulate throughout the entire body and lodge in organs and tissues including the brain, liver, heart, kidneys, spleen, bone marrow, and nervous system. Inside cells, they may interfere with normal cellular function, cause oxidative damage and even cell death. In the face of these real threats, we urge the Board to not leave open the possibility of allowing the petitioning of nanomaterials on a case-by-case basis and to specifically take that option off the table. This is more consistent with the ethos of the organic standard and the “overwhelming” demands of the organic community.

Failure to clearly and expressly prohibit nanotech undermines the credibility and authenticity of US organic products in the international marketplace. As the Board is undoubtedly aware, the UK and Canada already prohibit nanotechnology from being used in organics. The European Parliament also voted recently to recommend that the European Commission prohibit nanomaterials in *all* food, not just organic^{iv}. The USDA Organic Standard should be the world’s best and leading standard and we should not allow our government to fall behind its counterparts in other countries in taking the lead to protect organic integrity, worldwide. NOSB’s proposal to pass the buck here certainly does not fulfill that ideal or the public expectation that the U.S. organic standard is the international gold standard for organic production systems.

If NOSB votes to proceed with hosting the nano symposium to clarify what it still perceives as outstanding issues warranting further examination, then we urge the Board to ensure that the public interest community and independent scientific positions are given full and equal voice at such a meeting. The Committee recommendation is unclear regarding whether or not it supports the allowance of nanomaterials to be petitioned for inclusion on the National List of Prohibited Substances (NL) in the interim. We urge the NOSB to *not* allow petitioning of nanomaterials and, instead, to recommend that nanomaterials are explicitly prohibited and, therefore, cannot be petitioned for inclusion on the NL during the interim period prior to the symposium. Nanotechnology is antithetical to the letter and spirit of the Organic Foods Production Act (OFPA) which governs all aspects of organic production and, therefore, it must be strictly prohibited under section 205.105, without any caveats or exceptions whatsoever.

II. NANOMATERIALS SHOULD BE A PROHIBITED METHOD, NOT A SYNTHETIC THAT CAN BE PETITIONED ONTO THE NL.

We do not support allowing each and every nanomaterial to be petitioned for placement on the NL. In its proposal, the Material Committee suggests that in the future the NOSB should *potentially recommend a complete §205.105 prohibition, a §205.105 prohibition unless as provided in the NL, or a statement that these substance are synthetic and all the prohibitions regarding that policy would be in place.*

We believe that now, not sometime in the future, is the time for the NOSB to recommend a complete and clear prohibition on nanomaterials in organic food production and processing. Nanotechnology should be a prohibited method and substance for organics, just as genetic

engineering is a prohibited method and substance. Permitting nanochemicals to be petitioned for placement on the list would encourage companies to apply for exclusions to the prohibition of nano on a case-by-case basis and, fatally undermine the effectiveness of the prohibition.

Given the fact that there are now hundreds of nanochemicals in commerce, many of which are minor variations of other nanochemicals with only different particle sizes or admixture with other chemicals, allowing petitions for consideration on the NL could become a nightmare for the NOSB. It would bog down the already over-burdened Board with additional reams of paperwork, taking up valuable Board time and resources only to reach the same conclusion that nano is incompatible with organic systems of production. As we have discussed at length in our numerous comments previously submitted to the Board, proponents of the integrity of the standard would have to remain ever vigilant in challenging such pollutions of the standard. It would set up a never-ending battlefield. Eventually the public would lose confidence in the standard. Moreover, it contradicts the NOSB's own observation that the organic industry overwhelmingly opposes the use of nano in organic.

III. DEFINITION OF NANOMATERIALS

We support NOSB's proposed definition of *engineered nanomaterials* as "substances deliberately designed, engineered and produced by human activity to be in the nanoscale range (approx 1-300 nm) because of the very specific properties or compositions (e.g. shape, surface properties, or chemistry) that result only in that nanoscale." We also support excluding traditional food processing techniques from the nano definition such as milling, churning, freezing and homogenization as well as excluding naturally occurring particles at the nanoscale. Naturally-occurring nanoparticles, such as salt nanocrystals found in the ocean or carbon nanoparticles emitted from fire, are very different from nanoparticles that are deliberately engineered or manufactured. Nature makes them as nature intended, in the natural environment. These naturally-occurring nanoparticles that are neither manufactured, artificially synthesized or deliberately engineered, should be omitted from the definition of nanoparticles under the organic rules. Inadvertently created nano-sized particles are not the same as deliberately engineering nanoparticles designed to take advantage of novel properties such as increased conductivity and elasticity; greater strength, mobility, and color; and increased reactivity and toxicity.

We note that there are other definitions of nanotechnology, but believe that the 300nm range provides significant protections for human and animal health as 300m is just larger than the largest sized product that has been shown to experimentally cross animal cell walls. Please review our April 2010 comments for a longer discussion of this point. Some major authorities, including the Food and Drug Administration, are now using 1000nm as their cut off for nanomaterials.^v

IV. FOOD PACKAGING AND FOOD CONTACT SUBSTANCES NEED TO BE ORGANIC, TOO.

We support the recommendation that the NOP *work with the NOSB to determine whether enforcement of restrictions in primary packaging and food contact surfaces is possible, practical, and legal*. This is an area where a meeting hosted by the NOP for other government agencies might prove productive. Nonetheless, the NOSB should make it clear to organic food producers and processors that it supports the exclusion of nanomaterials from the packaging of organic products and the prohibition of nanomaterials coming into contact with the surfaces of organic foods during processing and storage.

The NOSB recognizes that the use of nano substances in primary food packaging and food contact substances will be a source of concern for organic consumers. Indeed, packaging and food contact surfaces are two of the major product categories related to food where nanotechnologies, especially anti-microbials like nano-silver are currently being deployed. Indeed, many of the hundreds of nano-silver products we cited in our 2008 petition to the EPA asking that untested nano-silver anti-microbials be taken off the market were used in food packaging and food contact substances.^{vi} This may be an area where the NOP needs to cooperate with other agencies, like the FDA, which regulates food contact substances, and the EPA, which regulates anti-microbial substances. However, the NOSB should insist that nanomaterials that can migrate into food should not contact organic food. Indeed, the NOP and the NOSB should be in the forefront of asking why these technologies and products known to cause health risks are being used with any food. The NOSB should help the food industry understand that these technologies may not be needed at all. Infusing plastic bags with nano-silver, so that spinach can be shipped across the continent with an undetermined shelf-life, is not what organic consumers want. Organic consumers want fresh food produced in a manner that positively supports public health and the environment. They do not want another scandal like the one associated with the use of the endocrine disruptor, BPA, which was routinely used in plastic liners of canned food and in drinking water bottles.

V. CONCLUSION

We look forward to continuing to work with the National Organic Standards Board (NOSB) as it completes its work on formulating recommendations with respect to nanotechnology and nanomaterials standards to the National Organic Program (NOP). We urge you to immediately adopt the decision that the organic sector overwhelmingly supports: a prohibition of nano to protect organic integrity, human health, the environment, and expanding organic markets. Please feel free to contact us if you have any clarifying questions or feedback prior to the upcoming NOSB meeting in Madison, WI.

Sincerely yours,

Jaydee Hanson

Policy Director, International Center for Technology Assessment, Center for Food Safety

Lisa J. Bunin, Ph.D.

Organic Policy Coordinator, Center for Food Safety

ⁱ See generally <http://www.centerforfoodsafety.org>.

ⁱⁱ See generally <http://www.nanoaction.org>

ⁱⁱⁱ <http://www.icta.org/global/actions.cfm?page=15&type=364&topic=8>

^{iviv} European Parliament, “Novel foods: MEPs vote to exclude food from cloned animals” May 5, 2010 press release

available at <http://www.europarl.europa.eu/en/pressroom/content/20100503IPR74029/>

^v In June 2010, the FDA released this definition of nanomaterials for drug and therapeutic products review: *Nanomaterial/Nanoscale Material: Any materials with at least one dimension smaller than 1,000 nm*. Available at: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ManualofPoliciesProcedures/UCM214304.pdf> pg.3.

^{vi} See list of nanosilver products provided the EPA by the International Center for Technology Assessment and other groups petitioning the EPA for the regulation of nanosilver products. Available at: http://www.nanoaction.org/nanoaction/doc/CTA%20Petition%20Appendix%20A_nano-silver_product_inventory.pdf