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Comments on National Organic Standards Board (NOSB) Materials Committee

Nanotechnology in Organic Production and Discussion Document

Introduction

The Center for Food Safety (CFS) thanks NOSB for this opportunity to comment on the issue of nanotechnology and organic standards. CFS notes that this is the first opportunity to address this important issue and urges NOSB to continue this discussion in further meetings. These comments summarize CFS's current position on this issue. CFS will also provide testimony at the May 4-5, 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.[i]

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 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*,[iii] 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.[iv] 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 NOSB might find helpful in its process.

Summary

- Nanotechnology is contrary to Organic Principles. Nanotechnology will further entrench industrial/chemical agriculture and industrial food as our dominant paradigm, to the detriment of public health and the environment. As such, nanotechnology is antithetical to organic principles should be prohibited from the USDA Organic standard.

- Nanotechnology is contrary to Organic Standards. Nanotechnology involves the manipulation of materials and the creation of structures and systems at the scale of atoms and molecules. The mere fact that a larger scale version of a material is a permitted substance should not suffice to allow the engineered or manufactured nanoscale version in Organic Standards. Intentionally created nanomaterials are novel, patented substances that have the capacity to be fundamentally different in ways the scientific community does not yet fully understand. As such, engineered and manufactured nanomaterials should be defined as synthetic or prohibited substances and should be presumed excluded.

- The Time to Act is Now. Nanotechnology commercialization is currently exploding without any oversight or labeling and little emphasis on risk research. Food and agriculture is a growing sector of nanomaterial research and development and commercialization. NOSB and NOP must act to protect organic.

- Size matters. “Nano” is best understood to mean more than merely tiny manufacturing and materials; rather it means substances that have the capacity to be fundamentally different, with new chemical, physical and biological properties. These same new properties that excite industry create new and novel risks to human health and the environment. Not all nanomaterials will be hazardous, but the materials’ safety cannot be assumed from testing or approval of larger cousins and should be assumed to have added risk. Nanomaterials should be excluded until and unless scientists can gain significantly more information about them, including adequate risk assessments.

- Examples. We support the UK Soil Association's 2007 organic standards prohibiting manufactured nanoparticles from organic certification.

Comments

Nanotechnology and products containing manufactured and engineered nanomaterials have arrived and represent the crest of a product wave spanning many industries. A rapidly expanding universe of products containing nanomaterials is currently widely available, being sold to the public and disposed of into the environment. This includes a growing sector in food and agriculture. These new materials can have fundamentally different properties from their bulk material counterparts–properties that also create unique human health and environmental risks–which create new oversight challenges for the regulatory agencies charged with protecting public health and the environment.

It is up to NOSB and USDA to ensure the integrity of organic on this issue, as the product commercialization curve is well ahead of oversight, risk assessment, and scientific study of potential risks.

What is Nanotechnology?

Nanotechnology is a powerful new platform technology for taking apart and reconstructing nature at the atomic and molecular level.[v] The nano-scale is exceedingly tiny; it is the world of atoms and molecules, involving the manipulation of matter at the nanometer scale (nm), one billionth of a meter. "Nano" means more than just tiny manufacturing: is well-known that materials engineered or manufactured to the nano-scale exhibit radically different fundamental physical, biological, and chemical properties from bulk materials.[vi]

One reason for these fundamentally different properties is that quantum physics comes into play at the nano-scale.[vii] Another is that the reduction in size to the nano-scale results in an enormous increase of surface to volume ratio, giving nanoparticles a much greater surface area per unit of mass compared to larger particles.[viii] Because growth and catalytic chemical reactions occur at the particle surface, a given mass of nanoparticles will have an increased potential for biological interaction and be much more reactive than the same mass made up of larger particles, thus enhancing intrinsic toxicity.[ix] This enormous increase in surface area can change relatively inert substances into highly reactive ones. A material in nano-scale form can then melt faster, absorb more, or simply become more explosive.

Thus, to say that a substance is "nano" does not merely mean that it is tiny, a billionth of a meter in scale; rather, the prefix is best understood to also mean that a substance has the capacity to act in fundamentally different ways. Altered properties can include color, solubility, material strength, electric conductivity, and magnetic behavior. For example, a gold wedding ring is yellow in color; but gold nanoparticles appear red. Carbon (like graphite in pencil lead) is relatively soft; but carbon in the form of carbon nanotubes (nano-scale cylinders made of carbon atoms) is a hundred times stronger than steel. An aluminum soda can does not burn; however, aluminum nanoparticles explode when used as rocket fuel catalysts.

The Human Health and Environmental Risks of Nanomaterials

Just as the size and chemical characteristics of engineered nanoparticles can give them unique properties, those same new properties—tiny size, vastly increased surface area to volume ratio, high reactivity— can also create unique and unpredictable human health and environmental risks.[x] Swiss Insurance giant Swiss Re noted that, "Never before have the risks and opportunities of a new technology been as closely linked as they are in nanotechnology. It is precisely those characteristics which make nanoparticles so valuable that give rise to concern regarding hazards to human beings and the environment alike."[xi] A growing number of peer-reviewed scientific studies have demonstrated the potential for nanomaterials to present serious toxicity risks for human health and ecosystems. Manufactured nanomaterials move excessively through the environment and have the potential to enter living cells and the environment in ways their larger counterparts do not. For example, the human body absorbs nanomaterials more readily than larger sized particles and nanoparticles cross biological membranes that larger sized particles normally cannot, such as the blood-brain barrier. In addition, research has shown that many types of nanomaterials can be toxic to human tissue and cell cultures, resulting in increased oxidative stress, inflammatory cytokine production, DNA mutation and even cell death.

Once loose in nature, these nanomaterials represent a new class of manufactured nonbiodegradable pollutants. Nanomaterials' unique chemical and physical characteristics create foreseeable environmental risks, including potentially toxic interactions or compounds, absorption and/or transportation of pollutants, durability or bioaccumulation, and unprecedented mobility for a manufactured material. Because of their tiny size, nanomaterials may be highly mobile and travel further than larger particles in soil and water. Because nanoparticles tend to be more reactive than larger particles, interactions with substances present in the soil could lead to new and possibly toxic compounds. Environmental impact studies have raised some red flags, including dangers from nano-silver to aquatic life; however, despite rapid nanomaterial commercialization, many potential risks remain dangerously untested due to the government's failure to prioritize and adequately fund environmental impact research.[xii] In addition, nanomaterials' unique chemical and physical characteristics create foreseeable, yet unexplored, risks. For example, nanoparticles are the subject of vigorous drug research because of their ability to carry and deliver drugs to specific targets. But this same transport propensity could give nanoparticles the ability to carry toxic chemicals present in the environment.

Nanomaterials, Toxicity and Risk Assessment

Studies assessing the role of size on toxicity have generally found that nanoparticles are more toxic than larger particles of the same substance.[xiii] Other studies have shown that some nanoparticles are toxic in ways that cannot be attributed to particle size alone.[xiv] Scientists have yet to determine what physicochemical properties will be most important in determining ecological and toxicological properties of nanomaterials.[xv]

"Experts are overwhelmingly of the opinion that the adverse effects of nanoparticles cannot be reliably predicted or derived from the known toxicity of the bulk material."[xvi] For example, the

European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concluded: "Experts are of the *unanimous* opinion that the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of material of macroscopic size, which obey the laws of classical physics."[xvii] Similarly, the U.K. Royal Society and the Royal Academy of Engineering emphasized: "Free particles in the nanometre size range do raise health, environmental, and safety concerns and their toxicology cannot be inferred from that of particles of the same chemical at a larger size."[xviii] And finally, the British Institute for Occupational Medicine similarly concluded:

> Because of their size and the ways they are used, they [engineered nanomaterials] have specific physical-chemical properties and therefore may behave differently from their parent materials when released and interact differently with living systems. It is accepted, therefore, that it is not possible to infer the safety of nanomaterials by using information derived from the bulk parent material.[xix]

Toxicology normally correlates health risks with the mass to which an individual is exposed, resulting in an accumulated mass as an internal dose/exposure. However, the biological activity of nanoparticles is likely to depend on physicochemical characteristics that are not routinely considered in toxicity screening studies.[xx] 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."[xxi] Size is one of many factors, but is crucial: The relevance of the nano-size is that unlike larger particles, we cannot predict the toxicity of nanomaterials from the known properties of larger substances. In fact, nanotoxicology is an emerging field in its own right, underscoring the differences of nanomaterial toxicity. In an agenda-setting 2006 article in *Nature*, fourteen international nanotechnology scientists put forth nanotechnology's five "grand challenges," which included the urgent need to develop methods for assessing nano-toxicity.[xxii]

Nanomaterials in Consumer Products: The Future Is Now

Nanotechnology and its material creations are no longer future predictions; they have arrived. Funding is astronomical: global nanotech research and development (R&D) is estimated at around $9 billion, with $1 trillion in U.S. dollars globally estimated by 2015.[xxiii] U.S. federal funding for nanotechnology has increased from approximately $464 million in 2001 to nearly $1.5 billion for the 2009 fiscal year. Private industry is investing at least as much as the government, according to estimates.[xxiv] Investments in federally funded nanotechnology activities coordinated through the National Nanotechnology Initiative (NNI) were approximately $1.3 billion in 2006, and about $2 billion annually of R&D investment is currently being spent by non-federal sectors such as states, academia, and private industry. State governments spent an estimated $400 million on facilities and research aimed at the development of local nanotechnology industries in 2004.

Unfortunately, only a paucity of this robust federal funding--4% of the NNI's FY08 budget--was earmarked for environmental health and safety (EHS) research. Other non-governmental estimates put the EHS funding number as actually closer to 1%.[xxv] Even so, there are number red flags raised almost weekly by scientific studies; in addition the risks stem from the failure to undertake or prioritize adequate risk research. For example, an analysis of nanotechnology-related environmental, health, and safety research, done by the Project on Emerging Nanotechnologies, could find no research on the impact of nanomaterials on the gastrointestinal tract, though this will be of primary concern for food applications.[xxvi]

Nanotechnology commercialization is moving forward at lightning speed. Thousands of tons of nanomaterials are already being produced each year.[xxvii] Many materials can be engineered into nanomaterials or nanoparticles with the most common being silver, carbon, zinc, silica, titanium dioxide, gold, and iron.[xxviii] Consumer products self-identified as containing nanomaterials have been in, and continue to enter, the market at a steady pace of about 3-4 new ones per week.[xxix] Actual numbers are much harder to ascertain because there is no mandatory labeling or labeling requirements. According to Lux Research's 2006 Nanotechnology Report, more than $32 billion in products incorporating nanotechnology were sold last year, more than double the previous year.[xxx] Lux predicts that by 2014, $2.6 trillion in manufactured products will be nano-products, 15% of total global manufacturing.

The only publicly available nanomaterial product inventory shows approximately 900 currently available on U.S. market shelves.[xxxi] The nano-products found include: paints, coatings for numerous products, sunscreens, medical devices, sporting goods, cosmetics, stain-resistant clothing, supplements, nanoceuticals, and vitamins, food and food packaging, kitchen and cooking ware, light emitting diodes used in computers, cell phones, and digital cameras, film and photo development products, automotive electronics, automotive exteriors, batteries, fuel additives, and tires, computer accessories, children's toys and pacifiers, laundry detergent and fabric softeners, personal hygiene products, cleaning agents, air conditioning units, pet products, jewelry, bedding and furniture, lubricants and foams, waxes, MP3 players and other electronics.[xxxii] But because there are no labeling requirements for products containing nanomaterials, the total number and range of nano-products is unknown.

Nanotechnology in Food and Food Packaging

The food industry is investing heavily in nanotech research and development. By 2010 the nano-food market could be worth $6 billion. Many of the world's leading food companies - including H.J. Heinz, Nestle, Hershey, Campbell, General Mills, PepsiCo, Sara Lee, Unilever, and Kraft - are investing heavily in nanotechnology applications. Nanoparticles of silver, titanium dioxide, and zinc oxide, materials now used in dietary supplements and food packaging, have been found to be highly toxic to cells in studies. Nano-silver, the most common commercialized nanomaterial, is being used in numerous food packaging items, cutlery, baby bottles, and kitchen appliances and cleaners for its "germ-killing" power. This same powerful strength can destroy important beneficial microorganisms in nature as well. ICTA's 2008 legal petition to EPA centers on this potential environmental risk.[xxxiii]

Many food companies now have nanotechnology based products on the market. Examples of such products include a nutritional supplement drink for children that contains iron nanoparticles, McDonald's hamburger containers, Cadbury chocolate bar wrappers, and Miller

Lite beer bottles. According to a recent Friends of the Earth Report, at least 104 nano-enabled, self-identified food products are now on sale internationally.

Clear data on organic and conventional food industry use of nanotechnology simply does not exist – at least in the public domain. This is due in part to the fact that many food manufacturers may be unwilling to advertise the nanomaterial content of their products, possibly fearing consumer backlash. At this time it is not required that manufacturers label products for their nano content or submit information about their nanoscale additives to government agencies. However, we do have data showing that conventional food and food packaging employing nanotechnology has entered the market. These products are mainly in the form of packaging and food contact materials, which incorporate antimicrobial nanomaterials. It is possible that sectors of the organic industry may already or soon be employing nanotechnology applications.

A 2009 report by the Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies took a detailed look at nanotechnology-based dietary supplements and their regulation in the United States.[xxxiv] Their research found at least a dozen dietary supplements on the market that contain nanoscale silver, at least a dozen more products contain other nanoparticulate ingredients. There is a serious concern that products containing ingredients with barely known biological properties are on the market backed only by a producer's claims. Very few studies have investigated the toxicity of nanoparticle nutritional additives. The failure of governments to require comprehensive safety testing of toxicity risks in nano additives is concerning. Dr Qasim Chaudhry who leads the nanotechnology research team at the United Kingdom's Central Science Laboratory warns that nanoparticle and nano-encapsulated food ingredients "may have unanticipated effects, far greater absorption than intended or altered uptake of other nutrients, but little, if anything, is known currently."

One of the earliest commercial applications of nanotechnology within the food sector is in packaging. According to the Friends of the Earth (FoE) report, "Out of the laboratory and onto our plates," nanotechnology used in food packaging was one of the first commercial applications of nano in food systems.[xxxv] FoE estimates that there are currently between 400-500 commercial nano-packaging products in use. One of the current applications of nanotechnology in food packaging includes the use of nano-composite materials to create greater impermeability to moisture, air, and light thus lengthening shelf life. An example of this is Durathan KU2-2601, manufactured by Bayer, which utilizes nanoparticle silica in plastic bottles to create a better barrier to oxygen.[xxxvi]A second common use of nanotechnology in food packaging is the incorporation of nano silver, nano zinc oxide, and other antimicrobial nano-particles in packaging for their antimicrobial properties. An example of this is food clingwrap treated with nano zinc oxide manufactured by Singsong Nano Technology Co., Ltd.[xxxvii]

A key purpose of nano packaging is to deliver longer shelf life by improving the barrier functions of food packaging to reduce gas and moisture exchange and UV light exposure. For example, DuPont has announced the release of a nano titanium dioxide plastic additive 'DuPont Light Stabilizer 210' which could reduce UV damage of foods in transparent packaging. In 2003, over 90% of nano packaging (by revenue) was based on nano-composites, in which nanomaterials are used to improve the barrier functions of plastic wrapping for foods, and plastic bottles for beer, soft drinks and juice. Nano packaging can also be designed to release antimicrobials, antioxidants, enzymes, flavors and nutraceuticals to extend shelf-life.

Anti-bacterial nanofood packaging and nano-sensor technologies have been promoted as delivering greater food safety by detecting or eliminating bacterial and toxin contamination of food. However it is possible that nanomaterials will migrate from antibacterial food packaging into foods, presenting new health risks. This appears inevitable where nano-films or packaging are designed to release antibacterials onto the food surface in response to detected growth of bacteria, fungi or mould.

An earlier report from the Wilson Center looked at potential food and agriculture applications as well.[xxxviii] This report is a few years old now but gives some good information about the types of food and agriculture applications currently being researched by government funding and that may soon come to market.

Nanotechnology, Food and Public Perceptions

A U.S. survey, commission by the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars revealed that, "Only 7 percent of Americans say they would purchase food enhanced with nanotechnology."[xxxix] Of those surveyed, "62 percent in the case of food and 73 percent in the case of nanotechnology-enhanced food containers – say they need more information about health risks and benefits before deciding whether to purchase such products."[xl] Furthermore, about 70% of the adults surveyed said their knowledge of nanotechnology was "just a little" or "nothing at all."

Nanotechnology, Novelty and Patents

By law, the issuance of a patent requires a determination of novelty and nonobviousness,[xli] and it is well-established patent case law that a mere change in size, scale, or dimensions of a known composition are not alone sufficient to establish novelty and nonobviousness and render new material patentable.[xlii] Nanomaterials are meeting this requirement because "the nano-scale is not just another step toward miniaturization, but a qualitatively new scale."[xliii] Taking advantage of quantum physics, nanotechnology companies have and are continuing to engineer materials that have entirely new properties never before identified in nature, and patenting them in the U.S and other countries. In August of 2004, the United States Patent and Trademark Office (USPTO) created an art collection of Nanotechnology, Class 977, in response to the desire to gather in one place all published US Patents and US PreGrant Publications (US PGPUBs) that claim subject matter related to nanotechnology.[xliv] In December of 2005, the USPTO revised the nanotechnology patent classification, replacing one comprehensive digest with 263 new subclasses for cross-referencing all nano-related patents. Class 977, which establishes the definitions and cross-references for these patents, has a two pronged definition of "nanostructures," a necessary ingredient of all patents for which the class provides disclosures,[xlv] to be an atomic, molecular, or macromolecular structure that both: 1) "has at least one physical dimension of approximately 1-100 nanometers;" <u>and</u> 2) "possess[] a special property, provides a special function, or produces a special effect that is uniquely attributable to the structure's nanoscale physical size."[xlvi] Thus, to be included in USPTO Class 977, a patent must not simply be a reduction in size of an existing element or particle; rather, that new size must alter the original substance creating a unique effect or property that is only possible at the nanoscale.

The President's Council of Advisors on Science and Technology (PCAST) reported in May 2005 that the Patent Office issued over 8,600 "nanotechnology-related" patents in 2003, an increase of 50% from 2000 (compared to about 4% for patents in all technology fields).[xlvii] More discrete surveys have found at least 5,000 nanotechnology patents as of March 2006, with the number of patents growing by over 30% every year since 2000.[xlviii] The "gold rush" for patents on the building blocks of the platform technology continues unabated.[xlix] Claims include composition of matter claims (claims to nanomaterials themselves, nanotubes, nanowires, and nanoparticles), device, apparatus, or system claims (claims to electrical, mechanical, and optical devices incorporating nanomaterials), and method claims (claims to processes for synthesizing nanomaterials or constructing devices or systems).

Responses to the Materials Committee Discussion Paper: Six Questions

The Materials Committee requested comment on six specific questions at the end of its discussion paper. CFS submits the following short answers to those questions:

1. *As currently understood, is Nanotechnology compatible with organic?*

Answer: No. Nanotechnology as a platform technology is antithetical to organic and will further entrench chemically engineered agriculture and industrial, processed food as our dominant paradigm. Intentionally-created nanomaterials are novel, patented substances that have the capacity to be fundamentally different in ways the scientific community does not yet fully understand.

2. *If not, are the current standards keeping nanoparticles out?*

Answer: Unclear, but several manufacturers of products that are claimed as "organic" also note that they are using nanomaterials in the products. In addition, in the current absence of any mandatory regulation or labeling of nanomaterial products, it cannot be determined whether or not nanomaterials are being infused into given products. Nanotechnology should be considered an excluded method and engineered and manufactuered nanomaterials should be considered synthetic or prohibited substances. Because NOSB has not yet addressed the issue, it should clarify through guidance or rule-making process that the standards exclude nanomaterials.

3. *Are any sectors of the organic industry already using Nanotechnology?*

Answer: Unknown, but some groups making cleaning materials and clothing that they claim to be 'organic' note in product advertisements or on their websites that they are using nanomaterials in their products. We do have data showing that conventional food and food packaging employing nanotechnology has entered the market. These products are mainly in the form of packaging and food contact materials, which incorporate antimicrobial nanomaterials.

The food industry is investing heavily in nanotech research and development. Many food companies now have nanotechnology based products on the market. Examples of such products include a nutritional supplement drink for children that contains iron nanoparticles, McDonald's hamburger containers, Cadbury chocolate bar wrappers, and Miller Lite beer bottles.

4. *What are the concerns about Nanotechnology in food, feed, petcare, textiles, personal care products, or any other product carrying the USDA Organic label?*

Answer: Knowledge about specific products is lacking due to lack of required labeling, government oversight or adequate funding or focus on risk research. The general concerns about nanomaterials are several-fold.

Human and animal health: Due to their size, nanoparticles can cross biological membranes, cells, tissues, and organs more readily than larger particles. When inhaled, they can go from the lungs into the blood system. There is growing evidence that 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. 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. Once inside cells, they may interfere with normal cellular function, cause oxidative damage and even cell death.

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. 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. Existing studies have raised red flags, such as damage to beneficial microorganisms from nano-silver. 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."

Broader Impacts: In addition to health and environmental impacts, nanotechnology is a platform, converging technology which will continue to industrialize food and agricultural. Some of these issues include: the use of nanotechnology in conjunction with biotechnology and synthetic biology; the use of nanomaterials in food packaging in order to ship further distances and increase shelf life, exacerbating climate change impacts and contrary to organic principles of small-scale and local farming; and the intellectual property privatization of nanotechnology's basic building blocks.

5. *Should organic standards (OFPA/ NOP rule) be updated to regulate the use or uses of Nanotechnology(ies).*

Answer: Yes. To the extent it is not yet clear, NOSB should recommend that NOP clarify that USDA organic standards prohibit nanotechnology and nanomaterials from organic certification. This should be done through guidance, or if necessary, rule-making process.

6. *How can the NOSB and the NOP protect the interests of the organic consumer, and the National Rule itself, vis a vis nanotechnology?*

Answer: Yes, NOSB and NOP can protect the interests of the organic community and the integrity of the National Rule by clarifying that nanotechnology and intentionally created nanomaterials are prohibited from organic. The language of the OFPA standards were intended to be flexible, to continue to accurately reflect organic principles and consumer preference in the future on unforeseen issues such as nanotechnology. The NOSB recommendations should reflect this intent, interpreting the language in order to protect the organic standard as well as accurately reflect the public's perception and preference that nanotechnology is wholly incompatible with organic.

Responses to the Materials Committee Discussion Paper: Other Comments

In general we thought the discussion paper provided an even handed and high quality discussion of the issue. A few comments:

- The Committee is correct (discussion paper, bottom of p.1) that the FDA's regulatory stance is seemingly at odds with its own recognition (and that of sister agencies, like the NNI) of what is nanotechnology and a nanomaterial. ICTA and CFS's 2006 legal petition to FDA had an entire section arguing precisely this and calling on FDA to revise its oversight position to properly reflect the scientific reality of nanotechnology and nanomaterials in consumer products under its jurisdiction (in particular, sunscreens and cosmetics) and the fact they require nano-specific oversight and testing.[1]

- We applaud the Committee for recognizing that nanotechnology creates "unique" regulatory and safety questions; have the potential to behave differently than larger materials; and have increased mobility concerns (discussion paper, p.2). However we are somewhat puzzled by the Committee's follow-up statement (discussion paper, p.2) that it is "likely" that some product of nanotechnology would be "required by law to be added to some types of food products" because of the "potential advantages" of these new properties in areas including medicine and food safety. First, we are not sure exactly what law or type of products the Committee had in mind, if any. It is true that the capacity for novel properties of nanomaterials make them potentially useful; however it seems just as likely to us that these properties could create unforeseen health or environmental problems that would outweigh any potential benefits. It seems just as likely then that a law would be required to prohibit a particular nanomaterial in the future as mandate its use.

  Second, it is always difficult to distinguish hype from promise. We caution the NOSB to be wary and recall the lessons of our culture's experiences with past "wonder materials." History is strewn with once-thought miraculous substances that turned out to be deadly or harmful to the environment. Asbestos was once considered an ideal material for clothing, buildings, and other goods; today, it kills 10,000 people annually. Similarly, for more than 50 years, chlorofluorocarbons (CFCs) were thought to be a miracle substance, used in innumerable household appliances and consumer products; scientists today know that CFCs are a catalytic agent in ozone destruction, leading to less protection from the sun's UVB rays, increasing the risk of skin cancer, and eventually leading to international and national bans on their release. Twenty-five years ago, biotechnology and genetic engineering promised to, among other things, feed the world and make the blind see. Instead what GE crops have wrought is lower yields,[li] increase herbicide use[lii] and the private corporate ownership of the farmer's right to save seed.[liii] Now the claims are that GE crops can solve climate change. Nanotechnology seems to be following a similar path. Called the "next industrial revolution,"[liv] nanotech has been touted to offer nothing less than fundamental transformation of society, industry and technology.[lv] Yet the reality of commercialization has been instead mundane in its applications, applications with increase marketability but limited actual benefit – sunscreens that are "cosmetically clear" instead of white because of nanoparticles of titanium dioxide or zinc oxide, or tennis rackets and golf clubs with increase strength from carbon nanotube, for example. Yet the potential risks and the gaping unknowns about these materials remain, despite limited societal benefits. Carbon nanotubes have been scientifically liked as similarly to asbestos, for example.[lvi] And the entire second half of our 2006 petition to FDA was about the toxicity, mobility and skin penetration risks of the nano-sunscreens.[lvii]

- We would like to see further discussion of the Committee's initial view that under its current definition most nanotechnology would not fall into the category of excluded methods (discussion paper, at bottom p. 2). As stated above and for the above given reasons, it is our position that nanotechnology is not compatible with organic should be an excluded method, either under the current definition or an amended one, if NOSB finds amendment necessary.

- We agree that public input and perspective (discussion paper, at p.3) on this topic is crucial to the NOSB process and hope the NOSB will facilitate open, full and meaningful public participation in this process. Given information about nanotechnology, we are confident the public will strongly conclude that it is incompatible with and a danger to the integrity of organic.

- We agree that the definition of nanotechnology as it applies to organic (discussion paper, at p3.) is an important one. We look forward to working with NOSB going forward on that issue. We would only caution that in other federal agency contexts the definitional question has been used by successfully by industry during the previous administration to delay or forestall needed regulatory oversight indefinitely. We hope that NOSB will analyze and answer this definitional question while concurrently moving towards answers to the nanotechnology and organic issue at large, in order to best protect the integrity of organic in a timely manner. We note that the Soil Association – the leading organic certifier in the UK – was able to answer the definitional question in implementing their standard prohibiting nanotechnology. A similar standard has been adopted by the

Biological Farmers of Australia (BFA), the largest organic representative body in that country.

Respectfully submitted,

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[i] See generally http://www.centerforfoodsafety.org.

[ii] See generally http://www.nanoaction.org

[iii] http://nanoaction.org/nanoaction/doc/nano-02-18-08.pdf

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

[v] The National Nanotechnology Initiative (NNI) defines nanotechnology as
the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale.

[vi] National Nanotechnology Initiative, *What is Nanotechnology?*, at http://www.nano.gov/html/facts/whatIsNano.html.

[vii] Nanotechnology Now, *Nanotechnology Basics*, at http://www.nanotech-now.com/basics.htm.

[viii] See, e.g., Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCIENCE 622 (2006). For example, a gram of nanoparticles has a surface area of a thousand square meters.

[ix] See, e.g., European Commission's 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; Warheit, D.D., *Nanoparticles: Health impacts?*, 7 MATERIALS TODAY 32-35 (2004).

[x] See, e.g., Andre Nel et al., *Toxic Potential of Materials at the Nanolevel*, 311 SCIENCE 622-27, 622, 623 Fig. 1 (2006); see generally Florini et al., *Nanotechnology: Getting It Right the First Time*, 3 NANOTECHNOLOGY L. & BUS. 38, 41-43 (2006).

[xi] Swiss Re, *Nanotechnology-Small Matter, Many Unknowns*, (2004), at 17.

[xii]Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, Press Release, *Nanotechnology Development Suffers from Lack of Risk Research Plan, Inadequate Funding & Leadership*, September 21, 2006, at http://www.wilsoncenter.org/index.cfm?topic_id=166192&fuseaction=topics.item&news_id=201894

[xiii]Science Policy Council, *U.S. Environmental Protection Agency Nanotechnology White Paper,* U.S. EPA, at 54 (February 2007).

[xiv] Id.

[xv]See, e.g., Maynard et al., *Safe Handling of Nanotechnology*, Vol 444 NATURE 267-69 (November 16, 2006); Oberdorster et al., *Nanotoxicology: an emerging discipline evolving from studies of ultrafine particles*, 113 ENVIRON HEALTH PERSPECT 823-839 (2005).

[xvi] The Allianz Group and the Organisation for Economic Co-operation and Development (OECD), *Small Sizes that Matter: Opportunities and risks of Nanotechnologies*, (June 3, 2005) at § 6.4, at 30.

[xvii] European Commission's 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*, at 6 (adopted September 28-29, 2005) (emphasis added); id. at 34.

[xviii] See, e.g., The Royal Society and the Royal Academy of Engineering, *Nanoscience and nanotechnologies: Opportunities and uncertainties*, London, 2004, at 49 (emphasis added).

[xix] Tran et al., *A Scoping Study to Identify Hazard Data Needs For Addressing The Risks Presented By Nanoparticles and Nanotubes*, INSTITUTE OF OCCUPATIONAL MEDICINE Research Report (December 2005), at 34 (emphasis added).

[xx]European Commission's 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*, at 6 (adopted September 28-29, 2005), at 32; Nuala Moran, *Nanomedicine lacks recognition in Europe*, 24 NATURE BIOTECHNOLOGY, No. 2 (February 2006).

[xxi] Andrew Maynard, *Nanotechnology: The Next Big Thing, or Much Ado about Nothing?*, at 7 Annals of Occupational Hygiene, 7 September 2006.

[xxii] Maynard et al., *Safe Handling of Nanotechnology*, NATURE November 16, 2006.

[xxiii] See, e.g., Lux Research, *The Nanotech Report, 4th Edition*, 2006, http://luxresearchinc.com/TNR4_TOC.pdf

[xxiv] http://www.nano.gov/html/facts/faqs.html)

[xxv] Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, Press Release, *Nanotechnology Development Suffers from Lack of Risk Research Plan, Inadequate Funding & Leadership*, September 21, 2006, at http://www.wilsoncenter.org/index.cfm?topic_id=166192&fuseaction=topics.item&news_id=201894

[xxvi] *Nanotechnology Health and Environmental Implications: An Inventory of Current Research*.Washington, DC: Project on Emerging Nanotechnologies,Woodrow Wilson International Center for Scholars, November 2005. Available at http://www.nanotechproject.org/inventories.

[xxvii] See, e.g., The Royal Society and the Royal Academy of Engineering, *Nanoscience and nanotechnologies: Opportunities and uncertainties*, London, July 2004, pp. 26-27 & Table 4.1, available at http://www.nanotec.org.uk/finalReport.htm (hereafter Royal Society Report).

[xxviii] Lloyd's of London, Risks: Lloyd's Emerging Risks Team Report, *Nanotechnology Recent Developments, Risks and Opportunities*, at 10, 2007.

[xxix] http://www.nanotechproject.org/news/archive/6697/

[xxx] See, e.g., Lux Research, 2006, http://luxresearchinc.com/TNR4_TOC.pdf

[xxxi] The Woodrow Wilson International Center for Scholars, Project on Emerging Nanotechnologies, *Nanotechnology Consumer Products Inventory*, available at http://www.nanotechproject.org/consumerproducts

[xxxii] Id.

[xxxiii] ICTA petition to EPA, http://www.icta.org/nanoaction/doc/CTA_nano-silver%20petition__final_5_1_08.pdf

[xxxiv] http://www.nanotechproject.org/process/assets/files/7056/pen17_final.pdf

[xxxv] Friends of the Earth (2008). Out of the laboratory and onto our plates – nanotechnology in food and agriculture. Available online at http://www.foe.org/pdf/nano_food.pdf

[xxxvi] Id. at 52.

[xxxvii] Id. At 16.

[xxxviii] http://www.nanotechproject.org/news/archive/new_report_on_nanotechnology_in/

http://www.nanotechproject.org/file_download/files/PEN4_AgFood.pdf

[xxxix] Peter D. Hart Research Associates. 2007. Awareness of and attitudes toward nanotechnology and federal regulatory agencies: A report of findings based on a national survey among adults. Conducted on behalf of: Project On Emerging Nanotechnologies at The Woodrow Wilson International Center For Scholars. Washington, DC. Available at: http://www.nanotechproject.org/process/assets/files/5888/hart_nanopoll_2007.pdf (accessed 20 April 2009).

[xl] Id.

[xli] 35 U.S.C. §§ 102-103.

[xlii] Application of Troiel, 274 F.2d 944, 949 (C.C.P.A. 1960) ("It is well established that the mere change of the relative size of the co-acting members of a known combination will not endow an otherwise unpatentable combination with patentability.").

[xliii] Nat'l Sci. Found., *Societal Implications of Nanoscience and Nanotech*. at 1 (Mihail C. Roco & Sims Bainbridge eds., 2001), http://www.wtec.org/loyola/nano/NSET.Societal.Implications/nanosi.pdf

[xliv]Patent office Classification Definitions, Class 977, Nanotechnology, (November 2005), available at http://www.uspto.gov/web/patents/classification/uspc977/defs977.htm#C977S000000.

[xlv] Id. The definition of nanotechnology as a class includes "nanostructures" and their chemical compositions, devices that include at least one nanostructure, mathematical algorithms for modeling confiurations or properties of nanostructures, or specified uses of nanostructure.

[xlvi] Id.

[xlvii] President's Council of Advisors on Science and Technology (PCAST), *The National Nanotechnology Initiative at Five Years: Assessment and Recommendations of the National Nanotechnology Advisory Panel*, at 15-17 & fig. 4, May 2005, available at http://www.nano.gov//FINAL_PCAST_NANO_REPORT.pdf ; Julie A. Burger et al., *Nanotechnology and the Intellectual Property Landscape,* Chapter 14, p.3, NANOSCALE: ISSUES AND PERSPECTIVES FOR THE NANO CENTURY, ED. NIGEL CAMERON ET AL., (Wiley Pub. 2007).

[xlviii] Nanowerk, *The patent land grab in nanotechnology continues unabated, creating problems down the road*, Marcy 30, 2006, at www.nanowerk.com/spotlight/spotid=386.php

[xlix] See, e.g., Charles Choi, *NanoWorld: Nano Patents in Conflict*, WASH. TIMES, April 25, 2005.

[l] ICTA petition to FDA, http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf at pp. 12-27.

[li] http://www.ucsusa.org/food_and_agriculture/science_and_impacts/science/failure-to-yield.html

[lii] http://www.greens.org/s-r/34/34-08.html

[liii] http://www.centerforfoodsafety.org/pubs/CFSMOnsantovsFarmerReport1.13.05.pdf

[liv] *See, e.g.,* Rick Weiss, *Nanotech Raises Worker-Safety Questions*, Wash Post, A1, at April 8, 2006 (To tour the gleaming offices of Altair Nanotechnologies Inc. is to see why the U.S. Commerce Department calls nanotech "the next industrial revolution" -- a revolution not of smelters and smokestacks but of precision-engineered carbon "buckyballs" one-ten-thousandth the size of the head of a pin and microscopic nanospheres that can pack the power of a car battery in a napkin-thin wafer. What could be more 21st-century?"); Charles Piller, *Science's Tiny, Big Unknown*, Los Angeles Times, at A1, (June 1, 2006) ("Nanotechnology has the potential to create revolutionary change across multiple, key areas of human endeavor, according to trade group NanoBusiness Alliance. To maintain its global economic lead and to keep the U.S. homeland secure, we must win the nanotech race.").

[lv] *See, e.g.*, National Science and Technology Council, National Nanotechnology Initiative, Nanotechnology: Shaping the World Atom by Atom 4 (1999) (proclaiming nanotechnology as "a likely launch pad to a new technological era because it focuses on perhaps the final engineering scales people have yet to master."); id. at 8 ("If present trends in nanoscience and nanotechnology continue, most aspects of everyday life are subject to change."); id. at 1 (stating the nanotechnology revolution will result in "unprecedented control over the material world."); see also Asia-Pacific Economic Cooperation Industrial Science and Technology Working Group, Nanotechnology: The technology for the 21st Century. Vol II: The Full Report 24 (2002), ("If nanotechnology is going to revolutionize manufacturing, health care, energy supply, communications and probably defense, then it will transform labor and the workplace, the medical system, the transportation and power infrastructures and the military. None of these latter will be changed without significant social disruption.").

[lvi] Carbon nanotubes introduced into the abdominal cavity of mice show asbestos-like pathogenicity in a pilot study; *Nature Nanotechnology* 3, 423 - 428 (2008), Craig A. Poland, Rodger Duffin, Ian Kinloch, Andrew Maynard, William A. H. Wallace, Anthony Seaton, Vicki Stone, Simon Brown, William MacNee & Ken Donaldson

[lvii] *See* ICTA FDA petition, http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf at 38-79.