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Recent Government Briefs

Organization for Economic Cooperation and Development (OECD)

• On April 28, 2006, OECD released the document "Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication." The OECD workshop was held in Washington DC from December 7-9, 2005, and was one of the first opportunities for international governments to work together alongside stakeholders to address the potential implications of manufactured nanomaterials on human health and the environment. Participants included delegates from 23 OECD member countries, non-member countries, environmental non-governmental organizations (NGOs), and invited experts. The meeting agenda included discussions on the nomenclature system for nanomaterials, physico-chemical characterization of nanomaterials, and regulatory frameworks. The report provides a summary of the plenary presentations and discussions at the meeting, results of breakout sessions, results of questionnaires/surveys of participants, and general conclusions and recommendations of the workshop. For more information, visit: [http://appli1.oecd.org/olis/2006doc.nsf/43bb6130e5e86e5fc12569fa005d004c/b69b32217944d8a1c125715e0038d403/\\$FILE/JT03208175.DOC](http://appli1.oecd.org/olis/2006doc.nsf/43bb6130e5e86e5fc12569fa005d004c/b69b32217944d8a1c125715e0038d403/$FILE/JT03208175.DOC).

UK Department for Environment, Food, and Rural Affairs (DEFRA)

• On June 23, 2006, the consultation period ended for the voluntary reporting scheme proposed by DEFRA in its March 2006 document "Consultation on a Proposed Voluntary Reporting Scheme for Engineered Nanoscale Materials." The purpose of this proposal and consultation period was to gain sufficient information on nanomaterials to assist the United Kingdom (UK) in its development of appropriate controls for the protection of human health and the environment. As outlined in the proposal document, DEFRA hoped to gather data on the kinds of engineered nanoscale materials that are likely to be produced in the UK, along with their properties and characteristics, from the consultation. The DEFRA proposal document outlines a framework for the voluntary reporting scheme, which the Agency expects to accelerate the information-gathering process and also to facilitate decisions on risk-based

policymaking and the types of research to be funded. The voluntary scheme is expected to begin at the end of July, 2006. For more information, visit: <http://www.defra.gov.uk/corporate/consult/nano-tech-vrs/index.htm>.

Reports, Reviews, White Papers, and Books

Legal Action Filed With FDA on Regulation of Nanomaterials in Cosmetics

http://www.icta.org/press/release.cfm?news_id=19
<http://www.icta.org/doc/Nano%20FDA%20petition%20final.pdf>

A formal petition has been filed with the FDA by the International Center for Technology Assessment and a number of consumer, health, and environmental groups. The petition calls for the Agency to take specific actions regarding nano-product regulation, with a primary focus on sunscreens that contain nanomaterials. The petition is sure to draw public attention and increase awareness with respect to consumer safety and nano-products. While no date has been set, FDA had previously announced plans to hold a public meeting on nanotechnology materials in FDA-regulated products (<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01356.html>).

Governing at the Nanoscale People, policies, and emerging technologies

By Matthew Kearnes, Phil Macnaghten, and James Wilsdon

<http://www.demos.co.uk/catalogue/governingatthenanoscale>

This free publication is the result of a collaboration between Demos, a think tank focused on analyzing social and political change, and Lancaster University. The group conducted interviews with scientists and policymakers, spent time in nano labs, held public focus groups, and ran a workshop for nano-scientists and citizens—all of which were aimed at understanding "the social and scientific visions that are influencing nanotechnology research," and developing "opportunities for 'upstream' dialogue between scientists and the wider public." The project's final work is this "pamphlet," which describes the group's findings. For example, in the focus groups, the project found that people had little knowledge or familiarity with nanotech. As discussions progressed and more information was provided, many participants called for innovations to "slow down" and "not move ahead of wider public values". Reference was made

In This Issue

- Recent Government Briefs
- Reports, Reviews, White Papers, and Books
- Upcoming Meetings and Conferences
- Hot-off-the-Presses Peer-reviewed Research Articles of Note
- Guest Contributor

to government and business mishandling of genetically modified food/crops in Europe. Participants generally remained skeptical and ambivalent at the end of the discussions.

Upcoming Meetings and Conferences

The 3rd International Congress of Nanotechnology (ICNT 2006)

Road Map for the Next Frontier

San Francisco, CA, Oct. 30–Nov. 2, 2006

http://www.nanotechcongress.com/#The_3rd_International_Congress_of_Nanotechnology

This meeting for scientists and corporate executives alike will cover a far-reaching list of topics including nanotoxicology, environmental impacts, intellectual property, and international standards. The format will include symposia, panels, workshops, and an open public forum and debate on “Nano Economy.”

Commercialization of Nanomaterials 2006

Producing Results in Nanotechnology Today

Pittsburgh, PA, Sept. 18–20, 2006

<http://www.tms.org/meetings/specialty/nano06/home.html>

The goal of this meeting is to provide an opportunity for dialogue among industry, small and emerging businesses, academia, and government – and for the various groups to understand each other’s needs and the opportunities for nanomaterial solutions. Workshop and presentation topics will include case studies of successful nanomaterials and EH&S issues relevant to commercialization.

Hot-off-the-Presses Peer-Reviewed Research Articles of Note

Chen X et al., 2006. “Interfacing carbon nanotubes with living cells.” *J. Am. Chem. Soc.* **128**: 6292–6293.

<http://pubs.acs.org/cgi-bin/abstract.cgi/jacsat/2006/128/i19/abs/ja060276s.html>

Synopsis:

- This article describes experiments designed to investigate the ability of surface coatings to reduce the toxicity of carbon nanotubes (CNTs).
- CNTs, coated with a “biomimetic” polymer tailored to mimic cell surface mucin glycoproteins, were introduced into cultures of Chinese Hamster Ovary (CHO) cells. Binding of the CNT-coated complexes to the CHO cells was confirmed through fluorescence microscopy and flow cytometry techniques.
- The toxicity of CNTs were tested in additional experiments where the CHO cells were incubated with the coated CNTs (100 µg/mL), uncoated CNTs (100 µg/mL) or media alone (controls), for three days. At the end of the experiments, the authors found that the number of viable cells was comparable in the control and CNT-coated cultures.

- In contrast, cells incubated with uncoated CNTs had approximately 1/8th the number of viable cells compared to the controls. The authors hypothesize that the uncoated CNTs either inhibited cell growth or induced cell death at rates comparable to those of cell proliferation.

Implications:

- The present study demonstrates that coating CNTs with “biomimetic” polymers can substantially reduce, or eliminate, their cytotoxicity and ultimately expand their application into areas of drug delivery and cancer therapeutics. Several experiments have already shown that various cell types can readily engulf CNTs.
- These results are especially important in light of recent studies that have shown that, depending on dose, CNTs can be highly toxic to animals and cells in culture, thereby raising concerns CNTs they may present harmful health effects, potentially limiting their uses.
- The use of “biomimetic” polymers as a coating agent on CNTs will allow for receptor-specific interactions with cells, thereby accelerating the use of CNTs in the study of biological systems.
- Coating CNT surfaces may result in altered electrical conductance and mechanical properties, thereby changing some of the intrinsic properties that make CNTs unique. For example, charge transfer from the coating material to the CNT may occur and alter the local bonding structure of the CNTs.

Maynard AD, 2006. “Nanotechnology: assessing the risks.” *Nano Today*. **1**:22–33.

http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B82X8-4W1D36N&_coveDate=05/31/2006&_at=419371471&_rdoc=1&_fmt=&_qig=search&_qd=1&_cid=33024&_sort=d&view=o&_acct=0000050221&_version=1&_uiVersion=0&_userid=10&md5=e09c82b402d6665f127b5c15f04639a2

Synopsis:

- This article discusses the current state of knowledge of the human health risk assessment of nanomaterials, along with future research activities that are required to develop safe and publicly acceptable nano-based products and technologies.
- Three broad areas regarding nanotechnology risks are discussed: materials of relevance to human health, behavior of nanomaterials in and on the body (hazards), and nanomaterials’ behavior outside the body (exposure).
- Currently available information on nanomaterial entry into the body, deposition into target organs, mechanisms of toxic action, and physico-chemical characteristics of the nanomaterials is presented in detail.
- The article also considers the potential of nanomaterials to structurally and chemically transform from the time they are released into the environment to when they actually make contact with the human body—and the complexity that this adds to predicting the risks of nanomaterials.

- Finally, the various methods for measuring exposures to nanoparticles (e.g., measuring mass vs. surface area) and the various advantages and disadvantages of these methodologies are discussed along with the need for improvement in the currently available technologies.

Implications:

- Currently available risk assessment methodologies may not always be appropriate for nanomaterials because of their unusual characteristics. Thus, in regulating nanomaterials, it is important to distinguish between products with which humans will have frequent and direct contact from those where such exposures are unlikely (e.g., nanoparticles in sunscreens vs. semiconductors), in order to avoid inappropriate and sweeping regulations.
- In identifying nanomaterials that may pose a potential for risks to humans, there should be evidence that the material is biologically available and that it is able to elicit a biological response that is associated with its nanostructure.
- Classes of nanomaterials thought to pose the greatest risk to human health include unbound particles such as powders and aerosols, agglomerates where the nanostructure-based functionality is retained, and nanomaterial composites that present evidence of attrition.
- It is important to consider public perception when managing nanotechnology risks since this will play a large role in determining the success or failure of its use in society.
- Due to the complexities associated with assessing the risks of nanotechnology, there is a need for establishing a comprehensive regulatory framework so that nanomaterials can be developed and used in a safe and responsible manner.

Guest Contributor

How Early EH&S Planning Can Pay Off in the Long Run By John M. Garvey, J.D., Ph.D.¹

The nanotechnology industry has seen some initial success stories, but the sector still faces a difficult climate for startups, characterized by a paucity of venture capital for all but the most seasoned entrepreneurs. Nanotech companies present a challenge to venture capitalists (VCs) for several reasons. Primarily, the companies are difficult to value, given a lack of comparable successful companies, no clear model for exit for the investors, and even an uncertainty over the suitability of nanoscale products for various applications. Many nanoscale products are poorly understood, not just in terms of their potential application, but also in terms of their unusual physical properties. The potential biological and environmental effects of nanoscale products are often unknown. A great deal of these products, and the manufacturing processes for them, are still somewhat experimental. Nevertheless, against this backdrop, new nanotech ventures are regularly initiated.

With early planning, companies can address many potential EH&S concerns that investors may have. This will likely become increasingly important as the public becomes more aware of nanotech products through increasing media coverage of “nano risks.” A nanotech company contemplating sale of itself should perform a review of their products and manufacturing processes, to ensure there are no latent EH&S issues that might need to be managed prior to any transaction. A proper EH&S due diligence allows a company to avoid unnecessary delays in the transaction process. It also provides a degree of comfort as to the appropriate contractual representations and warranties, and indemnification rights, that will be negotiated as part of the transaction. Insurance may also be obtained as a risk management tool. Insurance companies will probably perform an extensive investigation of their own, to assess the risk and set the policy restrictions and premiums. Since regulation of nanotech companies, products, and materials is in flux, it is important for companies to be proactive in their approach to EH&S issues. Regulatory agencies, such as the US Environmental Protection Agency, are engaged in active discussions regarding regulatory frameworks, the possibility of voluntary programs, and research needs in order to conduct proper EH&S assessments. Risk frameworks are being developed to facilitate the assessment of EH&S issues. It is in the best interest of nanotech executives to stay on top of where these changes are going and incorporate such considerations into their own assessments.

A nanotech venture is often initially created and funded with government grants. These allow the entrepreneurs to build the company infrastructure, and develop initial products, prototypes, and ultimately, intellectual property (IP). All companies looking to extract maximum value from business deals need to be cognizant of their IP and how it meshes with the needs of potential business partners or acquirers. New IP can frequently be created to add value, or to gain negotiating leverage during the transaction. To properly prepare a company for sale, a due diligence needs to be initiated by the company well in advance of any contemplated transaction. This coupling of strong IP with effective due diligence will likely pay off in the end for any company. For nanotech companies, the opportunities are certainly rich for IP and so the importance of EH&S due diligence should become a primary focus for outward looking executives.

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Coming Next Month

- Recent research linking titania nanoparticles with potential neurotoxicity.
- German risk survey on nanotechnology.

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