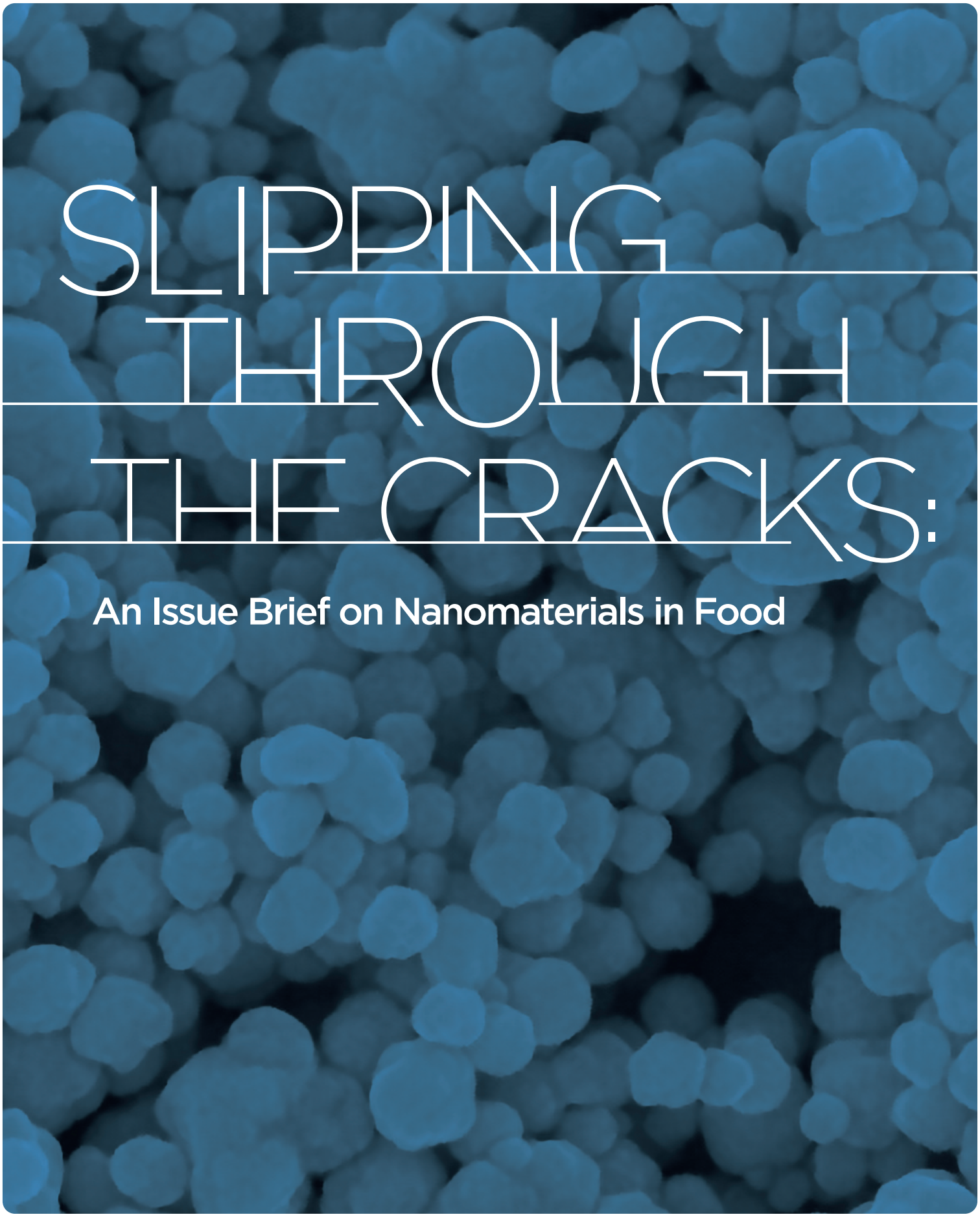

SLIPPING THROUGH THE CRACKS:

An Issue Brief on Nanomaterials in Food

AS YOU SOW®

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Cover and Other Images: Transmission electron microscope of nanoparticles, courtesy of the International Society for Optics and Photonics.[1]

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EXECUTIVE SUMMARY

Engineered nanomaterials are beginning to be used and sold in common food products, but there is a lack of transparency by companies on this issue. In fact, many companies that sell products containing nanomaterials commercially may not even know that nanomaterials are in their supply chain.

This issue brief is intended to inform companies, investors, and consumers about the emerging use of engineered nanomaterials in food and food related products, and to highlight the potential unknown risks of this technology. The state of knowledge about how nanomaterial food additives may react in the body and what their health impacts may be is in its infancy and, while there is currently an effort to understand these issues in greater depth, the authors believe much deeper scientific inquiry should occur before nanomaterials continue to be sold in food and food-related products.

INTRODUCTION

Nanomaterials are often heralded as having the potential to revolutionize the food industry – from enabling the production of creamy liquids that contain no fat, to enhancing flavors, improving supplement delivery, providing brighter colors, keeping food fresh longer, or indicating when it spoils. It is reported that nanotechnology is already used in food and food related products, but due to lack of transparency about the issue, concrete information has been difficult to obtain. The majority of food companies have not been responsive in providing information about their specific uses, plans, and policies on this topic and no U.S. laws require disclosure. In addition, there are few, if any, studies adequately demonstrating the safety of nanoparticles in food additives or packaging. In fact, scientists are still investigating how the broad range of nanoparticles, with their myriad potential uses, will react in the body and what the appropriate testing methodologies are to determine this.

To understand more fully if, and how, nanomaterials are being used in food or food packaging, in 2008 As You Sow filed the first shareholder resolutions on nanomaterials and food safety, asking McDonald's and Kraft Foods to report on their use of nanomaterials in their food products and packaging. Our subsequent dialogue with McDonald's resulted in the company publicly stating that it "does not currently support the use by suppliers of nano-engineered materials in the production of any of our food, packaging, and toys."[2] Similarly, in 2009, Kraft Foods posted a statement on its website that it was not using nanotechnology: "Currently we're not using nanotechnology. But as a leading food company, we need to understand the potential this technology may hold for us in terms of food safety, product quality, nutrition and sustainability."[3]

In 2010, As You Sow, working with several investor firms including Calvert Investments, Domini Social Investments, Green Century Capital Management, and Trillium Asset Management, contacted some of the largest and most iconic food companies in the world including YUM! Brands, PepsiCo, and Whole Foods about their use of nanomaterials. Most companies did not know whether or not nanomaterials were used in their products and had to check with their suppliers. This lack of knowledge about nanomaterials in the supply chain prompted As You Sow to publish its paper, *Sourcing Framework for Food and Food Packaging Products Containing Nanomaterials*, in December 2011.[4]

In 2012, As You Sow surveyed companies in the food industry to better understand the current status of nanomaterial use in the U.S. food market. We sent a survey to 2,500 companies including:

- the 100 largest food processing companies
- the 50 largest food distributors
- the 75 largest food retailers
- the 25 top food packaging companies
- the 50 top fast food companies
- 187 nutritional supplement companies

Despite this outreach, only 26 companies responded to the survey. This lack of response appears to be characteristic of the food industry when addressing nanomaterials in food. For instance, in 2009, the U.S. Environmental Protection Agency (EPA) estimated that approximately 90% of the nanoscale materials that are likely to be commercially available were not reported under the Nanoscale Materials Stewardship Program.[5] The lack of disclosure by food companies about their use or potential use of nano-enhanced products is an indicator that consumers, workers, shareholders, and government agencies are currently unable to assess how companies are evaluating and managing the potential safety concerns around the use of nanomaterials in food and food packaging.

ARE NANOMATERIALS IN OUR FOODS?

Whether and to what degree nanomaterials are currently in our foods remains a murky issue. A study by American, Swiss, and Norwegian researchers entitled *Titanium Dioxide Nanoparticles in Food and Personal Care Products* estimates and quantifies the human exposure resulting from nanoparticle sized titanium dioxide (TiO_2) found in processed foods.[6] The study measured nanoparticles in food-grade TiO_2 and derived estimates of nano TiO_2 in foods including M&M's, Betty Crocker Whipped Cream Frosting, Jell-O Banana Cream Pudding, Mentos, Trident and Dentyne gums, Vanilla Milkshake Pop Tarts, and Nestlé Original Coffee Creamer. The authors state that "electron microscopy and stability testing of food-grade TiO_2 […] suggests that approximately 36% of the particles are less than 100nm in at least one dimension."

To confirm the presence of nano TiO_2 in specific products, As You Sow conducted independent laboratory tests on two commercially available donuts with white powdered sugar frosting. Test data revealed TiO_2 nanoparticles of 10 nm or smaller in the white powdered sugar on both Dunkin' Donuts Powdered Cake Donuts and Hostess Donettes (see appendix A for testing methodology). Whether these TiO_2 nanoparticles were engineered or a byproduct of manufacturing processes is not known. As You Sow plans to to continue to test more products including M&M's, Trident gum, and Pop-Tarts as well as a range of other food products in the near future.

In addition to the potential for nanoparticles being used in food-grade titanium dioxide, other planned uses of food-related nanomaterials exist. In their report, *Opportunities and Risks of Nanotechnologies*, the industrial insurance giant Allianz and the Organisation for Economic Co-operation and Development (OECD) found that there are four main areas of concern regarding nanomaterials in food:[7]

> Tests revealed titanium dioxide nanoparticles in the powdered sugar on Dunkin' Donuts Powdered Cake Donuts and Hostess Donettes.

1. **Nano Foods:** Nestlé, Unilever, and others are employing nano technology to change the structure of food. Kraft is creating interactive drinks containing nanocapsules that can change color and flavor, while Unilever and Nestlé are using nanoparticle emulsions to improve texture in their spreads and ice creams. Others are inventing nanocapsules that will smuggle nutrients and flavors into the body (what one company calls "nanoceuticals").
2. **Nanofeed for Chickens:** Funded by the U.S. Department of Agriculture (USDA), Clemson University researchers are feeding bioactive polystyrene nanoparticles that bind with bacteria to chickens as an alternative to chemical antibiotics in industrial chicken production.
3. **Nanoparticle Pesticides:** Monsanto, Syngenta, and BASF are developing pesticides enclosed in nanocapsules or made up of nanoparticles. The pesticides can be more easily absorbed by plants if they are in nanoparticle form. Nanocapsules can also be programmed to be "time-released."
4. **Nano Ponds:** One of the U.S.'s biggest farmed fish companies, Clear Spring Trout, is adding nanoparticle vaccines to trout ponds, where they are ingested by fish.

NANOMATERIALS IN FOOD PACKAGING

Nanomaterials are also being explored for their promise to improve food packaging, including providing longer shelf-life for foods, better barrier properties, improved heat resistance and temperature control, and anti-microbial and fungal protections, among others.[8] Although many reports describe a substantial market for nanomaterials in food packaging, as with food producers, there is a lack of concrete information as to how extensively nanomaterials have moved into food packaging, especially in the U.S.

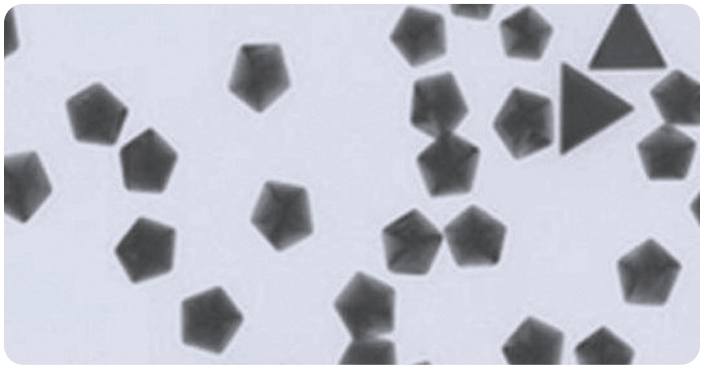
Nanocomposites that enhance barrier properties appear to be commercially available. Silver nanoparticles that act as antibacterial agents or nanoclay coatings are also examples of nanomaterials likely to currently be in use in food packaging.[9] As with food producers, actual disclosures by companies using nanomaterials in food packaging would help shed light on the issue and could foster an improved discussion and analysis of the safety benefits or potential harms associated with its use.

Despite nanomaterial's possible benefits for food packaging, "[t]here are still knowledge gaps as to the migration of nanoparticles from packing into food," and what, if any, the health impacts of such migration would be.[10]

NANOMATERIALS AND FOOD SAFETY

Consumer acceptance of nanofood products will ultimately hinge on the question of its safety. In the 2012 report *Effects of Silver Nanoparticles on the Liver and Hepatocytes In Vitro* the author states:

> At the moment, there is not much information available on the topic of ingested nanoparticles and human health. There is evidence that a small percentage of these particles or particle components [of nano titanium dioxide or nano silver] can move on from the intestinal tract into the blood, and reach other organs. This is why we believe it is important to assess the risk of even small amounts of particles in the human body.[11]



Engineered nanomaterials are designed so that their small scale imparts unique physical properties. An important aspect of nanotechnology is the vastly increased ratio of surface area to volume present in many nanoscale materials.

Because of their small size, nanoparticles are able to go places in the body that larger particles cannot.[12] Nanoparticles in food or food packaging can gain access via ingestion, inhalation, or skin penetration. When ingested, the nano-sized particles facilitate uptake into cells and can allow them to pass into the blood and lymph where they circulate through the body and reach potentially sensitive target sites such as bone marrow, lymph nodes, the spleen, the brain, the liver, and the heart.[13] Nanoparticles penetrating the skin can distribute through the body via lymphatic channels.[14] Inhaled nano TiO_2 has been found to act like asbestos and silicone in that it accumulates in the lung and causes inflammation and can impact DNA proteins and cell membranes.[15]

Nanoparticles have been shown to translocate to the bloodstream following ingestion and inhalation. A 2010 National Institutes of Health funded Swedish study, *Influence of Nanoparticles on Blood-Brain Barrier Permeability and Brain Edema Formation in Rats*, shows that:

> (1-100 nm) particles derived from transition metals, silver, copper, aluminum, silicon, carbon and metal oxides [...] can easily cross the blood-brain barrier (BBB) and/or produce damage to the barrier integrity by altering endothelial cell membrane permeability [… and] induce brain edema formation.[16]

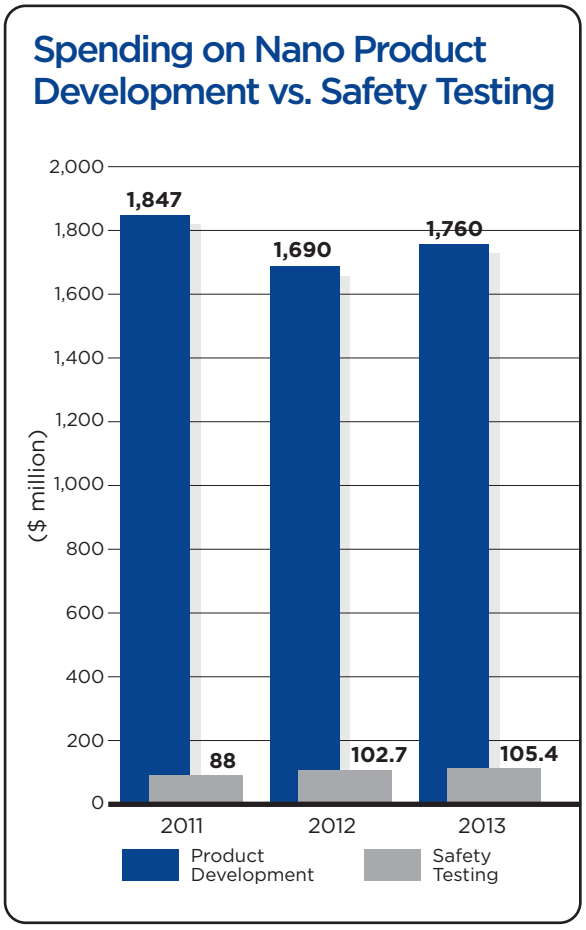
UCLA researchers in the report *Titanium Dioxide Nanoparticles Induce DNA Damage and Genetic Instability In Vivo in Mice* state, "(nanoparticles) are able to penetrate cells" and interfere with several subcellular mechanisms.[17] Indeed, some studies show that some nanoparticles can penetrate into cell nuclei and may therefore directly interfere with the structure and function of genomic DNA.[18] Additionally, after oral administration in mice, TiO_2 particles were shown to translocate to systemic organs such as the liver and spleen as well as lung and peritoneal tissues."[19]

Further clouding the issue is the lack of consensus on what size constitutes a nanomaterial. In June 2011, the Food and Drug Administration's (FDA) draft guidance on nanotechnology classified particles as nanomaterials if they are smaller than 1,000 nm.[20] This was significant because many argued for a cut-off at 100 nm even though materials that measure less than 300 nm can be taken up by individual cells.[21] The U.S. National Organic Standards Board has called for nanomaterials smaller than 300 nm to be excluded from organic food.[22]

> Nanoparticles are able to penetrate cells and interfere with several subcellular mechanisms. Some studies show that some nanoparticles can penetrate into cell nuclei and may therefore directly interfere with the structure and function of genomic DNA.

Perhaps more important than size are the unique physical and chemical properties of nanomaterials. Properties such as bioavailability, reactivity, and persistence can vary significantly between a material at nano versus normal scale. Consequently, known toxicity profiles of normal size materials might not apply at the nanoscale. Nano-engineered materials need to be safety tested at the size that will be used in commercial products where people may be exposed or environmental releases may occur.

Initial studies are already raising health concerns. For instance, nano silver is being used as an antimicrobial for food preparation and packaging materials despite studies showing that it can cause lung toxicity and inflammation in mice.

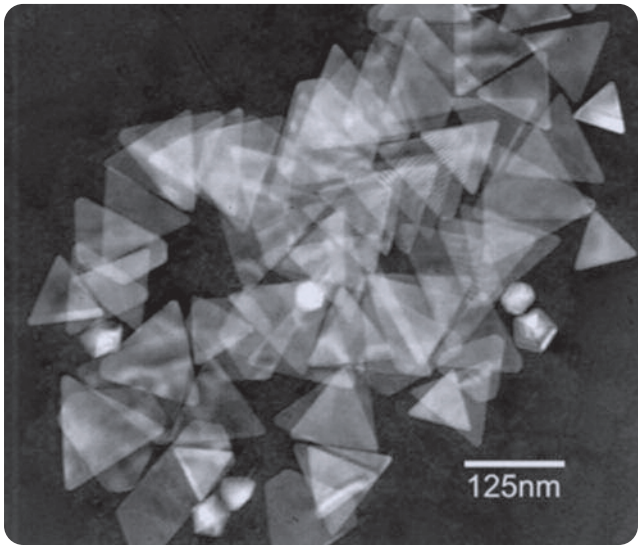


The lack of disclosure of nanomaterials in food and food packaging is particularly concerning because there is a minimal amount of funds going into safety testing in comparison to that of new nano product development. For example, the National Nanotechnology Initiative (NNI) "expedites the discovery, development and deployment of nanoscale science and technology to serve the public good, through a program of coordinated research and development aligned with the missions of the participating agencies."[23] Funding in 2011 was $1.847 billion, $1.69 billion in 2012, and $1.76 billion is proposed for 2013.[24] During those years, the funding for work in environmental health and safety related to nanomaterials was $88 million, $102.7 million, and $105.4 million, respectively.[25] The discrepancy in funding between engineered nanomaterial product and safety testing is of likely concern to consumers and should be of utmost concern to the food industry where human exposure is virtually guaranteed.

In the current environment – where little safety data, or even agreed-upon study methods, exist and where state and federal laws and regulations have not yet been developed to ensure product and consumer safety for nanomaterials in food and food packaging – companies should be clear about whether they are sourcing products containing or manufactured using nanomaterials. Before using or allowing nanomaterials to be used in their food products, companies should ensure that any such nanomaterials have been proven safe in both the short and long term, for that particular use, to protect their workers, their customers, and the environment.

PUBLIC CONCERN ABOUT NANOMATERIALS IN FOOD

Historically, new technologies such as genetically engineered and irradiated foods have faced challenges in gaining consumer acceptance. Growing consumer demand for safer, more environmentally friendly food products, combined with the current lack of transparency regarding use of nanoparticles, and the lack of testing regarding the effects of nanoparticles in human bodies, is likely to result in roadblocks to consumer acceptance of nanofood products.

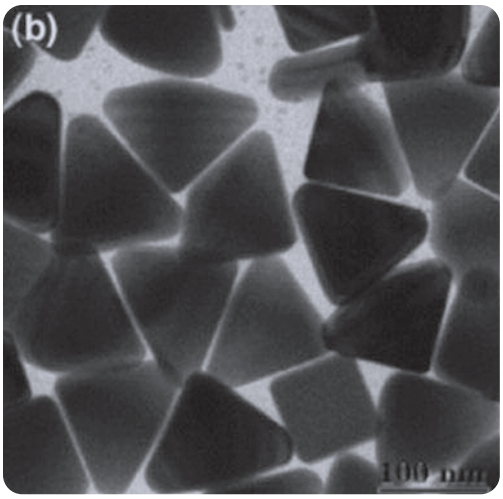


In an article in *Nature Nanotechnology* entitled "Risks and Nanotechnology: The Public is More Concerned than Experts and Industry," the authors summarize that:

> The public perception of nanotechnology will have a major influence on the success of new applications of nanotechnology […] Lay people perceive more risks associated with nanotechnology than experts and, moreover, that companies may not sufficiently address public concerns, even though the importance of implementing risk assessment procedures during the early stages of technology development is well known.[26]

What's holding back the introduction of nanofoods is the hesitation of the food industry, fearing a public backlash along the lines of what happened with genetically modified foods.

Timothy Duncan, a research chemist from the FDA, similarly described potential roadblocks to the introduction of nanotechnology in foods. Writing in the journal *Nature Nanotechnology*, Duncan says, "[w]hat's holding back the introduction of nanofoods is the hesitation of the food industry, fearing a public backlash along the lines of what happened with genetically modified foods, and public fears in some countries about tampering with nature."[27]



Recent studies indicate that consumer concern already exists. A 2012 Swiss-German study on consumer perception of nanomaterials titled *Nanotechnologies from the Consumers' Point of View: What Consumers Know and What they Would Like to Know* found that 67% of respondents feared health risks from nanotechnology, up from 55% in 2008.[28] This study also found that people are less convinced of the benefits of nanotechnology and that "consumers appear to be more informed about details of the risk debates and are able to describe the risks better than in 2008."[29]

There is historic precedent for consumer perceptions to be cause for concern to the food industry. Genetically modified organisms (GMO) have been suspect among consumers since their introduction and currently six nations in the European Union have restricted or prohibited GMO sale or use.[30] Forty countries around the world now require labeling for GMOs, and a study by Thomson Reuters in 2010 found that 93% of Americans think that GMOs should be labeled and 63% were unsure if GMOs were safe.[31] Fourteen states are considering bills or initiatives requiring the labeling or banning of GMOs.[32] In 2012, food companies spent more than $56 million in California alone to fend off a ballot initiative calling for labeling of GMO ingredients. The initiative lost by only 2% of the vote.

A recent report by the Science and Technology Committee of the U.K. House of Lords, *Nanotechnologies and Food*, acknowledged the potential for a similar public backlash to nanomaterials as occurred with GMOs in food:

> Consumers are particularly sensitive about new technologies involving the scientific manipulation of food and understandably cautious about their introduction. The public response to the development of genetically modified food illustrates how quickly the views of some sectors of the public can change if action is not taken to meet concerns they may have about new food technology.[33]

EMERGING POLICIES AND REGULATIONS

Europe has taken the lead in the study and regulation of nanomaterials in food. In May 2011, the European Food Safety Authority (EFSA) published "[t]he first practical guidance for assessing nano applications in food and feed."[34] This guidance is the work of the Authority's Scientific Committee and is the first of its kind to give practical guidance for addressing potential risks arising from food-related applications of nanoscience and nanotechnologies. The guidance covers risk assessments for food additives, enzymes, flavorings, food contact materials, novel foods, feed additives, and pesticides. The EFSA guidance sets out considerations for risk assessment that may arise from engineered nanomaterials' (ENM) specific characteristics and properties. Importantly, the ENM guidance complements existing guidance documents for substances and products by stipulating the additional data needed for the physical and chemical characterization of ENM in comparison with conventional applications, and outlines different toxicity testing approaches to be followed by applicants.

In July 2011, the European Union passed regulations on the labeling of nanomaterials in food. The new law combined two directives into one piece of legislation: 2000/13/EC on labeling, presentation, and advertising of foodstuffs, and 90/496/EEC on nutrition labeling for foodstuffs.[35] The new law contains a definition of the term "nanomaterials" and mandates the labeling of all ingredients falling under this definition.

> The FDA recognized that ingredients that are generally recognized as safe at the macro level may not be safe at the nanoscale.

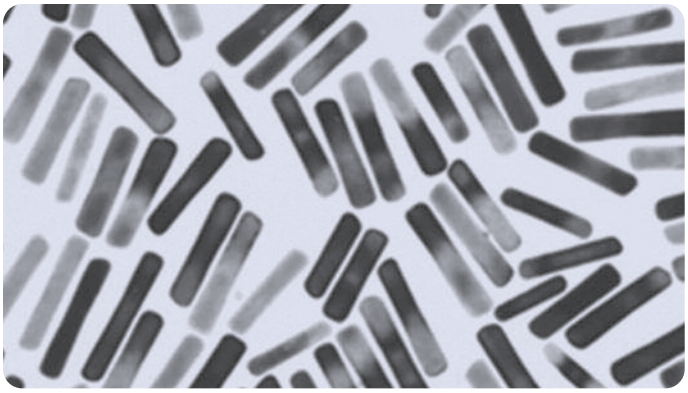
In contrast, the FDA has not issued regulations regarding nanomaterials in food, and for a long time there was a question as to whether the FDA would even address nanomaterials as a separate substance. In April 2012, the FDA took a significant step towards answering that question when it announced that:

> 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].[36]

The FDA recognized that ingredients that are GRAS at the macro level may not be safe at the nanoscale because: "[t]he application of nanotechnology may result in product attributes that differ from those of conventionally-manufactured products."[37] In addition, "nano-engineered food substances can have significantly altered bioavailability and may, therefore, raise new safety issues that have not been seen in their traditionally manufactured counterparts."[38]

The FDA further notes that:

> Extrapolation from data on traditionally manufactured food substances can generally be accomplished only on a case-by-case basis […] When 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. Where nano-engineered food substances have new properties, additional or different testing methods may be necessary to determine the safety of the food substance.[39]



In June 2011, the FDA issued draft guidance for industry, *Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology*, intended to provide a starting point for the nanotechnology discussion. In the draft, the FDA states that it "believes that evaluations of safety, effectiveness or public health impact of such products [containing nanomaterials] should consider the unique properties and behaviors that nanomaterials may exhibit."[40]

This was a significant step because it prioritizes the properties and behavior of the material over its size. In the same document, the FDA also states that it would adhere to the "Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials."[41] Yet, questions exist as to the FDA's capacity to conduct such evaluations—its ability to regulate the safety of nanomaterials in food is severely limited by lack of information, lack of resources, and the agency's lack of statutory authority in certain critical areas.[42]

These two statements—that nanomaterials are not GRAS and that their designation is a function of their properties and not their size—is all that the FDA has formally stated. FDA's finding that nanomaterials are not GRAS indicates that at least another layer of testing must be done in order to determine that a nanomaterial is safe to use in food or food packaging, but how the FDA determines the toxicity exposure of nanomaterials in food substances is yet to be determined. At present, no parameters, tests, or testing equipment or methodology have been established to identify or decide how to measure exposure, absorption levels, or behaviors of nanoparticles in the human body.[43] Once that has been agreed upon, a process for determining the safety of nanomaterials proposed to enter the food supply should be set up and adhered to, a process that will take years.

Regardless of the lack of U.S. government policies, some industry leaders have taken it upon themselves to develop their own public positions on nanomaterials in foods and food packaging.

Examples of Current Public Corporate Positions on Nanomaterials in Foods

McDonald's

McDonald's Corporation is working to understand the use of nanotechnology and its application in food and packaging products. Given the current uncertainty related to potential impacts of nano-engineered materials, McDonald's does not currently support the use by suppliers of nano-engineered materials in the production of any of our food, packaging and toys.[44]

Kraft Foods

Nanotechnology is an emerging scientific field. It involves the design and application of structures, devices and systems by controlling their shape and size at an extremely small scale—in range of one-to-100 nanometers (for reference, one nanometer is one-billionth of a meter). And this technology holds a lot of promise across industries.

Currently we're not using nanotechnology. But as a leading food company, we need to understand the potential this technology may hold for us in terms of food safety, product quality, nutrition and sustainability. That is why our research and development teams always keep their eyes on the scientific research, as well as consider potential applications where nanotechnology may be used in packaging material.

In particular, we're looking at packaging that requires less material, which helps to reduce waste. We would only consider those uses that meet regulatory requirements and are considered safe by the scientific community. We also take into account what our consumers think and feel.

If we ever intend to use nanotechnology, we will make sure that the appropriate environmental, health and safety concerns have been addressed. This includes going through our own stringent quality-control processes, as well as working with our suppliers to make sure the proper assessments have been completed.[45]

Learn more about current activities on this issue from the National Nanotechnology Initiative (http://www.nano.gov/) and the Woodrow Wilson Project for Emerging Nanotechnologies (http://www.nanotechproject.org/).

SURVEY FINDINGS

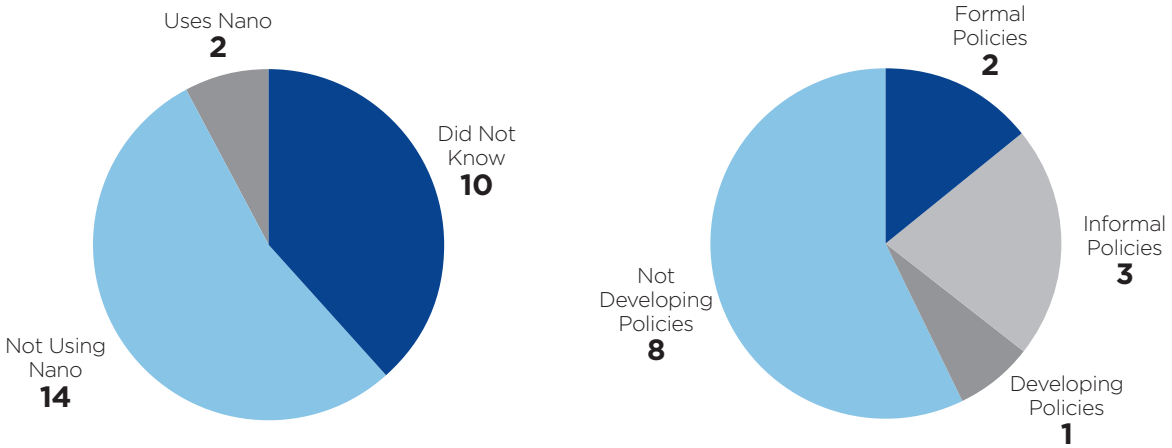
As You Sow's survey was sent to 2,500 corporations including the 100 largest food processing companies, the 50 largest food distributors, the 75 largest food retailers, the 25 top food packaging companies, the 50 top fast food companies, and 187 nutritional supplement companies. However, after multiple follow up calls and emails, only 26 survey responses were received and an additional 38 companies responded to follow-up Facebook inquiries.

The survey asked five questions, with subparts, including whether the company is using nanomaterials in its food or food packaging and, if so, how it is being used; whether the company is interested in or exploring the use of nanomaterials; whether the company has a policy on the use of nanomaterials or, if not, whether it plans to develop such a policy; how the company learns about and evaluates the use of nano products; and whether any person in the company is specifically responsible for product safety related to nanomaterials.

> 2,500 corporations including the largest food processing companies, food distributors, food retailers, food packaging companies, fast food companies, and nutritional supplement companies received the survey. Only 26 responded.

The companies' failure to respond to this survey highlights the general lack of transparency in the industry. This is especially true in light of an online search As You Sow performed for nearly 200 of the companies that received the survey. In this search, As You Sow found a variety of news articles indicating that at least 69 of the companies have an interest in nanotechnology or are currently producing products containing nanomaterials.

Responses to the Nanomaterials in Food Survey



Of the 26 companies that did respond to the survey, 10 said that they did not know if they had nanomaterials in their products or supply chains and 14 companies stated that they were not using nanomaterials. Two companies stated they have nanomaterials in their products: one company uses silver as an antibacterial in its products and the other uses nanomaterials in its packaging. Neither of these two companies has a policy on nanomaterials nor has plans to develop one. Of the 38 responses from Facebook inquiries, 30 made a statement that the company does not use nanomaterials in its food products without providing information about whether nano was added in their supply chain.

Of the 14 companies responding to the survey that indicated they are not currently using nanomaterials, two stated they have formal policies on nanomaterials, three have informal policies, and one is developing a policy. The other eight companies are not in the process of developing policies on nanomaterials. Five companies not using nanomaterials stated an interest in using them and are tracking the field, and two are actively exploring the use of nanomaterials for a future date.

Most of the responding companies stated that they learn about nanomaterials primarily from their suppliers, followed by trade associations, industry media, and lastly, company research staff. Six companies plan to survey their suppliers on this issue in the next year and seven companies have a specific staff person responsible for product safety related to nanomaterials.

One supplement manufacturer that is not using nanomaterials felt there was not enough data to satisfy safety requirements, while another supplement manufacturer indicated it is actively exploring using nanomaterials in its products.

The above responses highlight a significant challenge for consumers. Companies are divided on the safety of nanomaterials and make independent decisions based on their own interests, research, and interpretations of data, without providing such information to the public. Further, companies are not required to disclose the presence of nanomaterials in their products or on what, if any, safety data the company relied.

RECOMMENDATIONS

Given the lack of transparency within the industry; lack of information within individual companies; lack of investments in environmental, health, and safety testing in the development of nanotechnologies; lack of regulatory oversight; and the overall increase in consumer concern over food safety and demand for healthy products, As You Sow has the following recommendations.

Every company should:

- Develop a policy on nanomaterials
- Disclose its position or policy on nanomaterials to consumers, investors, and stakeholders
- Survey suppliers to see if they are using nanomaterials in their production of food or supplement products or packaging
- Survey suppliers to see if they know whether their food, supplement products, or food packaging contains nanomaterials
- Communicate preferences regarding nanomaterials to all suppliers
- Have someone in the company uniquely responsible for product safety related to nanomaterials if the company is using or considering using nanomaterials in its products
- Disclose all environmental, health, and safety risks to consumers on nano-enhanced products and packaging
- Disclose all environmental, health, and safety risks to shareholders in its public filings
- Implement responsible sourcing practices such as those outlined in the *Sourcing Framework for Food and Food Packaging Products Containing Nanomaterials*.[46]

Investors should:

- Introduce questions about nanomaterials and nanomaterial use at company presentations, webinars, and meetings, as well as in shareholder dialogues around product safety and environmental impacts
- Encourage companies to survey their suppliers regarding the presence of nanomaterials in their supply chains
- Encourage companies to develop a position on nanomaterials and state that position publicly
- Encourage companies that are considering using nano-enhanced products to ensure complete safety testing has been performed for the nanomaterials being used, including the contexts in which they are being used, and that they demonstrate such materials are safe for human health and the environment
- Press companies to label food products and food packaging that contain nanomaterials

Consumers and stakeholders should:

- Question companies on their use of nanomaterials
- Learn about the benefits and risks of nano-enhanced food and food packaging
- Let companies know how they feel about nanomaterials in their food products
- Request that companies label food products and packaging that contain nanomaterials

CONCLUSION

The public is becoming increasingly sophisticated in its food choices. No longer content with label information on daily allowances of vitamins and minerals, U.S. consumers are following the lead of their counterparts in many other countries by demanding more information about where and how their food is grown and whether it is safe. California's recent $56 million battle over a nearly victorious GMO labeling initiative demonstrates consumers' increasing emphasis on their right to know what is in their food. In contrast, most companies have not been forthcoming about their use of nanomaterials in foods and food packaging.

For an emerging technology such as nanomaterials in food, even though communicating risks to consumers is challenging, the public's perception of safety will be paramount in determining consumer acceptance. This is especially true for a technology for which the FDA has acknowledged a lack of understanding regarding the safety of these materials when used in food products. In a situation where even the regulatory agencies lack a sure footing, it is imperative that companies recognize the risks of using nanomaterials in their products—including risks from lawsuits, reputational risk, and even bans on the technology. To avoid these potential pitfalls, any movement toward use of nanomaterials in food should be undertaken with deliberation, knowledge, comprehensive safety testing, and full transparency to consumers and shareholders.

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APPENDIX A:
TITANIUM DIOXIDE NANOPARTICLE LABORATORY RESULTS

As You Sow contracted Analytical Sciences, LLC, an independent and state-certified laboratory, to test 10 powdered sugar donut products for the presence of titanium. Titanium concentrations were found in nine out of 10 donut products tested, with concentrations ranging between 19 to 75 parts per million (ppm). The presence of titanium is a likely indicator that these products contain food-grade titanium dioxide (TiO_2), since TiO_2 is the only form of titanium allowable in foods. While titanium was found in 90% of the products, only six of the 10 products listed TiO_2 as an ingredient on the packaging.

Laboratory Methodology

Approximately a third of the white powder covering one Dunkin' Donuts Powdered Cake Donut and three Hostess Donettes (one serving) was carefully removed from the donut surface using a clean stainless steel spatula. The two samples of white powder were placed in separate crucibles and ashed at a temperature of 575 degrees centigrade for over one hour to incinerate sugars, flour, and other organics present in the white powder; titanium dioxide and other inorganic compounds not affected by the high temperature remained. After cooling, the ash present in each crucible was transferred to a clean vial into which 30 milliliters of de-ionized water was added. The vial was sealed and agitated to suspend the particles present.

Donut Products Tested for TiO_2

Two of the donut products in which titanium concentrations were found—Hostess Donettes and Dunkin' Donuts Powdered Cake Donut—were subsequently tested for the presence of nanoparticle sized titanium dioxide. Titanium dioxide materials of less than 10 nm were found in both of the donuts tested, as set forth in more detail below. While there are varying definitions of what constitutes a nanoparticle, our testing assessed a conservative particle size of less than 10 nm. The test results underscore that the low-end of the nanoparticle-sized spectrum (<10 nm) titanium dioxide is present in our food supply.

Product	TiO_2 Listed as Ingredient	Total Ti PPM
Conchitas – Fine Pastry		Not Detected
Dolly Madison – Donut Gems	●	58
Dunkin' Donuts – Powdered Cake Donut	●	19
Entenmann's – Pop'ems Donuts		73
Hostess Brand – Donettes	●	75
Kroger – Sugared Cake Donut Holes	●	43
Little Debbie – Mini Powdered Donuts	●	43
Sunnyside Farms – Mini Powdered Donuts	●	71
Van de Kamp's – Donuts	●	43
Walmart The Bakery – Powdered Mini Donuts		63

After incineration of organics and suspension of the residue in 30 milliliters of water, the water suspension was passed through filters of varying pore sizes to assess the particle size distribution. The first filter was at 15 microns pore size (meaning particles larger than 15 microns were removed from the water suspension and trapped on the filter). The water that passed through the 15 micron filter was then passed through a filter at 2 microns pore size. This second filter collected particles in the size range from 2 microns to 15 microns. The remaining water was further filtered through a 0.01 micron filter, collecting materials between 0.01 microns to 2 microns size range. The final filtrate passing through the 0.01 micron (10 nm) filter was placed in a clean crucible and dried to remove water present. The titanium dioxide residue from this final water suspension was weighed and represents particles smaller than 10 nm. Test data show that the consumption of one serving size of Hostess Donettes (three small donuts) would result in the ingestion of 13.8 mg of TiO_2 in the nanoparticle size of less than 10 nm, while one serving (one donut) of a Dunkin' Donut Powdered Cake Donut would result in the ingestion of 8.9 mg of TiO_2 less than 10 nm in size.

ENDNOTES

1 Luis M. Liz-Marzan, "Tuning Nanorod Surface Plasmon Resonances," *International Society for Optics and Photonics*, July 16, 2007, **http://spie.org/x15074.xml**.

2 "Nanotechnology," McDonald's, **http://www.aboutmcdonalds.com/mcd/sustainability/library/policies_programs/sustainable_supply_chain/product_safety/Nanotechnology.html**.

3 "Nanotechnology," Kraft Foods, **http://www.kraftfoodsgroup.com/DeliciousWorld/food-safety-quality/nanotech.aspx**.

4 Amy Galland and Michael Passoff, *Sourcing Framework for Food and Food Packaging Products Containing Nanomaterials*, (As You Sow, December 2011), **http://www.asyousow.org/health_safety/nanoframework.shtml**.

5 U.S. Environmental Protection Agency Office of Pollution Prevention and Toxics, "Nanoscale Materials Stewardship Program: Interim Report," January 2009, **http://www.epa.gov/oppt/nano/nmsp-interim-report-final.pdf**.

6 Alex Weir, Paul Westerhoff, Lars Fabricius, et al., "Titanium Dioxide Nanoparticles in Food and Personal Care Products," *Environmental Science & Technology* 46, no. 4 (2012): 2242-2250, **http://pubs.acs.org/doi/abs/10.1021/es204168d**.

7 *Small Sizes that Matter: Opportunities and Risks of Nanotechnologies*, (Allianz AG and The Organisation for Economic Co-operation and Development, 2005), **www.oecd.org/dataoecd/32/1/44108334.pdf**; Allianz Life Insurance Company of North America, **https://www.allianz.com/en/index.html**; The Organisation for Economic Co-operation and Development, **http://www.oecd.org/**.

8 Alexia Karpilov, "Nanomaterials in Food Packaging: Promise and Potential Peril," (February 14, 2006), 4, **http://www.iopp.org/files/public/RITkarpilovIPTAsubmission.pdf**.

9 "Nanomaterials in Food Packaging: Keeping Food Fresh for Longer, Less Waste," European Commission's Joint Research Centre, Institute for Health and Consumer Protection, **http://ihcp.jrc.ec.europa.eu/our_activities/nanotechnology/Nano_Food/nanomaterials-in-food**.

10 "Nanomaterials in Food Packaging," European Commission's Joint Research Centre.

11 Birgit K. Gaiser, Stephanie Hirm, Ali Kermanizadeh, et al., "Effects of Silver Nanoparticles on the Liver and Hepatocytes *in Vitro*," *Toxicological Sciences*, July 19, 2012, **http://toxsci.oxfordjournals.org/content/early/2012/10/19/toxsci.kfs306.abstract**.

12 *Nanotechnology in Food Contact Applications*, (PIRA International, November 16, 2010).

13 Jiangxue Wang, Guoqian Zhou, Chunying Chen, et al., "Acute Toxicity and Biodistribution of Different Sized Titanium Dioxide Particles in Mice after Oral Administration," *Toxicology Letters* 168, no. 2 (2007): 176-185, **http://nanosafety.ihep.ac.cn/2007/2007.19.pdf**; Gaiser et al., "Effects of Silver Nanoparticles on the Liver;" Bing Wang, Weiyue Feng, Meng Wang, et al., "Acute Toxicological Impact of Nano- and Submicro-Scaled Zinc Oxide Powder on Healthy Adult Mice," *Journal of Nanoparticle Research* 10, no. 2 (2007): 263-276, **http://www.springerlink.com/content/8341mm2055271683/fulltext.pdf**.

14 Christie M. Sayes, Rajeev Wahi, Preetha A. Kurian, et al., "Correlating Nanoscale Titania Structure with Toxicity: A Cytotoxicity and Inflammatory Response Study with Human Dermal Fibroblasts and Human Lung Epithelial Cells," *Toxicological Sciences* 92, no. 1 (2006): 174–85, **http://toxsci.oxfordjournals.org/content/92/1/174.full.pdf+html**.

15 Simon Bradley, "Health Concerns Raised over Nanoparticles," *swissinfo.ch*, January 20, 2011, **http://www.swissinfo.ch/eng/science_technology/Health_concerns_raised_over_nanoparticles.html?cid=29293290**.

16 H.S. Sharma, S. Hussain, J. Schlager, et al., "Influence of Nanoparticles on Blood-Brain Barrier Permeability and Brain Edema Formation in Rats," *Acta Neurochir Suppl.* 106 (2010): 359-364, **http://www.ncbi.nlm.nih.gov/pubmed/19812977**; *Nanotechnology: Recent Developments, Risks and Opportunities*, (*Lloyd's*, 2007), 13, **http://www.nano.dtu.dk/upload/centre/nanet/nyheder/lloydsemergingrisksteamreport_nanotechnology_report.pdf**; Thomas C. Long, Navid Saleh, Robert D. Tilton, et al., "Titanium Dioxide (P25) Produces Reactive Oxygen Species in Immortalized Brain Microglia (BV2): Implications for Nanoparticle Neurotoxicity," *Environmental Science and Technology* 40, no. 14 (2006): 4346-4352, **http://pubs.acs.org/doi/abs/10.1021/es060589n**; Saber M. Hussain, Amanda K. Javorina, Amanda M. Schrand, et al., "The Interaction of Manganese Nanoparticles with PC-12 Cells Induces Dopamine Depletion," *Toxicological Sciences* 92, no. 2 (2006): **456-463, http://toxsci.oxfordjournals.org/content/92/2/456.full.pdf**.

17 Benedicte Trouiller, Ramune Reliene, Aya Westbrook, et al., "Titanium Dioxide Nanoparticles Induce DNA Damage and Genetic Instability *In Vivo* in Mice," *The American Association for Cancer Research* 69 (2009): 22, **http://cancerres.aacrjournals.org/content/69/22/8784.full?sid=daa3b32c-a97f-413a-b044-93e1ffdd980**.

18 M. Chen and A. von Mikecz, "Formation of Nucleoplasmic Protein Aggregates Impairs Nuclear Function in Response to SiO_2 Nanoparticles," *Exp Cell Res* 305, no. 1 (2005): 51–62, **http://www.sciencedirect.com/science/article/pii/S0014482704007335**.

19 Praful U. Jani, David E. McCarthy, and Alexander T. Florence, "Titanium Dioxide (Rutile) Particle Uptake from the Rat GI Tract and Translocation to Systemic Organs after Oral Administration," *International Journal of Pharmaceutics* 105, no. 2 (1994): 157–168, **http://www.sciencedirect.com/science/article/pii/0378517394904618**.

20 U.S. Food and Drug Administration, *Draft Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology*, June 2011, **http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm**.

21 European Commission, *Commission Recommendation of XXX on the Definition of Nanomaterial*, 2011, 5, **http://ec.europa.eu/environment/chemicals/nanotech/pdf/commission_recommendation.pdf**; M. C. Garnett and P. Kallinteri, "Nanomedicines and Nanotoxicology: Some Physiological Principles," *Occupational Medicine* 56, no.5 (2006): 307-11, **http://occmed.oxfordjournals.org/content/56/5/307.full**.

22 U.S. National Organic Standards Board, *Guidance Document—Engineered Nanomaterials in Production, Processing and Packaging*, October 28, 2010, 3-4, **http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5087795&acct=nosb**.

23 "NNI Vision, Goals, and Objectives," National Nanotechnology Initiative, **http://www.nano.gov/about-nni/what/vision-goals**.

24 National Science and Technology Council Committee on Technology Subcommittee on Nanoscale Science, Engineering, and Technology, *Supplement to the President's 2013 Budget: The National Nanotechnology Initiative – Research and Development Leading to a Revolution in Technology and Industry*, February 2012, 9-10, **http://www.nano.gov/sites/default/files/pub_resource/nni_2013_budget_supplement.pdf**.

25 National Science and Technology Council Committee on Technology, *Supplement to the President's 2013 Budget*.

26 Michael Siegrist, Arnim Wiek, Asgeir Helland, et al., "Risks and Nanotechnology: The Public is More Concerned than Experts and Industry," *Nature Nanotechnology* 67 (2007): 2, **http://www.nature.com/nnano/journal/v2/n2/full/nnano.2007.10.html**.

27 Twilight Greenaway, "Nanoparticles in Your Food? You're Already Eating Them," *Grist*, December 3, 2012, **http://grist.org/food/nanoparticles-in-your-food-youre-already-eating-them/**; Timothy V. Duncan, "The Communications Challenges Presented by Nanofoods," *Nature Nanotechnology* 6 (2011): 683-688, **http://www.nature.com/nnano/journal/v6/n11/full/nnano.2011.193.html**.

28 Antje Grobe, Mikko Rissanen, Philippe Funda et al., *Nanotechnologies from the Consumers' Point of View: What Consumers Know and What They Would Like to Know*, (The Swiss Confederation Federal Department of Home Affairs and Federal Office of Public Health, March 2012), 4, **http://www.bag.admin.ch/nanotechnologie/index.html?lang=en**.

29 Grobe et al., *Nanotechnologies from the Consumers' Point of View*.

30 "Rules on GMOs in the EU – Ban on GMOs Cultivation," European Commission, **http://ec.europa.eu/food/food/biotechnology/gmo_ban_cultivation_en.htm**.

31 Eliza Barclay, "Activists Say Americans Support Labeling Genetically Modified Food," *NPR*, March 27, 2012, **http://www.npr.org/blogs/thesalt/2012/03/27/149474012/activists-say-americans-support-labeling-genetically-modified-food**; *National Survey of Healthcare Consumers: Genetically Engineered Foods*, (Thomson Reuters, October 2010), **http://www.factsforhealthcare.com/pressroom/NPR_report_GeneticEngineeredFood.pdf**.

32 Cookson Beecher, "Calls for GMO Labeling Keep Cropping Up," *Food Safety News*, January 27, 2012, **http://www.foodsafetynews.com/2012/01/calls-for-gmo-labeling-keep-flaring-up/**.

33 House of Lords Science and Technology Committee, *Nanotechnologies and Food - Volume I*: Report, January 8, 2010, 8, **http://www.publications.parliament.uk/pa/ld200910/ldselect/ldsctech/22/22i.pdf**.

34 European Food Safety Authority, "EFSA Publishes First Practical Guidance for Assessing Nano Applications in Food & Feed," news release, May 10, 2011, **http://www.efsa.europa.eu/en/press/news/sc110510.htm**.

35 Nanotechnology Industries Association, "European Union Passes Regulation on the Labelling of Nanomaterials in Food," news release, October 6, 2011, **http://www.nanotechia.org/global-news/european-union-passes-regulation-on-the-labelling-of-nanomaterials-in-food**.

36 FDA, *Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives*, April 2012, **http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/**. This guidance includes recommendations that demonstrate its current thinking on an issue. They are not requirements. This document notes that the word should in guidances "means that something is suggested or recommended, but not required."

37 FDA, *Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes*.

38 FDA, *Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes*.

39 FDA, *Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes*.

40 FDA, *Draft Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology*; U.S. Office of Science and Technology, Office of Management and Budget, Office of the United States Trade Representative, "Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials" (June 9, 2011), 4, **http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf**.

41 FDA, *Draft Guidance for Industry: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology*; U.S. Office of Science and Technology, "Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials."

42 *Assuring the Safety of Nanomaterials in Food Packaging: The Regulatory Process and Key Issues*, (Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies and GMA, 2008), 45, **http://www.nanotechproject.org/process/assets/files/6704/taylor_gma_pen_packaging1.pdf**; The report found that the "FDA and EPA pre-market reviews do not […] address the full range of circumstances in which possible adverse impacts could occur and in which preventive efforts are appropriate."

43 "Workshop on Measurement Methods for the Release of Engineered Nanomaterials from Food and Absorption by the Body," (webinar, NanoRelease Food Additive, Washington DC, December 11, 2012), **http://www.ilsi.org/ResearchFoundation/RSIA/Pages/NRFA_2012Workshop.aspx**.

44 "Nanotechnology," McDonald's, **http://www.aboutmcdonalds.com/mcd/sustainability/library/policies_programs/sustainable_supply_chain/product_safety/Nanotechnology.html**.

45 "Nanotechnology," Kraft Foods, **http://www.kraftfoodsgroup.com/DeliciousWorld/food-safety-quality/nanotech.aspx**.

46 Galland and Passoff, *Sourcing Framework for Food and Food Packaging Products Containing Nanomaterials*, **http://www.asyousow.org/health_safety/nanoframework.shtml**.

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