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Comment on Docket AMS-TM-09-0060; TM-09-07  
CC: submitted to [www.regulations.gov](http://www.regulations.gov)

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

### **Nanotechnology in Organic Production, Processing, and Packaging; September 8, 2009 Committee Recommendation**

#### **Introduction**

The Center for Food Safety (CFS) thanks NOSB for this opportunity to again comment on the issue of nanotechnology and organic standards. CFS incorporates herein our comments and testimony from the May 4-5, 2009 NOSB meeting. CFS will also provide testimony at the November 2-5, 2009 NOSB meeting. We welcome any clarifying questions or feedback from NOSB and the opportunity to provide further comments in this important area.

#### **CFS and Nanotechnology**

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 that support organic agriculture and regularly purchase organic products.<sup>i</sup>

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*,<sup>ii</sup> through which we

coordinate campaigns and represent our members. ICTA also spearheads a coalition of international non-profit organizations working on nanotechnology that in 2007 published a principles document, *Principles for the Oversight of Nanotechnologies and Nanomaterials*,<sup>iii</sup> that has now been endorsed by over 80 organizations spanning six continents and translated into five languages. ICTA has also 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.<sup>iv</sup> 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.

### **Comments**

- CFS supports the Materials Committee recommendation that nanotechnology be prohibited from the Organic Standard.

CFS supports the Committee Recommendation:

*The NOSB Materials Committee recommends the NOP amend the regulations to exclude and prohibit the use of nanotechnology and the products of nanotechnology in certified organic production, processing, handling and packaging, except as required by law.*

CFS provided significant comments to the Board in May 2009 in support of the view that nanotechnology and nanomaterials should be excluded from the standard. *See CFS Comments, Docket No. AMS-TM-09-0014, Comments on National Organic Standards Board (NOSB) Materials Committee Nanotechnology in Organic Production and Discussion Document, April 20, 2009.* Our comments, as well as many others to the Board, provided information about the converging, platform nature of nano-science, the novel properties of its materials, and the environmental, health and broader societal risks nanotechnology and nanomaterials pose. Allowing nanomaterials in organic products will erode the distinction between organic and industrial agricultural processes. Nanotechnology will further entrench industrial/chemical agriculture and industrial food as our dominant paradigm, to the detriment of public health and the environment. In short, nanotechnology is antithetical to organic principles and should be properly banned from the USDA Organic standard.

CFS applauds the Committee for recognizing that the public is overwhelmingly in favor of banning nanotech from organic. Consumers buying organic products do not expect or want them to contain novel engineered nanomaterials, as shown by public comments previously received by the NOSB. We are certain that the public comments on, before, and at the November 2009 NOSB meeting will reiterate this position. As the substantial feedback illustrates, permitting nanotechnology in any form would greatly erode consumer confidence in the integrity of the organic standard.

- CFS supports the Committee recommendation for a definition of nanotechnology with slight revisions.

CFS supports the definition proposed by the Materials Committee in general. The one exception is that the size scale should be increased from approximately 1-100 nanometer range to 1-300nm range, because there is growing international recognition that some particles greater than 100nm exhibit similar anatomical and physiological behavior. Novel, size-dependent behavior seen in particles which measure a few hundred nanometers includes very high reactivity, bioactivity and bioavailability, increased influence of particle surface effects and strong particle surface adhesion.<sup>v</sup>

Moreover, the standard should consider any material to be “nano” if any dimension of the material is engineered to be less than 300nm, even if it later agglomerates. This is due to the fact that the surface area of the agglomerate would still be vastly larger than traditional bulk substances as a result of the surface area of the nanomaterials clustered together.

- CFS supports the Committee’s recognition that “the development and use of nanotechnology creates unique safety and regulatory questions because nanoparticles have the potential to behave differently than larger sized materials.” However, CFS urges the Board also to formally recognize that nanomaterials’ fundamentally different properties cannot be predicted from larger materials or testing based on larger materials.

The Committee properly recognizes that nanotechnology and its materials raise unique safety and regulatory questions because of their propensity to act different than larger materials. However, the Board’s recommendation should go further and clarify that, crucially, these different characteristics and their associated risks cannot be predicted from the behavior of the same material in bulk form. Scientists are just beginning to understand the toxicity of nanomaterials. The biological activity of nanoparticles is likely to depend on physicochemical characteristics that are not routinely considered in toxicity screening studies.<sup>vi</sup> There are many more factors affecting the toxicological potential of nanoscale materials, up to at least sixteen in fact, including: size, surface area, surface charge, solubility, shape or physical dimensions, surface coatings, chemical composition, and aggregation potential -- a far cry from the two or three usually measured. CFS provided a plethora of scientific evidence and citation in support of this position in its previous comments. See CFS Comments, Docket No. AMS-TM-09-0014, *Comments on National Organic Standards Board (NOSB) Materials Committee Nanotechnology in Organic Production and Discussion Document*, April 20, 2009, at pp. 4-5 and accompanying footnotes.

- CFS strongly opposes the minority opinion position and requests that it be stricken from the record. Classifying nanotech materials as synthetics is a bad policy idea belied by sound science that will fail to protect organic integrity and create unnecessary administrative burdens on the NOP.

Classifying nanotech materials as “synthetic” as the minority opinion recommends is a dangerous idea that creates a future scenario where, as nanomaterial food and food packaging products become more and more prevalent, their proponents petition for inclusion on the National List. Because nanotechnology, like genetic engineering, animal cloning, irradiation, and sewage sludge, is antithetical to the organic standard, every single nano-food and nano-food packaging ingredient would require an individual petitioning battle, a significant foreseeable drain on administrative and community resources. It would be the same as if each type of genetically engineered (GE) crop that USDA has approved over the past decade had been classified “synthetic” and its proponents would have petitioned to be considered organic. Consequently the integrity of the standard would be in constant jeopardy and organic advocates would have to remain forever vigilant. The only way to protect Organic is by prohibiting nanotechnology as a class because it is antithetical to the principles and purpose of the Organic Standard.

- The minority opinion’s errs in conflating natural and manufactured/engineered nanomaterials.

The Minority Opinion erroneously argues that natural nanoparticles, present in homogenization for example, can “evolve” into nanotechnology. In truth, natural nanoparticles are very different from nanoparticles that are engineered or manufactured. Nature produces some nanoparticles, like salt nanocrystals found in ocean air or carbon nanoparticles emitted from fire. However, it is only recently that scientists have developed the techniques for synthesizing and characterizing many new materials with at least one dimension on the nanoscale. The process of homogenization produces nano-sized globules of fat as a coincidental byproduct, but the purpose is not to nano-size them, but rather to stabilize them. It becomes nanotechnology when you manufacture or engineer a material at the nanoscale in order to use the new properties that come from the nanoscale.

To be sure, nanomaterials now in development and manufacture are different from anything that exists in nature: the very reason that nanotechnology is hyped so heavily is because it allows people to create products that do things that natural substances cannot. These new manufactured and engineered nanoparticles, the very building blocks of these new technologies, are patented for their novelty. Accordingly, the assessment of environmental and human health risks associated with nanomaterials is largely regarding the new materials that are being so formed and generated, the increased exposure levels from engineered nanostructures now being manufactured and marketed in greater and greater quantities, and the new routes/scenarios by which human and environmental exposure can occur with the current and anticipated nanomaterial applications. The processes and materials in question are contrary to the standard and organic principles; the issue cannot “evolve” beyond that crucial fact. Any hopes to the contrary are belied by sound science and contrary to sound policy.

- The minority opinion errs in assuming nanotechnology will offer future benefits to organic. Any purported benefits are irrelevant if, as here, the means is antithetical to organic.

It is always difficult to separate the hype from the reality with new technologies. For more than twenty years, genetically engineered crop manufacturers have promised to feed the world with GE crop technology; yet, the reality is that the vast majority of GE crops are merely herbicide-resistant crops, increasing herbicide sales for the manufacturers but doing nothing to help solve world hunger.<sup>vii</sup> Similarly, the current uses of nanomaterials in consumer products are overwhelmingly mundane and marketing-based: “cosmetically clear” sunscreens, stain-resistant pants, etc.. Assumptions based on unsubstantiated hype should not be used to greenwash and the Board should not assume that nanotechnology might provide any future benefit to organics.

Further and most relevantly, nanotechnology is an industrial engineering process for design and manipulation of nature at its most fundamental components, a technology that is antithetical to organic principles and standards. Accordingly, just as with other production systems contrary to organic (e.g., pesticides, genetic engineering, cloning) it is irrelevant whether or not it might bring some purported predicted or promised benefit.

- The minority opinion should be stricken from the record and not included in NOSB’s recommendation because it is based on erroneous assumptions and would unnecessarily cause administrative burdens on the agency and community, to the continued danger of the organic standard’s integrity.

Because the minority opinion is based on a faulty premise that presents a bad policy option to USDA that would indefinitely endanger the organic standard, CFS respectfully requests it be stricken from the record. As noted above, the basis assumption of the minority opinion – that there will be some versions or manifestations of nanotechnology that might be considered organic and that therefore we should classify nanomaterials as a synthetics so it will be easier to have said materials be considered organic – is without merit. Natural nanomaterials are simply different than those intentionally manufactured or engineered. Any purported benefits from a methodology that is antithetical to organic should not be used to justify that system’s allowance in organic. The minority opinion undercuts its own position when it asks how the Board will discern why some types of nanotechnology are “compatible” with the standard and other types are not. The only answer supported by sound science and good policy is to maintain the integrity of the organic standard and expectations of organic consumers and prohibit all manifestations of the technology.

The minority opinion’s concern about future adoption based on some unknown, yet to be discovered nanotech method that is compatible with organic, could of course be addressed in a future rule-making. Just because the Board will recommend that nanotech be excluded as is genetic engineering and irradiation and pesticides does not mean those decisions cannot be revised at some future point. The minority opinion admits as much but worries that such a rule-making would then be seen as weakening of the organic standards. But this proves too much: such a rule-making would be *seen* as a weakening of the standards because it *would* be a weakening of the standards. This rationale is all the more reason to have a full public notice and comment rather than to allow the use of the synthetic petitioning process.

- CFS urges the Board to formally recognize the many potential health, environmental, and broader societal risks of nanotechnology not discussed in the Committee's report.

The Committee's report properly notes some of the changes that can occur to materials manufactured or engineered to the nano-scale, including changes in absorption, the ability to move within the body, increased occupational exposure to workers, increased risk to the environment via multiple pathways, and decreased rates of biodegradation. The Committee report also notes that these changes create unique safety and regulatory questions, but does not elaborate on these risks. CFS urges the Board to formally recognize the significant risks that nanotechnology presents. Some of these risks are summarized below. The risks summarized below are discussed in more detail in CFS's previous comments (and citations). *See CFS Comments, Docket No. AMS-TM-09-0014, Comments on National Organic Standards Board (NOSB) Materials Committee Nanotechnology in Organic Production and Discussion Document, April 20, 2009.*

*Human and Animal Health:* Due to their size, nanoparticles can cross biological membranes, cells, tissues, and organs more readily than larger particles.<sup>viii</sup> When inhaled, they can pass through the lungs into the bloodstream.<sup>ix</sup> There is growing evidence that some nanomaterials may penetrate intact skin and gain access to systemic circulation.<sup>x</sup> When ingested, nanomaterials may pass through the gut wall and into the bloodstream.<sup>xi</sup> Once in the blood stream, nanomaterials can circulate throughout the body and can lodge in organs and tissues including the brain, liver, heart, kidneys, spleen, bone marrow, and nervous system.<sup>xii</sup> Once inside cells, they may interfere with normal cellular function, cause oxidative damage, and even cell death.<sup>xiii</sup>

*Environmental Impacts:* There are serious concerns about environmental impacts that conflict with organic's land stewardship ethos. Once loose in nature, manufactured nanomaterials represent a new class of manufactured pollutants that we currently lack means to detect, measure, and remove.<sup>xiv</sup> Potentially damaging environmental impacts stem from the novel nature of manufactured nanomaterials, including mobility and persistence in soil, water and air, bioaccumulation, and unanticipated interactions with chemical and biological materials.<sup>xv</sup> Existing studies have raised red flags, such as damage to beneficial microorganisms from nanosilver, which is used in many food packaging products.<sup>xvi</sup> The U.K. Royal Society has recommended that, "the release of nanoparticles and nanotubes in the environment be avoided as far as possible" and that, "factories and research laboratories treat manufactured nanoparticles and nanotubes as hazardous, and seek to reduce or remove them from waste streams."<sup>xvii</sup>

*Broader Impacts:* In addition to health and environmental impacts, nanotechnology is a platform, converging technology which will continue to industrialize food and agricultural production.<sup>xviii</sup> Some of these issues include: the use of nanotechnology in conjunction with biotechnology and synthetic biology;<sup>xix</sup> the use of nanomaterials in food packaging to increase shelf life and transportation distance, exacerbating climate change impacts and contrary to organic principles of small-scale and local farming;<sup>xx</sup> and the intellectual property privatization of nanotechnology's (and therefore nature's) basic building blocks.<sup>xxi</sup>

CFS thanks the Board for this opportunity to provide comment and welcomes any further questions on this matter.

Respectfully submitted,

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

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

<sup>iii</sup> <http://nanoaction.org/nanoaction/doc/nano-02-18-08.pdf>

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

<sup>v</sup> Garnett M, Kallinteri P. 2006. Nanomedicines and nanotoxicology: some physiological principles. *Occup Med* 56:307-311; Wang B, Feng W-Y, Wang T-C, Jia G, Wang M, Shi J-W, Zhang F, Zhao Y-L, Chai Z-F. 2006. Acute toxicity of nano- and micro-scale zinc powder in healthy adult mice. *Toxicol Lett* 161:115–123; Ashwood P, Thompson R, Powell J. 2007. Fine particles that adsorb lipopolysaccharide via bridging calcium cations may mimic bacterial pathogenicity towards cells. *Exp Biol Med* 232(1):107-117.

<sup>vi</sup> See, e.g., European Commission (EC), Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Opinion on the Appropriateness of Existing Methodologies to Assess the Potential Risks Associated with Engineered and Adventitious Products of Nanotechnologies (Adopted September 28-29, 2005), at 6, 32, *available*

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at <[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihp/docs/scenihp\\_o\\_003.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihp/docs/scenihp_o_003.pdf)> (last visited June 1, 2009); A. Maynard, "Nanotechnology: The Next Big Thing, or Much Ado about Nothing?" *Annals of Occupational Hygiene* 51, no. 1 (2006): 1-12, at 7; G. Oberdorster et al., "Principles for Characterizing the Potential Human Health Effects from Exposure to Nanomaterials: Elements of a Screening Strategy," *Particle and Fibre Toxicology* 2, no. 8 (2005), available at <<http://www.particleandfibretoxicology.com/content/pdf/1743-8977-2-8.pdf>> (last visited June 1, 2009); A. Nel et al., "Toxic Potential of Materials at the Nanolevel," *Science* 311, no. 5761 (2006): 622-627; G. Oberdorster et al., *supra* note 40; A. Maynard et al., "Safe Handling of Nanotechnology" *Nature* 444, no. 7117 (2006): 267-269.

<sup>vii</sup> Friends of the Earth, International. *Who Benefits from GM Crops? Feeding the biotech giants, not the world's poor*. February 2009, Issue 116.

<sup>viii</sup> See, e.g., Holsapple et al., Research Strategies for Safety Evaluation of Nanomaterials, Part II: Toxicological and Safety Evaluation of Nanomaterials, Current Challenges and Data Needs, 88 *Toxicological Sciences* 12 (2005).

<sup>ix</sup> *Id.* at 829, 837.

<sup>x</sup> Monteiro-Riviere N. et al., Penetration of Intact Skin by Quantum Dots with Diverse Physicochemical Properties, 91 *Toxicological Sciences* 159 (2006); Rouse J et al., Effects of Mechanical Flexion on the Penetration of Fullerene Amino Acid-Derivatized Peptide Nanoparticles through Skin, 7(1) *Nano Letters* 155 (2007); Monteiro-Riviere N. et al., Skin Penetration of Fullerene Substituted Amino Acids and their Interactions with Human Epidermal Keratinocytes, 827 *The Toxicologist* 168 (2006); Rouse J. et al., Effects of Mechanical Flexion on the Penetration of Fullerene Amino Acid-Derivatized Peptide Nanoparticles through Skin, 7(1) *Nano Letters* 155 (2007).

<sup>xi</sup> Florence A. et al., Transcytosis of Nanoparticle and Dendrimers Delivery Systems: Evolving Vistas, 50 *Adv Drug Deliv Rev* S69 (2001); Hussain N. et al., Recent Advances in the Understanding of Uptake of Microparticulates Across the Gastrointestinal Lymphatics, 50 *Adv Drug Deliv Rev* 107 (2001); Hillyer J. F. et al., Gastrointestinal persorption and tissue distribution of differently sized colloidal gold nanoparticles, 90 *J Pharm Sci* 1927-1936 (2001).

<sup>xii</sup> See, e.g., Oberdörster et al., Nanotoxicology: An Emerging Discipline From Studies of Ultrafine Particles, 113 *Environmental Health Perspectives* 823-839 (2005).

<sup>xiii</sup> Borm PJ, Kreyling, W, Toxicological hazards of inhaled nanoparticles--potential implications for drug delivery, 4 *J Nanosci Nanotechnol* 521-531 (2004).

<sup>xiv</sup> European Commission (EC), *Nanosciences and Nanotechnologies: An Action Plan for Europe 2005-2009: First Implementation Report 2005-2007* (2007), at 9, available at <[ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/com\\_2007\\_0505\\_f\\_en.pdf](http://ftp.cordis.europa.eu/pub/nanotechnology/docs/com_2007_0505_f_en.pdf)> (last visited June 1, 2009) ("Because of uncertainties, the current risk assessment procedures require modification for nanoparticles. Knowledge gaps have been confirmed in areas such as nanoparticle characterization, detection and measurement; their fate and persistence in humans and the environment; and all aspects of the associated toxicology and ecotoxicology. These should be addressed to allow satisfactory risk assessments for humans and ecosystems.").

<sup>xv</sup> See generally EPA, *Draft Nanomaterial Research Strategy*, at 23 (Jan. 24, 2008), available at [http://es.epa.gov/ncer/nano/publications/nano\\_strategy\\_012408.pdf](http://es.epa.gov/ncer/nano/publications/nano_strategy_012408.pdf).

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<sup>xvi</sup> See generally ICTA nano-silver petition to EPA, [http://icta.org/nanoaction/doc/CTA\\_nano-silver%20petition\\_final\\_5\\_1\\_08.pdf](http://icta.org/nanoaction/doc/CTA_nano-silver%20petition_final_5_1_08.pdf) ; S. Luoma, *Silver Nanotechnologies and the Environment: Old Problems or New Challenges?* (Washington, DC: Project on Emerging Technologies, 2008), available at [http://www.nanotechproject.org/process/assets/files/7036/nano\\_pen\\_15\\_final.pdf](http://www.nanotechproject.org/process/assets/files/7036/nano_pen_15_final.pdf) (last visited June 1, 2009); C. Baker et al., "Synthesis and Antibacterial Properties of Silver Nanoparticles," *Journal of Nanoscience and Nanotechnology* 5, no. 2 (2005): 244-249.

<sup>xvii</sup> The Royal Society and the Royal Academy of Engineering, *Nanoscience and nanotechnologies: Opportunities and uncertainties*, London, 2004.

<sup>xviii</sup> [http://www.foe.org/pdf/nano\\_food.pdf](http://www.foe.org/pdf/nano_food.pdf)

<sup>xix</sup> [http://www.etcgroup.org/en/materials/publications.html?pub\\_id=171](http://www.etcgroup.org/en/materials/publications.html?pub_id=171) ;

<sup>xx</sup> [http://www.etcgroup.org/en/materials/publications.html?pub\\_id=80](http://www.etcgroup.org/en/materials/publications.html?pub_id=80) ;  
[http://www.etcgroup.org/en/materials/publications.html?pub\\_id=45](http://www.etcgroup.org/en/materials/publications.html?pub_id=45)

<sup>xxi</sup> [http://www.etcgroup.org/en/materials/publications.html?pub\\_id=53](http://www.etcgroup.org/en/materials/publications.html?pub_id=53) ;  
[http://www.etcgroup.org/en/materials/publications.html?pub\\_id=54](http://www.etcgroup.org/en/materials/publications.html?pub_id=54)