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Nanotechnology for Food Applications: More Questions Than Answers

This article highlights the scientific evidence to date on a variety of nanotechnology issues important to consumers with a focus on food applications. Nanotechnology is technology at the atomic or macromolecular levels on the scale of approximately 1–100 nm. There are unlimited potential applications of nanotechnology for food, dietary supplements and food contact materials. However, there are more questions than answers about the safety risks of nanotechnology, its environmental, health and other impacts, and its costs and benefits. Benefits and costs will likely be specific to the nanomaterials used, the application and other conditions (e.g., temperature).

Nanotechnology is the purposeful manipulation or engineering of atoms and molecules at the nanoscale so that familiar materials have new and often unique properties and behavioral traits that can be used in new applications. Nanomaterials are designed to have at least one dimension (length, width, height) at the nanoscale of 1–100 nm. The nanoscale dimension is a size so small that it is 1/100,000 of a typical sheet of paper or 1/80,000 of a human hair. Nanomaterials that have a nanoscale length, width and height are known as nanoparticles. Nanotechnology, with its almost limitless range of novel food and other applications, has been promoted by some as the driving spark for the next industrial revolution (Priestly, Harford, and Sim 2007). For example, scientists can manipulate silver on the nanoscale and create *nanosilver*, which has potent antimicrobial properties beneficial for many applications, including refrigerators embedded with nanosilver.

Although many nano-sized particles occur in nature, such as lactose and whey proteins found in human milk, the focus here is on those purposely manipulated or engineered for new applications. This article focuses on nanotechnology for *food applications*, such as for foods (with new nano-ingredients and additives), nutritional supplements and food contact materials. Here, *food contact materials* include materials used to

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produce, package, store, handle or serve food that comes or may come into contact with food. As the first examination of nanotechnology in the *Journal of Consumer Affairs*, this article contributes to a broader understanding of issues associated with nanotechnology by openly discussing these issues using balanced information and scientific findings in non-technical language. Because the science and marketing of nanotechnologies are evolving at a rapid pace, the aim here is to present the current evidence to date in a way that addresses a series of questions that will be important to consumers, industry, policymakers and others in the United States as nanotechnologies for food applications become increasingly developed and commercialized. These questions were chosen to highlight the key issues that are likely to be of particular interest to consumers. These issues range from safety of the technology, to consumer acceptance of the technology, to legal and regulatory oversight for food-related applications of nanotechnology.

Nanotechnology is a new and rapidly emerging field, with most of the expansion occurring in the past decade. In 1997, worldwide nanotechnology research and development was estimated at $432 million, but by 2005, this amount rose ninefold to around $4.1 billion (Roco 2005a). The Institute of Food Science and Technology (2006) estimates that more than 200 companies are involved in nanotechnology worldwide and identifies the United States, Japan and China as the world leaders for food applications. The European Union is another world leader for food and agriculture applications. According to Chaudhry et al. (2008), a market-analysis report by Cientifica estimates that there were as many as 400 companies used nanotechnology for food applications in 2006. In 1996, the Nanotechnology Working Group estimated that the international market for products incorporating nanotechnology would reach $1 trillion by 2015 (Roco 2005b). In the food and beverage packaging sector alone, worldwide sales of products using nanotechnology grew almost sixfold in two years from $150 million in 2002 to $860 million in 2004 (Helmut Kaiser Consultancy 2009).

The Project on Emerging Nanotechnologies (PEN) by the Woodrow Wilson International Center for Scholars and the Pew Charitable Trusts was established in April 2005. On an ongoing basis, PEN compiles and publishes an online inventory of nanotechnology-based consumer products currently marketed worldwide. This inventory is not comprehensive and listed items are claimed by manufacturers rather than certified by an independent third party as an actual use of nanotechnology. Nevertheless, this inventory is believed by many to provide the most accurate account of commercial nanotechnology applications worldwide. As of July 29,

2009, the inventory included slightly over 800 manufacturer-identified nanotechnology-based consumer products, some of which were listed in more than one product category. The listing included seventy-four food and beverage applications, comprising forty-three supplements (57.3%), such as colloids of zinc nanoparticles and other minerals; twenty storage applications (26.7%); nine cooking applications (12%) (e.g., nanosilver teapots and kitchen- and table-ware); and three foods (4%). The three food and beverage items included: (1) a canola active oil from Israel that is claimed to inhibit cholesterol transportation into the bloodstream and allow greater penetration of vitamins, minerals, and phytochemicals that are insoluble in water or fats; (2) a tea from China that is claimed to provide health benefits; and (3) a chocolate shake drink from United States that is claimed to use an advanced form of cocoa to enhance flavor without the need for excess sugar. Although nanosilver is not claimed to be in any commercially available food products, there has been a patent application by a South Korean company to use nanosilver as an additive in the production of antibacterial wheat flour (Chaudhry et al. 2008). In general, nanotechnology is used for many current and potential food applications (Table 1).

KEY QUESTIONS ABOUT NANOTECHNOLOGY FOR FOOD APPLICATIONS

Important questions for consumers, industry and policymakers in the United States have been raised about nanotechnology for food applications. This article addresses six such questions.

Is Nanotechnology for Food Applications Safe?

The safety risks will likely depend on the specifics, such as the type of nanotechnology used, the type of application (Bouwmeester and Sips 2007) (i.e., the specific food, nutritional supplement or food contact materials) and other conditions (e.g., temperature). Broad statements that nanomaterials are safe or not safe are meaningless just as it makes little sense to claim that chemicals as a whole are safe or not safe (Magnuson 2008). In other words, nanoparticles "are structurally and chemically diverse and should not be considered as a group of similar compounds" in a safety assessment (ASCC 2006). Nevertheless, bearing this in mind, it is useful at times, such as in this article, to provide basic and balanced information to consumers, industry and policymakers to help the growing dialogue as nanotechnology applications are developed and commercialized.

TABLE 1
Examples of Current and Potential Food Applications of Nanotechnology[a]

Applications Already Commercialized

- Nanosilver is incorporated in food cutting boards, cleaning sprays, kitchenware, food storage containers and refrigerator compartments for its antimicrobial properties (PEN Inventory 2009).
- Nanoparticles in nanoceuticals and nutritional supplements, such as colloids of zinc nanoparticles and other nano-sized minerals, and nano-encapsulates are on the market with claims of having enhanced uptake and/or targeted delivery of content (Bouwmeester et al. 2009; PEN Inventory 2009).
- Nanoparticles such as nanoclays are incorporated into plastic beer bottles to increase strength, make them more shatterproof, and extend shelf life by acting as a barrier to keep oxygen outside the bottle and carbon dioxide inside (PEN Inventory 2009).
- Nanochips or nanosensors are commercially used to detect storage conditions conducive to spoilage (e.g., temperature or moisture problems) (Bouwmeester et al. 2009). For example, nanosensors are used on food pallets during transport in refrigerated trucks to detect temperature violations.

Applications Proven in Concept but not yet Commercialized

- Non-nanotechnology biosensors are currently commercially available for detecting *E. coli* O157, *Campylobacter* and *Salmonella* in food and nanotechnology could lead to the next generation of these sensors (Patel 2002). For example, flexible, color-changing nano-based inserts are being developed to indicate detection of *Salmonella*, *E. coli*, and other pathogens. These inserts could be placed on milk cartons, inside ready-to-eat packaged salads, and on other food packaging to warn consumers that the product is no longer safe to eat.
- Nanosensor inserts in food packaging have been developed which could warn consumers that there has been a temperature violation and the product may be spoiled.
- In addition to detecting some foodborne pathogens like *Salmonella* and *E. coli* under the Centers for Disease Control and Prevention's list of "Category B" agents, nanosensors can also be developed for food biosecurity to detect "Category A" agents like the pathogens that cause anthrax and botulism as well as other poisonous contaminants, such as heavy metals (e.g., arsenic, mercury and lead) and chemicals (e.g., dioxins, harmful pesticide residues, furans and polychlorinated biphenyls [PCBs]) (Tzeng and Branen 2005). Lee et al. (2009) have used nanotechnology to detect the DNA of SARS, Ebola and Anthrax.

Applications that Exist Mainly as Promising but Unproven Research Ideas

- Nanosized devices are under development that may help trace food or food ingredients to its source of origin (Chaudhry et al. 2008).
- Targeted delivery of salty taste using nanomaterials could potentially be developed and lead to reduced salt intake, in turn reducing hypertension and health disease (Chen, Weiss, and Shahidi 2006).

[a]The PEN inventory is not comprehensive and listed items are manufacturer-claimed, so they are not certified by an independent third party as an actual use of nanotechnology.

To date, scientific studies on the safety of nanotechnology to human health have shown mixed results. For example, two studies indicating safety concerns for some types of nanomaterials include Chaudhry et al's. (2008) review of scientific reports and a 2006 study commissioned

by the Australian government on the potential occupational health and safety implications of nanotechnology. Chaudhry et al. (2008) found a growing body of evidence from examinations of inhaled nanoparticles that some types of free engineered nanoparticles can cross cell walls and damage cells. The Australian government study found that "bioaccumulation and biopersistence are common characteristics of nanoparticles" and that there exists "sufficient uncertainty in the human health effects of all nanoparticles, following either short term or long term exposure" (ASCC 2006). The influence of the foods ingested with the nanoparticles on the behavior of these nanoparticles is not well studied, but could change the uptake of nanoparticles in the gut. Bouwmeester et al. (2009) provide a brief overview of nanotechnologies currently used in food applications. They expect that consumers will likely be exposed to nanoparticles via food and, given the information currently available, they speculate about the likelihood of consumer exposure to nanoparticles for some of the different applications. It is important to note that several international bodies and governments find the current risk assessment framework to be applicable to estimate risks to human health and the environment from the use of nanotechnology in the food sector (COT 2007; EFSA 2009; FDA 2007b, FSA 2008; SCENIHR 2007). Use of this framework will identify areas where further research could allow better risk estimation.

The reality, however, is that most of the studies on nanotechnology and human health are on exposure to humans via inhalation (e.g., during the production of nanomaterials) or through the skin (Magnuson 2008) and not on human exposure via oral routes and in the gastrointestinal (GI) tract. Most of the few studies that investigated exposure to nanomaterials via the GI tract found that nanoparticles pass through the GI tract and are rapidly eliminated (Oberdörster, Oberdörster, and Oberdörster 2005). Scientists cannot credibly extrapolate from data on inhalation or through the skin to what happens via ingestion to determine the human health effects (Magnuson 2008). Similarly, "only few specific nanoparticles have been investigated in a limited number of test systems and extrapolation of this data to other materials is not possible," according to a review conducted for the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC; Borm et al. 2006). Different food applications of nanotechnology may need to be studied initially on a case-by-case basis.

The science of nanotechnology is growing worldwide as an increasing number of researchers in many fields are investigating the human and environmental exposure to and risks from nanomaterials as well as other related issues. As evidence of this research, there were roughly 1,000 scientific publications on nanotechnology in 1990, but by 2002, there

were over 22,000 (Heinze 2004). Most questions on the safety risks of nanotechnology for human health are just starting to be addressed. For example, will using nanomaterials to deliver nutrients result in greater amounts absorbed by the body and could this potentially be in higher, toxic amounts than those supplied through traditional counterparts (e.g., nanonutrients vs. traditional nutrients and vitamin supplements)?

What Are the Potential Environmental Impacts?

Using nanotechnology in food applications also raises questions about whether there are potential environmental impacts. For example, if nanotechnology-embedded food packaging material ends up in a landfill, could these materials potentially contaminate water supplies or spill over and affect other parts of the environment, such as fish and wildlife or other animals consumed by people? Once again, there are more questions than answers, particularly as there are so many kinds of potential nanomaterials and applications. As of now, there are no proven risks to the environment from nanomaterials in food applications. It is possible that nanomaterials behave differently in the environment than their bulk material counterparts (Breggin and Pendergrass 2007b).

One nanomaterial that some feel may potentially have environmental effects is nanosilver. Although to date adverse effects of nanosilver on the environment have not been identified, hazards could conceivably arise if substantial amounts of silver and silver nanoparticles are released if and when the manufacture and use of nanosilver proliferates in new products and becomes more widespread (i.e., silver is classified as an environmental hazard due to its toxicity and potential for bioaccumulation and persistence) (Luoma 2008). In general, disposal of most nanomaterial-containing consumer products will be considered as household waste, and thus is likely to be exempt from hazardous waste regulations (Breggin and Pendergrass 2007a).

Some believe that a comprehensive study would need to take a life cycle assessment or systems approach to environmental protection by covering the nanomaterials' processing, manufacturing, distribution, use, and, possibly, recovery management (i.e., reuses, remanufacture, and recycling) (Maynard 2005). Luong, Male, and Glennon (2008) estimate that annual global spending on nanotechnology is currently around $9 billion, of which roughly 4% ($39 million) is for analyzing potential risks to human health and the environment. It is unclear if this includes research conducted by insurance companies that are writing nanotechnology-specific policies.

What Are the Key Marketing Concerns?

Consumer acceptance of nanotechnology is clearly a key marketing concern. It is literally unknown at the moment whether American consumers will accept nanotechnology for food applications because most consumers know little or nothing about it. In a 2004 national survey of 1,536 adults in the United States, 83.6% had "heard nothing" or "heard a little" about nanotechnology (Cobb and Macoubrie 2004). A few years later, an August 2008 national survey of 1,003 adults found similar results where 49% had "heard nothing at all" about nanotechnology, 26% had "heard just a little," and 17% had "heard some" (Peter D. Hart Research Associates 2008). This lack of awareness means that consumers are unable to make informed assessments of the potential risks and benefits of foods produced with new technologies (Siegrist 2008).

Consumer acceptance of new food technologies is influenced by many factors, including consumers' perceptions of the risks and benefits as well as perceived quality, perceived naturalness, price, and general attitudes, values and cultural norms (Siegrist 2008). Diverse cultures, traditions and values in different parts of the world may also have a significant impact on consumer acceptance of new technologies and products. A mail survey of 337 adults in Switzerland showed that both trust and naturalness were important in influencing perceived risks and benefits of food applications of nanotechnology (Siegrist et al. 2008). This survey also found that foods that incorporate nanotechnology appear more problematic to consumers than food packaging that incorporates nanotechnology.

Consumers' trust in industry and government as a source of nanotechnology information and oversight will be important when they frame their impressions of the perceived risks and benefits of nanotechnology for food applications and when deciding whether or not they will ultimately accept nanotechnology. Recent literature suggests that there is a low public trust in both industry and government when it comes to nanotechnology. For example, a 2004 US national survey found that 95% of respondents did not trust industry leaders to effectively manage nanotechnology risks (Macoubrie 2005). This survey was part of a broader effort which included a study of 152 people in experimental groups. Most of the participants (95%) in this smaller study had little or no trust in government to effectively manage the potential risks from nanotechnology (Macoubrie 2005). Therefore, it is important to develop and maintain trust in industry and government so that information from these sources is deemed credible. However, in both the national survey and the smaller study, participants had little initial awareness of nanotechnology.

Levels of trust expressed by informed individuals would have been more meaningful.

Macoubrie (2005) found that consumers often draw analogies for nanotechnology to previously introduced technologies, such as with genetically modified foods. The paper claims that these analogies may lead to a consumer perception that industry may short change consumer safety by marketing products without adequate safety testing. A US national telephone survey of 503 respondents about consumer perception of nanotechnology versus other technologies revealed that genetically modified organisms were perceived as having lower benefits and higher risks than nanotechnology (Currall et al. 2006). Historically, negative consumer acceptance of genetically modified organisms in some countries has had an adverse effect on both government-funded research and the commercialization of genetically modified products and crops, particularly in Europe. Therefore, educational and oversight materials for consumers about nanotechnology may be more effective if they identify and incorporate the lessons learned about consumer acceptance of genetically modified foods, food irradiation and other technologies. Cobb and Macoubrie (2004) believe that the best way to prevent uninformed consumer opinion from coalescing around negative perceptions about nanotechnology is to openly discuss with consumers the critical issues with balanced information and principles that scientists rely upon. For example, as part of the US Food and Drug Administration's (FDA) task force on nanotechnology, FDA held public meetings to give interested parties a chance to share their views.

Another key marketing concern involves if, whether, and how mandatory labeling of nanotechnology will be implemented in the United States and elsewhere. Informative labeling is hindered by the lack of a worldwide consensus on the definition of nanotechnology, which means a product labeled as using nanotechnology in one country might mean something different in other parts of the world. According to the National Nanotechnology Initiative (NNI), *nanotechnology* "is the understanding and control of matter at dimensions between approximately 1 and 100 nm, where unique phenomena enable novel applications" (NNI 2007). However, this current nanometer range is an arbitrary measure and was not set on any real meaning or relationship between particle size and toxicological effects or kinetics (Bouwmeester et al. 2009), such as chemical reaction rates. A more science-based and widely accepted definition of nanoparticles is needed to help prioritize research, facilitate regulatory discussions and compare study results (Bouwmeester et al.

2009). FDA has since adopted this definition of nanotechnology but the definition has not been universally accepted worldwide.

The lack of a widely accepted definition of nanotechnology complicates the development of appropriate labeling to inform consumers. There is also the question about whether labeling of food products on nanotechnology will help consumer decision making. Labeling food technologies could potentially have unintended negative effects if the public interprets such labeling as a warning about potential risks (Siegrist 2008). Therefore, industry is unlikely to label food applications with information on nanotechnology unless they are required to do so or they feel there is a clear benefit for their products and their company. Of course, if products are not labeled for nanotechnology, then those consumers opposed to the technology may not be able to identify the products they wish to avoid. Currently, the United States does not require food products to be labeled with information about nanoingredients. Chau, Wu, and Yen (2007) claim that terms like "ultrafine" or "nanofood" are now used on some food packaging.

Who Benefits from the Use of Nanotechnology in Food Applications?

Across all types of nanotechnologies, significant economic and societal benefits are anticipated (Maynard 2005). The use of nanotechnology in food may improve food security through new materials to detect pathogens and other contaminants and may improve disease treatment; packaging, storage and handling materials; delivery systems; and bioavailability. According to Davies (2008), "If the right decisions are made, nanotechnology will bring vast improvements to almost every area of daily living. If the wrong decisions are made, the American economy, human health and the environment will suffer." These benefits will accrue to industry, consumers and society in general. Hypothetically, if the public becomes healthier, it may be possible that less federal medical assistance may be needed and the government burden on taxpayers may be reduced. However, societal benefits will be tied to the specific nanotechnologies and applications.

Once a nanotechnology application has been developed and commercialized, industry would benefit. After all, a firm would not implement the technology unless the economic benefits to the firm outweigh the costs. In the food industry, profit margins are thin, so implementing a new technology that either reduces production and marketing costs (e.g., through improved efficiency, reduced food spoilage and/or extended shelf life) or raises the price consumers are willing to pay for the product(s) owing to

the added benefits can help make firms' products more profitable. This can result in firms having a comparative advantage over their competitors, particularly over a large volume of products sold. Early adopters of nanotechnology may benefit relatively sooner and possibly more than those late adopters in industries where its use has become the norm.

Consumers may also reap some of the benefits of nanotechnology if the costs savings are passed on to them in the form of lower prices for food and nutritional supplements. Although nanotechnology for food production has not been discussed in much detail here because of space limitations, nanotechnologies that control pests or make production agriculture more efficient (e.g., nanocapsules for pesticide delivery or nanosensors to monitor soil conditions) could mean that more food can be produced for the same cost.

Consumers also benefit if the food applications using nanotechnology lead to a higher-quality product for the same price, such as healthier foods. For example, if nanotechnology-created nutritional ingredients (e.g., vitamins and minerals) added to foods or used to make supplements are more bioavailable or potent, this may mean that smaller amounts are needed during production. This in turn might reduce nutritional ingredient costs per food product produced and allow a given amount of nutrients to be more widely spread among more people, thus potentially helping address nutrient shortfalls in developing nations.

Consumers will also benefit if the resulting products are safer than those that do not incorporate nanotechnology. Currently, the widely cited US estimate by Mead et al. (1999) at the US Centers for Disease Control and Prevention is that there are 76 million foodborne illnesses annually in the United States resulting in 325,000 hospitalizations and 5,200 deaths. If nanotechnology prevents a portion of these foodborne illnesses, hospitalizations and deaths, then consumers, governments and the health care sector will benefit from the monetary and non-monetary savings (e.g., improved quality of life) from these reductions (see Buzby and Roberts (2009) for details on the costs of foodborne illness).

Society as a whole may benefit from certain nanotechnologies for food applications. For example, continued development and implementation of nanocomposites for food packaging and other food contact materials that are biodegradable, recyclable or reusable without harmful residue could mean that less landfill space will be needed, thus reducing landfill-related costs. Sorrentino, Gorrasi, and Vittoria (2007) discuss the potential of nanocomposites for food packaging applications. Additionally, it is possible that the continued expansion of nanotechnology may increase the number of jobs in research, development and the food sector.

Who Pays the Costs of Using Nanotechnology in Food Applications?

As with other key issues addressed here, who pays the costs of nanotechnology depends on the specific nanotechnology and food application. However, costs to industry clearly include research and implementation costs, which may be substantial and may mean that the resulting food applications are not necessarily less expensive than their non-nano counterparts. The commercial success of a new technology, including new nanotechnologies, depends on low cost, ease of use and consumer acceptance. Costs to firms may also include costs from product liability, workers compensation and liability from improper disposal of waste products. In general, any negative or adverse impacts on human health and the environment from the use of nanotechnology in food applications may impose costs on industry and individuals as well as on government and the public at large (e.g., through taxes).

Costs to consumers from nanotechnology could hypothetically include any associated adverse acute or chronic health effects that may arise. Additionally, consumers may have to pay a premium for some products that incorporate nanotechnology though it is also possible that firms might pass on production cost savings to consumers in the form of lower prices. Potentially, costs to the environment may also occur. The government may incur higher costs for nanotechnology research, consumer education and regulatory oversight. However, these costs may be offset by any benefits of nanotechnology that may occur, such as reduced disease costs from improved nutrition and food safety.

What Kind of Legal and Regulatory Oversight Will There Be for Food-Related Applications of Nanotechnology?

As nanotechnology becomes a greater commercial reality, there are growing concerns about the ability of existing oversight tools to adequately protect human health and the environment (Greenwood 2007). Here, oversight tools refer to both mechanisms and institutions, like existing laws, statutes and regulations; regulatory agencies; and labeling and other practices to manage safety risks. There has been considerable research on the legal and regulatory oversight of nanotechnology (e.g., Davies 2008, 2009a, 2009b; FDA 2007a, 2007b; Michelson and Rejeski 2006; Taylor 2008a, 2008b, 2008c).

One consistent finding among the studies is that as of now, it is unclear if the US system of laws and regulations can handle the growth of

nanotechnology for commercial applications. The American Bar Association (2009) has a multi-phase project to assess the applicability of key statues for nanotechnology. Phase 1 evaluated six core environmental statutes and concluded that the Environmental Protection Agency (EPA) is provided "with sufficient legal authority to address adequately the challenges EPA is expected to encounter as it assesses the enormous benefits of and potential risks associated with nanotechnology." Phase 2 will analyze the applicability of the Food Quality Protection Act, the Federal Food, Drug, and Cosmetic Act, and two other Acts for nanotechnology. In short, there are currently legal and regulatory tools for oversight of some nanotechnologies to prevent harm or compensate those who have been harmed (e.g., common law). Although these tools may not explicitly contain nanotechnology provisions, some may only need refinement. Other tools may need to be developed and enacted.

A second consistent finding is that it is unclear what the future oversight of nanotechnology should be. For example, right now, the FDA does not have specific regulations for nanotechnology to date because it regulates products, not technologies (Bouwmeester et al. 2009). The current product-based regulations are unable to address the whole spectrum of potential risks, such as environmental releases of nanomaterials during production and use and also waste management issues arising at the end of nanomaterials' life cycle (Greenwood 2007). There are different views about nanotechnology oversight. Some believe that the United States will need an oversight system that functions across the entire life cycle of nanomaterials with greater focus on managing those steps with the greatest risks (Greenwood 2007). Some advocate that the United States change to a regulatory system to regulate the technology, like what is now done for biotechnology. Others (e.g., the United Kingdom as reported by IFST 2006; Chau, Wu, and Yen 2007) believe it may be wise or more appropriate to adopt a precautionary approach in developing regulatory control as opposed to a proactive approach, until evidence is provided otherwise. Some advocate for a case-by-case assessment.

A third finding is that it is unclear which US agency or agencies should have oversight of nanotechnology. The wide range of nanotechnology applications for food, electronics, medicine and other industries means that, right now, there is no single federal agency with clear jurisdiction over nanotechnology. Even looking only at food applications, the jurisdiction is blurry because of the many potential uses of nanotechnology in agriculture and food applications, the life cycle of nanomaterials, and the potential for health and environmental risks. In the United States, there

are three main regulatory agencies with federal jurisdiction over food and food ingredients (adapted from the President's Council on Food Safety 2001):

- Food Safety and Inspection Service (FSIS) within the U.S. Department of Agriculture (USDA) ensures the safety of all domestic and imported meat, poultry and processed egg products. Exceptions covered by the FDA include game and exotic meats and fowl (e.g., kangaroo, quail and duck), and multi-ingredient meat and poultry products that contain less than 2% cooked or 3% raw meat by volume. FSIS is also developing its coverage of catfish.
- FDA within the Department of Health and Human Services (DHHS) has in its purview all domestic and imported foods marketed in interstate commerce not covered by FSIS plus oversight of animal feed, veterinary drugs, food additives, dietary supplements and food packaging (see FDA 2001 for information on supplements).
- EPA licenses pesticide products and establishes maximum allowable limits (tolerances) for pesticide residues in food and animal feed. (FDA and FSIS enforce pesticide tolerances for the commodities under their jurisdiction.) In addition, EPA manages regulatory and research programs related to water- and foodborne toxic chemicals, such as dioxin.

The food safety efforts of these agencies are supported by a number of other government organizations, including state, tribal and local governments.

The FDA Nanotechnology Task Force found that FDA's oversight is generally comprehensive for products that must meet pre-market authorization requirements (e.g., food and color additives), and this allows FDA to receive detailed scientific information on safety and effectiveness (FDA 2007b, iii). According to FDA (2007b, 25), *food additives* "include those substances added directly to food, substances that may become components of food as a result of their use in processing, and components of food contact materials that can reasonably be expected to migrate to food." In addition to pre-market notification to FDA for substances that come into contact with food (there are some exceptions), other key elements of the US regulatory system for food packaging include FDA's use of detailed chemistry and toxicology guidance to perform its pre-market scientific review (i.e., what and how much migrates into the food, is it safe), and EPA's review of antimicrobial packaging materials (Taylor 2008a). Although this process is streamlined, the resulting clearances are application- and company-specific, and it is

ultimately up to industry to prove to FDA reviewers that the products are safe and the methods used were appropriate (Taylor 2008a).

FDA's oversight is less comprehensive for products that are not required to meet pre-market authorization requirements (e.g., dietary supplements and generally recognized as safe [GRAS] food ingredients) because manufacturers don't have to provide safety and other information (e.g., on adverse events) prior to putting their product on the market (though they can be voluntarily provided by firms). The exception is for *new dietary ingredients*, which are defined as those not marketed in the United States prior to October 15, 1994. For these new ingredients, firms are required to give FDA a pre-market notification unless the ingredients have been "present in the food supply as an article used for food in a form in which the food has not been chemically altered" (FD&C Act 21 U.S.C. 350b). This raises the question if nano-sized versions of conventional-sized materials are considered "new dietary ingredients." So far, nanomaterials in supplements have not been considered new dietary ingredients for FDA approval and so can be marketed "without any meaningful government oversight" (Michelson and Rejeski 2006).

Most laws and regulations under which FDA conducts its oversight were written before the commercial development of nanotechnology. The 2007 FDA Nanotechnology Task Force made several recommendations and provides greater detail on FDA oversight (FDA 2007b). Within the past decade, FDA reorganized its offices and opened the Office of Food Additive Safety to handle requests for approval for food packaging, food additives and food colors, including those involving nanotechnology (Michelson and Rejeski 2006).

CONCLUSIONS

This article contributes to a broader understanding by consumers of the issues associated with nanotechnology for food applications by openly discussing these issues using balanced information and scientific findings in non-technical language. The past decade has seen worldwide increases in the number of firms investing in nanotechnology, commercial products that use nanotechnology, and scientific publications and patent applications for nanotechnologies. According to J. Clarence Davies (2009a), who has published several papers on nanotechnology oversight, "We are undergoing a rapid period of development unprecedented in human history." There are an almost unlimited number of current and potential applications of nanotechnology to food. However, there may be unintended and unforeseen effects on food safety, the environment and

society. The amount of research and development underway worldwide by both the public and private sectors, forecasts of market size and sales, and the potential for important health and safety benefits means that the stakes are high economically. Therefore, for society to fully benefit from nanotechnology, it is important to successfully overcome the major challenges facing the continued innovation, development, and commercialization of nanotechnology-based products, including food applications.

The challenges for nanotechnology include having well-prioritized, targeted research to keep pace with the development of nanotechnology and the commercialization of products that incorporate nanotechnology. Appropriate legal and regulatory oversight of nanotechnologies must also be in place to adequately protect the environment, consumers, workers and society in general without critically impeding technological innovation and incentives for industry to develop, market and seek regulatory approval (where applicable) of new products. The complexity of nanotechnology means that applications extend across the regulatory oversight of different agencies and that particular nanotechnology applications may need to be studied from different perspectives. Consumer acceptance of nanotechnology is critically important, particularly considering the public reactions in some countries following the introduction of irradiated foods, rBST and genetically modified foods. Achieving safe and widely accepted commercial uses of nanotechnology will require concerted effort across countries, Federal agencies, disciplines and sectors. Ultimately, the success or failure of nanotechnology may hinge on how and the extent that these challenges are overcome.

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