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Editorial/Editoriale

Nanomaterials: brief review of policy frameworks in the US and Europe and recommendations from an occupational and environmental perspective

Nanomateriali: breve rassegna degli orientamenti politici negli Stati Uniti e in Europa, e indicazioni di ordine professionale ed ambientale

Jennifer Sass*, Tony Musu**, Kathleen Burns***, Ian Illuminato****
* Natural Resources Defense Council, Washington, DC, USA
** European Trade Union Institute, Brussels, Belgium
*** Sciencecorps, Lexington, Mass, USA
**** Friends of the Earth, Vancouver, Canada

Summary

Nanomaterials are already incorporated into over 800 consumer products, according to self-disclosures by industry in their consumer advertising. Increasing numbers of toxicological studies have reported on the toxicity of different nanomaterials, suggesting a potential public and occupational health risk associated with exposure to at least some classes of nanomaterials. At this time, the US is primarily relying on a voluntary corporate stewardship to provide oversight of nanomaterials. European Union leaders are voicing the need for precaution although no significant protective actions have been taken thus far. This manuscript provides a brief review of relevant chemical policies, and identifies the weaknesses and loopholes in some of the US and European Union chemical policies that are relevant to nanomaterials. The long-term goal of this project is to support effective health-protective policies for managing hazardous chemicals. Eur. J. Oncol., 13 (4), 211-218, 2008

Key words: **nanomaterials, health risks, protective polices**

Riassunto

I nanomateriali sono già inseriti in oltre 800 generi di consumo, secondo le autocertificazioni dell'industria nelle avvertenze per i consumatori. Un numero crescente di studi tossicologici ha valutato la tossicità di vari nanomateriali, indicando un rischio potenziale per la salute della popolazione e dei lavoratori, connesso con l'esposizione ad almeno alcune classi di nanomateriali. Attualmente gli Stati Uniti si affidano principalmente all'orientamento volontario delle ditte a fornire una sorveglianza sui nanomateriali. I leader dell'Unione Europea sostengono la necessità di precauzione, anche se finora non sono state intraprese significative iniziative di protezione. Questo lavoro presenta una breve rassegna di importanti direttive inerenti i prodotti chimici, e identifica le debolezze e le scappatoie di alcune direttive degli USA e dell'Unione Europea che riguardano i nanomateriali. Lo scopo a lungo termine di questo progetto è di sostenere efficaci politiche di protezione della salute nella gestione dei composti chimici pericolosi. Eur. J. Oncol., 13 (4), 211-218, 2008

Parole chiave: **nanomateriali, rischi per la salute, azioni protettive**

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Address/Indirizzo: Dr. Jennifer Sass, Senior scientist, Health and Environment Natural Resources Defense Council, 1200 New York Avenue, NW, Suite 400, Washington, DC 20005, USA - Tel. +1/202/2896868 - Email: jsass@nrdc.org

Introduction

Nanotechnologies are the engineered convergence of chemistry, physics, and engineering at the nanoscale. The products of these efforts are called nanomaterials, consisting of nanoparticles (having one or more dimensions of 1-100 nanometers in size) and the grouping of these particles into structures that may be larger than nanoscale. Nanoscale materials dissolve in different ways, take on different magnetic properties, react differently to chemicals, or reflect light differently than they would at normal size. The very qualities that make nanomaterials commercially desirable can also make them more hazardous than their normal-sized counterparts. Because they are so small – the head of a pin is about 1 million nanometers across – nanomaterials can be extremely mobile. Many inhaled nanoparticles can pass from the lungs into the blood stream and from the blood circulation to organs and tissues including the brain, supporting the need for measures to prevent unintended exposure or environmental releases of these materials[1, 2].

Carbon nanotubes are formed from sheets of carbon atoms that are rolled up into either single-walled or multi-walled tubes. In this form, they can theoretically be designed to be 100-times stronger and six-times lighter than steel, suggesting many useful applications such as for construction materials. They are already found in a number of consumer products including some super-strong tennis rackets, hockey sticks, racing bike frames, car parts, and golf clubs[3]. The rope-like filaments of carbon nanotubes are rigid, thin, and insoluble, though they often exist as tangled bundles. Although they may be harmful in either form, their disaggregated fibre-like form shares many characteristics with asbestos and other deadly fibres. In 2008 several significant studies were reported in the peer reviewed literature on the potential for carbon nanotubes to cause tissue damage similar to that found for asbestos. In one study, mesothelioma-related changes were observed in the abdomen of mice following direct injection of long multiwalled carbon nanotubes (MWCNT) into the abdominal cavity[4]. In another study inhalation of single-walled carbon nanotubes by test rodents resulted in inflammation, oxidative stress, and some fibrosis[5]. These data are a potential catalyst for action among the occupational and environmental health communities who have not in the past been engaged on the nanotechnology health and safety issues.

Other types of nanoparticles made of titanium dioxide or zinc oxide are commonly used in cosmetics, lotions and sunscreens because of their high surface areas and high chemical reactivity[3]. Silver nanoparticles, shown to be effective at killing both harmful and beneficial microbes, are used increasingly as an antimicrobial agent in consumer products such as food storage containers and athletic clothing[3]. While the potential for toxicity of intentionally engineered nanoscale materials is still being explored, studies on the health effects of unintentional nanoscale air pollutants is relevant[6]. These data demonstrate that inhalation of nano-sized chemical pollutants is associated with asthma attacks, heart disease, strokes, and respiratory disease.

Despite good reason for concerns, early warnings of the potential hazards of nanomaterials have largely gone unheeded by our regulatory agencies. Investment in the future applications of nanotechnologies is taking place across most sectors including exploring applications in sports equipment, cosmetics, food packaging, aerospace research, medical imaging and drug delivery systems, electronics, and energy capture and storage systems[7]. Lighter, faster, stronger, and more efficient products are predicted to benefit from these new technologies.

However, unique physical properties are likely to be associated with a unique toxicity profile. In other words, carbon as diamond is not the same as carbon as graphite in your pencil, and neither forms of carbon share an identical toxicity profile with carbon in a nanotube form or in a spherical form known as buckyballs. Further, carbon-based nanomaterials will differ significantly from cadmium, titanium, or aluminum nanomaterials. Thoughtful scientific studies will need to be designed to assess the varied potential hazards of these new materials that are formed from such diverse chemicals[8, 9].

The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)[10], an independent scientific committee of the Directorate General on Health and Consumer Protection (SANCO)[11] of the European Commission, issued a

report in March 2006 that concluded: "In general, and in spite of a rapidly increasing number of scientific publications dealing with nanoscience and nanotechnology, there is insufficient knowledge and data concerning the characteristics of nanoparticles, their detection and measurement, their behaviour in living systems, and all aspects of their harmful potential in humans and in the environment, to allow for satisfactory risk assessments for humans and ecosystems to be performed[11]."

A 2008 report by the Royal Commission on Environmental Pollution identified as barriers to conducting risk assessments the "profound ignorance and uncertainty about the behaviour of some types of nanomaterial in the environment or the risks that they pose for human health", and "the nanoform of an element or material may have significantly different properties to its bulk form"[12]. While safety research is progressing, its pace is much slower than the pace of commercialization of nano-enabled products. Here we provide a brief overview of some relevant statutory authorities in the US, and the relevant sections of the European Union chemical assessment programme recently initiated, to see how they may be expected to perform in identifying the potential hazards of nanomaterials. We conclude that current authorities are either inadequate or are not being exercised appropriately, leaving nanomaterials essentially unregulated. We further identify key intervention points to either close loopholes or develop new approaches to address these materials.

US relevant policies

The US Toxic Substances Control Act (TSCA) is enforced by the US Environmental Protection Agency (EPA) and was enacted by Congress in 1976 to gather information about chemical substances and to control those deemed dangerous to the public or the environment[13]. It is the most obvious candidate for regulating engineered nanomaterials in the US that do not fall under other regulatory jurisdictions. But the Act lacks an effective means of requiring companies to provide risk data, and has therefore been a weak tool to prevent untested or potentially unsafe chemicals from being commercialized. If the government does not respond to evidence of harm within months of a new product application, a company may market its product by default[14]. Although the Act also requires EPA to establish preliminary safe handling guidelines for workers, as yet this has not been done for nanomaterials by government agencies. Some companies and workplaces have launched voluntary initiatives with the goal of providing some protections for workers, although the efficacy of these initiatives has yet to be determined[15].

Section 5 of TSCA provides EPA with two possible approaches to gathering existing information regarding nanomaterials. If EPA considers the material to be "new" then Section 5 gives EPA the authority to require Premanufacture Notice (PMN) from manufacturers or importers. Alternately, EPA may issue a "significant new use rule" (SNUR) if EPA determines that a nanomaterial is not a new material, but does constitute a new use of a material already on the TSCA inventory. In either case, this section requires information to be submitted to EPA on the manufacture, processing, use, distribution in commerce, and disposal of the materials. Unfortunately, EPA has used this authority only for carbon nanotubes, identifying them as "new" materials needing PMN submissions prior to commercialization[16]. While this is an important step by EPA to use its regulatory authorities to gather important information, by limiting it to only carbon nanotubes it leaves a gaping regulatory hole for other nanomaterials to fall through, along with consumer confidence.

Section 4 of TSCA authorizes EPA to require manufacturers and/or processors of chemical substances to develop new data on health and environmental effects if the manufacture, distribution, use, and disposal practices present an unreasonable risk of injury. However, to our knowledge EPA has not chosen to use this authority to require manufacturers to provide safety and other relevant data to assess potential risks, possibly because TSCA Section 4 rules have been extensively challenged in court, reducing them to near-impossible to enforce. Promulgating Section 4 rules routinely take several years or more, and would require EPA to demonstrate either: a) that the manufacture, distribution, use, and disposal practices may present an "unreasonable risk of injury" or b) that the chemical would

lead to exposures in "substantial quantities" and that there are insufficient data to evaluate the effect of manufacture, distribution, etc. The frustrating paradox is that EPA may arguably need more data than what is publicly available to meet the threshold to require a test rule to generate data.

A review of TSCA as it would apply to nanotechnologies is detailed in two reports by the Project on Emerging Nanotechnologies which recommend that EPA classify all nanomaterials as new chemicals under TSCA[14, 17].

At this time, EPA is primarily relying on a voluntary reporting programme launched in early 2008, called the Nanoscale Materials Stewardship Program (NMSP), to provide oversight of nanomaterials. Companies that sign up are agreeing to submit basic data on the physical and chemical properties of their materials, and any toxicity data they have on hand, but are under no obligation to generate new data. Unfortunately, the programme, already weak by its voluntary nature, failed to incorporate recommendations from an EPA advisory committee that in November 2005 advised EPA to include a deadline by which companies should sign up to participate, defined program requirements, and specified timelines by which the success or failure of industry submissions could be measured[18]. Without these elements, the voluntary programme is unlikely to elicit much more than already publicly-available information.

Other laws have also thus far been inadequate in preventing untested or potentially unsafe nanomaterials from being commercialized. The US Federal Food, Drug, and Cosmetic Act (FFDCA), enforced by the US Food and Drug Administration (FDA), does not have the authority to require cosmetics manufacturers to submit safety data, essentially leaving the cosmetics industry unregulated despite the rapid incorporation of nanotechnologies and nanomaterials in cosmetic and personal care products[19]. For all other food and consumer products, FDA does not have the authority to obtain post-market health and safety data for products already approved for sale. The FFDCA is both inadequate and inadequately implemented by FDA in the areas of pharmaceuticals, as evidenced by the many drug and food-related product recalls in recent years, while both sectors are rapidly evolving to rely on nanomaterials[20]. A review of existing statutes and their failure to respond to nanomaterials is detailed a reporter entitled "Nanotechnology oversight: an agenda for the next administration", in which the author recommends the FDA be given authority to "review safety tests on nano-enabled food and cosmetics ingredients and to require post-market monitoring and surveillance of many types of products[17]".

Over eight hundred consumer products are made using nanotechnologies, according to manufacturer's claims, including baby bottle nipples, infant teething rings and teddy bears, as well as widely distributed consumer products such as sports equipment, skin creams, kitchen cutting boards, and clothing. Despite widespread public exposure to these consumer products, the Consumer Product Safety Commission (CPSC) is possibly the weakest of all the federal agencies. The Consumer Product Safety Act (CPSA) actually prohibits the Commission from imposing mandatory safety standards if the industry agrees to write its own standards, and prohibits the Commission from informing the public about a product without pre-approval of the manufacturer[21]. Further, the CPSC lacks the authority to require pre-market testing, and must rely on its authority to implement post-market product recalls and recall alerts after a hazard has been identified by consumer use[22].

Many diverse stakeholders have called for ingredient labelling of products containing nanomaterials to be a priority, including civil society, public interest, environmental and labour organizations[23]. Advocacy groups have demanded that labelling of nanomaterials should not be artificially restricted to 100 nm, given the early evidence that larger particles still in the nanometer range may pose similar health risks[20]. Yet, at this time no governments are requiring ingredient labelling of consumer products.

Scientists have also called for ingredient labelling of nanotechnology products, including one of the oldest and most respected scientific bodies, the UK Royal Society which, in a joint study with the UK Royal Academy of Engineering, states: "we recommend that the ingredient lists of consumer products should identify the fact that manufactured nanoparticulate material has been added"[24]. However, rule makers in the United States have thus far failed to respond to this recommendation. In a report by the

FDA's Nanotechnology Task Force, potential health risks are acknowledged: "Because of some of their special properties, nanoscale materials may pose different safety issues than their larger or smaller (i.e., molecular) counterparts"[25]. Nonetheless the FDA fails to recommend ingredient labelling, "because the current science does not support a finding that classes of products with nanoscale materials necessarily present greater safety concerns than classes of products without nanoscale materials"[25]. This essentially leaves consumers exposed to nanomaterials, but not informed.

In contrast to FDA, the Austrian Ministry of Health, Family and Youth, recently presented its view on nanomaterials and safe food production, stating: "Manufactured nanoparticles contained in food should be identified as such on list of ingredients"[26]. The Austrian government even went so far as to call for a moratorium on the inclusion of nanomaterials in products until methods for identification and risk assessment had been developed[26]. Nonetheless, no action has been taken either in the US or the EU on this or similar recommendations.

EU chemical policy, REACH

The European Registration, Evaluation and Authorisation of Chemicals law (REACH) is predicted to be more protective than current US chemical policies, through its requirement that chemical manufacturers provide some basic health and safety data on their products during a pre-market registration process[27]. REACH is premised on the requirement that the industry (manufacturer or importer) must provide data on the risks posed by its products prior to market access. However, because of the complexity associated with toxicity testing of nanomaterials, the REACH legislation did not specifically address nanomaterials, instead flagging the issue for further consideration.

Some important potential weaknesses in the REACH legislation that may impair the ability of the European Union to effectively regulate nanomaterials are as follows:

- All substances manufactured or imported at under 1 tonne/year do not need to be registered under REACH (1 metric tonne =1,000 kg = 2,204 pounds = 1.1 tons). Current nanomaterials now in widespread production such as carbon nanotubes and titanium dioxide may exceed 1t/yr, and therefore trigger registration requirements. However, many nanomaterials enhance products when used in small quantities, and may not reach the trigger level. A weight threshold is not an optimal approach for protection from highly reactive ultra-small materials. New substances and niche or boutique applications may not meet the simplistic weight thresholds, thereby escaping safety data requirements.
- All substances manufactured or imported at under 10 tonnes/year do not need a chemical safety assessment and a chemical safety report (CSR). If a CSR is required, it is submitted as part of the registration dossier, and includes a human health hazard assessment, a physico-chemical hazard assessment, and an assessment as to whether the material may be persistent, bioaccumulative, and/or toxic. An exposure assessment and a risk characterization are required if the substance meets the criteria to be classified as dangerous, or is found to be either: a) persistent, bioaccumulative, and toxic, or b) very persistent and very bioaccumulative[28].
- Polymers are exempted from regulation under REACH, and also from TSCA in the US. This is particularly worrisome for nanomaterials that could be considered polymers, such as carbon nanotubes, which have the shape and rigidity of asbestos fibres, and damning scientific evidence that they are at least as hazardous as asbestos and other fibres to human health[29].
- Medicinal products for human or veterinary use are exempted under REACH, where they fall under another regulatory jurisdiction. In the US these products fall under the jurisdiction of the FDA, and it is likely that the therapeutic applications for nanomaterials will do the same. There are many nanomaterials and nano-enabled devices already finding applications in medicine, including drug delivery systems and imaging devices.
- Food and food additives are exempted under REACH, where they fall under another regulatory jurisdiction. As with medical products, in the US, most of these products fall under the

jurisdiction of FDA, and it is likely that the food applications for nanomaterials will do the same. Many nanomaterials are already being engineered for this purpose, including food packaging materials, food nano-preservatives, nano-enhanced food flavourings, and nano-sensors as indicators for food spoilage.

Many of the above potential 'loopholes', such as the weight thresholds, are the topic of continuing discussions, and it is hoped that they will be addressed in future amendments to REACH. At this time, nanomaterials are not mentioned explicitly in the text of the REACH regulation; this is up for review, but most likely not until 2012. According to the European Commission's Manual of Decisions: "The decisive criterion whether a nanomaterial is a new or existing substance is the same as for all other substances, i.e. whether or not the substance is on the EU inventory of existing substances (EINECS)"[30]. The EINECS is comparable to the U.S. TSCA Chemical Substance Inventory (TSCA Inventory)[31]. Substances at nanoscale which are already listed in EINECS are to be regarded as existing substances, whereas those that are not in EINECS are to be regarded as new substances. This means that a substance like titanium dioxide which is listed in the EU inventory of existing substances (EINECS) and which is a high production volume chemical (HPV)[32] will need a full registration dossier, including a chemical safety report, as would other HPV phase-in substances covered by REACH. The chemical safety report will have to take into account all the identified uses of titanium dioxide including the uses in the nano-form. Additional examples of HPV phase-in substances with a nano-form use are zinc oxide, iron oxide, silicon oxide and carbon black.

Substance such as fullerenes (carbon buckyballs) which are carbon allotropes not listed in EINECS will be considered as non-phase in substances under REACH and will therefore need to be registered before being manufactured or placed on the market (provided that production volume is over 1 metric tonne per year, equal to 2,200 pounds). The amount of data to be provided by the registrant will depend on the production volume. If annual production is over 10 metric tonnes (22,000 pounds) per year, a chemical safety report will be required including risk management measures for all identified uses.

The REACH authorization process specifically flags materials as 'substances of very high concern' (SVHC) if they are: carcinogens, mutagens, or reproductive toxicants (CMRs), persistent, bioaccumulative, and toxic (PBTs), very persistent and very bioaccumulative (vPvBs), or have irreversible serious effects on humans and the environment such as endocrine disrupting chemicals (EDCs)[33]. Some nanomaterials will fall into these categories, because many are both very persistent and toxic[34]. With more study it is very likely other 'high concern' properties will be identified.

Under REACH, all materials that are identified as SVHC are subject to an authorization assessment, irrespective of production volume[35]. For SVHC materials, authorization is granted under either of two conditions. First, if there is a demonstrated threshold below which the substance is considered to be safe and the applicant can demonstrate that the risks can be adequately controlled. Under these conditions, the material can be authorized even if there is a safer alternative available. Second, the material could be authorized if there are no safer alternatives, and the socio-economic advantages outweigh the risks.

Discussion

One of the most significant business concerns associated with the exploding field of nanotechnology is the likelihood of significant liability exposure for investors and those selling nanomaterials, including, among others, nanomaterial and product manufacturers, and retailers who sell nano-containing products to the public. Some experts have already begun to compare certain nanomaterials to asbestos – probably the most notorious commercial product from a liability standpoint. To the extent that nanomaterials are sold to the public at large without adequate testing to ensure safely, and without any notice or warning of their presence or potential hazard, nanomaterial retailers and manufacturers place themselves in potential peril. The extensive scientific and policy discussions of nanomaterials' potential for harm have put manufacturers on notice. Ongoing activities by industry to encourage and expand the commercialization of nanomaterials, combined with steps to retard regulations and avoid

public notice, will bolster liability arguments and charges that adequate product stewardship was lacking.

Corporate retailers and their supply chain will want to understand their potential liability risks from the incorporation of untested or unsafe nanoscale chemical ingredients in their consumer products. Retailers should request safety information from their supply chain, and make this information publicly accessible. The Investor Environmental Health Network (IEHN) is already proposing shareholder resolutions to encourage companies to adopt some of the precautionary policies that call for publicly accessible safety data of nanomaterials in consumer products[36].

Tort claims, especially strict liability defective product claims, are most likely to emerge in connection with nanomaterial uses in consumer products where the greatest numbers of consumers will experience the largest degree of exposure. Other types of claims are also possible, including those brought by workers harmed during employment in development, production, or disposal of nanomaterials. Public entity suits may be brought to recover the cost of responding to a health crisis or of cleaning up environmental contamination. Foreign nations could also sue for damages associated with adverse impacts within their borders. Given these circumstances, the best way to protect the public and to prevent unnecessary litigation-related financial losses is to avoid commercialization of products that contain nanomaterials unless those materials/products have been deemed safe following a robust evaluation for human health and environmental safety, and to label all products that contain nanomaterials.

Recommendations

We strongly recommend that all products that contain nanoscale ingredients disclose on the ingredient label the chemical name and specify that it is present at a nanoscale. This should not be limited to materials less than an arbitrary size threshold of 100 nanometers, but should be required of all ingredients in the nanoscale where the size causes the material to have unique characteristics such as increased chemical reactivity.

Additionally, we strongly recommend that at a minimum all nanoscale materials be required to be registered, and that a chemical safety assessment and a chemical safety report be prepared. We recommend that this be a minimum standard for the European Union REACH requirements, and be incorporated into current relevant US regulatory statutes, as well as into any future comprehensive chemical policy. This is consistent with the recommendations of the European Trade Union Confederation[37] and with US public interest and worker health advocacy groups[23].

These recommendations are fundamental to prevent the introduction of carcinogens, teratogens, and other highly hazardous materials into our workplaces and communities and, as such, represent sound occupational and public health practice.

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