

Research Strategies for Safety Evaluation of Nanomaterials, Part VII: Evaluating Consumer Exposures to Nanoscale Materials

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Abstract

Considerable media attention has recently been given to novel applications for products that contain nanoscale materials. These products could have utility in several industries that market consumer products, including textiles, sporting equipment, cosmetics, consumer electronics, and household cleaners. Some of the purported benefits of these products include improved performance, convenience, lower cost, as well as other desirable features, when compared to the conventional products that do not contain nanoscale materials. Although there are numerous likely consumer advantages from products containing nanoscale materials, there is very little information available regarding consumer exposure to the nanoscale materials in these products or any associated risks from these exposures. This paper seeks to review a limited subset of products that contain nanoscale materials, assess the available data for evaluating the consumer exposures and potential hazards associated with these products, and discuss the capacity of US regulatory agencies to address the potential risks associated with these products.

Key words: nanoscale materials; consumer products; regulatory agencies; product safety; exposure assessment

Introduction

The use of materials that have been created through nanotechnology is expected to dramatically increase over the next few years, and have a significant impact on products found in commerce. There are several hundred companies within the United States that are involved in the development or manufacturing of products with nanotechnology (Emtech Research, 2005). The definition of nanotechnology and terms associated with this technology varies, and there are efforts underway to create consistent terminology for nanotechnology (<http://www.astm.org/COMMIT/COMMITTEE/E56.htm>). The National Nanotechnology Coordinating Office (NNCO) and the Nanoscale Science, Engineering, and Technology (NSET) Subcommittee support interagency coordination of federal activities involving the development, commercialization, and regulation of nanotechnology (<http://www.nano.gov>). The NNCO defines nanotechnology as the understanding and control of matter at dimensions of roughly 1 to 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale. At the nanoscale, the physical, chemical, and biological properties of materials differ in fundamental and valuable ways from the properties of individual atoms and molecules or bulk matter. Nanotechnology research and development is directed toward understanding and creating improved materials, devices, and systems that exploit these new properties (<http://www.nano.gov>).

Nanoscale materials are currently being used in a number of household products to enhance their performance. The specific products that are discussed in this paper include textiles, sporting equipment, and cosmetics. The supposed benefits of these products include stain and wrinkle

resistance for textiles, greater strength and structural integrity for sporting equipment and enhanced performance for cosmetics (http://www.nnin.org/nnin_nanoproducts.html). These product classes were chosen for this review as they provide a diverse range of chemistries and industrial sectors, and they likely represent a substantial portion of the existing consumer exposure to products that contain nanoscale materials. This paper will also explore the potential approaches to regulating products that contain nanomaterials by federal agencies with jurisdiction over these products.

Products Containing Nanoscale Materials

Many of the products that claim to contain nanoscale materials refer to prototypes that have not been commercialized, or approved by regulatory agencies (for those products that need premarket approval). However, there are multiple products that are currently on the market, where the manufacturers' claims include the use of nanoscale materials. Some of these products do not require pre-market approval, such as cosmetics, textiles, and sporting goods. Other products are required to undergo pre-market testing to establish safety and efficacy, prior to receiving regulatory approval and subsequent market access, such as over-the-counter drugs, prescription drugs, imaging agents and medical devices.

Exposure to these products, whether intentional or unintentional, may occur via various routes, including orally, dermally and through inhalation. It is also likely that the population currently exposed to nanoscale materials in consumer products would be representative of the entire population, and not exclusive to a particular age, sex, ethnic background or disease condition, because many of these products appeal to a diverse range of individuals.

Cosmetics

The smaller size of UV radiation-blocking particles in nanotechnology-based sunscreens and cosmetics has been advertised as having advantages such as transparent application and improved efficacy compared to traditional sunscreen products. It appears that few (if any) cosmetic products found in retail stores contain nanoparticles at this time. One large cosmetic company advertises on its United Kingdom website that one of their products contains "nanosomes" but the U.S. website for the same product says that product ingredients are "encapsulated".

A number of biotechnology companies are developing nanoscale systems for localized topical delivery, controlled release, and stabilization of cosmetic ingredients. Nanosized liposomes, nanoemulsions, and nano-encapsulation are terms used to describe these various systems designed to improve the effectiveness of cosmetic products (<http://www.Happi.com/June05>). Some of the potential impacts from dermal exposure to nanoscale materials include the following: (1) enhanced amount and depth of penetration of active ingredients in cosmetics into the skin resulting in increased activity; (2) ingredients that are chemically unstable in air and light such as retinol and Vitamin E may be more readily used in topical products following encapsulation in nanoparticles; and, (3) timed release of ingredients may become more feasible in topical products and could allow for improved effectiveness equivalent to current controlled release orally administered drugs. However, the potential usefulness of nanoparticles in cosmetic products is not fully understood at this time because it is not clear to what extent these nano-sized systems can penetrate the skin.

Sporting Equipment

Nanomaterials are being used or considered for use in a variety of different types of sporting equipment. The use of nanotechnology in sporting equipment is creating unique opportunities to develop lighter materials that can be stronger than their traditional counterparts. Frequently, the nanomaterials in sporting equipment are embedded in a matrix within the product. For example, nanomaterials are being used in tennis rackets and baseball bats to reportedly improve their strength and stability (http://www.smalltimes.com/document_display.cfm?document_id=7326). One manufacturer injects silicon oxide particles into the voids in the graphite frame of a tennis racket to make it stronger, while another manufacturer uses a nanocomposite material in the yoke of the racket to minimize the extent to which the racket bends when it comes in contact with the ball. This is thought to provide more speed for the ball after contact with the racket. In addition, carbon nanotubes are also being injected into the resin in carbon fiber baseball bats to improve their strength (<http://baseball.eastonsports.com/index2.php>). Also, soccer and tennis balls are being modified with nanomaterials to improve their air retention, to provide a more consistent bounce and to extend their useful life. The inner rubber lining of the tennis balls contain a nanocomposite coating technology based on aqueous suspensions of nanodispersed silicates in a polymer matrix. (<http://www.inmat.com/tech-elastomer.shtml>).

Currently there is not much published information regarding the human health or environmental impact of the use of nanomaterials in sporting equipment. While the human health impact would be expected to be minimal because the nanomaterials are generally imbedded in a matrix as a constituent of the sports product, the potential for these materials to be released from the products over time and the expected use conditions for each product should be evaluated

carefully to fully understand the likely disassociation characteristics of the nanomaterials. In addition, a better understanding of the life-cycle of these products would allow development of a comprehensive assessment of the complete human health and environmental impacts of these materials.

Textiles

Consumer textile products are among the most widely used materials in the world. Over the past decade, the textile industry has become a significant user of nanotechnology. Novel uses for nanotechnology have infused the U.S. textile industry with innovative niche products, or improved versions of existing ones (Popowitz, 2003). These new systems are increasingly replacing traditional textile finishing processes which typically involved surface chemical applications. Several nanotechnology applications for clothing textiles have already been used in mass commercial production in the U.S. These include stain, water and wrinkle resistance. Clothing with wrinkle and stain resistant properties was one of the top apparel trends in 2005 (Agin, 2004). In addition, two major mattress manufacturers are using nanotechnology products in their bedding (Popowitz, 2003).

There are a variety of systems and chemistries used in nanotechnology textile applications. Based on information provided by manufacturers, the nanomaterials that are commonly applied to textiles are nanoscale fibers that range from 50 to 100 nm in length (Cole, 2004). These materials, often referred to as nanofibers or “nanowhiskers”, are attached to natural (such as cotton) or synthetic fibers (such as polyester) by means of polymer chemistry applications. Textiles are not coated with a stain or water resistant chemical, the change to the fabric occurs at

the molecular level, and the nanomaterials can be configured to give the finished fabric a particular desirable attribute (Rodie, 2001). Nanofibers are created through electrospinning, a textile manufacturing process that dates back to the 1930s. Using electrospinning, manufacturers apply electrical charges to water-based polymer solutions containing nanoparticles. When enough electrical charge is applied to the solution, an unstable jet of solution and nanoparticles, moving like a whip through air, is formed. While, the whipping motion elongates the jet, the solvent evaporates, producing a tiny fiber containing the nanoparticles (Doshi and Reneker, 1995).

Other nanotechnologies in development and not yet commercially viable include electrospun nanofibers that are able to encapsulate materials, such as anti-bacterials (Azoulay, 2005). New flame-retardant systems are expected to enter the market using nanotechnology by synergistic effects of nano-dispersable fillers with classical flame retardants (Beyer, 2005). These systems are of particular interest in the area of home furnishings, such as mattresses, bedding and upholstered furniture.

The potential benefits to consumers from the use of nanotechnology in textiles include fabrics with desirable enhancements, such as stain and water resistance, anti-static properties, moisture wicking, wrinkle resistance, antibacterial and UV absorbency properties, with no discernable alteration of aesthetics. Textile end products, including clothing and home furnishings, are in intimate contact with consumers during every moment of their daily lives. Along with the potential benefits, there may be potential implications (health concerns) about consumer exposures to nanomaterials applied to textiles.

Textiles go through numerous processes from fiber production to finishing. Given the degree of processing for finished textiles, it is unlikely that the original fibers contained in these products would cause any health concerns to consumers (Wakelyn, 1994). However, given the limited data available regarding the behavior of nanoscale materials in textiles, more thorough testing should be performed to fully characterize the fate of nanoscale materials in textiles over time to assess potential implications for human exposures to these materials.

Consumer Exposures and Hazards Associated with Nanoscale Materials

The lack of available information on the potential health and environmental risks of nanomaterials is being addressed by a number of organizations including the National Science Foundation, the U.S. EPA, and academic researchers (Dreher, 2004). However, an important component in addressing potential health risks that is often not sufficiently addressed is the potential exposure to the consumer. The presence of a toxic substance in a consumer product does not constitute a health hazard if the product design or use prevents the consumer from being exposed to the substance. If there is no exposure, then there will be no risks. Exposure assessment therefore plays a key role in determining whether there are any risks of adverse health effects from any compound. For consumer product applications, if the nanomaterial is attached to the product in a manner that minimizes its release, the exposure potential will be minimal. If the nanomaterials are released in significant quantities during reasonably foreseeable product use or foreseeable misuse, exposure may result via dermal contact, ingestion, or inhalation. Questions concerning consumer exposure to nanomaterials include: (1) what type of contact would result in exposure and what is the extent of that exposure; (2) are the

nanomaterials likely to become dislodged from the product matrix during use or disposal: (3) what might be the potential exposures resulting from unintended use – e.g., a child mouthing a garment made of nano fibers or ingesting a cosmetic; (4) are there groups of individuals who are more susceptible to any potential adverse health effects that may be associated with nanoparticles; and, (5) do cosmetics, textile finishes, and skin applications composed of these nanomaterials enter the blood stream and, if so, where are they ultimately translocated to in the body and with what resultant effects?

If nanoscale particles can be released in some products in significant quantities, identifying the specific form of the nanomaterial is crucial. The nanomaterials may be applied to products as discrete nanoscale entities, having unique size and compound-specific properties. However, nanoparticles may agglomerate into larger particles or longer fiber chains which may change their properties and may impact their behavior in the indoor and outdoor environments as well as their potential exposure and entry into the human body. The conditions of use may also impact the form of the compound. During typical consumer use, the particles may be released in one particular form, but under more stressful conditions, the form may change. For example, textiles are subjected to washing, drying, and ironing. During washing, warm or hot water along with detergent may increase the release of nano-compounds or remove the compound. Drying textiles will subject the nanofibers to heat and agitation. Ironing applies a significant amount of heat, pressure, and abrasion. What impact will the heat and physical stress have on the nanofibers? Could it cause them to aggregate into larger particles, chemically alter them into new compounds or lead to release of nanoparticles?

The use patterns described above can potentially change the form or structure of the nanomaterial and subsequently influence consumer exposure. The exposure may occur through a number of pathways and routes under various exposure scenarios. By examining the potential activities that may lead to exposure to nanomaterials, studies can be conducted to quantify the amount of nanomaterial release from products and determine what risks of adverse health effects, if any, might arise from using products containing nanoscale materials.

U.S. Regulatory Capacity to Address Consumer Risks From Engineered Nanoscale Materials

The emergence of engineered or manufactured nanomaterials into commerce, incorporated into a variety of diverse consumer products ranging from sunscreens and cosmetics to electronics to clothing, will have a major effect upon the various federal regulatory agencies. In addition, several non-governmental organizations (NGOs), consumer advocate groups, the media, and public citizen consortia are taking a heightened interest in these materials, including their manufacture, use and disposal. Each of these groups will play a role in shaping how nanotechnology-derived products are handled, valued, and regulated. The regulatory agencies that have oversight over the vast array of consumer products that contain nanoscale materials are the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), the U.S. Consumer Product Safety Commission (CPSC), and the U.S. Department of Agriculture (USDA).

Regulatory Agencies

EPA

The U.S. Environmental Protection Agency (EPA), whose mission is to protect human health and safeguard the environment, in anticipation of the significant impacts upon the manner in which its mission is accomplished, is currently engaging in several activities to improve the scientific basis for evaluating the risks associated with exposure to nanoscale materials. These activities include sponsoring research and product development on the potential applications and implications of nanotechnology, developing a white paper identifying the critical issues for the Agency, coordinating and participating in strategic research planning meetings concerning the potential role(s) for emerging technologies with respect to environmental protection, and providing information at a variety of conferences and workshops composed of academic, industrial, government, and Non-Governmental Organization (NGO) representatives dealing with possible societal and environmental impacts of novel technologies.

Risk management decisions at EPA are decisions based on the program area within the Agency, i.e. air, water, toxic substances, etc. and also on the statute involved (for example, Clean Air Act, Clean Water Act, Toxic Substances Control Act). If nanomaterials are entrained in a wastewater stream, the stream and the producer of the stream will be subject to the effluent guidelines of the Clean Water Act. The Safe Drinking Water Act (SDWA) authorizes the Agency to establish health-based Maximum Contaminant Level Goals (MCLGs) which are recommendations, and Maximum Contaminant Levels (MCLs) which are regulations. Nanotechnology has the potential to influence the setting of MCLs. The Comprehensive Environmental Response Compensation

and Liability Act (CERCLA) authorizes the Agency to respond to actual or threatened “releases” of “hazardous substances” to the environment.

The Toxic Substances Control Act (TSCA) gives EPA authority to regulate the manufacture, use, distribution in commerce, and disposal of chemical substances. This Act authorizes the Agency to regulate both new and existing compounds and is currently undergoing scrutiny by the Agency to determine to what extent it can incorporate engineered nanomaterials.

One potential application of nanotechnology for the environment is the development of rapid, accurate, miniature environmental sensing and monitoring devices that have the potential to eliminate the risks presented by hazardous compounds to ecosystems and the public. Novel sensing technologies that incorporate “smart” technology, i.e., the ability to perform some specified action depending upon the nature, concentration and location of the detected substance (s) and to self-repair in the event of failure or trauma, will provide the Agency with enhanced environmental protection capabilities.

Treatment and remediation techniques can also be greatly improved through the development of nanotechnology. The potential exists to develop inexpensive, in-situ remediation and treatment technologies that enable the rapid and effective clean up of recalcitrant compounds, especially those located in inaccessible areas. Currently, many of the methods that the EPA employs to remove toxic contaminants from the environment involve laborious, time-consuming, expensive techniques that often require pre-treatment processes and/or removal of portions of the surrounding environment. Potential implications with this novel approach include the unknown

fate, transport, transformation, and bioavailability of these materials for human health and the environment. .

FDA

The mission of the U.S. Food and Drug Administration (FDA) is to ensure that drugs, drug delivery systems, cosmetics, medical devices, vaccines, and food products are safe and effective for the consumer. The FDA regulates a wide range of products, including foods, cosmetics, drugs, devices, and veterinary products, some of which may utilize nanotechnology or contain nanomaterials. FDA regulates on a "product-by-product" basis. Products regulated by the Agency undergo a three-tiered examination: Premarket Approval; Premarket "Acceptance"; and Post Market Surveillance.

The FDA expects many nanotechnology products will span the regulatory boundaries between pharmaceuticals, medical devices and biological compounds. These will be regulated as "Combination Products" for which the regulatory pathway has been established by statute. In such cases, FDA will determine the "primary" mode of action of the product. This decision will determine the regulatory framework for the product, i.e. a drug, medical device or biological product. The Agency has formed a NanoTechnology Interest Group (NTIG) to facilitate the regulation of these products. This group is comprised of representatives from all the FDA Centers. The product application will be managed by the appropriate FDA Center with consultations from the other Centers.

FDA regulates very few materials but many types of products. Accordingly, the stage at which the FDA becomes engaged in the regulation of a nanotechnology-derived product will depend upon the actual consumer product, rather than its component parts or materials. Specifically, FDA regulates only when "claims" are made by the product developer. If there is no claim made by the manufacturer regarding product performance or capability, FDA regulatory jurisdiction is not applicable.

Cosmetic products are not subject to pre-market approval by the U.S. Food and Drug Administration (FDA) (21 U.S.C. § 361). Therefore, the Office of Cosmetics and Colors at FDA would not necessarily be informed by a company that introduces a product containing nanoparticles into the marketplace. However, cosmetics must be safe and truthfully labeled. The manufacturer of a cosmetic product is responsible for the safety of the product and its ingredients. If the FDA considers that there is a safety concern resulting from the use of any cosmetic ingredient, including nanoparticles, then it has several options to prohibit the marketing and sale of those products.

Sunscreens are considered cosmetics in Europe; in the United States they are considered to be drugs. In the U.S., while some sunscreens undergo the New Drug Application (NDA) review process, others are marketed Over-The-Counter (OTC), and the sunscreen actives are produced according to OTC and United States Pharmacopeia (USP) monographs. For NDA, data to support safety, efficacy and Chemistry Manufacturing and Controls (CMC) are reviewed. Once the product becomes OTC, efficacy is assessed by the sun protection factor (SPF) of the product and the quality of the active ingredient is determined by the USP and OTC monographs. It is the

manufacturer's responsibility to ensure that the monographs are followed correctly. However, FDA can always collect marketed product samples to assess the quality of that product. If the product is not made according to specified standards, then the FDA can take regulatory action. Inert ingredients known as excipients contained in OTC products must be excipients that are known to be safe. However, for sunscreens that are reviewed under the NDA, a new excipient may be used, since the final formulation will undergo a rigorous review for safety, efficacy, toxicology and CMC. Despite this process, there are sunscreens with nanoparticles in the market that have not been studied. The OTC and USP monographs on sunscreens do not currently specify particle size of titanium dioxide and zinc oxide, and at this time, there are products on the market that contain these ingredients in the nanoscale range. If a sunscreen containing titanium dioxide and zinc oxide is clear, the particles of titanium dioxide and zinc oxide are likely present in the nanoscale range. As particle size increases, out of the defined nanoscale range, the sunscreen product becomes more opaque.

Currently the FDA is involved in studies of marketed sunscreens in collaboration with the National Toxicology Program, Rice University and the National Institute for Standards and Technology. These studies will help identify those sunscreens that contain nanoscale particles of titanium dioxide and zinc oxide, and characterize the size ranges for these nanoscale particles. The results will help elucidate the relationship between nanoscale particle size and dermal uptake, and whether there are legitimate safety concerns associated with dermal penetration of nanoscale particles. This information is not available in the existing toxicology literature and would help agencies such as the FDA assess the risks associated with the use of nanoscale particles in drugs and cosmetics.

CPSC

The U.S. Consumer Product Safety Commission (CPSC) is charged with protecting the public from unreasonable risks of serious injury or death from over 15,000 types of consumer products under the agency's jurisdiction. Fire, electrical, chemical, or mechanical hazards are potential hazards posed by consumer products. Products under CPSC's jurisdiction include, but are not limited to, toys, furniture, appliances, cigarette lighters, and household chemical products. Nanotechnology-derived products entering commerce, containing materials with novel chemical, physical, biological, optical and electronic properties, will require assessment to determine if there may be exposure to a potential health risk that might negatively impact consumer safety. CPSC staff is particularly concerned with exposures and the likelihood of risk in the most vulnerable populations (e.g., children). Whether nanotechnology materials separate or come apart upon contact, and how and if these materials affect children, are important issues to be considered.

The potential health risk of nanomaterials can be assessed with existing CPSC statutes, their administering regulations, and interpretative guidelines. CPSC staff may assess a product's potential to cause chronic adverse health effects from exposure to a hazardous substance under the Federal Hazardous Substances Act (FHSA). The definition of a hazardous substance under the FHSA is risk-based and the regulation addresses both acute and chronic hazards. To be considered a "hazardous substance" under the FHSA (15 U.S.C. § 1261 (f)(1)(A)), a consumer product must satisfy a two-part definition. First, the substance (or mixture of substances) must be toxic under the FHSA, or present one of the other hazards enumerated in the statute. Second,

it must have the potential to cause "substantial illness or substantial personal injury during or as a proximate result of any customary or reasonably foreseeable handling or use." Therefore, exposure and the likelihood of risk must be considered in addition to inherent toxicity when assessing whether a product meets the definition of a hazardous substance under the FHSA.

The Commission staff uses the CPSC's Chronic Hazard Guidelines (*57 Fed. Reg.* 46633; Oct. 9, 1992) to determine whether a product presents a chronic hazard and whether a product is properly labeled under the FHSA. The first step in the risk assessment process is hazard identification, that is, a review of the available toxicity data for each substance under consideration and a determination of whether the substance is considered to be "toxic" under the FHSA. If it is concluded that a substance is toxic because it presents a chronic hazard under the FHSA, then a quantitative assessment of exposure and risk is performed to evaluate whether the substance may be considered a "hazardous substance" under the FHSA and require cautionary labeling.

If a substance is considered a hazardous substance, the FHSA requires cautionary labeling to address the principal hazard presented by the product and instructions for safe use, handling and storage of the product. If labeling required under the act is determined to be inadequate to protect the public health and safety, the Commission can, by regulation, ban the substance (if such substance is intended or packaged for use in households). Any toy or other product intended for use by children which is a hazardous substance or contains a hazardous substance accessible to a child would generally be considered a banned hazardous substance. The FHSA does not provide for pre-market registration or approval. This places the responsibility on

manufacturers to ensure that their products are labeled as required by the FHSA. Staff will encourage manufacturers to use the chronic hazard guidelines to assess their products, and ensure that the use of nanomaterials in their products do not present a hazard to consumers.

Conclusions

Nanoscale materials are commercially available and are being used in a number of consumer product applications including textiles, cleaning products, sporting equipment, drugs and cosmetics. Manufacturers of the products suggest that they offer a variety of enhancements over similar products that do not contain nanoscale materials, such as improved strength and structural integrity, enhanced shelf life, greater stain and contaminant resistance, and improved UV protection.

While the potential benefits of nanotechnology have been widely reported, little has been done to characterize the safety or identify potential hazards associated with products containing nanoscale materials. Some limited studies have been conducted to evaluate the hazards associated with these materials, but sufficient hazard and exposure data are not yet available to conduct comprehensive risk assessments for products containing nanoscale materials. More studies are needed to evaluate the stability of these matrices in a variety of test systems to fully determine the potential for human exposure to the nanoscale components of commercially available products, as well as future products.

Several U.S. regulatory agencies have authority to review, regulate, and/or approve products containing nanoscale materials. These agencies have broad experience with conducting

toxicological assessments for a number of chemical, pharmaceutical, and consumer products. This experience will be useful as these agencies begin to evaluate products containing nanoscale materials. In addition to obtaining more experience evaluating the safety of products containing nanoscale materials, these agencies also need better hazard and exposure data to develop risk assessments for these materials. In particular, more data is needed to characterize the stability of the matrices that contain the nanoscale constituents of commercial products. In addition, better data is needed on the dispersion characteristics of the nanoparticles in the typical consumer environments in which they are used. This would help in the development of reliable exposure data for these materials. Also, quality controlled hazard data is needed for commercially-relevant nanoscale materials. To date, most of the hazard studies have used a very limited set of nanoscale materials including single and multi walled carbon nanotubes, fullerenes, and to a lesser extent quantum dots.

Reportedly, consumers are already benefiting from products containing nanoscale materials. As more data becomes available, the safety and potential hazards of existing products that contain nanoscale materials will continue to be evaluated.

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