

Sourcing Framework
For Food and
Food Packaging
Products Containing
Nanomaterials

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As You Sow

As You Sow is a nonprofit organization dedicated to increasing environmental and social corporate responsibility. Founded in 1992, As You Sow envisions a safe, just, and sustainable world in which environmental health and human rights are central to corporate decision making. Its Energy, Environmental Health, Waste, and Human Rights programs create positive, industry-wide change through corporate dialogue, shareholder advocacy, coalition building, and innovative legal strategies.

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Introduction

The following framework provides guidelines for food and food packaging companies to assess exposure to and potential risks from sourcing products that contain nanomaterials. Nanomaterials offer many new opportunities for food industry applications, such as nutritional additives, stronger flavorings and colorings, or antibacterial ingredients for food packaging. However, their unique properties have raised scientific concerns about their impact on human health and the environment. As food and food packaging companies explore the use of nanomaterials to enhance products, they need also attend to potential risks introduced.

This framework presents tiered recommendations of steps companies should take and information they should obtain from their suppliers regarding the safety testing of nanomaterials and products containing nanomaterials. Until there are firm regulatory requirements and/or a central repository for safety data on nanomaterials, information requested in this framework should be provided to food and food packaging companies by their suppliers.

Nanotechnology is the science of manipulating matter at the molecular scale to build structures, tools, or products, known as nanomaterials. Nanomaterials addressed in this framework are those whose small scale imparts unique physical properties. The risks and benefits of this emerging technology are still being discovered, yet the development, use, and manufacturing of nanomaterials are being conducted with little transparency and inadequate regulatory oversight. This is particularly concerning to the food industry where human exposure is virtually guaranteed. The food industry is reported to be extensively researching and developing the use of nanomaterials, however there is little known about the extent to which nanomaterials are used in food products, processing, or packaging.

Uncertainty and lack of transparency pose unnecessary risks for consumers, workers, companies, and investors. Companies need to ask themselves:

- Do we use nanomaterials in food products and packaging and how do we find out?
- How do we know if it is safe to use nanomaterials in food products and packaging?
- Are there certain risks or liabilities that we should explore in further detail?
- Is our supplier being transparent and providing “best practice” safety reporting on nanomaterials?

This sourcing framework is designed to help food companies obtain information on the level of risk posed by the nanomaterials in their products. The Framework:

1. Provides an introduction to key terms and issues
2. Describes the current state of regulations
3. Makes recommendations regarding the information companies should request and receive from suppliers who offer food products and packaging that contain nanomaterials by presenting best practices from existing scientific, industry, and governmental frameworks

1. Terms and Issues:

Definition

Nanomaterials addressed in this framework are materials “intentionally engineered” to take advantage of unique properties at the nanoscale — from 1-1000 nm (nanometers or billionths of one meter). Materials reduced to the nanoscale either through engineered or natural processes can suddenly show very different properties compared to what they exhibit on a macroscale, enabling unique applications such as alterations in color, electrical conductance, or permeability.

Accessibility

Because of their small size, nanoparticles are able to go places in the body that larger particles cannot.¹ Nanoparticles gain access via inhalation, ingestion, or skin penetration or injection (in medical applications). Inhaled nanoparticles have been found in all areas of the respiratory tract. When ingested, their small size facilitates uptake into cells and allows 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, and the heart.² Nanoparticles also can cross the blood-brain barrier.³

Nanoparticles penetrating the skin distribute through the body via lymphatic channels.⁴ Nanomaterials such as silver, titanium dioxide, zinc, and zinc oxide, have been found to be toxic to cells in laboratory studies.⁵ These materials are used in some nutritional supplements, food packaging, and food contact materials.⁶

Unique Properties

The physical and chemical properties of these and other nanoscale materials, including reactivity, persistence, and bioavailability, can differ significantly from their larger scale counterparts and may impart changes in toxicity that are poorly characterized. Nanomaterials have increased surface area to mass ratios which makes them more chemically reactive.⁷ Having unique physical properties at the nanoscale makes it more likely that the toxicity profile at the nanoscale is also altered, compared with the normal scale materials — making it harder to draw any conclusions from known toxicity profiles of their bulk-sized counterparts. Any material that is engineered to have size-dependent properties should be safety tested at the size that will be used in commercial products where people may be exposed or environmental releases may occur.⁸

No Magic Number

There is no scientifically-defensible size where a nanomaterial is determined to be safe or unsafe. The relationship between size and behavior is affected by many factors, including a material's shape, surface properties, and coatings. The European Commission has defined a nanomaterial as a material with 50% or more of the particles with “one or more external dimensions [...] in the size range 1 nm – 100 nm,” yet materials that measure less than 300 nm can be taken up by individual cells.⁹ This has led to some

calls that 300 nm in size would be the safer alternative. This standard makes particular sense for food products which offer exposure via ingestion, the skin, inhalation, and other membranes. The U.S. National Organic Standards Board has called for nanomaterials smaller than 300 nm to be excluded from organic food.¹⁰ In June 2011, the Food and Drug Administration's (FDA) Draft Guidance on nanotechnology recognized nanomaterials up to 1,000 nm.¹¹

Lack of Transparency

The Environmental Protection Agency (EPA) found that approximately 90% of the different nanoscale materials that are likely to be commercially available for industry were not reported under its voluntary reporting program, and nearly two-thirds of the chemical substances from which commercially available nanoscale materials are based were not reported either.¹² Thus, the government and, in turn, industry does not have full access to either the potential existence of nanomaterials or the risks related to the nanomaterials enhancing products.

2. Regulatory Status:

The Need for Assessing Food Safety

Nanomaterials in food products and packaging are of particular concern because they have direct contact with human populations. Among uses, nanomaterials could be introduced in pesticides, to make enhancements to food products or flavorings, or to extend shelf-life. In the absence of effective federal regulations, corporations need to develop frameworks for evaluating the risks and benefits of sourcing products containing nanomaterials that include appropriate safety testing for the specific applications of the nanomaterials in the sourced products, as well as safety testing from their potential suppliers and environmental and occupational risk analyses.

General U.S. Regulatory Background

In June 2011, the FDA stated 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" but did not put forth specific guidelines for evaluating nanomaterials or products containing nanomaterials; the FDA instead affirmed that agencies will adhere to the Principles for Regulation and Oversight of Emerging Technologies.¹³ Questions arise regarding the FDA's capacity to conduct such evaluations given that its ability to regulate the safety of dietary supplements using nanomaterials is severely limited by lack of information, lack of resources, and the agency's lack of statutory authority in certain critical areas.¹⁴

Since January 2009, the EPA has been examining its regulatory authority to require data on nanomaterials because of limited participation in its voluntary Nanoscale Materials Stewardship Program.¹⁵ In June 2011, the EPA proposed a policy to collect information on nanomaterials in pesticides. The EPA effort, if approved, will determine "whether the registration of a pesticide may cause unreasonable adverse

effects on the environment and human health."¹⁶ This follows its April 2010 announcement that it would be issuing new regulations that would treat nano antimicrobials used in food processing and other processes as new pesticides. The latter regulation has been held up at the Office of Management and Budget.¹⁷

The Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center for Scholars and the Grocery Manufacturers Association, in a joint 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."¹⁸

This lack of information on risks related to nanomaterials is not limited to the United States; the European Food Safety Authority found that "in view of the present difficulties in detection of ENMs [engineered nanomaterials] in food and feed matrices, knowledge regarding the present use of ENMs relies on information provided by industry itself on the addition of ENMs to their products."¹⁹

Concerns that emerge due to the lack of regulation of and preventative efforts to understand nanomaterials include:

- Toxicity risks of nanofoods and nano agrochemicals remain very poorly understood.
- Existing laws are inadequate to assess the risks posed by nanofoods, nano food packaging and nano agrochemicals.
- Not all nanomaterials are required to be assessed as new chemicals.

3. Framework:

As You Sow's framework for evaluating whether or not to source products that contain nanomaterials includes best practices from current frameworks and voluntary codes of conduct and provides a way for companies to:

1. Assure transparency through the supply chain
2. Receive details on materials
3. Obtain data on risk at different levels of uncertainty²⁰

The following framework outlines the phases of action a company can take in collecting information from its suppliers and disclosing information to stakeholders in order to mitigate its exposure to risks related to the use of nanomaterials in food and food packaging. These actions outline the minimum level of responsible activity to address nanomaterials in the supply chain and final products, as well as recommended and preferred additional actions.

Transparency

Companies should insist upon full transparency on nanomaterials that will be in direct contact with their customers — either through ingestion or exposure. They should also require transparency throughout their supply chains on nanomaterials, testing, and management.

Phase 1:

At minimum, a company should:

- Disclose all ingredients that are engineered to take advantage of unique properties associated with small size and the quantities of those ingredients

Phase 2:

It is recommended that, in addition, suppliers disclose:

- Size-specific safety testing data and information at every stage of the supply chain
- All non-proprietary information relating to supplier's safety testing data from nanomaterials currently under consideration for inclusion in products
- Updates of new safety testing information for both nanomaterials and full products from nanomaterial manufacturers, and suppliers whose products contain nanomaterials

Phase 3:

It is preferred that, in addition, suppliers have:

- Someone uniquely responsible for all Environmental Health and Safety (EHS) controls implemented or someone trained to be responsible for implementing controls
- A matrix for handling nanomaterials and organizational control systems
- An EHS department

Accountability to Stakeholders

On emerging technologies, it is critical that companies engage with stakeholders and, when appropriate, enter into stakeholder dialog in conjunction with suppliers.

Phase 1:

At minimum, a company should:

- Provide a public policy or position statement regarding the use of nanomaterials in food products and packaging
- Confirm that suppliers participate in voluntary reporting programs, including but not limited to the U.S. EPA's Nanoscale Materials Stewardship Program and the United Kingdom's Department for Environment Food and Rural Affairs (DEFRA) Voluntary Reporting Scheme for Engineered Nanoscale Materials, for all nanomaterials in their products and in their supply chains (including nanomaterials used in the manufacturing process)

Phase 2:

It is recommended that a company also:

- Provide public transparency of safety testing information of nanomaterials to consumers of the company's final product
- Confirm that all nanomaterials in the products in its supply chains have been registered with the EPA or the Project on Emerging Nanotechnologies in the U.S.

Phase 3:

It is preferred that in addition, a company should:

- Participate in dialogues with stakeholders regarding the application, health, and safety of nanomaterials and products containing nanomaterials
- Obtain commitments from suppliers certifying the information reported and that reports will be updated when new information is confirmed

Materials

Information on the materials, and particularly risks, related to human exposure is critical to the food industry where exposure is inherent to the product's use. Companies should request information from their suppliers on the nanomaterial in the products and those used to make products.

There are three spheres in which companies should obtain information regarding materials.

1) Companies should have a complete description of nanomaterials.

Phase 1:

At minimum, companies should require from suppliers:

- The source of the material – name and contact details of the supplier or importer
- A description of the nanomaterial and its intended uses

Phase 2:

It is recommended that companies also request from suppliers:

- A detailed description of the benefit or added value of the nanomaterial in comparison to the conventional product

Phase 3:

It is preferred that, in addition, companies also request from suppliers:

- A report on the lifecycle (cradle to grave) of the nanomaterial including its physical and chemical properties and its potential health, safety, and environmental hazards
- The nano-specific effects/actions of the material

2) Companies should obtain information on opportunities for human or environmental exposure to nanomaterials during manufacturing.

Phase 1:

At minimum, companies should require from suppliers:

- A characterization of the nature, route, level, and duration of any exposure

Phase 2:

It is recommended that companies also request suppliers to provide:

- A description of the manufacturing process of the substance to help characterize the potential sources of release to the workplace and environment
- Access to the manufacturing facility for companies to perform on-site inspections

Phase 3:

It is preferred that, in addition, companies also request suppliers to provide:

- An analysis of if/how the disposal or recycling of the nanomaterial during manufacturing may result in exposure of humans or environmental species and ecosystems

3) Companies should require suppliers to provide information related to worker and consumer exposure to nanomaterials.

Phase 1:

At minimum, companies should require suppliers to provide:

- Disclosure of results from toxicology tests including utility of data on conventional scale versions of nanomaterials

Phase 2:

It is recommended that companies also request suppliers to provide:

- Information on the material's intended use and correlating route of exposure from multiple tests conducted and verified by third-parties

Phase 3:

It is preferred that, in addition, companies also request suppliers to provide:

- Information on toxicological data requirements and testing protocols

Risks

In the food industry, consumers are exposed to nanomaterials in two ways: directly – where an individual consumes a product containing nanomaterials, or indirectly – where a consumer comes into contact with a food product exposed to nanomaterials via either packaging materials or manufacture of either the food products or packaging. Therefore, to assure safety, companies should require full testing data related to exposure via ingestion, the skin, inhalation, and other membranes including how each nanomaterial behaves as it travels through the body. In addition, companies should require testing data on a nanomaterial's potential impact on the ecosystem after the manufacturing process or end-of-life of packaging.

There are three areas in which companies should obtain information regarding risks.

1) Companies should require suppliers to disclose if a nanomaterial is in a food product or food-contact material. In this case, there is only one level of responsibility with two areas of disclosure.

Phase 1:

At minimum, companies should require suppliers to disclose if a nanomaterial is present in a food product or food-contact material and demand:

- Disclosure of whether the nanomaterial will remain as a nanoparticle in the body
- Disclosure of results from migration studies including:
 - Data and information on whether the nanomaterial dissolves in the food-simulating solvent or is released as nanoparticles
 - Data and information on whether extracted nanoparticles agglomerate in food simulants or change their properties in the simulant in other ways

2) Companies should require suppliers to provide disclosure of potential risks. This framework outlines two levels of responsibility as per disclosure of potential risks.

Phase 1:

At minimum, companies should require suppliers to:

- Identify and characterize the nature, magnitude, and probability of exposure and risk through intended use, accidental release, and worker health and safety
- Implement risk management practices including:
 - Lifecycle analyses
 - Risk assessment

Phase 2:

It is recommended that companies also request suppliers to disclose:

- An evaluation of available options for managing risks identified in Phase 1 and a recommended course of action
- Data and information on the fate, transport, and effects of nanomaterials in an ecosystem including information on field and laboratory methods such as:
 - Information on biotic and abiotic degradation
 - Information on adsorption/desorption coefficients in soil (if land-applied or deposited to soil) or sludge (if discharged from wastewater treatment)
 - Information on the bioaccumulation factor

3) Companies should disclose information on its end-of-life procedures for nano-enhanced products and require data from its suppliers regarding procedures and risks. This is particularly important because the final product may change the end-of-life scenario of the nanomaterials it contains. This framework outlines two levels of responsibility as per treatment of nanomaterials at end-of-life.

Phase 1:

At minimum companies should:

- Disclose recycling and disposal procedures specific to nanomaterials and products containing nanomaterials

Companies should require suppliers to provide:

- Recycling and disposal procedures to be employed both during manufacture and for consumers of the end products
- Data and information on the recyclability of the nanomaterial, including free and bound in products
- Disclosure of additional information on management practices that reduce or remove the risks associated with the material, including worker-safety practices

Phase 2:

It is preferred that, in addition, companies request suppliers to provide:

- Information on end-of-life recycling options and the environmental risks and accumulation for all products containing nanomaterials
- Information on if and how unfavorable effects may be neutralized
- Conditions under which the material may be destroyed

Summary

Nanotechnology, like any new technology, offers promises and pitfalls. In this case the promise includes improvements in taste, texture, nutrient availability, product-life, transportation, and storage. Hundreds of nano applications are currently being developed for food products and packaging.

Consumer confidence is needed for the acceptance of new technologies. This is especially true in the food industry where consumer concern over safe and healthy food products and packaging is at an all-time high.

New nanofood products should only be used if safety testing ensures that there are no negative impacts on human health or the environment. Current regulatory controls are inadequate to assess or ensure safety and the scientific consensus is that there is a lack of knowledge regarding how nanomaterials interact at the molecular or physiological levels and their potential impacts on health and the environment.

Consequently, companies looking to purchase or sell nanofood products or packaging have to take specific steps to protect themselves from financial and reputation risk through a thorough evaluation of the safety of these products and transparency to address any consumer concerns.

Good information is critical. Find out if your company has nanomaterials in its products and supply chain.

Put a policy in place that suppliers must disclose if their products contain or were manufactured with the use of nanomaterials.

Transparency is key and companies should require that their supply chain disclose any use of nanomaterials and all related safety testing data and safety management procedures. Verification that suppliers are engaged in voluntary reporting programs and will provide updated safety testing reporting should be required.

Risk assessment of nanomaterials needs to be at a higher level than for other products that have more established scientific data or regulatory oversight. Companies need to clearly understand what the nanomaterial is, its use, and its effects. Questions regarding key areas of concern such as exposure, human and environmental toxicology, migration, lifecycle analysis, and risk management will be instrumental in helping companies assess the benefits and risks associated with nanofood products and packaging.

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- 14 Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies, GMA, "Assuring the Safety of Nanomaterials in Food Packaging: The Regulatory Process and Key Issues," 2008, http://www.nanotechproject.org/process/assets/files/6704/taylor_gma_pen_packaging1.pdf. The FDA, however, issued a guidance* for food additives that states that particle size will be reviewed as part of the review process: "If the particle size is important for the additive to achieve its intended technical effect, such that the additive is produced or processed using techniques or tools that manipulate the particle size and may contain altered particles that are formed as manufacturing by-products, data on the size (average and distribution), shape, surface area (average and distribution), surface charge (zeta potential), and morphology of the particles, as well as any other size-dependent properties (e.g., agglomeration, aggregation, dispersion) should be included, as appropriate." U.S. Food and Drug Administration, "Guidance for Industry Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions," revised March 2009, <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm124917.htm>. *Note that a "guidance" document does not have the force of law, as would a regulation, but serves to give applicants notice of the FDA's approach to regulating in this area.
- 15 Pat Rizzuto, "Limited Participation in Nano Program Spurs EPA to Examine Regulatory Authority," *BNA Daily Environment Report*, January 14, 2009, page A-3. In 2008 the EPA instituted a voluntary reporting program called the Nanoscale Materials Stewardship Program. In 2009, the EPA estimated that approximately 90% of the nanoscale materials that are likely to be commercially available were not reported. 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>. U.S. Environmental Protection Agency, "Notice on Nanoscale Materials Stewardship Program," January 28, 2008, <http://www.epa.gov/fedrgstr/EPA-TOX/2008/January/Day-28/t1411.htm>.
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- 17 Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies, "New EPA definition for "nano" could affect state of regulations," <http://www.nanotechproject.org/news/archive/8309/>. Jaydee Hanson, personal communication on a meeting the Center for Food Safety and others had with the Office of Management and Budget, January 26, 2011.
- 18 Woodrow Wilson International Center for Scholars Project on Emerging Nanotechnologies, GMA, "Assuring the Safety of Nanomaterials in Food Packaging: The Regulatory Process and Key Issues," 2008, 45, http://www.nanotechproject.org/process/assets/files/6704/taylor_gma_pen_packaging1.pdf.
- 19 European Food Safety Authority, "Scientific Opinion The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety," 2009, 13-39, <http://www.efsa.europa.eu/de/scdocs/doc/958.pdf>.
- 20 For additional information, please see the publications listed in References for the following topics: description of materials: EDF/DuPont, DEFRA, IG DHS; end-of-life/recycling: DEFRA; exotoxicology: DEFRA; exposure: EDF/DuPont, DEFRA, SCENIHR; migration studies: PEN/GMA; risks: EDF/DuPont, DEFRA, PEN; toxicology: DEFRA, PEN/GMA.



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