Comments of Consumers Union on Agricultural Marketing Service, Notice of the Meeting of the National Organics Standards Board (Docket No. AMS-TM-09-0014)

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Consumers Union (CU) would like to provide the following comments to the six questions posed by the Materials Committee of NOSB on nanotechnology:

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

It all depends on what one means by nanotechnology, although in general the answer is no. A simple definition of nanotechnology is "the study of the control of matter at the atomic and molecular scale."[1] Nanotechnology has also been defined as the "design, characterization, production and application of functional materials, structures, devices and systems based on nanoparticles."[2] In general, nanotechnology refers to nanoparticles and nanostructures that have one or more dimensions at the scale of 100 nanometers or less (often people say nanoparticles are in the range of 1 – 100 nm). While nanoparticles and nanomaterials can occur naturally—as the result of combustion or in colloidal solutions (such as milk)—the vast majority of interest in the field of nanotechnology is about constructing or synthesizing nanoparticles and nanomaterials. Thus, engineered nanomaterials (ENM) can be defined as: discrete materials having structures with at least one dimension between 1 and 100 nanometers and that are intentionally created, as opposed to those that are naturally or incidentally found[3]. Some research has shown that the potential adverse effects associated with nanoparticles can be see at sizes above 100 nanometers and some have called for the cut off to be particles smaller than 300 nanometers[4]. Clearly, ENMs should be excluded as a synthetic or prohibited substance. In addition, since nanotechnology as popularly understood is about the production and synthesis of compounds at the atomic and molecular scale, it should be an excluded method. Part of the great interest in nanotechnology comes from the fact that at the nanometer level, a substance can behave very differently and have different properties than at the macrolevel. It is precisely this fact—that nanomaterials can have unique properties at the nanoscale that cannot be predicted by their properties at the macroscale—which should make it an excluded methos.

[1] http://en.wikipedia.org/wiki/Nanotechnology
[2] Cheriaa, N. et al. 2007. Calixdendrimers. Chp. 5 in J. Vicens and J. Harrowfield (Eds.) *Calixarenes in the Nanoworld*. Springer Verlag Press.
[3] http://www.lbl.gov/ehs/chsp/html/nanomaterials.shtml
[4] http://www.foeeurope.org/activities/nanotechnology/Documents/Nano_food_report.pdf

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

It is not clear if the current standard are keeping nanoparticles out of organic. At present, a number of synthetic substances are permitted in organic. Since there is no definition nor standard of identify for nanomaterials, it is possible that the presently permitted synthetics could be produced by nanotechnology and so be an ENM. Thus, the current standards would not be sufficient to keep out ENMs. The critical question is what constitutes a "synthetic" substance. Normally to be considered synthetic a substance has to be changed chemically in the lab. We would argue that the production of a nano-scale material would constitute a chemical change that would make it "synthetic." Indeed, experts on nanotechnology are virtually unanimous that nano-scale materials have the potential for structure-dependent health effects that are uniquely different than their larger counterparts[5].

A seminal report published in July 2004 by the Royal Society and Royal Academy of Engineering highlighted unique chemical and physical properties of 'nanoparticles' and 'nanotubes,' and discussed their potential adverse impacts on human and environmental health. Ann Dowling, chair of the study said, "Nanoparticles can behave quite differently from larger particles of the same material … it is vital that we determine both the positive and negative effects they might have."[6] The report concludes: "we believe that chemicals in the form of nanoparticles and nanotubes should be treated separately to those produced in a larger form. Given the evidence that increased surface area can lead to greater toxicity per unit mass, regulation of exposure on a mass basis to nanoparticles and nanotubes may not be appropriate."[7] The European Commission Scientific Committee on Emerging and Newly Identified Health Risks reported that "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 obeys the laws of classical physics."[8]

Given these expert opinions—that behavior of nanoparticles cannot be predicted based on behavior of larger particles of the same material—we feel that NOSB must clearly state that all ENMs are considered synthetic or prohibited substances. In addition, a nano-scale version of a synthetic that is already permitted in organic should not automatically be permitted. NOSB must say that any created nanoparticle is uniquely different than their larger/macroscale counterpart and must be treated as a new entity.

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6 Royal Society. 2004. "Nanotechnologies bring great potential and need for responsible development," (press release), 29 July 2004

7 Royal Society and Royal Academy of Engineering. 2004. *Nanoscience and Nanotechnologies: Opportunities and Uncertainties*. p. 79. At: **http://www.nanotec.org.uk/report/chapter9.pdf**.

8 European Commission Health and Consumer Protection Directorate-General, Scientific Committee on Emerging and Newly Identified Health Risks, "modified Opinion on The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies," Adopted during the 10th preliminary meeting of 10 March 2006, p.6

We urge NOSB to address this issue through guidance or rule-making to clearly state that the standards exclude all ENMs.

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

Since there are no reporting requirements, we do not really know. However, there are many products on the market that contain nano-silver that is added for antimicrobial purposes, although it is unclear whether this is true for oganic foods or not. There are companies that are selling socks on the internet made with organic cotton that are advertised as containing silver ions (although this could be considered nanotechnology)[9]. In addition, companies are selling packaging and food contact substances which utilize antimicrobial nanomaterials, so that the package itself acts as an antimicrobial. The products usually use nanoparticles of silver. The Project on Emerging Nanotechnologies has produced a list of over 200 manufacturer-identified products on the market that contain nanosilver.[10] These products span the range of clothing, washing machines, cosmetics, and dietary supplements. We would expect that the use of nanoparticles of silver, or other compounds with antimicrobial action (such as copper oxide, zinc oxide or chlorine dioxide) in food packaging materials may be of interest to the organic community.

We have concern about use of nanoparticles as food additives, food contact substances (e.g. indirect food additive), cosmetics, clothing, and personal care products—all which can be associated with organic. In addition, there is the potential for making nano-scale copper, since copper is permitted as a fungicide in organic production.

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

The main concerns have to do with unanswered questions about the potential adverse effects of nanoparticles on human and animal health, as well as on the environment. But there have been few studies on particular products and there are methodological problems with even doing proper risk assessments for many nanomaterials. The major health concern related to nanoparticles has to do with their smaller size and greater surface area, and potentially greater reactivity, which could greatly increase their potential toxicity. Exposure to ENMs can occur through inhalation, dermal contact, or ingestion. Due to their small size, ENMs can penetrate deep into lungs and can be translocated to other organs in the body following pathways that have not been demonstrated in studies with larger particles. Some engineered nanoparticles have been shown to bypass the blood-brain barrier in various ways, such as via the trigeminal or olfactory nerves.[11] ENMs, if small enough, can even penetrate into cells, disrupting cellular function and leading to cell death.

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[9] See http://www.alibaba.com/product/tr105583401-105272402-101281487/Silver_Ion_Socks.html
[10] See http://www.nanotechproject.org/process/assets/files/7039/silver_database_fauss_sept2_final.pdf
[11] Pg. 24, 26 in Institute of Medicine. 2005. Implications of Nanotechnology for Environmental Health Research. The National Academies Press, Washington, D.C.

Though many studies suggest that dermal penetration of some nanomaterials is limited, differences in study designs show how critical factors can influence findings. Physiological differences among exposed individuals, such as the thickness and condition of hair and skin, physical activity, and duration of exposure may affect dermal penetration and toxicity of nanomaterials. For example, researchers at the National Institutes of Occupational Safety and Health (NIOSH) found that kinetic energy produced by flexing motions such as those involving the wrist, is sufficient to move certain nanoparticles such as beryllium oxide, into the skin where they can activate a cell-mediated immune response. Their study suggests that percutaneous nanoparticle exposure may make workers more vulnerable to beryllium sensitization at lower concentrations, which may help to explain why respiratory exposure limits have failed to reduce the prevalence of chronic beryllium disease in exposed workers.[12]

There are also serious concerns about environmental impacts due to release of nanoparticles into the environment. ENMs represent a new class of manufactured pollutants and there has not been a lot of studies of potential environmental impacts. For example, a study last year found that silver nanoparticles can have a dose-dependent adverse effect on developing zebrafish embryos, while silver ions showed no such toxicity.[13] The UK Royal Society has recommended, "the release of nanoparticles and nanotubes in the environment be avoided as far as possible" and "factories and research laboratories treat manufactured nanoparticles and nanotubes as hazardous, and seek to reduce or remove them from waste streams."[14]

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

Definately yes. The NOSB should clearly recommend that the NOP clarify that ENMs are all synthetic substances that are prohibited from organic certification. The NOP should make clear that the definition of what constitutes a synthetic substance should not include any ENMs. In particular, the NOP should not allow the use of grinding or high pressure to create nanoparticles; these should be considered ENMs and be prohibited from organic certification. NOP may need to do this through rule-making process if it cannot be done via guidance.

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

The NOSB and NOP can protect the interests of the organic consumer by making it crystal clear that ENMs are synthetic prohibited substances. And, given the

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[12] Tinkle, SS, JM Antonini, BA Rich, et al. 2003. Skin as a Route of Exposure and Sensitization in Chronic Beryllium Disease, Environmental *Health Perspectives*, 111(9):

[13] Asharani, PV, Wu, YL, Gong, Z and S Valiyaveettil. 2008. Toxicity of silver nanoparticles in zebrafish models. *Nanotechnology*, 19(25): At: http://www.iop.org/EJ/abstract/0957-4484/19/25/255102/

[14] Pg. 46 in Royal Society and Royal Academy of Engineering. 2004. Nanoscience and Nanotechnology: Opportunities and Uncertainties.

many unknowns about nanoparticles, the NOSB and NOP should state that, at present, nanotechnology is not compatible with organic. We note that at present, the general public does not know much about nanotechnology. In a Consumer Reports National Research Center poll, conducted in October 2007, some 36% of those polled said they "don't know/I haven't heard of engineered nanomaterials;" only 13% could identify the true statements about ENMs (e.g. "very small synthetic ingredients that can have different properties" and "chemicals created on the scale of a billionth of a meter."[15])

Yours,

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[15] Pg. 16 in http://www.greenerchoices.org/pdf/foodpoll2008.pdf