Nanomaterials Fact Sheet

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Evidence indicates that engineered nanomaterials are beginning to be used and sold in common food products, but companies and their suppliers are failing to provide consumers with information about whether their products contain nanomaterials. In fact, many companies that sell products containing nanomaterials may not even know that nanomaterials are in their supply chain.

Given recent scientific findings about potential health and environmental harm from engineered nanomaterials, companies that use, intend to use, or simply allow the use of nanomaterials in their food and food packaging products may face significant financial, legal, or reputational risk.

Definition of Nanomaterials

A nanomaterial is an engineered or manufactured[1] material containing particles in the nanoscale range (1-1000 nm) in one or more external dimension, or in an internal or surface structure[2], or a material whose nanoscale particles have different properties or functions than macro-scale particles of the same material. This definition also applies to incidental nanoparticles, and those not intentionally engineered, but that are manufactured by-products and incorporated in company products.

Nanomaterials Are Already Used in Foods and Food Packaging

In 2012, a landmark study of titanium dioxide in consumer food products found nanoparticles of titanium dioxide in several foods, including candy, gum, and soup products.[3] In three recent peer-reviewed studies, all food-grade titanium dioxide products that were tested had between 10% and 35% of their particles smaller than 100 nm.[4,5,6] In 2013, laboratory testing identified titanium dioxide

nanoparticles in white powdered donuts.[7] In April of 2014, the U.S. Environmental Protection Agency (EPA) identified a company selling plastic food storage containers containing silver nanoparticles.[8] As of 2014, dozens of food and food-related products on the market claim to contain nano-silver.[9]

Nanomaterials Are Not Regulated by the Food and Drug Administration for Use in Foods

The U.S. Food and Drug Administration has not enacted any nanomaterial-specific regulation to protect consumer health. The FDA has published guidance regarding nanomaterials in food products, providing that:

- Nanoparticles can have chemical, physical, and biological properties that differ from those of their larger counterparts;[10]
- "[w]hen a food substance is manufactured to include a particle size distribution shifted more fully into the nanometer range, safety assessments should be based on data relevant to the nanometer version of the food substance;"[11]
- *Nanomaterials in food cannot be Generally Recognized As Safe*: "At this time, we are not aware of any food ingredient or FCS [food contact substance] intentionally engineered on the nanometer scale for which there are generally available safety data sufficient to serve as the foundation for a determination that the use of a food ingredient or FCS is GRAS [Generally Recognized As Safe];"[12]

Insurance Groups, Scientists, and Regulators Are Concerned

2008: The insurance giant Swiss Re noted that "what makes nanotechnology completely new from the point of view of insuring against risk is the unforeseeable nature of the risks it entails and the recurrent and cumulative losses it could lead to, given the new properties – hence different behavior -- of nanotechnologically manufactured products."[13]

2009: The European Union's Scientific Committee on Emerging and Newly Identified Health Risks concluded that "health and environmental hazards have been demonstrated for a variety of manufactured nanoparticles;" that "nanoparticles are similar to normal chemicals/substances in that some may be toxic and some may not;" and that "a case-by-case approach for the risk assessment of nanoparticles is still warranted."[14]

2011: Gen Re, a large re-insurer, noted that "[t]here are, at this time, dozens of studies associating exposure to various nanoparticles with adverse health effects."[15]

2012: The National Research Council conducted an EPA-requested study of nanotechnology research and found that "despite increasing budgets for nanotechnology-EHS research and a growing number of publications, *regulators, decision-makers, and consumers still lack the information needed to make informed public health and environmental policy and regulatory decisions*."[16]

2013: The President's Council of Advisors on Science and Technology, in its assessment of the National Nanotechnology Initiative (NNI), expressed concerns about "a lack of integration between

nanotechnology-related [environmental health and safety] research funded through the NNI and the kind of information policymakers need to effectively manage potential risks from nanoparticles." [17]

Nanomaterials May Be Harmful If Ingested

Peer-reviewed scientific research suggests that nanomaterials (including those larger than 100 nm) may not be safe for ingestion. There is no consensus on what size is safe. Selections from a growing body of nanotoxicology studies show that:

- Nanoparticles up to 240 nm were able to pass through cell membranes in organisms, and their interactions with biological systems are relatively unknown.[18]
- Based on a review of the scientific literature on nanotoxicology and endocytosis (the mechanism by which cells absorb molecules), materials up to 300 nm may be able to pass through cell membranes. The review did not address the absorption of larger nanomaterials. It also concluded that "non-degradable nanoparticles which accumulate intracellularly are likely to have a number of effects" including cell damage, inflammation, and toxicity.[19]
- The first multi-institutional study examining the health effects of engineered nanomaterials found that several nanomaterials, including three forms of titanium dioxide and three forms of carbon nanotubes, cause lung inflammation and damage.[20]
- Mice fed titanium dioxide nanoparticles with their drinking water for five days demonstrated that "*in vivo* after oral exposure, TiO2 nanoparticles induce DNA strand breaks and chromosomal damage in bone marrow and/or peripheral blood."[21]
- Male offspring of pregnant mice injected with titanium dioxide nanoparticles experienced genital malformations and neurologic damage[22] as well as changes in gene expression in the brain.[23]
- Human lung epithelial cells absorbed a range of TiO_2 nanoparticles. Exposure to these nanoparticles, even as aggregates or agglomerates, triggered inflammatory responses from the cells.[24]
- Other *in vitro* studies have suggested that some types of titanium dioxide and zinc oxide nanoparticles are toxic to human brain and lung cells.[25,26]
- Silver nanoparticles had a toxic effect on human and mice testicular cells, suppressing cellular growth and multiplication and causing cell death.[27]

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[1] Naturally-occurring organic nanoscale particles (e.g. milk proteins, essential minerals) are not considered engineered or manufactured materials for this purpose. The term "naturally occurring" excludes engineering or manufacturing processes that reduce the size of materials, as well as naturally-occurring inorganic nanomaterials, such as asbestos.
[2] Aggregates and agglomerates of nanoparticles are considered to be nanostructured substances.
[3] Alex Weir and Paul Westerhoff. "Titanium Dioxide Nanoparticles in Food and Personal Care Products." Environmental Science and Technology. Published Feb 21, 2012. http://www.ncbi.nlm.nih.gov/pubmed/22260395/
[4] Weir and Westerhoff 2012
[5] Peters, Ruud J.B. et al. "Characterization of Titanium Dioxide Nanoparticles in Food Products: Analytical Methods To Define Nanoparticles." Agricultural and Food Chemistry. Published July 8 2014.

http://www.rivm.nl/Documenten_en_publicaties/Wetenschappelijk/Wetenschappelijke_artikelen/2014/augustus/Characterization_of_titanium_dioxide_nanoparticles_in_food_products_Analytical_methods_to_define_nanoparticles

[6] Alex Weir, Paul Westerhoff et al. "Characterization of Food-Grade Titanium Dioxide: The Presence of Nanosized Particles." Environmental Science & Technology. Published 2014. http://www.medscape.com/medline/abstract/24754874

[7] As You Sow. *Slipping Through the Cracks: An Issue Brief on Nanomaterials in Food*. Published 2013. http://www.asyousow.org/ays_report/slipping-through-the-cracks/

[8] Plastics News. "EPA halts sales of plastic food containers with nanosilver content." Published April 4 2014. http://www.plasticsnews.com/article/20140404/NEWS/140409951/epa-halts-sales-of-plastic-food-containers-with-nanosilver-content

[9] Center for Food Safety. "Nanosilver in Food and Food Contact Products." Accessed Dec 15 2014. http://www.centerforfoodsafety.org/files/nano-silver_product_inventory-in-food-12514_66028.pdf

[10] Food and Drug Administration. "Nanotechnology." Accessed Feb 5 2015. http://www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/default.htm;

[11] Ibid.

[12] Food and Drug Administration. *Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes*. Paragraph III Section E. Published June 2014. http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm300661.htm

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[15] Gen Re. *Insurance Issues*. Published November 2011. http://www.sheetsdatago.com/pdf/44-1/datasheet-InsuranceIssues201111-en.htm

[16] Congressional Research Service. *The National Nanotechnology Initiative: Overview, Reauthorization, and Appropriations Issues.* Published 2013. p.41. http://www.fas.org/sgp/crs/misc/RL34401.pdf

[17] Ibid.

[18] Wick et al. "Barrier Capacity of Human Placenta for Nanosized Materials." Environmental Health Perspectives. Published 2012. http://ehp.niehs.nih.gov/0901200/

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