DANGER!!! Nanotechnology

6-4-2008

PDF Contents:

Danger!!! Nanotechnology

Tell Congress to Stop Nanotechnology Bill 5940
www.loka.org/Documents/NanotechRDBillAmendments.pdf.

Dangers come in small particles

http://www.hazards.org/nanotech/safety.htm

Hundreds of nanotechnology applications are already in commercial production despite a huge health and safety question mark. *Hazards* looks at how an industry the safety authorities admit they know precious little about has been allowed to grow, unregulated, into the biggest thing since the microchip.

In the 1951 film classic "The man in the white suit," Alec Guinness played a man who invented a fabric which never wore out and never got dirty. The story ended in humiliating disaster. Self-cleaning, long-lasting fabrics are among of the promises of the nanotech industry.

Danger! Dollar signs!

In the two decades since the birth of the nanotechnology revolution, it has been a strict case of small is beautiful. Dollar signs have blotted out the warning signs, and the technology has developed, as one observer put it, "at warp speed." This is a modern day gold rush - forget precaution, get to production.

When President Clinton launched the National Nanotechnology Initiative, now third in the research funding pecking order in the US behind the war on cancer and the Star Wars programme, he gushed about the potential. Tiny sensors would in the future speed through arteries detecting cancers at an early stage, exotic new lightweight materials would have be 10 times the strength of steel [1].

Media reports marvel at promised nano-based cancer cures and desktop nanomachine factories. The European Commission talked this year of "atom-scale 'nano-robots' that can be injected in the human body to cure diseases, electronic 'nano-chips' that can store and process much more information than today's microchips, 'nano-fibres' for better and always-clean clothes, and 'nano-materials' for high-performance coatings, for instance in aircraft and space ships."

The whole world caught the nanotech bug, quietly ignoring the early but serious question marks over safety. In May 2004, the European Commission put the industry's value today at Euro 2.5 billion worldwide. By 2011, it could hit the US$1 trillion mark.

According to a July 2004 TUC briefing: "Despite the fact that there are very few practical applications for nanotechnology at present, it is already a huge industry with almost £2 billion spent on research and development worldwide last year. Within the UK there is around £100 million of public money being spent on developing the technology over the next five years and a further £200 million likely to be invested by the private sector." [2]
In 2003 there were reports that Mitsubishi Chemical in Japan had begun construction work

on a facility to manufacture hundreds of tonnes of "nano-tubes" each year. The US space agency NASA is scaling up production. A US Senate hearing in 2003 heard that most of

the Fortune 500 companies now have nanotechnology programmes. Household names and major employers in the UK - IBM, ExxonMobil, DuPont, Hewlett Packard - all have had major programmes operational for years.

Production not protection

The journey from nanoscience emergence to commercial exploitation was travelled at dizzying speed - carbon nanotubes were first produced in a lab in 1991. By 2000 they were in commercial use as sports stadium flood lights.

In the US, the epicentre of the nanotech revolution, this upturn in commercial exploitation predated the creation in February 2004 of a nanotechnology health and safety research programme, run by the government's safety research agency NIOSH. It has still to issue a promised "best practices" guide however.

In the UK, attention to safety has been more sluggish still. On 29 July 2004, the Royal Society and the Royal Academy of Engineering announced the findings of a UK study of the safety of nanoparticles and called for new rules to guard against dangers to health and to the environment [3]. In October, HSE's Health and Safety Laboratory will host an international conference on workplace nanotech risks in Buxton. For now though, it's business as usual.

Already hundreds of nanotechnology-based products are on the market, from new computer displays to self-cleaning windows, from wrinkle creams to wrinkle-resistant pants. We might not know for certain whether nanotech will make you sick, but industry knows it can certainly make you rich.

And our own safety watchdog knows it too. In the introduction to a March 2004 paper prepared for the Health and Safety Commission (HSC), the Health and Safety Executive's chief scientist, Paul Davies, notes: "In the absence of complete and robust evidence of the risks HSC/E must work with stakeholders to promote and assure risk management of this technology without unnecessarily stifling innovation and wealth creation." [4]

As the organisation charged with ensuring the health of the workforce, many would argue that concerns for "innovation" might be better left to other agencies, and HSE resources would be more appropriately spent arguing the "health" and not the "wealth" case.

Safety laws must be reviewed

A new report says the laws on safety and nanotechnology are not up the job and must be reviewed.

The 29 July 2004 report from the Royal Society and Royal Academy says there are uncertainties about the potential effects on human health and the environment of manufactured “nanoparticles” and “nanotubes” – ultra small pieces of material – if they are released.

The report recommends that the UK Government should fund a programme of research to understand the effects of such particles on humans and the environment.

Professor Ann Dowling, chair of the working group that produced the report, said: “Nanoparticles can behave quite differently from larger particles of the same material and this can be exploited in a number of exciting ways. But it is vital that we determine both the positive and negative effects they might have.”

Because of their novel chemical properties, the report recommends that nanoparticles and nanotubes should be treated as new chemicals under UK and European legislation, in order to trigger appropriate safety tests and clear labelling.

Furthermore they should be approved – separately from chemicals in a larger form – by an independent scientific safety committee before they are permitted for use in consumer products such as cosmetics. The report also calls for industry to publish details of safety tests showing that the novel properties of nanoparticles have been taken into account.

Professor Dowling said: “There is a gap in the current regulation of nanoparticles. They have different properties from the same chemical in larger form, but currently their production does not trigger additional testing. It is important that the regulations are tightened up so that nanoparticles are assessed, both in terms of testing and labelling, as new chemicals.”

The report says as a precautionary measure releases to the environment be minimised until the effects are better understood. The report recommends that the Health and Safety Executive should review existing regulations and consider setting lower exposure levels for manufactured nanoparticles, in order to provide the proper protection for workers in, for example, university laboratories.

Royal Society news release and full report

Wealth and safety

In May, the European Commission published its blueprint, *Towards a European strategy for nanotechnology*, "to help Europe to become world leader in the rapidly developing field of nanotechnology - the science of the infinitely small" [5]. The policy focuses on research and development, and calls for more investment in nanotechnology "to realise wealth generating products and services."

An EC news release accompanying the new research strategy does say it "also highlights the need to identify and address safety, health and environmental concerns associated with nanotechnologies and to promote risks assessment procedures at all stages of the technology's life cycle" [6]. But this is a real-life, real-time industry that is in place and is growing and unregulated.

HSE's Paul Davies suggests in his briefing it might stay that way for some time. He argues that a "precautionary approach" could hamper the development of nanotech-based safety technology and "would also earn the opprobrium of the government, which is strongly committed to the development of nanotechnology." Instead, a "Provisional Information Note" published in early 2004 says "control strategies should be based on the principle of reducing exposure to as low a level as is reasonably practicable" [7].

Reasonably dangerous

Applying the same control strategy you might apply to, say, grass cuttings or sugar dust to nanotechnology would guarantee widespread ill-health in the nanotech workforce if exposures were found to be anything other than low risk. This is a point not lost on John Howard, head of the US government's safety research body NIOSH.

He told a May 2004 conference: "Very little is known currently about how dangerous nanomaterials are, or how we should protect workers in related industries. Research over the past few years has shown that nanometre-diameter particles are more toxic than larger particles on a mass basis. The combination of particle size unique structures, and unique physical and chemical properties, suggests that a great deal of care needs to be taken to ensure adequate worker protection when manufacturing and using nanomaterials."

Howard added that nano products in development "are so far from our current understanding that we can not easily apply existing paradigms to protecting workers." [8] By late July 2004, HSE had, belatedly, shifted to a more precautionary stance. The finalised information note, *Nanotechnology: Horizons scanning information* [9], says "as the risks arising from exposure to many types of nanoparticles are not yet completely understood, control strategies should be based on a principle of reducing exposure as much as possible."

Nonetheless, this is an information note, not a law, is not legally binding and is not evidential. Nanoparticles are still not subject to the more stringent controls that have seen many industrial substances banned outright and others, for example substances that can cause cancer, subject to special and more exacting regulations.

But while some existing workplace safety regulations may be an ill-fit, some don't fit at all. Getting a new substance onto the market is normally regulated by the Notification of New Substances Regulations 1993 (NONS). But nanotechnology uses structural, smaller, variants of common industrial substances. Its properties might be utterly different to its non-nano namesake, but it still would not require notification.

Nano particles at work

You may already own or work with products using nanotechnology. The website of global technology watchdog ETC includes an unofficial document generated by the US Environmental Protection Agency (EPA) that lists well over 100 commercial products based on nanotechnologies.
These are already or soon will be on the market and include: stain-resistant fabrics for clothing and bedding, cosmetics and sunscreens, tennis balls and racquets, odour-eating socks, time-release perfumed fabrics, paints, capsules carrying haemoglobin (under development), sensors to test water impurities, sprayable vitamins, nanoparticle water

purifiers, ski wax, car parts, long-lasting paper, nanotubes for flat panel display screens, artificial silicon retinas, several drug delivery systems, flash memory devices and diagnostic agents for use in MRI scans. EPA listing [pdf]

What is nanotechnology?

Nanotechnology is engineering at the atomic scale. One nanometre is a billionth of a metre, or about 1/80,000 the width of a human hair. Nanotechnology works on a scale of up to 100 nanometres. A grain of sand is a million nanometres across. A red blood cell is 10,000 nanometres. We are talking small.

Physical properties of chemicals change at this scale, which creates new possibilities for products and applications. It also creates new and unknown hazards.

There are several commercially important nano materials. An HSE briefing highlights:

• Carbon tubes - high strength and conductivity; chemical derivatives can be added to their surface.

• Titanium dioxide - already used in sunscreens and self-cleaning glass, and as a photo catalyst.

• Silicon/Germanium - already widely used in semiconductor manufacturing.

• Calcium oxide based materials - used in bone replacement/reconstruction

• Metal cored coated particles - often gold cores with thiol derivatives. Used to create quantum nano-dots that allow high sensitivity labelling in a range of chemical or environmental environments.

• Proteins or DNA - mostly used as a mould or scaffold to deposit or assist the assembly of inorganic material.

Real cause for concern

Nanotech safety was an obsession of sci fi geeks long before the safety boffins twigged there might be problem.

Although fears that runaway self-replicating "nanobots" would one day reduce the world to a "grey goo" have subsided, a runaway industry is exposing workers - maybe 2 million will be directly employed in the industry within 15 years - to an array of substances not adequately covered by existing exposure standards or governed by existing regulations on new substances.

The HSE briefing acknowledges "there can be considerable uncertainty in any assessment of the health and safety risks because of lack of knowledge about the hazards. Similarly there may be also a lack of knowledge about the effectiveness of risks control measures." [4]

The evidence we do have, however, suggest real concerns about human and environmental health effects and should have been sufficient to justify a halt in the nanotech clamour until we had a better idea of the risks and how to control them.

Jim Thomas, an Oxford-based programme officer with the technology watchdog ETC, writing in *The Ecologist* in February 2004, revealed that US and other regulatory agencies are "privately admitting they have made a mistake in letting nanoproducts onto the market without safety studies, and are looking for ways to tweak existing regulations" [10].

A July 2004 ETC report [11] says only in recent months have governments on both sides of the Atlantic "reluctantly conceded that current safety and health regulations may not be adequate" for nano materials. "Ironically, they are talking about the need to be proactive, failing to admit that they are already at least one decade late: nanotech products are already commercially available and laboratory workers and consumers are already being exposed to nanoparticles that could pose serious risks to people and the environment."

According to Thomas: "Only a handful of toxicological studies exist on engineered nanoparticles, but not-so-tiny red flags are popping up everywhere."

Toxic warnings

In his May 2004 "Nanowatch" column in *The Ecologist*, Thomas points out that the first ever scientific conference on nano-toxicity, Nanotox 2004, only took place in January this year [12]. He lists "Ten toxic warnings" including NASA research in 2003 showing nano-tubes produce a more toxic response in rats than quartz dust and claims by top UK toxicopathologist Vyvyan Howard that that nano-particles can cross the blood-brain barrier in humans and gold nano-particles can move across the placenta from mother to fetus. According to Vyvyan Howard and ETC, nanoparticle toxicity is more related to their size than to the material from which they are made; while the reduction in size confers a variety of interesting and potentially profitable properties to substances, it can also confer unforeseen toxic properties. And they have high mobility not just within the body but getting into the body, by ingestion, inhalation or absorption through the skin [13].

Gold is a case in point - usually considered inert, it is highly reactive at the nano-scale. Similarly, titanium dioxide, one of the most commonly used substances in nanotechnology. Generally considered a relatively benign "nuisance dust" in normal industrial uses, it may have far more worrying properties in its nano applications.

The report of a March 2004 European Commission workshop, "Mapping out nano risks", looked at "the implications of these 'technologies of the tiny' for public health, health and safety at work and the environment" [14]. The findings of this workshop were in sharp contrast to the clamour for nano products encouraged and financed elsewhere in the Commission.

The EC report warned that "some engineered nanoparticles produced via nanotechnology may have the potential to pose serious concerns" and that "adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of bulk material." The experts recommended "striving for the elimination whenever possible and otherwise the minimisation of the production and unintentional release of nanosized particles."

The new asbestos?

The ETC report notes that there has been a long tradition of ignoring early warnings until the bodies are piled high, pointing to examples including tobacco, PCBs, radiation, benzene and the biggest industrial killer of all time, asbestos. For asbestos, the parallels may not end there.

A June 2004 report from the European Union sponsored Nanoforum notes "some scientists have already compared nanotubes with asbestos in terms of risks and danger. For example, Dr Wiesner at Rice University pointed out that carbon nanotubes resemble asbestos fibres in shape: because they are long and needle-like." [15]

It was 100 years before asbestos companies and their insurers claimed they were "crippled" by asbestos liabilities so couldn't not pay asbestos victims compensation for deadly diseases. For nanotechnology, the problem may start much earlier in the life of the industry. Reinsurance company Swiss Re has already warned that uncertainty about risks from nanotoxicity and nanopollution meant there was insufficient information to offer insurance on the industry [16].

Its 10 May 2004 report, *Nanotechnology: small matter, many unknowns*, notes: "Specialist circles and society at large have neither solid knowledge derived from the past nor a suitable method for definitely assessing the consequences of any changes that may arise in the future."

It adds: "There are indications that certain nanomaterials are potential health hazards. The danger is most probably not of an acute but of a chronic nature, and it could be some time before it manifests itself. That is where the real risk for insurers lies, and the comparison with asbestos should be seen in this light."

Nano particles can kill you

Two factors could make nanoparticles a particularly serious occupational risk. Firstly their size alone could present hazards; secondly their massive surface area may adsorb other toxins that can then be transported into the body.

And evidence already exists to make this more than theory. Before nanotechnology became an industry, there was workplace and environmental pollution on a nano scale. Pollution from power plants, incinerators, cement kilns and diesel engines all contain "ultrafine" airborne particles that fall in the right size range. These particles are attributed with thousands of pollution-related deaths each year - perhaps 60,000 per year in the US alone. A California study suggests that these ultrafines are 10 to 50 times more damaging to lung tissue than larger particles [17].

The point was echoed in October 2003 by Professor Ken Donaldson of the University of Edinburgh, who warned that "the development of nanotechnology is predicted to improve our lives, but these very small nanoparticles look to have considerable potential to cause harm to the lungs.

"Already, the damaging effects of air pollution in cities looks like it is driven mostly from traffic-derived nanoparticles."

When he looked at the effects of pure carbon and pure titanium dioxide, very common chemicals in both traditional and nanotech industrial production, he found larger particles caused no damage to the lungs of rats, but when crushed to nano scale (less than 100 nanometres) they were potent causes of lung inflammation. A re-run of the experiment with styrene produced similar results [15].

In the US, government safety research body NIOSH says it has found a close correlation between potentially life-threatening beryllium sensitisation in workers and the concentration of nanometre-diameter beryllium particles.

According to the 24 July 2003 issue of *Rachel's Environment and Health News* [17], "current research shows that nanoparticles in the lung cause the formation of free radicals, which in turn, cause lung disease, and cardiovascular disease. Furthermore, nanoparticles carry metals and carcinogenic hydrocarbons deep into the lung, where they exacerbate asthma and other serious breathing problems."

There are concerns that nanoparticles may also cause lung fibrosis and possibly Alzheimer's. *Rachel's* warns of the risks of ramping up the industrial production of nanoparticles similar to those old-style ultrafines already established to be prolific killers. It concludes: "Clearly, in the case of nanoparticles, we have reasonable suspicion of harm, and we have some remaining scientific uncertainty. There we have an ethical duty to take preventive (precautionary) action. If there ever was a proper time to invoke the precautionary principle, this is it."

The sentiment is echoed in the July 2004 TUC nanotechnology factsheet [2], which says: "Nanomaterials should be treated just like any other serious health risk." It adds: "For unions that means seeking to ensure that the production and use of nanoparticles is done within a contained process so that employees are not exposed to any potential unknown risk."

TUC concludes: "It is important that unions act now to ensure that we do not have a rerun of the asbestos tragedy where hundreds of thousands of people were exposed to a killer dust that even today kills over 3,000 people a year."

Insurance company Swiss Re concludes the highest levels of safety protection are justified. Its report notes: "Presumably, nanoparticles must be handled with the same care given certain bio-organisms or radioactive substances. Adequate protective measures, such as a nao-compatible 'glove box', will probably have to be developed to ward off possible dangers." [16]

References:

1. Rachel's Environment and Health News, No. 772. The Revolution, Part 1, 26 June 2003
Rachel's Environment and Health News, No. 773. The Revolution, Part 2, 10 July 2003

2. Nanotechnology. TUC factsheet, July 2004 and news release

3. Royal Society and the Royal Academy of Engineering report, 29 July 2004, and news release

4. Managing the risks from nanotechnology. A paper by Paul Davies, HSE chief scientist, HSC, 22 March 2004. Paper to the 6 April 2004 Health and Safety Commission meeting [pdf]

5. Towards a European strategy for nanotechnology, European Commission Communication, 12 May 2004.

6. Creating new knowledge in nanotechnology and turning it into better quality of life, competitiveness and jobs, European Commission news release, 12 May 2004.

7. Nanotechnology information note, version 0.9 [Annex 4, pdf]. *Annex to reference 4*.

8. Howard: Nanotechnology represents an "exciting challenge" for EHS, Occupational Hazards, USA, 7 May 2004.

9. Nanotechnology. HSE information note. Horizons Scanning Information Note No. HSIN1, July 2004.

10. Jim Thomas. Nanotech, The Ecologist, February 2004.

11. Nanotech: Unpredictable and un-regulated, ETC, news release, 8 July 2004. . Nanotech news in living colour: An update on white papers, red flags, green goo (and red herrings), ETC Communique no.85, 8 July 2004.

12. Jim Thomas. Nanowatch, The Ecologist, May 2004.

13. Nanotech under the microscope: Small is beautiful, but super-small particles may be a health risk. Utne, pages 15-16, July-August 2004.

14. European Commission, Nanotechnologies: A preliminary risk analysis on the basis of a workshop organised in Brussels on 1-2 March 2004 by the Health and Consumer Protection Directorate General of the European Commission, 2004.

15. Benefits, risks, ethical, legal and social aspects of nanotechnology, 4th Nanoforum Report, June 2004.

16. Nanotechnology: small matter, many unknowns, Swiss Re news release, and full report, 10 May 2004

17. Rachel's Environment and Health News, No. 774. The Revolution, Part 3: Ultrafines, 24 July 2003

Web Resources:

ETC group - action group on erosion, technology and concentration. www.etcgroup.org/en/

US National Institute for Occupational Safety and Health nanotechnology and health topic page. www.cdc.gov/niosh/topics/nanotech/

Nanotechnology and nanoscience. Royal Society and Royal College of Engineering website. www.nanotec.org.uk

Cordis nanotechnology website, European Commission. www.cordis.lu/nanotechnology/

Nanoforum.org European Nanotechnology Gateway. www.nanoforum.org

Please Pass This On!!!

Note: deletions from existing text are in [brackets]; *additions to existing text are italicized*

I. ADDITIONS TO THE DRAFT BILL

(1) Change the 21st Century Nanotechnology Research and Development Act of 2003, Section 2 (b) to read as follows:

"(b) Program Activities.--The activities of the Program shall include--

(1) [developing a] *increasing the* fundamental understanding of matter [that enables control and manipulation] at the nanoscale *for the benefit of society*;

([10]*2*) ensuring that ethical, legal, environmental, *health*, *safety*, and other [appropriate] societal concerns, including *the impact of nanotechnology on poverty and income-based health disparities* and the potential use of nanotechnology in enhancing human intelligence and in developing artificial intelligence which exceeds human capacity, are considered *at an accelerated pace as a priority in the further development* [during the development] of nanotechnology by-

Comment – We enter dangerous territory in specifying the outcome of science beyond the increased understanding of nature and society that is its basic aim. The changes proposed in (1) establish a more appropriate expectation for science, and state the rationale for supporting nanoscience.

Comment – Placing ethical and social concerns last in the list of program activities can be construed as a statement about their priority in the program. On the other hand, paragraphs 2 - 9 all concern administration of the program, rather than its goal or significance. They are most appropriately listed after the primary orders of concern are addressed, as per our suggestion to re-designate paragraph 10 as paragraph 2.

(A) establishing a research program to identify ethical, legal, environmental, and other [appropriate] societal concerns related to nanotechnology, *including community-based research originated by concerned citizens and completed by them independently or in collaboration with established academic, government, business, labor and/or nonprofit public interest research institutions;* and ensuring that the results of such research are widely disseminated;

(B) requiring that interdisciplinary nanotechnology research centers established under paragraph ([4] *5*) include activities that address societal, ethical, [and] environmental*, and health and safety concerns, including standardized procedures for protecting the health and safety of those working at or visiting those centers or residing nearby*;

(C) [insofar as possible,] integrating research *and public input* on societal, ethical, and environmental concerns with *natural science and engineering* [nanotechnology] research and development, and ensuring that [advances] *developments* in nanotechnology *(1) do no harm to Americans, (2)* bring about improvements in quality of life for all Americans, *and (3) support the achievement of United Nations Millenium Development Goals*; and

Comment - "Natural science and engineering" are substituted for "nanotechnology" here to include social research and public input within the scope of nanotechnological endeavors. We see nanotechnology as a system of practices that includes but is not limited to science and engineering (see proposed change in definition of nanotechnology, p. 11 of this document).

(D) providing, through the National Nanotechnology Coordination Office established in section 3, for *frequent* public input [and outreach] to be integrated into the Program by the convening of regular and ongoing public discussions *and deliberative public assessments*, through mechanisms such as citizens' panels, consensus conferences, *and other broadly participatory processes that provide opportunities for members of the general public to educate themselves, to take part in deliberative assessments of the impacts of nanotechnologies, and to publicize the results of those assessments* [and educational events, as appropriate];

([2] *3*) providing grants to individual investigators and interdisciplinary teams of investigators, *including community-based groups and other nonprofit organizations representing the public interest;*"

-re-number Section 2, sub-section (b), paragraphs 3 – 9 as paragraphs 4 – 10

(2) Change the 21st Century Nanotechnology Research and Development Act of 2003, Section 4 (b) to read as follows:

“(b) Qualifications.--The Advisory Panel established [or designated] by the President under subsection (a) shall consist primarily of members from academic institutions, [and] *from* industry, *from organizations representing labor, and from environmental and other nonprofit organizations with research, education, and/or public information programs concerned with nanotechnology.”*

II. CHANGES TO THE DRAFT BILL

Title and subtitle

A BILL

To authorize activities for support of nanotechnology research,

[and] development *and assessment* , and for other purposes.

Sec. 2 NATIONAL NANOTECHNOLOGY PROGRAM AMENDMENTS

Section 2 (C) (4)

"(A) how the Program will [move results out of the] *coordinate* laboratory *activities and public deliberative input, as described above in Section (b)(2)(D), with the implementation of nanotechnology policies* [and into applications] for the *long term* benefit of society, *guided by the ethical, social and environmental activities required by the 21st Century Nanotechnology Research and Development Act of 2003 in Section 2, subsection (b), paragraph 10, as amended by this Act,* [including] *implementing these objectives* through cooperation and collaborations with nanotechnology research, development and transition initiatives supported by the States;";

Section 2

"(d) PUBLIC INFORMATION.—(1) the Program budget, for the previous fiscal year, for each agency that participates in the Program, including a breakout of spending for the development and acquisition of research facilities and instrumentation, for each program component area, and for all activities pursuant to subsection (b) [(10)] [*(4)*]; *and including a breakout of spending for Environmental, Health and Safety and Ethical, Legal, and Social Issues projects within any of the program component areas. In order to be counted in these categories, the central research questions and the preponderance of research activities in such projects must be clearly focused on environmental, health and safety or ethical, legal and societal issues."*;

Add the last clause in the foregoing paragraph to the paragraphs re-designated as "2" and "3"

section 2 (2)

"(e) Standards Setting —The agencies participating in the Program may reimburse the travel costs of scientists, [and] engineers, *and citizens who have contributed to the ethical, social and environmental activities required by the 21st Century*

Nanotechnology Research and Development Act of 2003, as amended, in Section 2, subsection (b), paragraph [10] *(4)*, who participate in activities of committees involved in the development of standards for nanotechnology.";

Section 3

"(d) PUBLIC INFORMATION.—(1) The National Nanotechnology Coordination Office shall develop and maintain a database accessible by the public of projects funded under the Environmental, Health and Safety, the Education and Societal Dimensions, and the Nanomanufacturing program component areas, or any successor program component areas[,]. *This database shall clearly identify any Environmental, Health and Safety and any Ethical, Legal, and Social Issues projects within all of the above categories. In order to be counted in these categories, the central research questions and the preponderance of research activities in such projects must be clearly focused on environmental, health and safety or ethical, legal and societal issues. Each entry in the data base shall include* [including] a description of each activity, *an abstract describing the results (when available),* its source of funding by agency, and its funding history."

Section 3

"(2) The National Nanotechnology Coordination Office shall develop, maintain, and publicize information on nanotechnology facilities supported under the Program that are accessible for use by individuals from academic institutions, [and] from industry, *from labor organizations, and from nonprofit public interest organizations. The host nanotechnology facility will provide health and safety training for users as needed.*

> **Comment –** The host nanotechnology facilities should be available to a full range of appropriate guest users, and responsibility for validating their purposes and the health and safety preparedness of these users should rest solely with the host facility. Health and safety training should be provided by the facility when needed and feasible, in order to assure equal access.

Section 4 (a)

"(C) by inserting at the end "The Advisory panel shall form [a] *two* [subpanel] *subpanels on Environment, Health and Safety, and on Education and Societal Dimensions, respectively,* with membership having specific qualifications tailored to enable [it] *each subpanel* to carry out the requirements of subsection (c) (7)."

SEC. 5. TRIENNIAL REVIEW OF THE NATIONAL NANOTECHNOLOGY PROGRAM

"(a) IN GENERAL.—The Director of the National Nanotechnology Coordination Office shall enter into arrangements with the National Research Council of the National Academy of Sciences to conduct a triennial review of the program. The

Director shall ensure that the arrangement with the National Research Council is concluded in order to allow sufficient time for the reporting requirements of subsection (b) to be satisfied. Each triennial review shall include an evaluation of the—

"(1) research priorities and technical content of the Program, including whether the allocation of funding among program component areas, as designated according to section 2 (c) (2), is appropriate;

"(2) effectiveness of the Program's management and coordination across agencies and disciplines, including an assessment of the effectiveness of the National Nanotechnology Coordination Office;

"(3) Program's scientific and technological accomplishments and its success in transferring technology to the private, *public and nonprofit* [sector] *sectors* ;

> **Comment –** Technology transfer to public and nonprofit organizations should not be ignored, even if it is likely to be small in comparison to the private sector.

"(4) *public input activities, as described in Section 2 (b) (2) (D) above, and their success in communicating the results of environmental, health and safety research and development, and the results of public deliberations, to the private sector, to industry workers, and to the general public;*

"([4] *5*) [adequacy] *the effectiveness* of the Program's activities addressing ethical, legal, environmental, *health,* and other [appropriate] *societal* concerns [including human health concerns], *including issues of poverty and health disparities, in guiding the Program's goals and activities."*

> **Comment –** The interactions of technological change and income/social disparities are receiving increased attention and should be tracked for effective policy development and management. See, e.g., James K. Galbraith, *Created Unequal: The Crisis in American Pay*, 1998, and the ten country project on inequality and technology at http://www.resist-research.net/home.aspx

(8) in section 10

"(b) EVALUATION TO BE TRANSMITTED TO CONGRESS.—The National Research Council shall document the results of each triennial review carried out in accordance with subsection (a) in a report that includes any recommendations for ways to improve the Program's management and coordination processes and for changes to the Program's goals, funding priorities, and technical content, *incorporating to the extent possible participatory evaluation methods…"*

"(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Office of Science and Technology Policy to carry out this section—

"(1) [$500,000] *$600,000* for the fiscal year 2009

"(2) [$500,000] *$600,000* for the fiscal year 2010

"(3) [$500,000] *$600,000* for the fiscal year 2011; and

> **Comment –** The increased authorization is required to fund participatory evaluation.

(8) in section 10—

(A) by amending paragraph (2) to read as follows:

"(2) NANOTECHNOLOGY.—The term 'nanotechnology' means the [science and technology] *full array of scientific and technological practices and activities,* that *would* [will] enable *a society* [one] to (1) understand, measure, manipulate, and manufacture at the nanoscale [aimed at creating] materials, devices, and systems with fundamentally new properties or functions[,]*; (2) evaluate the social and environmental consequences of using these materials, devices and systems before any such consequence became irrevocable; (3) use these materials, devices and systems; and (4) contain, destroy, retire, isolate or otherwise safely manage such materials, devices and systems when they no longer serve a useful purpose.*

Comment – In a public policy context, nanotechnology should be understood as the full range of ideas, artifacts, uses, and consequences connected with the purposive manipulation of matter at the nanoscale. A definition that excludes purposes, uses and consequences marginalizes these concerns and relegates them to a structurally inferior status. This status is unambiguously demonstrated by existing funding priorities.

SEC. 3. SOCIETAL DIMENSIONS OF NANOTECHNOLOGY

Section 3 (a)

"(1) ensuring that a research plan for the environmental, health, and safety research activities required under subsection (b) is developed, updated, and implemented and that the plan is responsive the recommendations of the [subpanel] *subpanels* of the Advisory Panel established under section 4(a) of the 21st Century Nanotechnology

Research and Development Act (15 U.S.C. 7503 (a)), as amended by this Act;

"(2) encouraging and monitoring the efforts of the agencies participating in the Program to allocate the level of resources and management attention necessary to ensure that *frequent public input* and the ethical, legal, environmental, *health*, and other [appropriate] societal concerns related to nanotechnology [,including human health concerns] are *prioritized* [addressed] under the Program, including the implementation of the research plan described in subsection (b); and

"(3) encouraging the agencies required to develop the research plan under subsection (b) to identify, assess, and implement suitable mechanisms for the establishment of public-*private-nonprofit* partnerships for support of environmental, health and safety research *that includes labor, environmental , and community-based groups."*

Section 3 (b)

"(1) IN GENERAL- The Coordinator for Societal Dimensions of Nanotechnology shall convene and chair a panel comprised of representatives from the agencies funding research activities under the Environmental, Health, and Safety program component area of the Program, or any successor program component area, and from such other agencies as the Coordinator considers necessary to develop, periodically update, and coordinate the implementation of a research plan for this program component area. In developing and updating the plan, the panel convened by the Coordinator shall solicit and be responsive to recommendations and advice from--

(A) the [subpanel] *subpanels* of the Advisory Panel established under section 4(a) of the 21st Century Nanotechnology Research and Development Act (15 U.S.C. 7503(a)), as amended by this Act; and"

Section 3 (b) (3), insert after E

(F) specify the near-term and far-term goals that should be achieved before further commercialization, so that long term benefits to society can be provided in a safe, responsible, and democratically-directed manner.

Add after Section 3 (b)

"(c) FUNDING GUIDELINES.—Not less than 25 percent of the aggregate amount of funds appropriated for the activities carried out under the Program during any fiscal year shall be used for the activities constituting (1) the Environmental, Health, and Safety program component area, or any successor program component area, and (2) research and public participatory deliberations on other social and ethical issues related to nanotechnology. The impact on low-income communities and on worker safety in the United States, and in other countries with nanotechnology research or production that stems from federally-funded programs, should be priority subjects for study.

"(d) NANOTECHNOLOGY PARTNERSHIPS.—.

(1) ESTABLISHMENT.—As part of the program authorized by section 9 of the National Science Foundation Authorization Act of 2002, the Director of the National Science Foundation shall provide 1 or more grants to establish partnerships as defined by subsection (a) (2) of that section, except that each such partnership shall include 1 or more businesses engaged in the production of nanoscale materials, products, or devices, *and one or more worker representatives in such businesses, and one or more community-based groups in areas where those business production facilities are located, and one or more nonprofit public interest groups engaged in research or public education related to the environmental and social impacts of nanotechnologies.*

Comment – Current EHS research expenditures are about 1 percent of all nanotechnology R&D (Project on Emerging Nanotechnologies at http://www.azonano.com/news.asp?newsID=5907). A sensible guideline for risk, social effects, and public input expenditures for a technological revolution making "most aspects of everyday life … subject to change" (NNI, *Nanotechnology: Shaping the World Atom by Atom*, 1999) would be a dollar for every dollar spent hastening this change. Given the vast discrepancies in expenditures to date, an even higher proportion than the 25% recommended here is warranted. This conservative figure recognizes that transition to a rational balance among program areas would take time.

Section 3 (c) (2)

"[(B) enrichment programs for students, including access to nanotechnology facilities and equipment at partner institutions, to increase their understanding of nanoscale science and engineering, and to inform them about career possibilities in nanotechnology as scientists, engineers, and technicians; and]

[C] *B* identification of appropriate nanotechnology…"

Comment – The safety record at all these facilities should be well established over a minimum period of 3 years, and validated by an independent auditor, before putting children in a potentially dangerous situation that has been designed primarily for adult professionals.

Section 3 (d)

"(1) ACTIVITIES SUPPORTED.—As part of the activities included under the Education, Ethical, and Societal Dimensions program component area, or any successor program component area, the Program shall support efforts to introduce nanoscale science, engineering and technology -- *including their environmental, safety, ethical, and societal dimensions* -- into undergraduate science and engineering education through a variety of interdisciplinary approaches."

SEC. 4. TECHNOLOGY TRANSFER

"(a) PROTOTYPING

(1) ACCESS TO FACILITIES.—In accordance with section 2 (b) (7) of the 21st Century Nanotechnology

Research and Development Act (15 U.S.C. 7501 (b) (7), the agencies supporting nanotechnology research facilities as part of the Program shall provide access to such facilities*, and to federally supported researchers at those facilities,* to companies*, labor organizations, and nonprofit organizations*. Such access shall be for the purpose of assisting [companies] *these for-profit and nonprofit organizations* in the development of prototypes *that include evaluation of the full life-cycle implications* [involving] *of* nanoscale products, devices, or processes (or products, devices or processes enabled by nanotechnology) [for determining proof of concept], *including the evaluation of Environmental, Health, and Safety and the Societal Dimensions issues related to nanotechnology. The agencies shall publicize the availability of these facilities and the research personnel conducting federally funded studies, and encourage consultations with them by companies, labor organizations, and nonprofit public interest organizations as well as other researchers investigating the environmental, health, safety, ethical, and social dimensions of nanotechnologies.*"

Comment – Technology transfer and commercialization processes that exclude consideration of life-cycle costs and benefits encourage quick private gains that may overlook future social and environmental costs. The harm, conflict and litigation resulting from this approach have proven to be a detriment to both business and society. Potential public concerns should be an integral component of publicly-funded research and development in order to effectively incorporate these concerns into product design at the outset.

Section 4 (a) (2)

"(C) may require full or partial recovery of the costs associated with use of the facilities for projects under this subsection, *if prorated for nonprofit public interest users in accordance to their ability to pay."*

Section 4 (a)

"(3) SELECTION AND CRITERIA.— In cases when less than full cost recovery is required pursuant to paragraph (2)(C), projects provided access to nanotechnology facilities in accordance with this subsection shall be selected through a competitive, merit-based process, and the criteria for the selection of such projects shall include at a minimum—

"(A) the readiness of the project for technology demonstration *or for assessment or demonstration of environmental, health, safety, ethical, or social concerns;*

(B) evidence of a commitment by [the] *any* applicant for further development of the project to full commercialization if the proof of concept is established by the prototype;

Comment – The changes proposed here aim to incorporate EHS, societal dimensions, and public input within the purview of technology transfer.

(C) a plan detailing how further development of the project, including decisions about full commercialization, will not cause irrevocable environmental, health, safety or social harm, and how the results of frequent public deliberative inputs will be taken into account in such decisions, [and] *if there is*

([C] *D*) evidence of the potential for further funding from private sector sources following the successful demonstration of proof of concept[.] *,or*

(E) evidence that the project will assess the potential for nanotechnology-related products or processes that have already been commercialized to do environmental, safety, health, or social harm, including through the provision for public deliberative input into the project.

Section 4 (b)

(1) PARTICIPATING AGENCIES.—Each agency participating in the Program shall—

Comment – Small businesses should be encouraged to contribute to public purposes such as product labeling and environmental, health and safety developments particular to their industry segment.

(A) encourage the submission of applications for support of nanotechnology related projects to the Small Business Innovation Research Program and the Small Business Technology Transfer Program administered by such agencies, *including projects to enable identifying, measuring, and developing product labels on exposure to nanomaterials, or projects assessing the environmental, health, and safety impacts of nanotechnology,* ; and

Section 4

(c) INDUSTRY LIAISON GROUPS An objective of the Program shall be to establish industry liaison groups for all industry sectors that would be impacted by applications of nanotechnology. The Nanomanufacturing, Industry Liaison, and Innovation Working Group of the National Science and Technology Council shall actively pursue establishing such liaison groups, *including one focused on industries producing and employing composite materials. These liaison groups shall include representatives of labor, environmental and other nonprofit public interest groups, including community-based groups*.

Section 4

"(d) Coordination With State Initiatives- Section 2(b)(5) of the 21st Century Nanotechnology Research and Development Act (15 U.S.C. 7501(b)(5)) is amended to read as follows:

(5) ensuring United States global leadership in [the development and application] *research and democratic deliberations concerning the safe, effective, and responsible design and use* of nanotechnology, including through coordination and leveraging Federal investments with nanotechnology research, development, and technology transition initiatives supported by the States;."

SEC. 5. RESEARCH IN AREAS OF NATIONAL IMPORTANCE

"(a) IN GENERAL.—The program shall include support for [nanotechnology] research and development activities directed toward application areas that have the potential [for significant contributions to national economic competitiveness and for other significant societal benefits.] *to address significant social and environmental problems. Studies assessing the potential for these research and development activities, and any applications associated with them that generate new social and environmental problems, whether intended or unintended, shall be a priority for funding under this program.* The activities supported shall be designed to advance the development of research discoveries by demonstrating technical solutions to important problems in such areas as nano-electronics, energy efficiency, health care, and water remediation and purification, *and to thoroughly assess, including through frequent public deliberative input, the environmental, health, safety, ethical, and other social impacts of such applications before commercialization occurs.* The Advisory Panel shall make recommendations to the Program for candidate research and development areas for support under this section.

(b) Characteristics-

(A) include projects selected on the basis of applications for support through a competitive, merit-based process;

(B) involve collaborations among researchers [in] *from two or more of the following sectors:* academic institutions, [and] industry, [and may involve] nonprofit research institutions, [and] Federal laboratories, [as appropriate;] *labor organizations, other nonprofit, public-interest groups, and community-based organizations with concerns that can be addressed by the researchers.*; and

(C) when possible, leverage Federal investments through collaboration with related State initiatives; and

(D) include a plan for [fostering the transfer of research discoveries and the results of technology demonstration activities to industry for commercial development] *thoroughly evaluating potential applications of this research, including through frequent public deliberative input, in terms of the environmental, health,* *safety, ethical, and other social impacts, before commercial development*."

(2) PROCEDURES- Determination of the requirements for applications under this subsection, review and selection of applications for support, and subsequent funding of projects shall be carried out by a collaboration of no fewer than 2 agencies participating in the Program. In selecting applications for support, the agencies shall give special consideration to projects that include cost sharing from non-Federal sources, *or that involve collaborations with non-profit organizations that are analyzing the public interest aspects of nanotechnology applications*.

SEC. 6. NANOMANUFACTURING RESEARCH

Subsection (a) add

(3) the full range of environmental, health, safety, ethical, and other social impacts of nanomanufacturing, before commercial development proceeds.

Subsection (b)

"(3) providing for the education of scientists and engineers through interdisciplinary studies in the *ethics, societal dimensions,* principles and techniques for *efforts to design and develop* environmentally benign nanoscale products and processes.

(c) REVIEW OF NANOMANUFACTURING RESEARCH —

(1) PUBLIC MEETING.—Not later than 6 months after the date of enactment of this Act, the National Nanotechnology Coordination Office shall sponsor a public meeting with representation from a wide range of industries engaged in *evaluating whether to pursue* nanoscale manufacturing, *labor organizations representing workers in those industries, researchers, nonprofit public interest groups, and citizens representing the general public* to obtain the views of [such industries] *these parties* on the relevance and value of the research being carried out under the Nanomanufacturing program component area of the Program…"

Reporting Risk Assessment of Nanotechnology:

A reporter's guide to sources and research issues

Question every assumption you think you know about fundamentals, even if you've been covering health or physics for years. Engineered nanomaterials are a new class of materials—and definitions are not standardized, mechanisms are unfamiliar and exotic, and unknowns abound.

By Trudy E. Bell

I. Why small particles are a big story

For decades, scientists have anticipated from theory that if they could manipulate individual molecules, they could engineer materials with electronic, optical, and other properties not observed in bulk—and open new frontiers in electronics,[1] medicine, and consumer products.[2] Rather as cells use a few amino acids to assemble proteins with a wide range of characteristics and functions, nanotechnology may make it possible to design and engineer materials at the molecular level to have specific properties. "There is plenty of room at the bottom" is an often-quoted prophetic quip of the late Caltech physicist Richard A. Feynman in 1959.[3]

Half a century later, the promise of nanotechnology is becoming reality—not only in the lab but already in some commercial consumer products ranging from sunscreens to self-cleaning windows. More exciting are possibilities of targeted cancer therapies, where a tumor may be eradicated without making the rest of the body sick.[4] Environmental researchers are investigating the use of engineered nanoscale materials (engineered nanomaterials for short[5]) to purify or desalinate water, to improve energy efficiency, or to clean up hazardous wastes.[6] Indeed, people are starting to talk about engineered nanomaterials as a completely new class of materials, and nanotechnology as being a new industrial revolution—as significant to the twenty-first century as the first industrial revolution was to the nineteenth century and the information-technology revolution was to the twentieth.

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But with such a revolutionary new technology come questions about occupational, consumer, and environmental safety and health. If engineered nanomaterials have physical properties different from their bulk counterparts, might they also pose new risks to human health in their manufacture, use, and disposal?

As yet, no one knows. Current data basically suggest "it depends." But researchers both in government and private industry are keen to find out.[7]

First, toxicity itself can be useful. Indeed, it is highly sought for certain applications, such as cancer therapies. (Also, keep in mind that often toxicity depends on dose and administration: even table salt is toxic in high doses.)

Second, if toxicity is known, handling and packaging procedures can be devised to mitigate risks of undesired exposure in manufacturing processes, as is routinely done in industries using hazardous materials. Safe-handling procedures for engineered nanomaterials may need to differ from those now used for larger micrometer-sized particulates—especially important for nanomanufacturing workers.[8] Questions have also been raised about the safety of engineered nanomaterials in consumer products or in implantable medical devices, or to plants and animals in the environment after disposal.[9]

Third, nanotechnology developers are heeding a lesson in *perceived* risk from an unrelated high-tech field: consumer resistance that arose at the introduction of crops and products using genetically modified organisms (GMOs). In part, that resistance arose because biotech companies introduced GMO products without much open discussion of legitimate questions and concerns in the general public, with the result that the public felt it had to accept risks to health and environment while benefits were limited to increased profits for large agribusiness. The result was widespread public mistrust and suspicion. Wanting to avoid a similar fate (especially given that concern and calls for regulation already have been expressed in some quarters[10]), nanotech developers are pursuing what they call "responsible development." That specifically includes encouraging early, forthright press coverage of work in assessing risks as well as benefits of engineered nanomaterials, as well as straightforward regulations devised through transparent processes.[11]

But responsible coverage requires accurate understanding. And that's the rub, both for researchers and reporters: at the nanoscale, physical and biological processes may differ fundamentally from what is familiar at larger scales.

This backgrounder for science journalists and general-assignment reporters has three purposes: to sketch essential basics of the physics and biology of engineered nanomaterials (and, for that matter, also natural and incidental nanoparticles), to highlight key issues and resources, and—most importantly—to warn about contradictory findings and pitfalls of logic and to suggest insightful questions for sources, so that assertions in print don't come back to bite pen or keyboard.

The overall message: even if you're a veteran at covering physics or medicine, don't assume that the expertise you have gained at larger scales necessarily transfers exactly to the nanoscale. The science can differ. Check even what seem to be basic facts.

II. Uncertain terms

Disagreement on classification. According to the National Academies, a distinction is made between three types of nano-scale particles (often abbreviated in the literature as "NSPs"): natural, incidental, and engineered. Natural nanoparticles occur in the environment (volcanic dust, lunar dust, magnetotactic bacteria, mineral composites, etc.). Incidental nanoparticles, sometimes also called waste or anthropogenic particles, occur as the result of manmade industrial processes (diesel exhaust, coal combustion, welding fumes, etc.). Both natural and incidental nanoparticles may have irregular or regular shapes. Engineered nanoparticles most often have regular shapes, such as tubes, spheres, rings, etc.

Engineered nanomaterials can be produced either by milling or lithographic etching of a large sample to obtained nanosized particles (an approach often called "top-down"), or by assembling smaller subunits through crystal growth or chemical synthesis to grow nanoparticles of the desired size and configuration (an approach often called "bottom-up"). Since the specific production technique might influence human health risk, ask sources to specify.[12]

Recent questions about toxicity are directed at engineered nanomaterials. Nonetheless, the literature about natural and incidental nanoparticles is helpful, because more is known about them (in part, because of research on smog, welding fumes, coal dust, and ultrafine aerosols[13]), and because information about their behavior can be helpful for understanding the behavior of engineered nanoparticles.

Also according to the National Academies, nanoscale materials—whether engineered or natural—so far seem to fall into four basic categories.[14] The group currently with the largest number of commercial nanomaterials is the metal oxides, such as zinc or titanium oxides, which are used in ceramics, chemical polishing agents, scratch-resistant coatings, cosmetics, and sunscreens. A second significant group is nanoclays, naturally occurring plate-like clay particles that strengthen or harden materials or make them flame-retardant. A third group is nanotubes, which are used in coatings to dissipate or minimize static electricity (e.g., in fuel lines, in hard disk handling trays, or in automobile bodies to be painted electrostatically). The last group is quantum dots, used in exploratory medicine or in the self-assembly of nanoelectronic structures. But be aware: not every official source finds the same categorization useful. For example, the U.S. Environmental Protection Agency divides engineered nanoparticles into carbon-based materials (nanotubes, fullerenes), metal-based materials (including both metal oxides and quantum dots), dendrimers (nano-sized polymers built from branched units of unspecified chemistry), and composites (including nanoclays).[15]

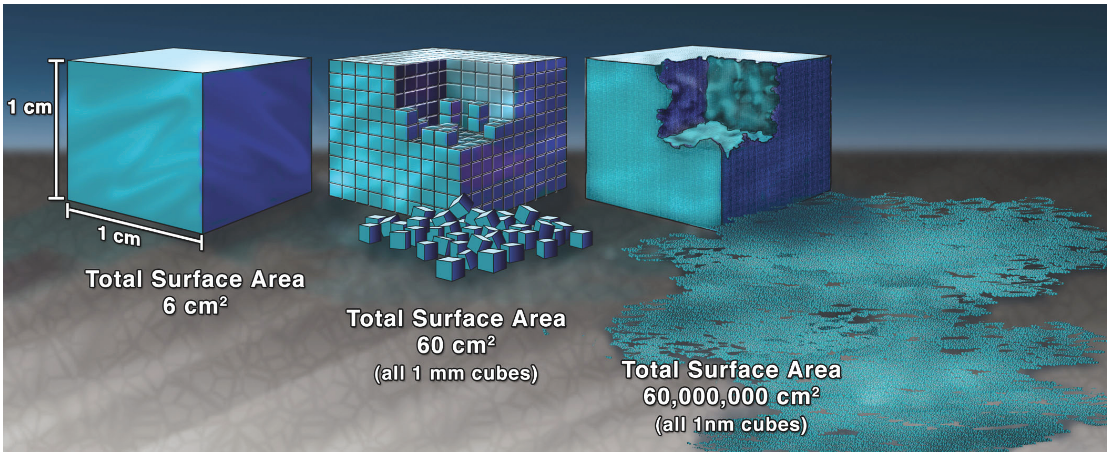
Until terminology is standardized, ask interviewees for definitions most pertinent for their particular research.

Disagreement on definition. Most U.S. and British nanotech experts define NSPs as particles smaller than 100 nanometers (nm)—that is, 0.1 micrometer or micron (µm)—in any one dimension. Thus, a fiber thinner than 100 nm would be considered an NSP, even if it were several micrometers long. This definition, however, is not universal. In Japan, particles between 50 and 100 nm are classed as "ultrafines" and only those below 50 nm in one dimension are considered genuine NSPs.[16] That being said, even some U.S. agencies also use the term "ultrafines" to describe particles under 100 nm[17] (although usually in the context of only natural or incidental nanoparticles—seldom referring to engineered nanoparticles).

To resolve such confusion, ISO, IEC, ANSI, ASTM, and other national and international standards bodies are now discussing the standardization of terminology, metrology, characterization, and approaches to safety and health.[18] Until all that is finalized, ask sources to clarify definitions and assumptions underlying their specific work. The distinctions might be crucial to the physics and biology being reported.

By the way, how can reporters give readers a feel for just how small 100 nm is? It's about one hundred-thousandth the diameter of a human hair (which is 50 to 100 µm). More usefully, 1 µm (1,000 nm) is about the size of a bacterium, about the limit of what is visible through most light microscopes. In contrast, 100 nm is about the size of a virus, a tenth the size of a

Figure 1. Surface Area Diagram



A simple thought experiment shows why nanoparticles have such phenomenal surface area per unit volume. A solid cube of a material 1 cm on a side—about the size of a sugar cube—has 6 square centimeters of surface area, about equal to one side of half a stick of gum. But if that volume of 1 cubic centimeter were filled with cubes 1 mm on a side, that would be 1,000 millimeter-sized cubes (10 x 10 x 10), each one of which has a surface area of 6 square millimeters. The total surface area of the 1,000 cubes adds up to 60 square centimeters—about the same as one side of two-thirds of a 3 x 5 notecard—because one must count the surface areas of all the millimeter cubes even in the interior of the original volume. But when that single cubic centimeter of volume is filled with cubes 1 nanometer on a side—yes, 10^{21} of them, each with an area of 6 square nanometers—their total surface area comes to 60 million square centimeters or 6,000 square *meters*. In other words, a single cubic centimeter of cubic nanoparticles has a total surface area a third again larger than a football field!

[Source: Trudy E. Bell; graphics courtesy of Nicolle Rager Fuller]

bacterium. NSPs, like viruses, are invisible even through the best light microscope, because they are smaller than wavelengths of light (which range from about 700 nm in the red to 400 nm in the violet); they can be imaged only with some higher-resolution instrument such as a scanning electron microscope. 1 nm is about the size of a single sugar molecule.[19]

Four anticipated generations. Already, scientists are talking in terms of generations of engineered nanomaterials. First-generation is passive nanostructures, such as individual particles, coatings, etc.—types of engineered nanomaterials already incorporated into some consumer products. Second-generation is nanostructures that perform an active function, such as transistors or sensors, or that react in an adaptive way; many are under development. Third-generation engineered nanomaterials might be three-dimensional systems that could self-assemble or be used to target drug delivery to specific parts of the body, anticipated to be developed about 2010. Fourth generation is anticipated to be molecular structures by design.[20]

III. The surprising physics of engineered nanomaterials

Size matters. At the nanoscale, fundamental mechanical, electronic, optical, chemical, biological, and other properties may differ significantly from properties of micrometer-sized particles or bulk materials.

One reason is surface area. Surface area counts because most chemical reactions involving solids happen at the surfaces, where chemical bonds are incomplete. The surface area of a cubic centimeter of a solid material is 6 square centimeters—about the same as one side of half a stick of gum. But the surface area of a cubic centimeter of 1-nm particles in an ultrafine powder is 6,000 square meters—literally a third larger than a football field. *(See Figure 1, above.)*

Thus, collections of NSPs with their enormous surface areas can be exceptionally reactive (unless a coating is applied), because more than a third of their chemical bonds are at their surfaces. For example, nanoparticles of silver have been found to be an effective bactericide—inspiring several companies to design reusable water-purification filters using nanoscale silver fibers.[21]

At what size do a material's properties start changing? Is it a gradual transformation as one proceeds from large to small, or is there a threshold below which the properties abruptly change? Both may be true, actually. Quantum-size effects begin to significantly alter material properties (such as transparency, color of fluorescence, electrical conductivity, magnetic permeability, and other characteristics) whenever they dominate thermal effects, which for many materials is around 100 nm.[22] For electronic properties, quantum-size effects increase inversely with decreasing particle size. Yet, for some materials, other distinct properties become pronounced at particular sizes—for example, gold nanoparticles have greatly increased catalytic properties at 3 nm. Characterizing material effects at different sizes is a hot area of basic research.

Shape matters. Engineered nanomaterials with the identical chemical composition can have a variety of shapes (including spheres, tubes, fibers, rings, and planes). Moreover, every one of these shapes may have different physical properties, because the pattern of molecular bonds differ even though they are composed of the same atoms.

For example, until 1985, it was believed that pure carbon

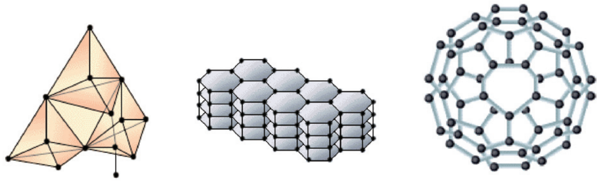


Figure 2. Structures of Diamond, Graphite and Buckminsterfullerene[23]

Carbon and some other elements (including sulphur, tin, and oxygen) are found in multiple structural forms, called allotropes, which have significantly different properties. For example, in crystalline form, pure carbon is found as graphite (very soft), diamond (very hard), and various sizes of Buckminsterfullerenes (depending on the number of carbon atoms).

[Source: http://home.att.net/~cat6a/allot_carbon-I.htm]

came in only two crystalline forms: graphite (whose hexagonal crystal lattice lies in a two-dimensional plane) or diamond (whose cubic crystal lattice extends in all three dimensions). That year, hollow cages of 60 carbon atoms in a soccerball shape were first made in the laboratory (and also independently discovered in distant stars and in combustion byproducts)—a new crystalline form of carbon so significant it was recognized by the Nobel Prize in Chemistry in 1996.[23] The new form, quite stable, was named a buckyball or fullerene after the architect Richard Buckminster Fuller, inventor of the geodesic dome of the same shape. Since then, stable fullerenes of 70, 74, and 82 carbon atoms have also been synthesized. *(See Figure 2, above)*[24]

Similarly, titanium dioxide (TiO_2) has been synthesized in NSPs of at least two different shapes and crystalline structures, each of which may have different toxicities. Although titanium dioxide is normally opaque white—indeed, is used to make white paints—as engineered nanoparticles, its optical qualities change, allowing it to become transparent. Yet it still effectively blocks ultraviolet light, a combination of properties attractive to makers of cosmetics and sunscreens.

Other properties matter. Other material properties that may be more important than just size include charge, crystal structure, surface coatings, residual contamination depending on method of synthesis, and tendency of individual nanoparticles to aggregate into larger clumps.[25] Ask sources to specify what characteristics are important—or unknown—in their own research or product development.

IV. Hazard, risk, and other terms of art

If the physical properties of NSPs are so different from bulk materials, what might be the implications for toxicology and the risk of human exposure? First, some essential definitions:

Hazard, risk, exposure, dose. Several everyday words have specific meanings in the fields of risk analysis, toxicology, or occupational safety and health; these distinctions must be explicit in stories, so readers can follow experts' reasoning and understand quotes.

"Hazard" is the potential to cause harm; it is an intrinsic property of a material. Sulfuric acid, for example, is a hazardous material by virtue of its chemistry. Nothing can change that, short of altering its chemistry to become something else.

"Risk" is the likelihood of harm occurring; it is a combination of a hazard with the probability of exposure and the magnitude and frequency of doses. Risks, unlike hazards, can be managed and minimized: a hazardous material poses low risk if the chances of exposure and the magnitude and frequency of the dose that might be received through that exposure are low. Leaving an unlabeled paper cup of concentrated sulfuric acid on a kitchen counter poses high risk because the chance of exposure and the potential dose are high; but the same acid, if properly labeled and locked in a chemistry lab to which only trained personnel have access, poses minimal risk.[26]

"Exposure" is a combination of the concentration of a substance in a medium multiplied by the duration of contact. For example, dilute sulfuric acid that splashes and is quickly washed off is a low-exposure dose that may only redden the skin; concentrated sulfuric acid allowed to sit on skin is a high-exposure dose that likely will cause serious burns.

"Dose" is the amount of a substance that enters a biological system and can be measured as systemic dose, the total amount taken up by the biological system, or as the amount in a specific organ (skin, lung, liver, etc.). And herein lie more unanswered questions.

Questions about dosimetry. Up to now, exposure to dust and toxic doses have been measured in terms of mass per unit volume, commonly milligrams per cubic meter. However, even very low concentrations of NSPs—whether natural, incidental, or engineered—in the air represent a phenomenal number of particles, as is well known from measurements of ultrafine pollutants. Exposing lab rats to 100-nm titanium dioxide particles has evoked the same amount of pulmonary inflammation as *10 times greater* mass of larger (1–2.5-μm) particles. In fact, in at least some cases, the amount of inflammation seems to be better correlated to particle surface area of administered NSPs than to their mass.[17] Thus, some toxicologists are now wondering whether surface area would be a better measure of dose for NSPs than mass. Until researchers know which counts most, many investigators are starting to specify both in their papers. Ask.

V. The surprising toxicology of nanoparticles

Size matters. Size may have another crucial biological consequence: *where* nanoparticles end up in the body.[27]

A complex of physical factors such as aerodynamics, gravity, and mass causes the largest inhalable dust particles to deposit primarily in the nose and throat. Any toxic effects occur at that site (for example, nasal cancers due to wood dust). Smaller particles are deposited in upper airways and are expelled by the "mucosociliary escalator;" the fingerlike cilia and the mucous lining of the trachea and bronchial tubes, which together move particles up into the throat and nose, where they are coughed, sneezed, blown out, or swallowed. Any toxic effects usually result from absorption through the gut (lead poisoning for example).

The next smallest particles penetrate deeper into the alveolar region (where oxygen and carbon dioxide are exchanged in and out of the blood) and are usually cleared when alveolar macrophages (special monocytic scavenger cells in the lungs) engulf the particles and carry them away. But if a high concentration of NSPs is inhaled, the sheer number of particles—especially if they do not agglomerate—can overwhelm those clearance mechanisms, and they can penetrate to different parts of the respiratory tract. Toxic effects are usually due to killing of the macrophages, which causes chronic inflammation that damages lung tissue (asbestosis and silicosis are examples).

At sizes less than 100 nanometers, inhaled particles begin to behave more like gas molecules and can be deposited anywhere in the respiratory tract by diffusion. Like gases, NSPs—whether natural, incidental, or engineered—simply because of their "nanoscopic" size, can pass through the lungs into the bloodstream and to be taken up by cells, within hours reaching potentially sensitive sites such as bone marrow, liver, kidneys, spleen, and heart.

As particles become small compared to the size of a cell, they can begin to interact with the molecular machinery of the cell. The central nervous system's olfactory bulb (where aromatic molecules are detected) seems to be able to absorb NSPs smaller than 10 nm from the nasal cavity—which then can travel along axons and dendrites to cross the blood-brain barrier.

Inhalation is not the only route into the body. When ingested, NSPs can end up in the liver, the spleen, and the kidneys. When touched, NSPs in the range of 50 nm and smaller tend to penetrate the skin more easily than larger particles (although other aspects such as charge and surface coatings of the particles are also important), sometimes, being taken up by the lymphatic system and localizing in the lymph nodes. *(See Figure 3, below.)*

By the same token, the mucosociliary escalator is also not the only way out of the body. There is evidence suggesting that nanoparticles could be excreted through urine.[28] However, excretion routes for nanoparticles (urine, feces, sweat) are likely to vary depending on exposure route, size, charge, surface coating, chemical composition, and many other factors.

For incidental exposure, all this uptake of NSPs into internal organs could be of concern. But for therapeutic exposure, it is exciting, as it suggests that engineered nanomaterials can be used to target therapies to specific organs, even ones normally quite difficult to reach (such as the brain).

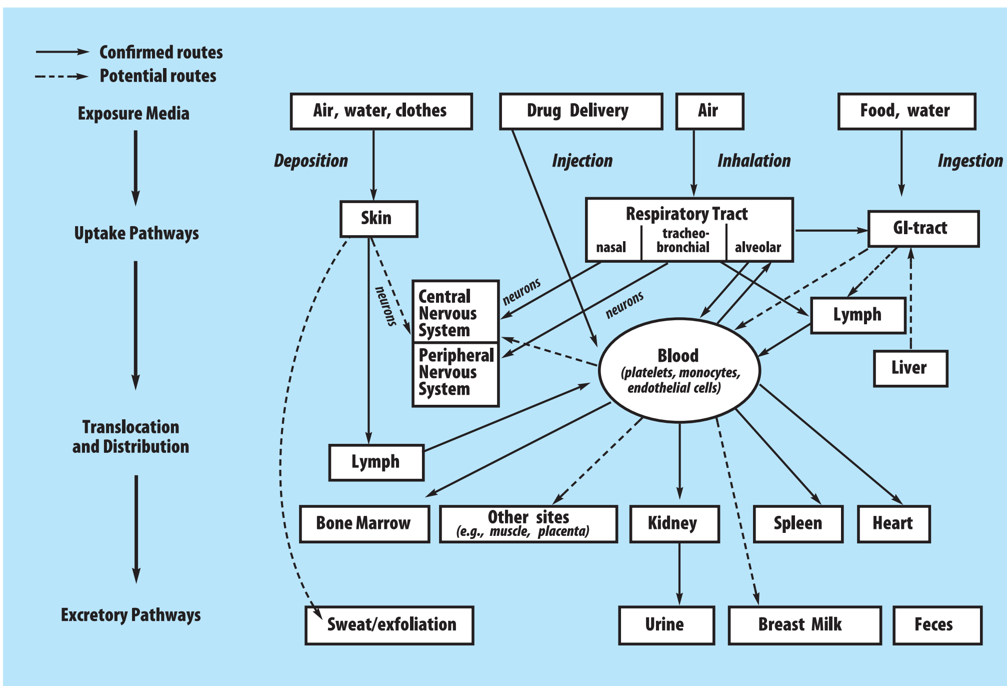
So far, results from different investigators are more suggestive than definitive. More research needs to be done on methods of administration, means of uptake, and on the body's clearance mechanisms. Also, when nanometer-sized particles are generated in combustion processes, most collide with other particles, are held together by the strong surface tension, and agglomerate into larger particles. The distribution of particles sizes will depend on the density of nanometer particles at the point of generation. One of the early priorities for nanotechnology health research is to gain a better understanding of the particle sizes that are likely to be associated with the production of engineered nanoparticles.

Still, size is not the only thing that matters for potential toxicity.

Figure 3. Biokinetics of Nanoscale Particles

Nanoscale particles can end up in different parts of the body depending on size and other characteristics as well as routes of entry. Although many uptake and translocation routes have been demonstrated, others still are hypothetical and need to be investigated. Translocation rates are largely unknown, as are accumulation and retention in critical target sites and their underlying mechanisms. These, as well as potential adverse effects, largely depend on physicochemical characteristics of the surface and core of NSPs. Both qualitative and quantitative changes in NSP biokinetics in a diseased or compromised organism also need to be considered.

[Source: Günter Oberdörster et al., *Environmental Health Perspectives,* 2005]



Shape matters. Although the shapes of NSPs also give them unique properties, under the Toxic Substances Control Act (TCSA) engineered nanoparticles may not be viewed as new compounds unless they have a unique composition.[29] For example, TiO_2 nanoparticles are handled the same way with respect to regulation as bulk TiO_2, even though the two forms have different properties.[30]

Some studies show that the materials having the same composition but of different shapes as well as sizes have different toxicities—moreover, not with a linear relationship as one might expect. For example, one study showed that nanoparticles 50 to 130 nm across of quartz-crystalline silica (a substance known to be toxic) were *less* toxic than 1.6-µm particles—but that 10-nm particles were actually *more* toxic.[31] But route of entry into the body as well as dose also affect toxicity. The lesson? Neither scientists nor reporters should generalize from just a few studies.

Purity matters. Bulk carbon in macroscopic components is medically useful because it is not poisonous to or rejected by the body. Yet, some researchers have observed from experiments that carbon nanotubes (especially single-walled or multi-walled carbon nanotubes) seem to be more toxic than other forms of carbon.[32] Others have debated that claim because the nanotubes used had trace impurities of iron or solvents. Indeed, some studies suggest that other forms of nanoscale carbon such as C_{60} fullerenes might prevent toxicity by being antioxidants.[33]

Possibly at stake here, or in similar debates over other engineered nanomaterials, may be the *purity* of the engineered nanomaterials. At this stage, people don't have absolutely repeatable control on manufacturing processes; nanotech production is now roughly where the production of indium gallium arsenide phosphide (InGaAsP) semiconductor lasers were in the early to mid 1980s—relatively low yield of reliable production. Thus, buckyball products from one supplier are not necessarily identical to those from another, so toxicity may differ. Ask sources careful questions about the size of particles, their manufacture, experimental methods, whether they characterized the materials themselves at the time when they performed the experiment or simply believed the statements made by the supplier, and the comparison of their results with other studies.

Stay tuned. With more research under way, there are more and new publications reporting on nanotoxicology.[34] Until more is certain, the National Institute for Occupational Safety and Health (NIOSH) has announced research needs and interim guidelines for protecting workers in nanotech industries in its report *Approaches to Safe Nanotechnology.*[35]

VI. Cautions for reporting

To avoid propagating errors that have already appeared, some guidelines may be helpful, especially for general-assignment reporters:

First, ***double-check original sources*** of popular stories for sources of error or exaggeration. For example, it has been widely quoted that already some 700 consumer products incorporate nanotech materials.[36] At the current time, that's a significant exaggeration. The 2005 report on which that figure was supposedly based, by EmTech Research, has an appendix that indeed lists some 700 products related to nanotech—only 80 of which are consumer products, the rest being raw materials, experimental equipment, and even software. The list of products will continue to grow each year, however, so ask questions to verify whether any future list represents actual nanotechnology end products, support technology, or marketing claims.

Use appropriate qualifiers. Yes, editors may want to delete such words as "preliminary" or "this particular material," especially when space is tight. For the sake of accuracy, resist. Explain to editors and readers that at this early stage of manufacturing, samples from different suppliers are by no means standard, having different percentages of trace impurities, different distributions of sizes, etc. The physical characteristics or toxicity of carbon nanotubes (CNTs) from one supplier are *not* necessarily representative of the behavior of all CNTs. Indeed, the lack of uniformity is a significant barrier to commercialization and medical use. Good R&D takes time. Until manufacturing technology becomes consistent, qualifiers are an essential part of any story. And when you read a story without qualifiers, consult the original sources about what was likely left out.

Contact scientist-authors before digesting a scientific report for a popular audience. In 2005, popular articles reported on a study that asserted that alumina (aluminum oxide) nanoparticles in soils appeared to slow the growth of plants[37]—possibly important for environmental disposal. What the scientific report failed to state, however, is that alumina *dissolved in solution* is highly toxic to plants.[38] So the observed toxicity may have been irrelevant to engineered NSPs. In other words, even though journalists had accurately reported the paper's findings, the scientific paper itself was faulty in ascribing cause and effect—and those deficiencies were magnified in the popular press. So question a paper's conclusions. Ask the author(s): "Is this substance also toxic in different forms or in solution? Are the effect(s) you report unique to its nanostructure? What do skeptics say about these conclusions?" Also ask other researchers for their views on the paper.

Verify whether reported exposures were actually to NSPs rather than micrometer-sized particles—and indeed, to individual NSPs. In solution or in air, it's quite difficult to keep NSPs separate, as they tend to clump in larger aggregates or agglomerates. Not only do those larger particles have different physical and biological properties than individual NSPs, they may also have properties different from the original materials from which the NSPs were manufactured. Furthermore, not all aggregates are alike, even when composed of identical nanoparticles! For example, when C_{60} fullerenes are mixed with water, they can crystallize into aggregates that can be circular, rectangular, or triangular, depending on how fast water is added[39]—and the properties of different-shaped aggregates may differ enough to be significant to environmental disposal.

Also, have sources clarify how the material may have changed from the time that it was manufactured, to when it is used in an experiment or toxicology study. The form may change because of the way the material was stored, handled during introduction to the experiment, or by effects on the material imposed by the experimental conditions. The journalist should ask what was done to characterize the material throughout the analysis process, to ensure that investigators were testing what they thought/claim they were testing.

Be cautious about generalizing results from one study to another. For example, some researchers hypothesize that nanoparticles may be easily absorbed trans-dermally (through the skin) because some quantum dots are. Quantum dots are used for such experiments because they fluoresce, so their passage through skin is easily tracked. Although quantum dots are indeed nanoparticles, their behavior may differ from nanoparticles of other shapes, sizes, or compositions (which are harder to track). Some cosmetic manufacturers may differ with these conclusions based on unpublished proprietary research, but do due diligence in tracing assertions back to primary sources.[40]

Ask whether or not experimental results can be extended to actual biological systems or the environment. Many toxicology experiments have been done *in vitro*—in Petri dishes or otherwise outside a biological system. But in an animal or human, the immune system responds; and in the environment, there are uncontrolled factors such as weathering from exposure to air or ultraviolet light that may complicate reactions, either increasing or decreasing risks to environmental or human health. Moreover, *in vivo* experiments may have introduced engineered nanoparticles into experimental animals by a route to which humans would never be exposed—such as injection directly into the blood stream or lungs. Thus, laboratory results may not be duplicated in actual systems. Ask sources for their thoughts on what their results may or may not mean in real-life systems.

Probe possible other reasons for toxicity. For example, one possible explanation for the toxicity of fullerenes is that they may cause oxidative stress, a mechanism that leads to cell damage or cell death.[41] On the other hand, some investigators have also run experiments with directly contradictory results, suggesting that fullerenes may act as antioxidants, actual protecting against oxidative stress.[42] Mechanisms for toxicity may differ from NSP to NSP. Ask.

Don't assume common-sense macroscopic physics holds at the nanoscale. Some current occupational safety and health protective measures may be completely adequate to protect nanoworkers—sometimes contradicting ordinary logic. For example, current HEPA filters are designed to capture as many airborne particles of different sizes as possible. At this time, HEPA filters trap 300-nm particles with a capturing efficiency better than 99.97%. But measurements demonstrate they also trap NSPs down to 3 nm—100 times smaller—with even greater efficiency. Tests reveal that airborne NSPs behave enough like gases that their random (Brownian) motion gives a surprisingly high chance of their hitting and sticking to the filter.[43]

Ask mop-up questions. After discussing results, ask sources: "What questions does your latest study/current work *not* answer?" "What did you find most exciting or unsettling?" "What are your next steps?" "Who else is doing valuable work, perhaps following a different approach?"

Indeed, with every source, I would highly recommend asking a question with which I have concluded every interview for decades: "Is there anything we have not discussed that you feel is important, or that readers should know?" This open-ended catch-all question almost always nets useful answers or corrections, and sometimes leads to stupendous revelations or to completely new stories. In a fast-moving field with so many fundamental unknowns, such questions can't help but be a lightning rod for further discussion.

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Endnotes

[1]For the promise seen by the electronics industry in nanotech, see the chapter "Emerging Research Devices" http://www.itrs.net/Common/2005ITRS/ERD2005.pdf of the *International Technology Roadmap for Semiconductors* 2005 edition, http://www.itrs.net/Common/2005ITRS/Home2005.htm.

[2]For just one example report of new frontiers, see *Technology Review's* review of nanotech developments in 2005 at http://www.technologyreview.com/NanoTech-Materials/wtr_16096,318,p1.html.

[3]Feynman's lecture "Plenty of Room at the Bottom" appears in full at http://www.its.caltech.edu/~feynman/plenty.html.

[4]See, for example, the National Cancer Institute's National Alliance for Nanotechnology in Cancer at http://nano.cancer.gov/index.asp.

[5]The term "engineered nanomaterials" includes both individual engineered nanoparticles, and also materials made of engineered nanoparticles bound together.

[6]See, for example, the EPA's white paper at http://es.epa.gov/ncer/nano/.

[7]See, for example, the review article "Toxic Potential of Materials at the Nanolevel" by Andre Nel, Tian Xia, Lutz Mädler, Ning Li, *Science,*311: 622–627 (3 February 2006 (3 February 2006). See also Kuzma, Jennifer (editor), *The Nanotechnology-Biology Interface: Exploring Models for Oversight* (report of a workshop on September 15, 2005), Center for Science, Technology, and Public Policy; University of Minnesota, January 2006 http://www.hhh.umn.edu/centers/stpp/nanotechnology.html.

[8]For questions regarding occupational health, see the regularly updated nanotechnology page of the National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/niosh/topics/nanotech/.

[9]For questions of environmental risk, see, for example, Environmental Protection Agency. Science Policy Council. *Nanotechnology White Paper* (external review draft, December 2, 2005) http://www.epa.gov/osa/nanotech.htm. See also Richard A. Denison, "Getting Nanotechnology Right the First Time", *Environmental Defense,* March 2005 http://www.environmentaldefense.org/documents/4446_EnvironmentalDefenseStatementNRCNanopanel25Mar05.pdf.

[10]See, for example, Montague, Peter, "2005 in Review—Dark Clouds on the Technology Horizon: Nanotech problems pile up and the industry asks to be regulated," *Rachel's Democracy & Health News,* Dec. 22, 2005, reprinted at http://www.pej.org/html/modules.php?op=modload&name=News&file=article&sid=4008. European Environment Agency, Late Lessons from Early Warnings: the Precautionary Principle 1896–2000; *Environmental Issue Report* No. 22, 2001, at http://reports.eea.eu.int/environmental_issue_report_2001_22/en. See also Peter Montague "Nanotechnology and the Precautionary Principle," *Rachel's Democracy & Health News #816,* April 28, 2005 http://www.rachel.org/bulletin/bulletin.cfm?Issue_ID=2498.

[11]See, for example, "How the Public Makes Sense of Nanotechnology" at the National Cancer Institute's web site (December 12, 2005) at http://nano.cancer.gov/news_center/nanotech_news_2005-12-12d.asp.

[12]Thomas, Karluss and Philip Sayre, "Research Strategies for Safety Evaluation of Nanomaterials, Part I: Evaluating the Human Health Implications of Exposure to Nanoscale Materials," *Toxicological Sciences 87* (2): 316–321 (2005); abstract at http://toxsci.oxfordjournals.org/cgi/content/abstract/87/2/316.

[13]See for example Maynard, Andrew D. and Eileen D. Kuempel, "Airborne Nanostructured Particles and Occupational Health," *Journal of Nanoparticle Research,* December 2005.

[14]Goldman, Lynn and Christine Coussens, Editors. *Implications of Nanotechnology for Environmental Health Research.* Roundtable on Environmental Health Sciences, Research and Medicine. The National Academies Press. 2005. Available from http://www.nap.edu/catalog/11248.html.

[15]Environmental Protection Agency. Science Policy Council. *Nanotechnology White Paper* (external review draft, December 2, 2005) http://www.epa.gov/osa/nanotech.htm.

[16]One attempt to start standardizing definitions is the British Standards Insitution's *Vocabulary—Nanoparticles,* Publicly Available Specification 71:2005, available from http://www.bsi-global.com/Manufacturing/Nano/index.xalter.

[17]See, for example, "NIOSH Current Intelligence Bulletin: Evaluation of Health Hazard and Recommendations for Occupational Exposure to Titanium Dioxide," Nov. 22, 2005, http://www.cdc.gov/niosh/docs/preprint/tio2/pdfs/TIO2Draft.pdf.

[18]See, for example, http://www.ansi.org/news_publications/news_story.aspx?menuid=7&articleid=1084.

[19]Example sizes appear at http://www.nano.gov/html/facts/The_scale_of_things.html.

[20]Environmental Protection Agency. Science Policy Council. *Nanotechnology White Paper* (external review draft, December 2, 2005) http://www.epa.gov/osa/nanotech.htm.

[21]Prashant Jain and T. Pradeep, "Potential of silver nanoparticle-coated polyurethane foam as an antibacterial water filter," *Biotechnology and Bioengineering 90* (1): 59 – 63, published Online: 18 Feb 2005; see also Shuixia Chen, Jinrong Liu, and Hanmin Zeng, "Structure and antibacterial activity of silver-supporting activated carbon fibers," *Journal of Materials Science.* 40 (23): 6223 – 6231, December 2005, abstract at http://www.springerlink.com/(3hbfvma34lyckd55sn2aeqnn)/app/home/contribution.asp?referrer=parent&backto=issue,26,44;journal,8,634;linkingpublicationresults,1:100181,1.

[22]See Haruta, Masatake and Msakazu Daté, "Advances in the catalysis of Au nanoparticles," *Applied Catalysis A: General 222:* 427-437 (2001).

[23]See http://nobelprize.org/chemistry/laureates/1996/presentation-speech.html.

[24]See http://home.att.net/~cat6a/allot_carbon-I.htm.

[25]Warheit. David B., see http://pubs.acs.org/cen/nanofocus/top/83/8351sci1.html.

[26]For more on hazard vs. risk, see Harper, Tim and Andrew Dunn, *Nanotechnologies: Risks & Rewards.* Cientifica, June 2005. http://www.innovationsgesellschaft.ch/images/publikationen/Cientifica_RisksandRewards_WP.pdf; for a primer on major risk-analysis techniques in other engineering fields, see "Managing Murphy's law: engineering a minimum-risk system," by Trudy E. Bell, *IEEE Spectrum 26 (6)*: 24–27, June 1986 [special issue on designing and operating a minimum-risk system].

[27]Günter Oberdörster, Eva Oberdörster, and Jan Oberdörster, "Nanotoxicology: An Emerging Discipline Evolving from Studies of Ultrafine Particles," E*nvironmental Health Perspectives* 113, (7): 823–839, July 2005, available at http://www.pubmedcentral.gov/articlerender.fcgi?tool=pubmed&pubmedid=16002369. Supplemental web sections by the same authors appears at http://ehp.niehs.nih.gov/members/2005/7339/supplemental.pdf.

[28]See, for example, Ravi Singh *et al.*, "Tissue biodistibution and blood clearance rates of intravenously administered carbon nanotube radiotracers," *Proceedings of the National Academy of Sciences* (February 21, 2006), abstract at http://www.pnas.org/cgi/content/abstract/0509009103v1.

[29]TCSA http://www.epa.gov/region5/defs/html/tsca.htm.

[30]EPA has many options under TOSCA by which it can regulate new chemicals. If a new substance is given a new name by the Chemical Abstract Service then it immediately falls under TOSCA regulation. The Chemical Abstract Service gives a new substance a CAS # once it has been described in the scientific literature enough that the Service decides that a new chemical name is justified. EPA can also decide that a chemical – e.g., carbon is being made available as a "new use" (carbon nanotubes) and declare that TOSCA regulation will be applied. The same is true for other engineered nanomaterials; macroscopic CdSe vs quantum dot sized CdSe. EPA is examining and will, following their voluntary program, make a decision about the nanosized TiO_2. The FDA monograph states that from the human health standpoint there is (or was not at the time of the decision) no data indicating any difference between the micro and the nano-sized TiO_2. If data become available showing otherwise they will surely reexamine this decision.

[31]David B. Warheit; see bottom story "Questioning Common Perceptions About Nanoparticle Toxicity" at http://pubs.acs.org/cen/nanofocus/top/83/8351sci1.html. . It should be noted that the samples used were of different origin (synthesised vs. natural) and most likely the observed singularity may be due to the difference in surface structure between different quartz samples.

[32]Cited in Thomas and Sayre, *op. cit.*

[33]Gharbi, N. *et al.,* "[60]fullerene is a powerful antioxidant in vivo with no acute or subacute toxicity," *Nano Letters 5* (12): 2578–2585, Dec. 2005, abstract at http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=pubmed&dopt=Abstract&list_uids=16351219&query_hl=5&itool=pubmed_docsum; written up in "Buckyballs Can be Nontoxic...Maybe," National Cancer Institute, Jan. 9, 2006, http://nano.cancer.gov/news_center/nanotech_news_2006-01-09c.asp. Yet, a report by Anna A. Shvedova *et al.,* "Unusual inflammatory and fibrogenic pulmonary responses to single-walled carbon nanotubes in mice," *American Journal of Physiology—Lung 289* (November 2005): 698–708, clearly demonstrates progressive diffuse interstitial pulmonary fibrosis in response to aspiration of dispersed single walled carbon nanotubes, which were purified to remove contaminating iron.

[34]A sample issue of *Nanotoxicology* can be obtained from *http://www.tandf.co.uk/journals/titles/17435390.asp*.

[35]National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), *Approaches to Safe Nanotechnology: An Information Exchange with NIOSH,* October 1, 2005, http://www.cdc.gov/niosh/topics/nanotech/nano_exchange.html.

[36]See, for example, "Nanotechnology Regulation Needed, Critics Say" by Rick Weiss, Washington Post, December 5, 2005 (http://www.washingtonpost.com/wp-dyn/content/article/2005/12/04/AR2005120400729.html), although the number was later corrected. See also "Can EPA Regulate Nano?" by Kevin Bullis, *Technology Review,* December 20, 2005, at http://www.washingtonpost.com/wp-dyn/content/article/2005/12/04/AR2005120400729.html.

[37]See press release "NJIT Study Shows Nanoparticles Could Damage Plant life," at http://www.njit.edu/publicinfo/press_releases/release_797.php, reporting on the work of Daniel J. Watts of New Jersey Institute of Technology. See also L. Wang and D. J. Watts, "Particle surface characteristics may play an important role in phytotoxicity of alumina nanoparticles" *Toxicology Letters 158:* 122–132 (2005).

[38]Murashov, Vladimir, "Comments on 'Particle surface characteristics may play an important role in phytotoxicity of alumina nanoparticles'...," and the affirmative response by Watts, accepted for publication in *Toxicology Letters,* in March 2006.

[39]Fortner, J. D., *et al.,* "C_{60} in Water: Nanocrystal Formation and Microbial Response," *Environmental Science & Technology 39* (11): 4307–4316, Nov. 11, 2005; abstract at http://pubs.acs.org/cgi-bin/abstract.cgi/esthag/2005/39/i11/abs/es048099n.html.

[40]A primer on quantum dots is "A Toxicologic Review of Quantum Dots: Toxicity Depends on Physicochemical and Environmental Factors," by Ron Hardman, *Environmental Health Perspectives,* vol. 114, no. 2, p. 165, February 2006, available at http://www.ehponline.org/members/2005/8284/8284.html.

[41]Goldman and Coussens, *op. cit.,* p. 27.

[42]Gharbi et. al, *op. cit.*

[43]Two mechanisms are at play here. Particles generally larger than 300 nm are collected by impaction due to particle intertia and particles smaller than 300 nm tend to be collected by diffusion, behaving more like a gas. The 300-nm "valley" is the minima between these two different particle collection mechanisms and is often quoted as the most penetrating particle size for filter media.

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EXECUTIVE SUMMARY

Legal Petition Challenges EPA's Failure to Regulate Environmental and Health Threats from Nano-Silver

On May 1, 2008, the International Center for Technology Assessment (CTA) and a coalition of consumer, health, and environmental groups filed a legal petition with the Environmental Protection Agency (EPA), demanding the agency use its pesticide regulation authority to regulate numerous consumer products now using nano-sized versions of silver. The petition is the first legal challenge to EPA's failure to regulate nanomaterials. Nano-silver is the most common commercialized nanomaterial.

Nanotechnology and Nano-silver Products have arrived

Nanotechnology takes apart and reconstructs nature at the atomic and molecular level. Nanotechnology and products containing manufactured nanomaterials have arrived and represent the crest of a product wave spanning many industries. Hundreds of consumer products composed of manufactured and engineered nanomaterials are now widely available. The largest percentage of the currently known commercial nanomaterial products are infused with forms of nanoparticle silver ("nano-silver") for its nano-enhanced ability to kill microorganisms and bacteria.

The Products

The petitioners discovered no fewer than 260 self-identified nano-silver consumer products being sold in the U.S. The products listed in the petition's appendix include: air and water purifiers and filters; bathroom, kitchen and multipurpose cleaning sprays and wipes, children's toys, baby bottles and infant products; laundry detergents and fabric softeners; food storage containers, cutlery, and cutting boards; numerous types of clothing including underwear, socks, shirts, outerwear, gloves and hats; various fabrics and fibers; soaps, personal care and hair products; pet accessories; refrigerators and washing machines; computer hardware; ingestible "health" drink supplements; automobile products; and powdered and liquid nano-silver in bulk form. The products come from the U.S., the U.K., Canada, Korea, Japan, Taiwan, China, New Zealand, and Germany.

The nano-silver products make broad claims about the power of their nano-silver ingredients, such as: "eliminates 99% of bacteria"; renders material "permanently antimicrobial and anti-fungal"; "kills approximately 650 kinds of harmful germs and viruses" and "kills bacteria in as little as 30 minutes, 2-5 times faster than other forms of silver."

The Environmental and Human Health Risks of Nano-silver

The same property that makes these nanomaterials attractive to manufacturers—their highly enhanced antimicrobial action—can be highly destructive to the environment and raise serious human health concerns. Even in bulk form, silver is toxic to fish, aquatic species and microorganisms and a 2005 study found that nano-silver is approximately 45 times more toxic than standard silver. In addition, nanomaterials such as nano-silver exhibit remarkably unusual physical, chemical and biological properties, such as the ability to be harmful in new ways. Impacts are occurring through use and disposal: A 2008 study showed that washing nano-silver socks releases substantial amounts of the nano-silver into the laundry discharge water, which will ultimately reach natural waterways and ecosystems and potentially poison fish and other aquatic organisms. Another 2008 study found that releases of nano-silver destroy benign bacteria used in wastewater treatment.

Many of the nano-silver infused products are for children (baby bottles, toys, stuffed animals, and clothing) or otherwise create high human exposures (cutlery, food containers, paints, bed sheets and personal care products) despite very little study on nano-silver's potential human health impacts. Studies have questioned whether traditional assumptions about silver's safety are sufficient in light of the unique properties of nano-scale materials. Potential health risks from nano-silver's widespread use also include increased bacterial and antibiotic resistance and risks created by nanomaterials' unprecedented mobility in the body.

EPA's Failure to Act

Concerns over nano-silver were first raised by national wastewater utilities in early 2006. Their concerns were highlighted by one then-new nano-silver product, Samsung's Silvercare Washer, which releases silver ions into the waste stream with every wash. In response, the media reported in November 2006 that EPA would regulate nano-silver products as pesticides. One year later, EPA published a guidance covering only the Samsung washer and allowed it to remain on the market. EPA denied that this guidance was "an action to regulate nanotechnology."

The Petition

Despite this nano-silver product explosion and its associated environmental and health risks, EPA has yet to take any meaningful regulatory action. The petitioners present both a legal blueprint and impetus to take such needed oversight action.

First, the petition calls on EPA to amend its regulations or otherwise act to clarify that nano-silver is a pesticide and those products incorporating it are pesticide products that must be registered, approved by the agency, and labeled prior to marketing. Nano-silver meets the pesticide law's (FIFRA) definition of a pesticide because it is a highly efficient antimicrobial or antibacterial agent and is intended to be used for that purpose. EPA should clarify that pesticidal intent and public health claims can be both implicit and explicit and that manufacturers cannot avoid pesticide classification simply by stripping their products of labeling, a potential loophole several manufacturers have already exploited.

Second, the petition calls on EPA to clarify that nano-pesticides, such as nano-silver products, are new pesticide substances that require new pesticide registrations, with nano-specific toxicity data requirements, testing and risk assessments. Nano-silver must be classified as a separate substance than macro-silver based on the nanomaterial's capacity for fundamentally unique and different properties and because nano-silver many new antimicrobial uses are not previously registered silver uses.

Third, EPA must assess the potential human health and environmental risks of nano-silver. These assessments are required by and must comply with FIFRA, as well as the Food Quality Protection Act (FQPA), the Endangered Species Act (ESA), and the National Environmental Policy Act (NEPA). As part of this assessment, EPA should analyze all existing scientific studies as well as require manufacturers to provide all necessary additional data on nano-silver. Pursuant to FQPA, EPA must assess the potential impacts of nano-silver on children and infants and ensure that no harm will result from aggregate exposures. Additionally, EPA must ensure that its activities regarding nano-silver comply with the ESA and the protection of endangered and threatened species. Finally, EPA must comply with NEPA by ensuring that it assesses the environmental impacts of its actions regarding nano-silver pesticide products.

Fourth, EPA should take immediate action to prohibit the sale of nano-silver products as illegal pesticide products with unapproved health benefit claims. The nano-silver consumer products currently on market are in clear violation of FIFRA's mandates. To this end, EPA should issue Stop Sale, Use or Removal Orders or other enforcement penalties or actions to those manufacturers and/or distributors currently selling these unregistered nano-silver pesticide products.

Fifth, should EPA after rigorous assessment approve any nano-silver products as pesticides, the agency must fully apply its pesticide regulations to any registered nano-silver pesticides. FIFRA's pesticide registration requirement instills with EPA the duty to prohibit, condition, or allow the manufacture and use of nanomaterials in nano-pesticides and prescribe conditions for manufacture or use. These include: requiring nano-specific ingredient and warning labeling; applying conditional registration; applying requirements for post-registration notification of adverse impacts; applying post-registration testing and new data development; and requiring the disclosure of all information concerning environmental and health effects, including confidential business information.

Finally, EPA should use its FIFRA authority to further review the potential impacts of nano-silver, including: undertaking either a Classification Review or a Special

Review of nano-silver pesticides; amending the FIFRA regulations to require the submission of nanomaterial and/or nano-silver specific data; completing a registration review of existing silver pesticides; regulation of nano-silver pesticide devices; and the setting of a Federal Food Drug and Cosmetic Act Tolerance for nano-silver.

The full petition is available at www.icta.org and www.nanoaction.org

Relief Requested

Should EPA grant the petition, the result would be that nano-silver is classified as a new substance and nano-silver products regulated as new pesticides. That would require current and future nano-silver products to undergo mandatory EPA pre-market approval. Current products would have to be removed until and unless they received EPA approval. Approval would only occur if the agency found the products did not create an unreasonable risk to the environment. EPA would also have to assess nano-silver's potential impacts on human health, particularly on children and infants, and on the environment, particularly on endangered species and their habitat. EPA would require manufacturers to submit any needed data about the nanomaterials and current EHS unknowns to conduct its assessments. If any of the nano-silver products were approved and registered as pesticides, their use would be conditioned as necessary to protect the environment and human health, including the use of warning labeling. EPA would also amend its regulations to require nano-specific data, testing, and risk assessments for nanomaterial pesticide products.

The Petitioners

Joining the CTA petition are: the Center for Food Safety, Beyond Pesticides, Friends of the Earth, Greenpeace, ETC Group, Center for Environmental Health, Silicon Valley Toxics Coalition, Institute for Agriculture and Trade Policy, Clean Production Action, Food and Water Watch, the Loka Institute, the Center for Study of Responsive Law, and Consumers Union.

CTA

CTA is a non-profit, non-partisan organization committed to providing the public with full assessments and analyses of technological impacts on society. CTA works towards adequate oversight of nanotechnology through its Nanotechnology Project, *NanoAction*, www.nanoaction.org

CTA's uses a variety of legal and policy tools to fulfill its mission, including administrative law petitions. This is the second legal action CTA has filed on the health and environmental risks of nanotechnology: in May 2006 CTA filed a legal petition with the Food and Drug Administration (FDA), calling on that agency to address the human health and environmental risks nanomaterials in consumer products, particularly nano-cosmetics and nano-sunscreens.