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Comments on National Organic Standards Board (NOSB)

Materials Committee

Classifying Engineered Nanotech Materials as “Synthetic” and Prohibiting Nanotechnologies and Materials in Organic¹

CFS/ICTA 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.

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

¹CFS and ICTA have twice submitted comments to NOSB regarding nanotechnology. *See* CFS/ICTA comments of April 2009 and November 2009. These comments are intended to supplement and expound on our earlier comments. These comments should not be interpreted to in supersede or supplant our previous comments in any way.

on society. ICTA has a specific project on nanotechnology, *Nano.Action*,² 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*,³ 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 2008.⁴ These petitions request 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 would assist NOSB in its process.

Summary

CFS/ICTA thanks the Board for this further opportunity to comment on this important topic. Below we supplement our previous spring and fall 2009 comments to the Board on the definition of nanotechnology and engineered nanomaterial. The bounds and terminology are important, but establishing such a definition need not be an insurmountable roadblock to addressing this issue. We applaud Committee's efforts and offer some suggestions below.

Once a definition is crafted, engineered nanomaterials should be prohibited in a manner that will protect the Standard. While we believe engineered nanomaterials are properly classified as synthetic materials, that classification alone is not enough. And, a much more proper fit is to simply classify engineered nanomaterials as an excluded substance and/or method, like sewage sludge, irradiation, genetic engineering, cloned animals and their offspring. Only such a recommendation would properly account for the nature of nanotechnology and engineered nanomaterials and adequately protect the Organic Standard.

Nanotechnology Should Be Prohibited From Organic Agriculture

Nanotechnology, like genetic engineering, irradiation, cloning of animals and sewage sludge, is antithetical to the intent and letter of organic law and the rules governing organic practices. We have previously submitted comments and numerous references in support of that conclusion. *See generally* CFS-ICTA comments 2009 (attached here). It is an industrial engineering process *intended* to engineer and manipulate nature at its most fundamental level. The platform technology allows industry to create or synthesize products that can behave in ways that naturally occurring substances simply cannot. The intent of nanotechnology is to manufacture or engineer a material at the nanoscale in order to use the new properties that emanate from the nanoscale, such as increased surface area, solubility, size, charge, physical

² www.nanoaction.org

³ <http://www.nanoaction.org/nanoaction/page.cfm?id=223>

⁴ <http://www.nanoaction.org/nanoaction/page.cfm?id=244>

dimensions, etc. To that end, it matters not whether the original bulk material comes from a natural source because, once nanotechnology is applied, the chemical and physical changes that result render it a non-agricultural, synthetic material.

Today's engineered nanomaterials and nanoparticles and those in development are different from anything that exists in nature, which is the precise reason why nanotechnology is promoted so heavily by industry. While proponents of nanotechnology may claim that their new products are "just the same" to a regulatory body, they also claim that they are entirely new materials with novel properties in order to secure patents.⁵ 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 has intended in the natural environment. As naturally occurring, and not manufactured, artificially synthesized or deliberately engineered, these natural nanoparticles could be omitted from the definition of nanoparticles or nanomaterials that should be prohibited under the Organic Rules.

Accordingly, the Board could choose to define and prohibit as excluded either the "method" of nanotechnology, like irradiation, or the engineered nanomaterial substances themselves, like sewage sludge, or both.

Section 2118 of the Organic Foods Production Act (OFPA) outlines the standard that must be met in order for a synthetic substance to be included on the National List ((NL). *See* 7 USC 6517. That standard includes, *inter alia*: "that the use of such substances (i) would not be harmful to human health or the environment, (ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products, (iii) is consistent with organic farming and handling." *Id.* at 6517(c)(1)(A). Nanotechnologies and materials as a class fail to meet this standard and, therefore, they should be prohibited now and in the future.

That said, if nanomaterials are classified as "synthetic" without a prohibition as an excluded substance and/or excluded method, every single nano-food and nano-food packaging ingredient would be allowed to be petitioned for inclusion on the NL. This would be equivalent to a future scenario in which each genetically engineered (GE) crop that USDA had approved over the past decade had been classified as "synthetic" and its proponents routinely petitioned for each new GE crop to be considered organic. Such petitions should (and hopefully would) be denied because the production of GE seeds and crops fundamentally contravene the intent and express language of OFPA. Even so, the integrity of the standard would be in constant jeopardy and/or question, and organic advocates would have to remain forever vigilant to ensure no one with an economic interest in promoting GE slipped a transgenic crop onto the NL. The only way to protect the integrity of Organic is to prohibit nanotechnology and/or engineered nanomaterials as a class because it is antithetical to the principles and purpose of the Organic Standard.

The assumption that there *may* be some type of nanotechnology application that *may* have a heretofore discovered potential to be considered organic in the future should not be the

⁵ Nearly 4400 nano patents were granted in the US alone in 2009; three times the number granted in 2006. See <http://nanopatentsandinnovations.blogspot.com/2010/01/2009-record-year-for-nanotechnology.html>

basis for setting organic policy. As such, retaining the possibility for nanomaterials to be added to the NL *just in case* some future promise might be fulfilled is without merit, and it would be an irresponsible public policy to leave open the door for nanotechnology on that basis. There is always a difference between hype and promise with new technologies. Again, biotech crops provide a recent example. Monsanto and others have promised to feed the world, increase yields, and most recently, ameliorate the impacts of global warming. Instead, in the fifteen years since their introduction, these companies have only created crops that increase pesticide use, in order to sell more of their flagship products, at the expense of farmers, consumers and the environment.

At this moment, there exists sufficient evidence to prohibit the use of nanotechnology by taking precautionary action because the platform technology intentionally manufactures or engineers synthetic substances.

The Size and Structure of Nanomaterials

We propose the following amendments to NOSB's draft definition of nanomaterials:

Technologies and the results of those technologies that intend to:

- a) create and use particles, fibers, plates, structures, devices and systems that have novel properties and functions because of their small size,
- b) maintain the ability to control or manipulate matter on the atomic or molecular or macromolecular scale, and
- c) research and develop technologies at a scale that is typically in the range of 1 to 300nm.

All nanoparticles and structures which have at least one dimension in the nanoscale range of *1 to 300nm* shall be considered synthetic and nonagricultural and excluded from organic agriculture. Such nanoparticles do not qualify as processing aids, adjuvant excipients, solvents or other inert or minor ingredient substances for the purpose of this chapter, even when present in insignificant amounts in the final product.

This prohibition does not include naturally occurring nanomaterials such, as sea salt, or nanomaterials that form during traditional food manufacturing and processing, such as homogenization, cheese making, and grain milling.

While we recognize that there is a variety of opinions exist regarding the size of nanomaterials, CFS recommends that the NOSB adopt 300nm as an approximate upper limit because most of the properties that make a substance “nano” occur below 300nm.

The Canadian definition of nanotechnology, for example, states “Nanotechnology is a field described generally as the control and structuring of matter at dimensions typically between

1 and 100 nanometres”⁶ The UK Soil Association definition of prohibited nanomaterials states: “Licensees must not use ingredients containing manufactured nanoparticles, where: the mean particle size is 200nm or smaller, and the minimum particle size is 125nm or smaller.”⁷

Yet since the UK and the Canadian standards were developed, it has become evident that many of the “nano” properties of concern begin to occur at sizes larger than the standard 1-100 nanometers cited as typical of ‘nano’ by many definitions. The ISO standard, issued in 2008, makes clear that while its definition of “nanoscale” is “approximately 1nm to 100nm” that “Properties...will typically, but not exclusively be exhibited in this size range. For such properties the size limits are considered approximate.”⁸

The 300nm threshold includes many nanotechnology processes already being used in the food packaging materials by companies such as Sono-tek.⁹ Its website advertises that its nano materials and nano-nutriceuticals can be sprayed onto bread and other bakery products.¹⁰ These sprays are said to be in the range of 200-300nm. Nano rods, nano fibers, and nanoplates are also encompassed in the size definition for nano as it is their nano

⁶ See Canadian Organic Standards:

1.4.1 When producing or handling organic products, it is forbidden to use any of the following substances or techniques:

1.4.1.1 intentionally manufactured nano-technology products, or nano-processes involving intentional manipulation of matter at the nano scale to achieve new properties or functions that are different than properties and functions of the materials at the macro scale, except naturally occurring nano sized particles, or those produced incidentally through normal processes such as grinding flour, or nano sized particles used in a way that guarantees no transference to product.

Nanotechnology

Nanotechnology is a field described generally as the control and structuring of matter at dimensions typically between 1 and 100 nanometres to create materials, devices, and systems with fundamentally new properties and functions. Nanoscale chemical substances, or nanomaterials, behave differently from their macroscale counterparts, exhibiting different mechanical, optical, magnetic, and electronic properties.

⁷ UK Soil Association’s Consumer guide to its nanotechnology standard is available at:

<http://92.52.112.178/web/sa/saweb.nsf/ed0930aa86103d8380256aa70054918d/444ed4dee8649ee18025739c003d0a49?OpenDocument>

⁸ See International Organization for Standardization, ISO/TS 27687 “Nanotechnologies-Terminology and definitions for nano-objects—nanoparticle, nanofibre and nanoplate” at p. 1. Note that a review of this terminology is also currently underway.

⁹ See Andrew Schneider, *Nanotechnology bringing food regulated or not to a grocery near you*, AOL News, March 25, 2010 at <http://www.aolnews.com/nation/article/nanotechnology-bringing-foods-regulated-or-not-to-grocery-near-you/19401246>

¹⁰ The food video on the company’s website, now located in the “industrial”, not nano section of the website, but if you watch it to the end, you will see that it is marketed as “nano” and “micro”. If the company is using its machines to spray in the nano range, there are potential problems for both workers breathing the spray and customers eating the products covered with the nano sprays. http://www.sono-tek.com/nanotechnology/subcategory/video_library

dimension in one dimension that makes use of their nano properties. Moreover, some nanomaterials like carbon nanotubes have been shown to be more toxic as they lengthen.¹¹

We also now know that many of the ‘nano’ changes, such as the ability to cross cell walls occur at sizes larger than 100nm, a size used in many of the definitions of nanotechnologies. Although the Clean Air Act puts limits on small particles beginning at 2.5 microns, or 2500nm, much larger than the proposed nano standard, existing research shows that such particles behave markedly different than the bulk materials from which they are derived. Still, we believe that for nanoparticles used in food 300nm is a reasonable precaution for the purposes of defining for the organic rule.

We have included two studies in attachments to our remarks to illustrate that the nano properties of most concern go up to about 300nm. One study, published in Environmental Health Perspectives this year, demonstrates that nano-polystyrene could cross the placental barrier at 240nm.¹² A 2006 study by Dr. Warheit and others found that marked ‘nano’ properties of nano titanium dioxide remained even at 300nm.¹³

Techniques

As mentioned previously, naturally occurring nanomaterials such as sea salt and nanomaterials that form during traditional food manufacturing and processing such as homogenization, cheese making, and grain milling should be excluded from the definition of nanoparticles or nanomaterials under the Organic Rule.

Intent and Control:

The definition of nanomaterials and particles and the basis for its prohibition pivots on two factors:

1. its non-agricultural synthetic nature
2. the fact that they are intentionally engineered or manufactured.

The NOSB definition of nanomaterials need not rest on the ability to detect nanomaterials through techniques such as electron microscopes or other metrological devices, as suggested

¹¹ See Craig A. Poland, Rodger Duffin, Ian Kinloch, Andrew Maynard, William A. H. Wallace, Anthony Seaton, Vicki Stone, Simon Brown, William MacNee, Ken Donaldson [Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study](#). Nature Nanotechnology 3, 423-428 (20 May 2008) doi:10.1038/nnano.2008.111 Letter

¹² Wick P, Malek A, Manser P, Meili D, Maeder-Althaus X, Diener L, et al. 2010. Barrier Capacity of Human Placenta for Nanosized Materials. Environ Health Perspect 118:432-436. doi:10.1289/ehp.0901200

¹³ Warheit DB; Webb TR; Sayes CM; Colvin VL; Reed KL. 2006. Pulmonary instillation studies with nanoscale TiO2 rods and dots in rats: Toxicity is not dependent upon particle size and surface area. Toxicol Sci 91: 227-236.

in the request for comments. The NOSB can best address this concern by making nanotechnology a prohibited method.

Advancements in the fields of nanomaterial detection will, however, in the future be a likely means of discovering mislabeled organic products when nanomaterials are excluded from organics. At present, the Food and Drug Administration is purchasing electron microscopes so that it need not rely on the Air Force laboratories to do its research in this area.

Unique Properties

The Board must be clear that the unique characteristics of nanomaterials and their associated risks cannot be predicted from the behavior of the same material in bulk form. *See generally* CFS-ICTA comments, 2009. Scientists are just beginning to understand the toxicity of nanomaterials, and this is reason enough for the NOSB to take precautionary action to prohibit their use in organic. Moreover, the biological activity of nanoparticles and their associated degree of harm to human health and the environment is likely to depend on physicochemical characteristics that are not routinely considered in toxicity screening studies. In fact, there are as many as sixteen or more factors affecting the toxicological potential of nanoscale materials -- a far cry from the two or three usually measured. These include, among others:

- chemical changes and composition
- size
- surface area
- surface charge
- solubility
- shape or physical dimensions
- surface coatings
- malleability
- agglomeration and aggregation potential.

CFS previously provided a large body of scientific evidence and citations 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. ICTA's 2008 petition to EPA also includes a body of relevant materials regarding this. (Petition also attached).

The Office of Research and Development (ORD) of the EPA has recently begun a series of studies on the research gaps related to the major nanotechnologies. ORD is focusing its research on seven manufactured nanomaterial types: single-walled carbon nanotubes, multi-walled carbon nanotubes, fullerenes, cerium oxide, silver, titanium dioxide, zero-valent iron. The ORD's goal is to develop predictive models and tools that will enable testing across these material types, given the fact that testing the many potential variations of materials

within each of these seven material types would be very resource intensive. Next month, ORD plans to complete the first, a study of nano-titanium dioxide.¹⁴

One of the most troubling papers on unique properties of nano-titanium dioxide raises key questions for nanomaterials in food but, unfortunately, it was not included in the EPA review because it had not been published. The study by UCLA researchers found that when mice ingested nano titanium dioxide they developed mutations in their DNA that caused cancer in the mice and their offspring.¹⁵

EPA's Office of Prevention, Pesticides and Toxics Substances recently convened a Scientific Advisory panel (SAP)¹⁶ on nano-silver to assess how to regulate nano-silver used in many food contact containers and plastic wraps. The SAP's review of nano-silver is in mostly supportive of the concerns presented by ICTA and a dozen partner groups¹⁷ raised in a petition¹⁸ to the EPA. The SAP specifically supports two of the main points of our six point petition—that EPA should: 1) require a full assessment of the environmental and health effects of nano-silver and, 2) require submission of nano specific data on nano-silver being used as a pesticide. The SAP review emphasizes the need for EPA to compile more and better data before allowing nano-silver pesticidal products on the market. It also makes clear that the argument about the similarity of nano-silver to bulk silver is simply untrue and that research exists to credibly counter that argument.

Industrial proponents of nano-silver often have claimed that when nano-silver agglomerates it is especially like bulk silver. The SAP review cites data that show the increased surface area of nano-silver agglomerates means that we should now even consider larger collections of nano-particles up to 1000 nanometers to have nano properties. This means that the phenomenal surface area of these agglomerates from the myriad indentions makes them behave more like the smaller nano form that they agglomerated from and not like solid particles of a comparable diameter. The SAP review also raises especially troubling questions about the very smallest nano-silver particles as they can most easily enter cell walls.

A coalition of groups has repeatedly requested that EPA remove these products from the market until the Agency identifies adequate methods for assessing the lifecycle effects of nano-silver and other nano-metals, and they are able to adequately test the toxicity of these nano-pesticides.

¹⁴ See External Review Draft of Nanotitanium Dioxide Case Studies available at:

oaspub.epa.gov/eims/eimscomm.getfile?p_download_id=490825

¹⁵ Trouiller B, Reliene R, Westbrook A, Solaimani P, and Schiestl R. Titanium Dioxide Nanoparticles Induce DNA Damage and Genetic Instability in vivo in Mice. *Cancer Res* 2009; 69: (22). November 15, 2009

¹⁶ See <http://www.epa.gov/scipoly/sap/meetings/2009/november/110309ameetingminutes.pdf>

¹⁷ The petitioning groups are: International Center for Technology Assessment, the Center for Food Safety, Beyond Pesticides, Friends of the Earth, Greenpeace, ETC Group, Center for Environmental Health, Silicon Valley Toxics Coalition, Institute for Agriculture and Trade Policy, Clean Production Action, Food and Water Watch, the Loka Institute, the Center for Study of Responsive Law, and Consumers Union.

¹⁸ The petition and all accompanying documents (including all scientific references) is available at <http://www.nanoaction.org/nanoaction/page.cfm?id=244>

Synthetic Classification

Nanotechnologies are “synthetic” in that they engineer materials to take advantage of their properties at the nanoscale. By engineering an element, mineral or a chemical compound at the nanoscale profound changes in the way the new nanomaterial’s functions can arise. Unlike synthetic chemistry in which the chemistry of a chemical is engineered to be different from that occurring in nature and a new chemical is formed, nanotechnological engineering can change both synthetic chemicals and “natural” minerals, metals, chemicals into a substance that is essentially a new synthetic because of scale, not chemical engineering.

The chemical reactions of a nanoscale material can change from that of the bulk substance from which it is derived, but the “chemistry” of the chemical is not necessarily altered. It is the *new properties* that make up the “synthetic” nature of nano-chemicals. These new property changes can be even more striking than those created through the application of traditional “synthetic chemistry.” Safe chemicals at the bulk scale can become dangerous at the nanoscale. The huge increase in surface area alone in a nanoscale chemical makes it much more highly reactive than the bulk scale chemical, but the ionization and the surface charge of the chemical may change. Chemicals that are not soluble at the bulk scale can be soluble at the nano scale. The agglomeration potential of the chemical changes, also results in a larger particle in many cases, with a surface area far greater than that of a dense particle of the same chemical. When two nano chemicals are fused together even more differences can appear.

In sum, nano-chemicals represent a new kind of synthetic not envisioned by the makers of the NL. Nanotechnologies are “synthetic” in that they are engineered to be at the nanoscale. Moreover though, if nanotechnology and the knowledge we now have about its hazards was used when OFPA was written, we are confident that it would have been considered and excluded method and excluded substance, akin to genetic engineering or sewage sludge. That is precisely how the Board should treat these substances today and in the future.

Conclusion

There will always be additional studies needed for us to better understand how emerging technologies affect the environment and human health, but the National Organic Standards Board should not wait until all of these studies are complete before prohibiting nanotechnologies and synthetic nanomaterials and particles. The NOSB should take immediate precautionary action to keep nanomaterials out of organics before nanotechnologies are infused into our food. The only way to take this necessary action is by prohibiting engineered nanomaterials as a prohibited method and/or substance. NOSB can and should craft a definition of engineered nanomaterials broad enough to cover those engineered materials intended to take advantage of the unique properties of their size but that would exclude natural nanoparticles. Defining engineered nanomaterials as synthetic substances alone would not sufficiently protect the integrity of USDA Organic and unnecessarily complicates the Board’s task. Engineered nanomaterials must be classified as sewage sludge, irradiation, and genetically engineered crops: as an excluded substance and method.

Respectfully Submitted,

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