ISSUE 1 | VOLUME 1 | JUNE 2006

A CONSTRUCTIVE
CONTRIBUTION TO THE
RESPONSIBLE DEVELOPMENT
AND USE OF ENGINEERED
NANOMATERIALS

nanoRISK

OPTIMIZING THE BENEFITS OF NANOTECHNOLOGY
WHILE MINIMIZING AND CONTROLLING THE RISKS

Insider Report

In this lead article of our first issue of we give you a broad overview of what the issues really are when people talk about the risks of nanomaterials

NANOTECHNOLOGY RISKS – THE REAL ISSUES

Nano-this and nano-that. These days it seems you need the prefix “nano” for products or applications if you want to be either very trendy or incredibly scary.

This “nanotrend” has assumed “mega” proportions: Patent offices around the world are swamped with nanotechnology-related applications; investment advisors compile nanotechnology stock indices and predict a coming boom in nanotechnology stocks with estimates floating around of a trillion-dollar industry within 10 years; pundits promise a new world with radically different medical procedures, manufacturing technologies and solutions to environmental problems; nano conferences and trade shows are thriving all over the world; scientific journals are awash in articles dealing with nanoscience discoveries and nanotechnology breakthroughs.

Nanotechnology has been plagued by a lot of hype, but cynicism and criticism have not been far behind. Science fiction writers exploit fears of nanorobots turning into killers; the media can run amok when news about potential health problems with nanoproducts surface (as recently happened with a product recall for a bathroom cleaner in Germany). Some see doomsday scenarios of molecular self-assembly turning the world into “grey goo.”

The emerging polarization of opinions on nanotechnology is reminiscent of controversies about genetically modified plants or nuclear energy. Vague promises of a better life are met by equally vague, generalized fears about a worse future. These debates have some aspects in common: the subject is complex and not easy to explain; there is no consensus on risks and benefits; scientists and corporations seem able to proceed unchecked, and it is unclear who is in control.

Often the problem of emerging, deeply transformative technologies is that they lack a “social constitution”[1] that addresses questions like: Where can I get information I can trust? On what terms is the technology introduced? What risks apply, with what certainty and to whom? Who benefits? Who takes responsibility for problems?

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[1] *A. Arnall, D. Parr “Moving the nano-science and technology debate forwards” in: Technology in Society* 27 (2005) 23–38

WELCOME TO THE FIRST EDITION OF nano*RISK*

Why a newsletter called “nanorisk”? Are we scaremongers? No; and we will not talk about killer nanobots and grey goo either. Much of nanotechnology today is about producing nanoscale particles that, due to their size, have significantly more catalytic active surface area than an equal mass of the same material in macro form.

This newsletter is not about stopping nanotechnology or scaring people. It is about providing a wealth of information, compiled in one comprehensive, easy-to-read newsletter, on scientific research, regulatory updates, and informed opinion about the risks posed by engineered nanomaterials and what is being done about them. You don’t have to be an opponent of nanotechnology to voice concern; and as professsionals dealing with nanotech on a daily basis, we are concerned. No uncontrollable nanotech-related risks have emerged so far, but if one were to arise, the world

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> ***“There is a large demand for nanotech risk research … as well as the need of exchanging results, networking, coordination, standardization, (certified) reference materials and processes. Moreover, research results should be made available to all stakeholders as quickly as possible: public authorities, regulatory bodies, industry, researchers and the public at large.”***
>
> *Renzo Tomellini, Head of the “Nanosciences and Nanotechnologies” Unit, European Commission*

nano*RISK* is published bimonthly by Nanowerk, LLC | Annual Subscription Rate US$49 | For subscription information e-mail subscriptions@nanorisk.org | Address all content-related inquiries to Editor, nanoRisk: editor@nanorisk.org | www.nanorisk.org

LESSONS FROM ASBESTOS?

Asbestos was widely used for its flame-retardant and insulating properties. The introduction of internationally accepted asbestos standards took 100 years despite early warnings about health risks.

The first asbestos products lawsuit in the U.S. was filed in 1966 and many more followed. As a result of these lawsuits, by the mid 1980s the entire asbestos textile industry in the U.S. was in bankruptcy.

Chrysotile, which constitutes up to 95% of all industrial asbestos, is a basic silicate of magnesium, a naturally occurring mineral that is not toxic. The chrysotile structure is a sheet that bends to form tubes, which give the mineral the fibrous habit related to asbestos. The problem is that one large asbestos fiber can become the source of many smaller fibers over the course of time. As they get progressively smaller (as thin as 10 nm) and lighter, they become more mobile and more easily airborne, often resulting in human respiratory exposure. The small fibers do not decompose or degrade. Exposure to these broken-down tubular forms is what causes a health hazard that kills thousands of people every year.

Like chrysotile, carbon nanotubes (CNTs) are the rolled-up version of a sheet-forming mineral that itself is not toxic – in this case, graphite. The comparison between asbestos fibers and CNTs has caused quite a stir. Although we have no definitive evidence that CNTs are dangerously toxic, there are studies that indicate potential health hazards with carbon nanostructures. As with other nanoparticles, there just is not enough data to either support or reject any statement as to the toxicity of CNTs.

Concerned citizens, researchers, manufacturers and regulators need to demonstrate that we learned our lesson from asbestos. We need to acknowledge and sufficiently fund research into the risks of nanomaterials now, not if and when the first serious hazards materialize.

ASBESTOS – A SAD STORY OF INACTION

1898	UK Factory Inspector Lucy Deane warns of harmful and “evil” effects of asbestos dust
1906	French factory report of 50 deaths in female asbestos textile workers and recommendation of controls
1911	“Reasonable grounds” for suspicion, from experiments with rats, that asbestos dust is harmful
1911, 1917	UK Factory Department finds insufficient evidence to justify further actions
1918	US insurers refuse to cover asbestos workers due to assumptions about injurious conditions in the industry
1930	UK Merewether Report finds 66% of long-term workers in Rochdale factory suffering from asbestosis
1931	UK Asbestos Regulations specify dust control in manufacturing only and compensation for asbestosis, but this is poorly implemented
1935-49	Lung cancer cases reported in asbestos manufacturing workers
1955	Doll establishes high lung cancer risk in Rochdale asbestos workers
1959-60	Mesothelioma cancer in workers and public identified in South Africa
1962/64	Mesothelioma cancer in asbestos workers, in neighborhood “bystanders” and in relatives, in the UK and the US, among others
1969	UK Asbestos Regulations improve controls, but ignore users and cancers
1982-89	UK media, trade union and other pressures provoke tightening of asbestos controls on users and producers, and stimulate use of substitutes
1998-99	EU and France ban all forms of asbestos
2000-01	WTO upholds EU/French bans against Canadian appeal

Source: D. Gee and M. Greenberg, “Asbestos: from ‘magic’ to malevolent mineral”. EEA Environmental Issue Report no. 22, 2001, p. 61 (for links go to www.nanorisk.org)

NEW MATERIALS:
WHAT IS SO SPECIAL ABOUT CARBON NANOSTRUCTURES?

Carbon is a nonmetallic, solid element that occurs in all organic life, is the basis of organic chemistry. It has the interesting chemical property of being able to bond with itself and a wide variety of other elements, forming nearly 10 million known compounds. Natural carbon can exist in two very different types: graphite and diamond. Two additional forms of carbon that were discovered between 1985 and 1991 cause the current excitement about carbon nanomaterials.

Fullerenes, which sometimes are mistakenly called a "new form of carbon", have been found to exist in interstellar dust as well as in geological formations on Earth. The discovery that carbon could form stable, ordered structures other than graphite and diamond stimulated researchers worldwide to search for other new forms of carbon. This lead to the discovery of **carbon nanotubes** (CNTs). They are quite different from fullerene-type materials and they have rather different properties.

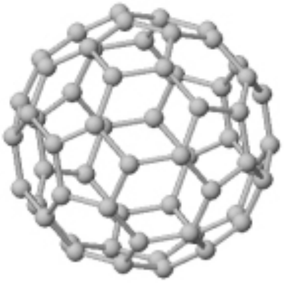
Fullerenes are spherical carbon-cage molecules with about 0.7-1.5 nm in diameter. They are fascinating because they show unusual properties for carbon materials. Fullerenes are studied for potential medical use: they are strong antioxidants; one could also bind specific antibiotics to the structure to target resistant bacteria and even target certain cancer cells such as melanoma. Heat resistance and superconductivity are some of the more heavily studied properties of fullerenes in mechanical engineering.

CNTs are rolled-up sheets of graphite forming cylindrical fullerenes. They are produced ranging from single to tens of nm in diameter and several microns in length. They have outstanding mechanical and electronic properties and are good thermal conductors. The tensile strength, or breaking strain of CNTs is 6-7 that of steel. They are among the stiffest and strongest fibers known. CNTs can be metallic or semiconducting depending on their structure. Some CNTs are the most efficient electrical conductors ever made, while others behave more like silicon. These properties, coupled with the lightness of carbon nanotubes, gives them great potential for use in reinforced composites, nanoelectronics, sensors and nanomechanical devices.

CNTs can have one or more walls. Single-walled CNTs (SWNTs) exhibit different electrical properties than multiwalled CNTs (MWNTs) and are prime candidates for applications in nanoelectronics. In general commercial applications have been rather slow to develop, primarily because of the high production costs of the best quality nanotubes, especially SWNTs.

TOXICOLOGY OF CARBON NANOMATERIALS

There is universal consensus among scientists and researchers that more work is needed on all of the new carbon nanomaterials that have been developed over the past years to adequately assess their toxicity and health risks.

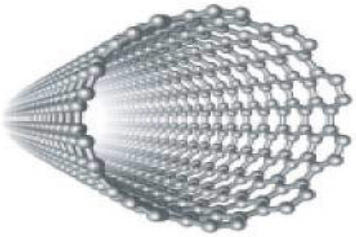


Buckminsterfullerene – or "buckyball" – the third form of carbon, after graphite and diamond, discovered in 1985 by Richard Smalley, Harold Kroto, and Robert Curl, for which they won the 1996 Nobel Prize in chemistry. Named to honor the architect of the geodesic dome, Buckminster Fuller, because the dome's shell resembles the fullerenes' hollow-core construction.

Carbon nanomaterials are arguably the most celebrated products of nanotechnology to date, encompassing fullerenes, nanofibers, nanotubes, and a variety of related forms.

A recent special issue of the journal *Carbon*[1] addresses the current status, trends and perspectives of the toxicology of carbon nanomaterials. The editors'[2] goal was to compile the most recent work by leading experts in the emerging field of nanotoxicology with a special focus on carbon. These nanomaterials can enter the human body through inhalation, skin contact, ingestion, or intentional injection, and may affect microorganisms, plants, or animals if released into the environment in significant quantities.

This combination of new materials, multiple exposure routes, and environmental fate and transport issues creates a complex set of research questions that scientists have just begun to tackle, and early studies of nanomaterial toxicity have produced apparently conflicting results and raised more questions than they answered. "Both biological systems and real nanomaterial formulations are complex, so fundamental progress in this new field will require teaming of toxicologists and materials scientists," co-editor Robert Hurt told us.



Carbon nanotubes (CNTs), discovered in 1991 by S. Iijima, are cylinders as small as 1 nm in diameter. Single-walled CNTs resemble a rolled-up sheet of graphite.

There is universal consensus among scientists that significantly more work is needed to adequately assess the toxicity and health risks of all the new carbon nanomaterials, and it is promising that research into the toxicity of nanomaterials has begun in earnest.

"These issues are being discussed openly. This is one of the few areas in toxicology that I've been involved in, where there has been discussion at the very beginning," says co-editor Agnes Kane.

In their lead article[3] the editors highlight some of the critical issues and research needs that are relevant in the developing field of nanotoxicology, especially as it relates to carbon nanomaterials:

- Need for detailed materials characterization: Toxicity of carbon materials may depend on byproducts or residues of complex carbon structures as much or more than on the primary structures.
- Need for realistic exposure scenarios: Risk is the product of hazard and exposure, and little is currently known about realistic exposure levels, especially for lung exposure.
- Need for methods to track nanomaterials in biological experiments: Sensitive methods of detection are required to quantitate the extent of systemic transport and persistence at distant organs following dermal exposure, inhalation, ingestion, injection or implantation.
- Issue of absorptive interferences with fluorescent assays: The question needs to be addressed whether nanomaterials such as carbon black may interfere with fluorescent probes through absorption or other means.
- Dose metrics: Sensitive detection methods are required to determine the dose metrics required in toxicology studies. However, it is possible that lipophilic nanomaterials (e.g., fullerenes) may interact with plasma membrane lipids and exert toxicity directly in the absence of cellular uptake.
- What are the most important indicators of toxicity? Carbon nanomaterials may elicit additional types of pathologic reactions and not be limited to the usually used short-term indicators of toxicity, altered cellular function or inflammation.

The authors specifically propose that future research reports in this area include the following minimal materials characterization:

"Complete bulk chemical composition (specifically including metals and heteroatom content >0.1%), specific surface area, and detailed descriptions of morphology (aspect ratios, secondary carbon forms, metals location) by electron microscopy examination of multiple fields.

"Further desirable characterization would include surface chemical composition, texture (spatial arrangement of graphene layers) and the degree of crystallinity, or perfection of the graphene layers."

"A realistic long-term goal for toxicologists as well as materials scientists is the development of 'green' nanomaterial formulations – those co-optimized and surface engineered for both function and minimal health impact," concludes Hurt.

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[1] *Carbon, Volume 44, Issue 6, Pages 1027-1120 (May 2006), Toxicology of Carbon Nanomaterials, Edited by Robert H. Hurt, Marc Monthioux and Agnes Kane.*

[2] *Professor Robert Hurt from the Laboratory for Innovation in Nanostructured Carbon and co-author Professor Agnes Kane from the Department of Pathology and Laboratory Medicine, both at Brown University in the U.S., together with Marc Monthioux from the Center for Material Elaboration & Structural Studies (CEMES) in France.*

[3] *"Toxicology of carbon nanomaterials: Status, trends, and perspectives on the special issue", Carbon, Vol 44, Issue 6*

(for links go to http://www.nanorisk.org)

NANOTECHNOLOGY RISKS – THE REAL ISSUES

Continued from page 1

A particular problem with nanotechnology lies in the huge gap between the public perception of what the hype promises and the scientific and commercial reality of what the technology actually delivers today and in the near future.

What's so special about nanotech and why is it an issue now?

Chemists have dealt with naturally occurring nanoparticles all along. Think molecules or viruses. Toxicologists have dealt with nanoparticles that are the result of modern human life such as carbon particles in combustion engine exhaust. Without being aware of it, tire manufacturers used nanoparticles, carbon black, to improve the performance of tires as early as the 1920s. Medieval artists used gold nanoparticles to achieve the bright red color in church windows (gold particles in nanometer size are red, not golden). You might even say that we are surrounded by, and made of, nanostructures – atoms and molecules are nanoscale objects after all. So what is all the fuss about, and where do the risk issues come from all of a sudden?

The ongoing quest for miniaturization has resulted in tools such as the atomic force microscope (AFM) and the scanning tunneling microscope (STM). Combined with refined processes such as electron beam lithography, these instruments allow us to deliberately manipulate and manufacture nanostructures. Engineered nanomaterials, either by way of a top-down approach (a bulk material is reduced in size to nanoscale pattern) or a bottom-up approach (larger structures are built or grown atom by atom or molecule by molecule), go beyond just a further step in miniaturization. They have broken a size barrier below which quantization of energy for the electrons in solids becomes relevant. The so-called "quantum size effect" describes the physics of electron properties in solids with great reductions in particle size. This effect does not come into play by going from macro to micro dimensions. However, it becomes dominant when the nanometer size range is reached. Materials reduced to the nanoscale can suddenly show very different properties compared to what they show on a macroscale. For instance, opaque substances become transparent (copper); inert materials become catalysts (platinum); stable materials turn combustible (aluminum); solids turn into liquids at room temperature (gold); insulators become conductors (silicon).

The adverse effects of engineered nanoparticles cannot be predicted or derived from the known toxicity of the bulk material.

A second important aspect of the nanoscale is that the smaller a nanoparticle gets, the larger its relative surface area becomes. Its electronic structure changes dramatically, too. Both effects lead to greatly improved catalytic activity but can also lead to aggressive chemical reactivity.

The fascination with nanotechnology stems from these unique quantum and surface phenomena that matter exhibits at the nanoscale, making possible novel applications and interesting materials.

Nanostructures need to be differentiated

In order to discuss the risks of nanotechnology we need to take a closer look at these nanostructures. The mere presence of nanomaterials is not in itself a threat. It is only certain aspects that can make them risky, in particular their mobility and their increased reactivity. Only if certain properties of certain nanoparticles were proven harmful to living beings or the environment would we be faced with a genuine hazard.

In addressing the health and environmental impact of nanotechnology we need to differentiate two types of nanostructures: (1) Nanocomposites, nanostructured surfaces and nanocomponents (electronic, optical, sensors etc.), where nanoscale particles are incorporated into a substance, material or device ("fixed" nanoparticles); and (2) "free" nanoparticles, where at some stage in production or use individual nanoparticles of a substance are present. These free nanoparticles could be nanoscale species of elements, or simple compounds, but also complex compounds where for instance a nanoparticle of a particular element is coated with another substance ("coated" nanoparticle or "core-shell" nanoparticle).

There seems to be consensus that, although one should be aware

DEFINITIONS: WHAT ARE WE TALKING ABOUT WHEN WE SAY NANOTECHNOLOGY?

The prefix ***nano*** means a factor of one billionth (10^{-9}) and can be applied, e.g., to time (nanosecond), volume (nanoliter), weight (nanogram) or length (nanometer or nm). In its popular use "nano" refers to length, and the ***nanoscale*** usually refers to a length from the atomic level of around 0.1 nm up to 100 nm. ***Nanostructures*** or ***nanomaterials*** are forms of matter at the nanoscale.

In describing nanostructures we need to differentiate between the number of ***dimensions of the nanoscale***. **Nanotextured surfaces** are one dimension on the nanoscale, i.e., only the thickness of the surface of an object is between 0.1 and 100 nm. **Nanotubes** are two dimensions on the nanoscale, i.e., the diameter of the tube is between 0.1 and 100nm; its length could be much greater. Finally, spherical ***nanoparticles*** are three dimensions on the nanoscale, i.e., the particle is between 0.1 and 100 nm in each spatial dimension. The terms ***nanoparticles*** and ***ultrafine particles*** (UFP) often are used synonymously although UFP can reach into the micron range.

It is hard to image things so small. Eight to 10 atoms span one nanometer. The human hair is approximately 70,000 to 80,000 nm thick. To put this in perspective: Precisely positioning a 1 nm structure inside one meter is analogous to being able to exactly position a peppercorn in the distance between New York and Miami (or if you prefer, between Copenhagen and Madrid, or Tokyo and Beijing).

There is ***nanoscience***, which is the study of phenomena and manipulation of material at the nanoscale, in essence an extension of existing sciences into the nanoscale. Then there is ***nanotechnology***, which is the design, characterization, production and application of structures, devices and systems by controlling shape and size at the nanoscale.

Nanotechnology should really be called ***nanotechnologies***: There is no single field of nanotechnology. The term broadly refers to such fields as biology, physics or chemistry, any scientific field really, or a combination thereof, that deals with the deliberate and controlled manufacturing of nanostructures.

of materials containing fixed nanoparticles, the immediate concern is with free nanoparticles.

Because nanoparticles are very different from their everyday counterparts, their adverse effects cannot be derived from the known toxicity of the macro-sized material. This poses significant issues for addressing the health and environmental impact of free nanoparticles.

To complicate things further, in talking about nanoparticles it is important that a powder or liquid containing nanoparticles is almost never monodisperse, but will contain a range of particle sizes. This complicates the experimental analysis as larger nanoparticles might have different properties than smaller ones. Also, nanoparticles show a tendency to aggregate and such aggregates often behave differently from individual nanoparticles.

Health Issues

There are four entry routes for nanoparticles into the body: they can be inhaled, swallowed, absorbed through skin or be deliberately injected during medical procedures. Once within the body they are highly mobile and in some instances can even cross the blood-brain barrier. How these nanoparticles behave inside the organism is one of the big issues that need to be resolved. Basically, the behavior of nanoparticles is a function of their size, shape and surface reactivity with the surrounding tissue. They could cause "overload" on phagocytes, cells that ingest and destroy foreign matter, thereby triggering stress reactions that lead to inflammation and weaken the body's defense against other pathogens. Apart from what happens if non- or slowly degradable nanoparticles accumulate in organs, another concern is their potential interaction with biological processes inside the body: because of their large surface, nanoparticles on exposure to tissue and fluids will immediately absorb onto their surface some of the macromolecules they encounter. Can this, for instance, affect the regulatory mechanisms of enzymes and other proteins?

Environmental Issues

Not enough data exists to know for sure if nanoparticles could have undesirable effects on the environment. Two areas are relevant here: (1) In free form nanoparticles can be released in the air or water during production (or production accidents) or as waste byproduct of production, and ultimately accumulate in the soil, water or plant life. (2) In fixed form, where they are part of a manufactured substance or product, they will ultimately have to be recycled or disposed of as waste. We don't know yet if certain nanoparticles will constitute a completely new class of non-biodegradable pollutant. In case they do, we also don't know yet how such pollutants could be removed from air or water because most traditional filters are not suitable for such tasks (their pores are too big to catch nanoparticles).

Health and environmental issues combine in the workplace of companies engaged in producing or using nanomaterials and in the laboratories engaged in nanoscience and nanotechnology research. It is safe to say that current workplace exposure standards for dusts cannot be applied directly to nanoparticle dusts.

To properly assess the health hazards of engineered nanoparticles the whole life cycle of these particles needs to be evaluated, including their fabrication, storage and distribution, application and potential abuse, and disposal. The impact on humans or the environment may vary at different stages of the life cycle.

Nanotechnology and Regulators

Regulatory bodies such as the Environmental Protection Agency and the Food and Drug Administration in the U.S. or the Health & Consumer Protection Directorate of the European Commission have started dealing with the potential risks posed by nanoparticles. So far, neither engineered nanoparticles nor the products and materials that contain them are subject to any special regulation regarding production, handling or labeling. The Material Safety Data Sheets that must be issued for certain materials often do not differentiate between bulk and nanoscale size of the material in question.

Studies of the health impact of airborne particles are the closest thing we have to a tool for assessing potential health risks from free nanoparticles. These studies have generally shown that the smaller the particles get, the more toxic they become. This is due in part to the fact that, given the same mass per volume, the dose in terms of particle numbers increases as particle size decreases.

There are tremendous differences in particle number concentrations and particle surface areas for particles of different sizes (assuming an airborne concentration of 10 μg/m^3 of unit density for particles of each size):

Particle Diameter (nm)	Number of Particles (per cm^3)	Particle Surface Area (μm^2/cm^3)
5	153,000,000	12,000
20	2,400,000	3,016
250	1,200	240
5,000	0.15	12

The extraordinarily high numbers of nanoparticles per given mass will likely be of toxicological significance when these particles interact with cells and subcellular components. Likewise, their increased surface area per unit mass can be toxicologically important.

Source: G. Oberdörster et al.: Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles; Environmental Health Perspectives Volume 113, Number 7, July 2005 (Reproduced with permission from Environm. Health Persp.)

Looking at all available data, it must be concluded that current risk assessment methodologies are not suited to the hazards associated with nanoparticles; in particular, existing toxicological and eco-toxicological methods are not up to the task; exposure evaluation (dose) needs to be expressed as quantity of nanoparticles and/or surface area rather than simply mass; equipment for routine detecting and measuring nanoparticles in air, water or soil is inadequate; and very little is known about the physiological responses to nanoparticles.

Regulatory bodies in the U.S. as well as in the EU have concluded that nanoparticles form the potential for an entirely new risk and that it is necessary to carry out an extensive analysis of the risk. The outcome of these studies can then form the basis for government und international regulations.

In our era of global trade it is imperative that national and international regulatory bodies cooperate closely not only with each other, but also with academia and industry, in developing harmonized terminology and standards, a framework for health and environmental risk assessment and, based on that, the necessary regulations and guidelines so that nanomaterials and nanotechnology can be developed responsibly. With that in place we can look forward to optimizing the benefits of nanotechnology while minimizing and controlling the risks.

Voluntary U.K. Reporting Scheme Is A Good Step In The Right Direction – The U.S. Is Still Considering

The U.K. government proposes to introduce a voluntary reporting scheme for free engineered nanoparticles, as part of an approach to build evidence on which to develop appropriate controls for any risks posed

The UK's Department for Environment Food and Rural Affairs, in consultation with other government departments, is taking the lead in building a framework for the UK's regulation of nanomaterials.

The purpose of the voluntary reporting scheme would be to encourage industry to submit existing data on the characteristics of engineered nanomaterials. This scheme would develop the evidence base available to Government on nanomaterials currently in production or use within the UK as quickly as possible, to allow development of appropriate controls where necessary.

The overall objective is to develop appropriate controls in respect of any risks to the environment and to human health from engineered nanoscale materials.

The consultation consists of 22 questions that were sent to 120 consultees: UK companies involved in nanotechnology, universities, associations and organizations such as Greenpeace, Friends of the Earth or World Wildlife Fund UK.

Comments are required by June 23, 2006. Views will then be considered in advance of detailed final proposals and implementation of the voluntary scheme. The aim is to start the voluntary scheme in the summer of 2006.

Meanwhile, the EPA (Environmental Protection Agency) in the United States is considering stakeholder input on potential elements of a pilot program for nanoscale materials under TSCA (Toxic Substances Control Act). The EPA held a public meeting on June 23, 2005 and created an "Interim Ad Hoc Work Group on Nanoscale Materials" as part of the National Pollution Prevention and Toxics Advisory Committee (NPPTAC). This workgroup has met several times and, among other things, proposes a "nanoscale materials voluntary program" (NVP). This NVP, similar to the UK program, is designed as a time-limited project with the goal to assist the EPA in assessing and addressing potential risks of engineered nanomaterials. In November 2005, NPPTAC forwarded its Overview Document for EPA's consideration. EPA has not made any decisions regarding the need for or nature of a mandatory program beyond existing requirements. The EPA is presently reviewing the stakeholder and NPPTAC comments as it considers a possible pilot

Fact

Federal nanotechnology funding in the U.S. through the National Nanotechnology Initiative (NNI) was $1.08bn in 2005. Of that amount only approximately $39 million – 3.6% of federal nanotech research dollars – was earmarked for environmental, health and safety R&D.[1]

Germany's Dialogue About Risk Of Synthetic Nanoparticles

Kicking off with a workshop in October last year, three federal organizations in Germany – The Federal Environment Ministry (BMU), the Federal Environmental Agency (UBA) and the Federal Institute for Occupational Safety and Health (BAuA) – launched a project to initiate a dialogue with other stakeholders to debate the impact of synthetic nanoparticles on health and the environment.

The main objectives in this project to identify and evaluate the environmental and health hazards posed by nanoparticles are:

- To pool knowledge of the opportunities offered by the new technology and of the risks it may harbor for health and the environment;
- To specify the need for research, action and coordination;
- To initiate a dialogue between different stakeholders (from industry, research, authorities, trade unions, media, consumer and environmental protection groups, etc.).

The conference proceedings and 13 presentations from the workshop "Dialogue on Nanoparticles" can be downloaded for free from the organizers' website (www.dialog-nanopartikel.de).

Fact

European nanotechnology funding through the EU's 6th Framework Program is €1.43bn for the 2002-06 period. Of that amount only approx. €8 million, or less than 1%, went to three projects – IMPART, NANOTOX and NANOSAFE2 – dealing with risk assessment and health and environmental impacts of nanomaterials [2]

Events In June/July
Looking At The Risky Side Of Nano

Nanotechnology in Food and Agriculture

June 6-7, 2006 Washington, DC (USA)

Potential applications of nanotechnology in food and agriculture. One section will look at the calls being made for regulation.

Nanotechnology in Environmental Protection and Pollution

June 18-21, 2006 Hong Kong (PR China)

Program topics include nanotechnology toxicity and environmental pollution

NanoBio 2006

June 19-21, 2006 San Francisco, CA (USA)

The conference will also deal with the topics of nanotoxicology and regulatory aspects.

IRGC: The Risk Governance of Nanotechnology

July 6, 2006 Rüschlikon (Switzerland)

An Int.'l Risk Governance Council conference preparing the IRGC's recommendations.

2006 Micro Nano Breakthrough Conference

July 24-26, 2006 Vancouver, WA (USA)

Includes a Roundtable Forum: Environmental, safety and health risk issues of nanotechnology

[1] *The NNI Supplement to the President's 2006 Budget, page ii*

[2] *Cordis, FP6 Budget; Note that individual EU countries are funding national programs as well, outside the EU Framework Program, e.g., Germany will spend €7.6 million from 2006-08 on the new NANOCARE project and €1 million on INOS during the same period*

WELCOME

Continued from page 1

would be quite unprepared. We want to support the debate on a very real issue: the fact that engineered nanomaterials such as carbon nanotubes or titanium dioxide particles are finding their way from scientists' laboratories into commercial products and we don't understand the risks they pose to health and environment.

Notwithstanding the occasional news article about a nanotechnology-related threat, the public does not (yet?) view nanotechnology as something to be concerned about. However, media interest is picking up and public perceptions of the benefits and risks of nanotechnology will start taking shape sooner rather than later.

We will contribute to this discussion by objectively and rationally informing readers about the risks of nanoparticles: what research is being done; what results are reported; what regulatory bodies decide; what experts have to say.

The problem is that nobody really knows the effects that engineered nanomaterials could have on living beings and the environment. There is just not enough data. There are conflicting reports about whether certain nanoparticles are toxic. There is no even a standard or consensus as to how toxicity of nanoparticles should be measured. There are no workplace safety regulations with regard to nanomaterials; no regulation about their classification; no product labeling requirements. In short, we are faced with an emerging technology but know very little about it.

Scientists have already started addressing the risk issues, but a lot more funding needs to go into risk research; politicians and bureaucrats have started discussing nanotechnology as a regulatory issue but, because it spans so many areas, it will affect the work of many regulatory bodies; insurance companies are addressing the risks posed by nanomaterials; and scientific magazines make space for articles taking up risk issues.

We will also look at the risks to the environment posed by nanotech manufacturing. For instance, top-down processes are usually very energy intensive, produce lots of waste and are resource-intensive.

Of course we need the feedback and input of readers like you to make nano***Risk*** as good as it can be. Please let us know (editor@nanorisk.org) what you like about it, what you don't like, what features are missing and what we can do to make this newsletter worth your time.

BOOKS
NEW RELEASES

Nanotechnology: Assessment and Perspectives
by: Harald Brune et al.
EAN: 9783540328193
ISBN: 354032819X
495 pages; published April 2006

Considering that large societal sectors will be impacted, the unique aspect of this two-year study was to assess nanotechnology from various interrelated perspectives: scientific progress, industrial relevance, economic potential, educational needs, potential adverse health effects, and philosophical aspects. The goal of this study was to derive integrated recommendations that consider the large range of societal implications reflecting the different views in an integrated manner. The study attempts to link previously isolated statements, bundling the various concepts and giving unified recommendations to decision makers in sectors such as politics, economy and research. The study was conducted by the nonprofit organization Europäische Akademie (European Academy) in Germany.

CRITICAL GAPS:
FURTHER KNOWLEDGE REQUIRED FOR RISK ASSESSMENT OF NANOPARTICLES

The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), a committee of the European Union, concluded as recently as September 2005 that "there is a paucity of information in a number of areas that are fundamental to the development of detailed guidelines on the risk assessment of nanoparticles." These areas include:

- Protocols need to be established that enable the release of nanoparticles from a very wide range of production processes, formulation and use of products to be assessed.
- Whether it is possible to extrapolate from the toxicology of non-nanosized fibers, particles and other physical forms of the same substance to nanosized materials, and between nanoparticles of different size ranges.
- The actual measured range of exposure levels (to man and the environment) experienced during use of nanoparticle-based products. This will require the development of new measurement techniques for routine use.
- Information on the health of workers involved in the manufacture and processing of nanoparticles, since this group may receive the greatest exposure to engineered nanoparticles.
- Information and measurement of environmental fate, distribution and persistence (including bioaccumulation) of nanoparticles.
- Effects of nanoparticles on various environmental species of each of the environmental compartments and representative of different trophic (nutrition-related) levels and different exposure (uptake) routes.
- There is a lack of background data on the current and historic exposure of humans and environmental species to nanoparticles. Such information is important to the assessment of a possible additional risk from exposure to nanoparticles arising from the development of nanotechnologies.
- Information on the possibility that simultaneous exposure to different particles could result in additive/cumulative effects.

Source: SCENIHR, Opinion on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies. Adopted by the SCENIHR during the 7th plenary meeting of September 28-29, 2005

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OPTIMIZING THE BENEFITS OF NANOTECHNOLOGY WHILE MINIMIZING AND CONTROLLING THE RISKS

The nanoRISK newsletter is dedicated to providing objective and accurate information about critical issues and developments related to the risks arising from engineered nanomaterials. nanoRISK appears bi-monthly in print. ISSN 1931-6941. A compilation of weblinks relevant to this edition of the newsletter can be found on www.nanorisk.org.

nanoRISK is published by Nanowerk LLC, a publisher and information provider in the area of nanoscience and nanotechnology. Editor: Michael Berger. For further information about Nanowerk visit www.nanowerk.com.