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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Food and Drug Administration-Regulated Products Containing Nanotechnology Materials - [Docket No. 2006N-0107]

Introduction

Consumers Union ("CU"), the non-profit publisher of *Consumer Reports* magazine, submits the following comments in response to the U.S. Food and Drug Administration's (FDA's) request for comments in the above docket. CU appreciates the opportunity to share our views about the rapid increase of nanoengineered ingredients for foods, drugs and cosmetics, the many scientific uncertainties concerning their safety, and the need for strong regulations to manage the unique risks that are anticipated to accompany these products. We recognize the important benefits that these materials can bring to certain product sectors including more effective medicines, safer drinking water, and energy savings. However, the benefits that consumers stand to gain depend on the responsible development of this technology.

We are also deeply concerned that widespread, unregulated use of many nanoengineered materials will bring about the kinds of severe, irreversible, unintended consequences that have resulted from similarly groundbreaking changes in product formulations that have come before. FDA needs to act quickly to institute measures to ensure nanoengineered materials for food, drugs or cosmetics are adequately tested for safety before they enter the marketplace such that their use is worthy of consumer confidence. Lack of evidence of harm should not be a proxy for reasonable certainty of safety.

Too often in the 70 years that we have been working to protect consumers, we have seen consumer health compromised when new technologies are pushed to market before their risks are adequately assessed and managed. Chemicals such as PCBS, and pesticides like DDT and dieldrin were brought on the market in the 1950's and 1960's and initially thought to be safe. Yet adequate regulations to address their serious impacts on human health and the environment, such as the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA) did not come until the 1970's, long after widespread human and environmental exposures occurred and damage was already done. In cases like these, failure to anticipate adverse effects led

to a long, difficult and sometimes unsuccessful process to get these products off the market and out of the environment and the food supply.

Such examples give us pause as we contemplate the widespread use of nanoengineered substances. The same unique nano-scale chemical and physical properties that can potentially make more effective drugs, more nutritious foods, and improved cosmetics may also generate unique and severe toxicological effects.

Action to regulate nanoengineered food, drugs, and cosmetics is urgently needed. New products are entering the marketplace daily. Regulatory review to effectively manage risks associated with these products will only be more difficult for FDA as time goes on. A number of different products we test, including sunscreens and face creams, claim to contain nano-particles. The Wilson Center's Nanotechnology Project has identified more than 275 products on the market,[1] many of which are highly exposure-intensive. And many more products are being developed. According to a study from Helmut Kaiser Consultancy, investments in the global nano-food market alone are expected to surge from a projected $7 billion for 2006 to $20.4 billion in 2010. Authors suggest that food production, processing, preservation, safety and packaging will all be significantly affected by advances in nanotechnology.[2]

It is precisely because the potential benefits that such innovations can bring are so heavily promoted that FDA must increase its commitment to characterize and manage their hazards. Unanticipated health concerns stand to undermine those benefits, and deny consumers and society as a whole the great promise of nanotechnology. And because foods, dietary supplements, cosmetics and color and food additives, and certain drugs can migrate to the environment,[3] their hazards can be disproportionate to their use, potentially affecting many consumers who are not choosing those products or enjoying their benefits. FDA has a responsibility to protect all consumers, including those who do not choose to purchase these products.

Public disclosure and transparency is important with respect to risk information and the use of nanomaterials in consumer products. Many consumers are not aware that nanoengineered materials are in use. In a recent poll, nearly half of those surveyed had heard nothing about the use of nanoengineered materials in consumer products. Nearly 40% of these participants expressed concern that the risks of nanoengineered materials may outweigh their benefits.[4] Such consumers may choose to avoid products that contain nanoengineered ingredients. Many have chosen to avoid other synthetic ingredients such as drug and pesticide residues – evidenced by the continued growth in demand for certified organic foods. Product labeling and public disclosure of all scientific studies relating to exposure and toxicity of nanoengineered ingredients will be key to consumer confidence in this new technology.

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[1] Maynard, Andrew, "Nanotechnology: A Research Strategy for Addressing Risk." Woodrow Wilson International Center for Scholars, Washington D.C., July 2006, p. 25.

[2] Helmut Kaiser Consultancy, "Nanotechnology in Food and Food Processing Industry Worldwide 2003-2006-2010-2015," p.1. Downloaded from http://www.hkc22.com/Nanofood.html, September 25, 2006.

[3] Daughton, C.G., T.A. Ternes, "Pharmaceuticals and Personal Care Products in the Environment: Agents of Subtle Change?", Environmental Health Perspectives Supplements Special Report, Volume 107, Supplement 6, December 1999.

[4] Peter D. Hart Research Associates, Inc., "Report Findings," Woodrow Wilson International Center for Scholars, Washington, D.C., September 19, 2006, p. 5 and 7.

We encourage FDA to revise its priorities in addressing nanotechnology to put greater emphasis on overcoming science and regulatory hurdles to *protecting consumers* from the adverse effects of these materials than on hurdles that *inhibit* the use of nanotechnology in commerce. We recommend that FDA adopt the following priorities in managing the use of nanoengineered materials in or as foods (including dietary supplements), cosmetics, and food and color additives:

1. **Understand the unique structure-dependant risks posed by nanomaterials**
   In our view, the first step towards a coherent policy on nanotechnology is to recognize that nano-scale materials have the potential for structure-dependent health effects that are uniquely different than their larger counterparts. Indeed experts in nanotechnology are virtually unanimous on this point.[5] FDA should embrace this paradigm shift and restructure its approach to nanomaterials accordingly.

2. **Develop regulations and standards needed to manage these risks**
   We agree with the recommendation of the Royal Society, the European Commission's expert panel, and others that calls for nanomaterials to be regulated as new chemical substances, subjected to a full battery of safety tests and government approval before use. FDA needs to lead the effort to define a minimum battery of appropriate tests for nanomaterials, especially those used in foods and cosmetics, and work in coordination with other agencies including EPA and OSHA to ensure that life cycle impacts are fully considered.

3. **Require comprehensive pre-market safety assessments to ensure reasonable certainty of no harm.**
   FDA should move to immediately require companies to submit existing safety data pertaining to the unique hazards associated with nanomaterials in foods and cosmetics. FDA should also work closely with NIH, NTP, and international/intergovernmental organizations to rapidly develop screening tools and a tiered approach that can be used as a preliminary basis for regulation. Priority should be given to materials already on the market, with high exposure-potential, such as carbon fullerenes in cosmetics, focusing on the exposure pathways most relevant to existing uses.

4. **Require disclosure and transparency for the use of nanoengineered materials in consumer products and related safety testing.**
   We urge FDA to require labeling of nanoengineered ingredients and the products in which they are used, e.g. foods (including dietary supplements), cosmetics, food and color additives, and act to fully inform and engage all stakeholders, including consumers, in the debate over their use.

A detailed discussion of each of the above points follows.

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[5] Institute of Medicine, Implications of Nanotechnology for Environmental Health Research, The National Academies Press, Washington, D.C., 2005, p.2, 23; Royal Society and Royal Academy of Engineering, Nanoscience and Nanotechnologies: Opportunities and Uncertainties. July 2004, p. 79. Downloaded on September 25, 2006 from http://www.nanotec.org.uk/report/chapter9.pdf

DISCUSSION

As summarized above, we strongly recommend that FDA adopt the following priorities:

Understand Unique Risks Posed by Nanomaterials

In our view, the first step toward a coherent policy on nanotechnology is to recognize that nano-scale materials have the potential for structure-dependant health effects that are uniquely different from their larger counterparts. Indeed experts in nanotechnology are virtually unanimous on this point.[4] FDA should embrace this paradigm shift and restructure its approach to nanomaterials in the products it regulates to consistently reflect this important principle.

A seminal report published in July 2004 by the Royal Society and Royal Academy of Engineering highlighted unique chemical and physical properties of 'nanoparticles' and 'nanotubes,' and discussed their potential adverse impacts on human and environmental health. Ann Dowling, chair of the study said, "Nanoparticles can behave quite differently from larger particles of the same material ... it is vital that we determine both the positive and negative effects they might have."[6] The report concludes: "we believe that chemicals in the form of nanoparticles and nanotubes should be treated separately to those produced in a larger form. Given the evidence that increased surface area can lead to greater toxicity per unit mass, regulation of exposure on a mass basis to nanoparticles and nanotubes may not be appropriate."[7] The European Commission Scientific Committee on Emerging and Newly Identified Health Risks reported that "experts are of the unanimous opinion that the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of material of macroscopic size, which obeys the laws of classical physics."[8]

In this country, members of an expert panel convened by the Institute of Medicine cited similar conclusions in their 2005 report. Dr. Vicki Colvin, Director of the Center for Biological and Environmental Nanotechnology at Rice University, said that "by changing surface coatings, the nano-material toxicity can almost be completely altered," noting, for example that a minor alteration can make a hydrophobic substance hydrophilic. Others raised concerns about the unique potential for nanoengineered particles to bypass the blood-brain barrier in various ways, such as via the trigeminal or olfactory nerves[9].

Such opinions are also shared by scientists from industries that stand to benefit most from commercial development of nanomaterials. Jim Romine, director for materials science and engineering at DuPont's global research campus has said "It would be unwise to claim that just because there are tiny amounts, it's harmless."[10] The company has also publicly recognized the

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[6] Royal Society, "Nanotechnologies bring great potential and need for responsible development," (press release), 29 July 2004.

[7] Royal Society and Royal Academy of Engineering, Nanoscience and Nanotechnologies: Opportunities and Uncertainties. July 2004, p. 79. Downloaded on September 25, 2006 from http://www.nanotec.org.uk/report/chapter9.pdf.

[8] European Commission Health and Consumer Protection Directorate-General, Scientific Committee on Emerging and Newly Identified Health Risks, "modified Opinion on The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies," Adopted during the 10th preliminary meeting of 10 March 2006, p.6.

[9] Institute of Medicine, *Op cit.*, p.24 and 26.

[10] Feder, B. "As Uses Grow, Tiny Material's Safety is Hard to Pin Down," New York Times November 3, 2003.

need to characterize the safety implications of nanomaterials' novel properties and reassess the regulations governing their use accordingly.

In contrast, the current regulatory structure and some opinions voiced by FDA staff continue to ignore these unique structure and size-related hazards posed by nanoengineered materials. For example, FDA's posted review of FDA regulation of nanotechnology products states that "FDA believes that the existing battery of pharmacotoxicity tests is probably adequate for most nanotechnology products that we will regulate. Particle size is not the issue."[11, 12] Nanoengineered silver in bandages, a dental restorative product containing nanoparticles developed by 3M, and carbon nanotubes in cosmetics, have all been approved despite many outstanding questions concerning the bioavailability and ultimate toxicity of the nano-scale ingredients in question.[13]

The scientific literature, though limited, shows cause for concern in a number of areas including enhanced bioavailability of nanoengineered substances, and their impact on absorption of other biologically active substances including pesticides and pharmaceuticals. Size and structural differences can also enable nanomaterials to migrate to different tissues and organs than their larger counterparts and elicit biological responses unique to their shape. They may also provide a new transport mechanism for adsorped substances to reach these sites, and may synergize adverse reactions with these or other substances. Of further concern is their potential to impact the efficacy and durability of conventional drugs and cosmetics.

Size and structure differences can enable nano-scale ingredients to absorb more completely in the body, delivering substantially greater doses to target organs than could otherwise be achieved with larger versions of the same chemicals. This is particularly worrisome for substances such as selenium for which there is a narrow margin between the recommended intake levels and the minimum toxic effect level, and those for which no toxic effect levels have been defined.[14]

Greater bioavailability of some nanoengineered materials could potentially make otherwise benign substances hazardous. Common nutrients like lycopene, in their nanoengineered form might reach harmful levels which could not otherwise be attained. A nanoengineered form of lycopene is currently being developed as a nutraceutical that the manufacturer claims can deliver up to 3 times the amount of lycopene that is otherwise available naturally from eating fresh tomatoes.[15] FDA recently approved a lycopene product for use as a color additive. However, it is unclear whether this product could be made with the Fortifying Nanovehicles (FNVs) that the manufacturer has developed to enhance lycopene bioavailability.[16] Though lycopene's benefits have been well--documented, a maximum tolerable upper limit for lycopene has not been established and it is

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[11] Sadrieh, Nakissa, Office of Pharmaceutical Science, CDER, "FDA Considerations for Regulation of Nanomaterial Containing Products," Downloaded from http://www.fda.gov/nanotechnology/OhioNano.ppt, September 28, 2006.
[12] USFDA, "FDA Regulation of Nanotechnology Products," (factsheet). Downloaded from http://www.fda.gov/nanotechnology/regulation.html, September 28, 2006.
[13] Sandrieh, Nakissa *Op Cit.*
[14] Agency for Toxic Substances and Disease Registry, Toxicological Profile for Selenium, September 2003; Koller, LD, JH Exon, "The two faces of Selenium-deficiency and toxicity – are similar in animals and man." Canadian Journal of Veterinary Research, 1986, Jul;50(2):297-306.
[15] Nutralease, Inc., Downloaded from http://www.nutralease.com/t_experiments.asp, September 28, 2006.
[16] 21 CFR Part 73 Docket No. 2001C-0486 "Listing of Color Additives Exempt from Certification: Tomato Lycopene Extract and Tomato Lycopene Concentrate." Downloaded from http://www.fda.gov/ohrms/dockets/98fr/01c-0486-nfr0002.pdf, September 28, 2006.

unclear what, if any harmful effects might occur at high doses attained with the nanoengineered form.

Nanoengineered substances may also alter the pharmacokinetics of drugs, supplements and other chemicals or exacerbate the kinds of problems associated with their macro-scale counterparts. Studies have shown that naturally-occurring compounds in grapefruit can increase the bioavailability of several important drugs, altering the delivered dose in ways that can negatively affect the course of treatment.[17] Products containing nanoengineered versions of such compounds could potentially generate even more severe interactions.

Nanoengineered materials also have the potential to enhance the bioavailability of known chemical toxins. A recent study found that micronized titanium dioxide in sunscreens increases the dermal absorption of several pesticides including 2,4-D.[18] This is particularly worrisome because sunscreens and insect repellants are often used simultaneously.

Though many studies suggest that dermal penetration of some nanomaterials is limited, differences in study designs show how critical factors can influence findings. Physiological differences among exposed individuals, such as the thickness and condition of hair and skin, physical activity, and duration of exposure may affect dermal penetration and toxicity of nanomaterials. For example, researchers at the National Institutes of Occupational Safety and Health (NIOSH) found that kinetic energy produced by flexing motions such as those involving the wrist, is sufficient to move certain nanoparticles such as beryllium oxide, into the skin where they can activate a cell-mediated immune response. Their study suggests that percutaneous nanoparticle exposure may make workers more vulnerable to beryllium sensitization at lower concentrations, which may help to explain why respiratory exposure limits have failed to reduce the prevalence of chronic beryllium disease in exposed workers. [19]

In addition, differences in the nanomaterials themselves, such as their stability or solubility, or the durability of particle coatings and encapsulating structures have also been recognized as critical to accurately replicate real-world consumer exposures. Size, shape and surface coating, for example, have been found to influence the permeability of quantum dots.[19a] Coatings can also limit the generation of reactive oxygen species following UV irradiation of titanium dioxide.[19b]

Titanium dioxide and zinc oxide are active photocatalysts. Their presence can ultimately degrade sunscreen formulations through the free radicals generated in the presence of sunlight. Though there is a risk that this mechanism also damages biological molecules in the process, the health risk associated with the diminished efficacy of the sunscreen itself is clearly apparent.[20]

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[17] Charbot, B, L. Becquemont, B.Lepere, et al., "Pharmacokinetic and pharmacodynamic interaction between grapefruit juice and halofantrine," Clin Pharmacol Ther. 2002 Nov;72(5):514-23.

[18] Brand, RM, J. Pike, RM Wilson, et al. "Sunscreens containing physical UV blockers can increase transdermal absorption of pesticides," Toxicol. Ind Health, 2003, Feb 19(1): 9-16.

[19] Tinkle, SS, JM Antonini, BA Rich, et al., "Skin as a Route of Exposure and Sensitization in Chronic Beryllium Disease," Environmental Health Perspectives, Volume 111, No. 9, July 2003.

[19a] Ryman-Rasmussen, JP, JE Riviere, NA Monteiro-Riviere, "Penetration of intact skin by quantum dots with diverse physicochemical properties," Toxicological Science, 2006 May; 91(1):159-65.

[19b] Tsuji, JS, AD Maynard, PC Howard, et al., "Research Strategies for Safety Evaluation of Nanomaterials, Part IV: Risk Assessment of Nanoparticles," Toxicological Sciences 89(1), 42-50 (2006).

[20] Colvin, V, " Potential environmental impact of engineered nanomaterials," Nature Biotechnology 21(10): 1166-1170.

Coatings and surface treatments containing nanoengineered silver, used for its antimicrobial properties, can degrade over time, potentially impacting their effectiveness and distributing nano-scale contaminants into surrounding environments. According to one source, 20% of applied nanoengineered silver in antimicrobial coatings is released from the treated matrix in the first 72 hours.[21] Given the broad spectrum activity of silver's antimicrobial effects, it is unclear what effects incidental ingestion of silver nanoparticles might have on the normal flora of the digestive tract. Additionally, the effects of the environmental release of silver nanoparticles on the environment and the indirect impact on food safety have yet to be fully considered.

FDA should also recognize the importance of size and structural differences of nanoengineered products on detection methods needed to find these substances in products, the human body and the environment. Accurate exposure and risk assessment, and the consumer's right to choose all depend on such protocols. For other regulated additives, FDA requires that such methods are available when these substances are approved.[22] As a minimum, nanoengineered materials should be subject to the same requirements, yet our own research suggests that few manufacturers have developed any reliable, standardized methods for accurately characterizing the presence and quality of the nanoengineered ingredients they sell.

Develop regulations and standards needed to manage these risks

Given that the scientific community has clearly established that the safety of nanoengineered materials cannot be predicted from their larger counterparts, e.g., that size matters, we agree with the recommendation of Royal Society, the European Commission's expert panel, and others who call for nanomaterials to be regulated as new chemical substances, subjected to a full battery of safety tests and approval by a government agency before use. FDA needs to lead the effort to define a minimum battery of appropriate tests and work in coordination with other agencies including EPA and OSHA to ensure that life cycle impacts are fully considered.

Because of the hazards associated with nanoengineered materials, we are particularly concerned with exposure-intensive uses in foods (including dietary supplements) and cosmetics, products that completely lack any pre-market safety testing requirements. We are also concerned about nanoengineered ingredients in food and color additives, nano-products that require no special testing because FDA currently considers them equivalent to their non-nano counterparts. We think these products should be held to the "reasonable certainty of no harm" standard that is applied to food additives and pesticides.[23]

Nanoengineered ingredients sold as foods or food ingredients, such as nanoengineered lycopene should be treated as new food additives, not dietary supplements. Likewise, nanoengineered versions of existing color and food additives should be treated as new substances, for which mandatory pre-market safety testing is required. For cosmetics and dietary supplements, pre-market safety testing is not currently required, but we urge FDA to actively seek any additional legal authority that may be necessary to enact such requirements.

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[21] Gibbins, Bruce, L. Warner, "The Role of Antimicrobial Silver Nanotechnology A new silver nanotechnology chemistry can prevent the formation of life-threatening biofilms on medical devices," Medical Device and Diagnostics Industry Magazine, August 2005.

[22] 21 CFR 170.35(c)(1)(iii)(a) and 170.39(c)4(iii).

[23] 21 CFR 170.3(i))

Despite significant gaps in critical areas, we believe sufficient science is available now to support the development of additional testing requirements for nanomaterials. The OECD Screening Information Data Set (SIDS) protocol and the High Production Volume Challenge Program, coordinated by the Environmental Protection Agency (EPA), offer good models for the basic battery of tests that should be required of all nano- and macro-scale chemicals in commerce – especially those with high exposure potential.[24] However, as several expert working groups have recommended, nano-scale materials also need additional or modified testing to characterize their unique absorption, distribution, metabolism and elimination mechanisms that enable greater contact with specific organs, tissues, cells and proteins and potentially greater overall body burdens than conventional substances. FDA should consider requiring a battery of tests that includes those that expert working groups recommend, such as tests for oxidative stress, C-reactive protein, platelet aggregation and other immune and inflammatory responses, GFAP (a biomarker for neuro-toxicity) and genetic toxicity.[25]

Where critical gaps do limit the development of test methods, FDA should not be passive in waiting for more detailed research. They should act quickly to review the existing science and work with industry and public interest stakeholders to lead and accelerate the development of appropriate test protocols relevant to new applications as they are being developed.

We urge FDA, in establishing standards and defining what substances are subject to regulation, to err on the side of caution rather than commercial expediency where scientific uncertainty is concerned. Though we appreciate industry's need for realistic protocols and standards that do not impede innovation, we feel that safe new foods (including dietary supplements), cosmetics, food and color additives are worth waiting for. If the potential risks and scientific uncertainties are clearly defined, industry is capable and well-suited to provide the information needed to fill the data gaps in ways to assure a reasonable certainty of no harm. Indeed such understanding is critical if we are to accurately determine the net costs and benefits of these new materials.

Industry has demonstrated its ability to innovate when government regulations challenge them to do so with clear, predictable mandates, deadlines and enforcement tools. Federal appliance efficiency standards have enabled companies to invest in research that has vastly reduced energy consumption; the global ban on ozone-depleting chlorofluorocarbons accelerated the shift to safer alternatives as did restrictions on levels of volatile organic compounds (VOC's) in consumer products. Many industry officials would agree that without these strong regulations, companies would not likely have made the necessary investments to bring about these important changes.[26] In all cases, product labeling, and strong standards played a critical role, just as we expect they will in ensuring the safe use of nanoengineered materials in consumer products.

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[24] US Environmental Protection Agency, "Public Access to Screening Information Data Sets" (fact sheet), updated June 28, 2006, Downloaded from http://www.epa.gov/opptintr/sids/pubs/overview.htm, September 26, 2006.

[25] US DHHS, National Toxicology Program, National Science Foundation, US Environmental Protection Agency, US Air Force, Office of Sponsored Research, University of Florida, "Final Report: Workshop on Developing Experimental Approaches for the Evaluation of Toxicological Interactions of Nanoscale Materials," November 3-4, 2004. AND European Commission Scientific Committee on Emerging and Newly Identified Health Risks, "modified opinion on The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies," adopted 10 March, 2006.

[26] INFORM, Inc., Stirring up Innovation: Environmental Improvements in Paints and Adhesives, New York, 1994.

Given the rapid influx of nanoengineered products in the marketplace these regulations need to be enacted quickly. FDA must give highest priority to regulating products already on the market where there are direct exposures that we already know to be hazardous. Some of the hazards documented in cellular and animal studies include platelet aggregation and vascular thrombosis associated with a number of carbon nanoparticles, fullerenes and nanotubes, and pulmonary inflammation and lung granulomas and lesions inhibiting oxygen absorption. FDA should first aim to manage these and other known hazards, then issue comprehensive regulations for new chemicals that reflect recognized toxicity indicators and that drive appropriate toxicity testing. FDA should develop a basic screening framework to guide such testing, such as the tiered approach proposed by Dr. Günter Oberdorster and others that would start with non-cellular tests to establish particle reactivity, followed by in vitro and in vivo tests for exposure pathways that are relevant to a chemical's anticipated use patterns and life cycle.[27] Given the number of products that have already entered the marketplace, we feel that new regulations need to be retroactive to cover existing products.

Lack of evidence of harm should not be a proxy for reasonable certainty of safety.

Require comprehensive pre-market safety assessments

Given that nanomaterials can in fact pose structure-dependant health hazards unique and unpredictable from their larger counterparts, effective regulation to manage these risks depends on accurate and comprehensive pre-market safety assessment.

We disagree with FDA that the existing battery of tests for these products is "probably adequate."[28] Protocols for establishing the "reasonable certainty of no harm" standard are needed for a great many materials, exposure pathways and mechanisms of action. FDA should work closely with NIH and NTP, and international/intergovernmental organizations to rapidly develop screening tools and a tiered approach that can be used as a preliminary basis for establishing which products to regulate first and what types of toxicity testing to require. Priority should be given to materials already on the market, such as carbon fullerenes in cosmetics, focusing on the exposure pathways most relevant to existing uses.

For most nanoengineered materials used in foods (including dietary supplements), cosmetics, and food and color additives, the limited safety studies that have been done have focused more on worker rather than consumer exposure. Despite the chasm of scientific knowledge about how these materials behave, some inferences can be drawn from what is known about other nanomaterials on certain biological systems. Particle toxicology has been described as a mature science, with established findings addressing mechanisms of lung injury by inhaled ultra-fine particles, pointing to their role in generating pulmonary inflammation, oxidative stress and distal organ involvement.[29] FDA should make full use of this knowledge to act as quickly as possible to manage risk.

Overcoming the scientific hurdles to ensure that consumers are protected from toxic effects of nanotechnology is a critical role for FDA and we strongly advise that they use their regulatory

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[27] Oberdorster, G., A. Maynard, K. Donaldson, et al., "Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy." Particle and Fibre Toxicology, 2005 Oct 6;2:8.

[28] US Food and Drug Administration, "FDA and Nanotechnology Products, Frequently Asked Questions" (fact sheet). Downloaded from http://www.fda.gov/nanotechnology/faqs.html on September 26, 2006.

[29] Nel, A., T. Xia, L. Madler, N.Li, "Toxic Potential of Materials at the Nano-level," Science Magazine, 3 February, 2006.

authority to require companies that may benefit from the sale of these products to invest in the necessary research to ensure their safety.

The need for such action is urgent. Knowledge must be effectively translated into meaningful regulatory standards that reflect both current scientific understanding and critical areas of uncertainty. Of particular concern is the scarcity of studies characterizing the effects of the growing number of nanomaterials in products that are ingested. By putting such products on the market, manufacturers are essentially conducting a human clinical trial without the informed consent of its subjects or any public or professional oversight.

Require disclosure and transparency

We are very concerned that basic consumer rights are being compromised by the lack of transparency about the use of nanomaterials in the consumer products and the limited disclosure of information concerning their safety. These rights, which were first recognized by President John F. Kennedy and later adopted by the United Nations, include the right to be informed, the right to choose, the right to be heard and the right to safety. [30]

Consumers are not well-informed about the presence of nanomaterials in consumer products. A recent survey commissioned by the Woodrow Wilson International Center for Scholars shows that nearly 70% of consumers surveyed had little or no knowledge about nanoengineered materials in consumer products.[31] Neither consumers, public interest groups, nor even regulatory agencies currently have a reliable means to identify products that contain nanoengineered materials, nor can they assess the safety of those which are identifiable. Manufacturers are not obligated to make public information concerning the health hazards associated with nanoengineered substances. As a result, consumers have no way to make informed choices about nanoengineered products.

Given the uncertainties about the safety of nanoengineered materials, many consumers may choose not to use products made with them, even if they are approved by the FDA. Consistent growth in demand for organic foods, increasing at a rate of 15%- 20% per year,[32] shows that a large segment of the population already wants to limit the use of synthetic materials in the products they buy, and evidence suggests that many will feel the same about nanoengineered substances. The Wilson Center survey found that when consumers were informed about the use of nanoengineered materials, fewer than half felt that benefits would be equal to, or outweigh the risks.

As a minimum, consumers need transparency so they can make informed decisions about the products they buy. We urge FDA to require labeling of nanoengineered ingredients and the products in which they are used, e.g. foods (including dietary supplements), cosmetics, and food and color additives. As a basis for labeling, FDA should undertake the difficult and important step to develop clear definitions of nanoengineered materials and nanotechnology– both for regulatory purposes and for minimizing consumer confusion. For instance, a consistent system of nomenclature could be established to allow consumers to readily identify nanoengineered ingredients in ways that are relevant to health concerns. Products containing nanomaterials that meet these definitions need to be labeled and materials contained to prevent contamination of nano-free products.

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[30] Consumers International "World Consumer Rights Day" (fact sheet), downloaded from http://www.consumersinternational.org on September 29, 2006.
[31] Peter D. Hart Research Associates, Inc., *Op cit.*
[32] Consumer Reports magazine, "When it Pays to Buy Organic," February 2006.

But besides enabling consumers to make informed choices, product labeling is also crucial to facilitate exposure assessment and product tracing in the event of unanticipated effects and to enable assessment of cumulative effects that occur from exposure to materials in multiple products.

Transparency is also urgently needed with respect to results of toxicity tests. Independent testing and disclosure of all findings is crucial to enable an informed public debate on the risks and benefits of nanotechnology that is based on a complete picture of what is and is not known about the safety of these new materials.

Finally, the FDA should strengthen efforts to inform and engage consumers in the debate over the widespread use of this new technology. We urge FDA to develop mechanisms by which to fully inform and engage consumers and other stakeholders in meaningful dialogue about the risks, benefits and unknowns associated with nanomaterials in consumer products. To be meaningful and build trust, the FDA should confront the full range of consumer perspectives and concerns in a way that has a direct and demonstrable impact on FDA decision-making.

CONCLUSION

Consumers Union appreciates the opportunity to share our views on this important consumer safety issue. We urge FDA to act quickly to adopt our recommended priorities and take a leadership role in developing the scientific research and regulatory tools needed to effectively assess, manage, and communicate the risks associated with nanoengineered materials, and to enable consumer choice in the marketplace through product labeling.

Respectfully submitted,

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