



REGULATORY DEVELOPMENTS

FDA Issues Draft Guidance on Use of Nanotechnology: “Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology”

On 9 June 2011 the FDA issued a draft guidance to provide greater clarity on the regulatory position of the FDA on the use of nanotechnology. In the document, the FDA listed characteristics such as size and exhibited properties that may be taken into consideration when determining the applications of nanotechnology. It plans to use the guidance to assess the products submitted for premarket review and gain further understanding of the traits and behavior of these engineered nanomaterials.

The draft guidance can be found here:

<http://www.fda.gov/RegulatoryInformation/Guidances/ucm257698.htm>

EPA Issues Significant New Use Rule (SNUR) for Multi-Walled Carbon Nanotubes

The EPA has issued a SNUR for multi-walled carbon nanotubes under the Toxic Substances Control Act. The SNUR will require notification to the EPA at least 90 days before manufacture, import, or process of multi-walled carbon nanotubes. The rule is effective 6 June 2011.

See announcement in Federal Register here:

<http://www.gpo.gov/fdsys/pkg/FR-2011-05-06/pdf/2011-11127.pdf>

Executive Memorandum: “Policy Principles for the U.S. Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials”

Issued by the White House Emerging Technologies Interagency Policy Coordination Committee (ETIPC), these policies reflect recommendations from an earlier report on nanotechnology published by the President’s Council of Advisors on Science and Technology. According to the Office of Science and Technology Policy (OSTP), the goal of this document is to create “consistent approaches across different emerging technologies and to ensure the protection of public health and the environment while avoiding unjustifiably inhibiting innovation, stigmatizing new technologies, or creating trade barriers.”¹

The memorandum can be found here:

<http://www.whitehouse.gov/sites/default/files/omb/foreg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf>

European Trade Union Institute (ETUI) Calls to European Commission for Nanotech Register

¹ <http://www.whitehouse.gov/administration/eop/ostp/blog?page=2>

ETUI has requested the European Commission to use its regulatory authorities to create a mandatory EU-wide register for food, packaging, cosmetics, and pharmaceutical industry, among others, to report products that contain nanomaterials. The request has risen out of ETUI concern that regulatory policy on nanomaterials has not kept up with the technology side. France was the first country to implement a mandatory nano-register, and other national regulations are being considered in Italy and the Netherlands.

Further information found here:

<http://www.in-pharmatechnologist.com/Packaging/EU-wide-nanotech-register-vital-to-ensure-safety-says-body>

5th International Nano Authorities Dialogue in Berlin

Members of ministries, agencies, industry, science, and civil organisations in Germany, Austria, Switzerland, and Liechtenstein met in Berlin on 3-4 May 2011 to discuss developments in the governance of nanotechnologies. They began with the findings of the NanoKommission Germany 2009-2011, which was established by the Federal Environment Ministry to assess the opportunities and risk of nanotechnologies and make recommendations to the government on their use. Participants emphasised the importance of stakeholder dialogue, and discussed several potential governance tools, including a nanomaterial register and a nanoprodut register.

Further information on the discussion can be found here:

<http://www.innovationsgesellschaft.ch/index.php?section=news&cmd=details&newsid=469&teaserId=7&setLang=2>

ISO Announces General Liability Classifications for Nanotechnology

ISO is issuing new general liability classifications for nanotechnology with accompanying estimated loss potentials. The new classifications will be implemented on 1 September 2011.

See announcement here:

<http://www.insurancejournal.com/news/national/2011/05/31/200585.htm>

France Issues Nano-risk Management Method

The French Agency for Food Environment, Health, and Occupational Safety (ANSES) has proposed a nano-risk management method using “control banding,” a procedure developed in the pharmaceutical industry for risk management when there is uncertainty about the data required. Since there is uncertainty on both the hazard of nanomaterials and exposure levels, the proposed French method assigns new products “bands,” which have been developed according to the hazard level of known similar products. The method was included in the French Standards Institute’s submission to the ISO on nano-safety.

Full report here: <http://www.foodqualitynews.com/Public-Concerns/France-issues-nano-risk-management-method>

University of California San Francisco Publishes Nanotechnology Policy Recommendations, “Recommendations for Addressing Potential Health Risks from Nanomaterials in California”

Commissioned by the State of California’s Office of Environmental Health Hazard Assessment (OEHA), the Program on Reproductive Health and the Environment in UCSF’s School of Medicine has published a document reviewing nano materials and their potential exposure risks. The report also makes policy recommendations to the State on how to address these potential risks, some of which can be implemented under the current regulatory framework, while others are outside its scope.

A list of their recommendations can be found here:

<http://www.nanolawreport.com/2011/05/articles/california-1/university-of-california-san-francisco-publishes-nanotechnology-regulatory-policy-recommendations/#axzz1OoMmTuRM>

OECD issues “Current Developments/Activities on the Safety of Manufactured Nanomaterials”

The OECD document is compiled from each member country’s report on the developments on safety of manufactured nanomaterials given in the country at each meeting of the Working Party on Manufactured Nanomaterials. “Current Developments/Activities on the Safety of Manufactured Nanomaterials” also includes a section on nanotechnology activities in other international organisations such as the ISO and the Food and Agriculture Organisation of the UN and WHO. The objective of this report is to provide stakeholders with an overview of developments in nanotechnology at both the national and international levels.

The report can be found here:

[http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono\(2011\)12&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2011)12&doclanguage=en)

REVIEWS AND OTHER PUBLICATIONS OF INTEREST

- 1. Physical and Biophysical Characteristics of Nanoscale Tungsten Oxide Particles and Their Interaction with Human Genomic DNA.** Journal of Nanoscience and Nanotechnology, June 2011, Vol. 11, No. 6, pp. 4659-4666. Vijay Bhooshan Kumar, Clair Ermine Sawian, Dambarudhar Mohanta, Shashi Baruah, and Nashreen S. Islam.
<http://www.ingentaconnect.com/content/asp/jnn/2011/00000011/00000006/art00001?token=00441d133c3dae846319f7e41225f40386f2c3167547d66463e4423576b64276a5ce>
- 2. Fabrication of New Chitosan-Based Composite Sponge Containing Silver Nanoparticles and Its Antibacterial Properties for Wound Dressing.** Journal of Nanoscience and Nanotechnology, June 2011, Vol. 11, No. 6, pp. 4733-4738. Donghong Li, Junlin Diao, Jiaotao Zhang, and Jianchang Liu.

<http://www.ingentaconnect.com/content/asp/jnn/2011/00000011/00000006/art00010?token=003c1810c5c578617e41225f40386f2c3167547d702544702e576b64276a>

3. **Lipid Nanocarriers (GeluPearl) Containing Amphiphilic Lipid Gelucire 50/13 as a Novel Stabilizer: Fabrication, Characterization, and Evaluation for Oral Drug Delivery.** Nanotechnology, 8 July 2011, Vol. 22, No. 22. Abhijit A. Date, Nimish Vador, Aarti Jagtap, and Mangal S. Nagarsenker.
http://iopscience.iop.org/0957-4484/22/27/275102/pdf/0957-4484_22_27_275102.pdf
4. **Synthesis and Characterization of Human Transferrin-Stabilized Gold Nanoclusters.** Nanotechnology, 8 July 2011, Vol. 22, No. 22. Xavier Le Guével, Nicole Daum, and Marc Schneider.
http://iopscience.iop.org/0957-4484/22/27/275103/pdf/0957-4484_22_27_275103.pdf

CONFERENCES AND WORKSHOPS

Nanotech Conference & Expo 2011

June 13-16, 2011, Boston, MA

- Tracks on fabrication, characterization and tools, advanced materials, electronics and microsystems, medicine and biotech, and energy and environment
- Over 5,000 attendees and 300 exhibitors expected

<http://www.techconnectworld.com/Nanotech2011/>

7th NanoBioEurope 2011

June 21-23, 2011, Cork, Ireland

- Sessions on integrated systems, biophotonics, biomaterials, nanobioanalytics, nanobio in Ireland, in vitro diagnostics, nanoenabled drug delivery technologies, nanoenabled innovations in surgical devices and systems.

<http://www.tyndall.ie/conferences/nanobio-europe//index.php>

Pharmaceutical Nanotechnology: Applications & Commercialization

June 29-30, 2011; London, UK

- Engineering, formulation and drug delivery
- Nano-enabled nucleic acid therapeutic delivery
- Translating discoveries into commercial successes
- Regulatory considerations, IP issues and partnering opportunities

<http://smi-online.co.uk/events/overview.asp?is=4&ref=3484>

NanoFormulation2011

June 26 – July 1, 2011 ; Singapore

- Formulation of Nano-Biomaterials
- Handling and processing of Nanopowders
- Processing and Stabilization of Nanoparticle Suspensions
- Smart and Functional Materials in Formulations: Coating, Films and Tapes

- Safety and Health Effects and Nanoscale Materials – Towards Sustainable and Safety

<http://www.nanoformulation2011.com/>

Biological Responses to Nanoscale Particles

September 11-15, 2011, Essen, Germany

- Organised by Priority Programme (SPP1313) of Deutsche Forschungsgemeinschaft (DFG) and University of Duisburg-Essen (UDE)
- Topics include interactions of nanoscale particles with biomolecules and membranes, mechanisms of cellular uptake and intercellular trafficking, biological impacts of nanoscale particles, synthesis and characterisation of nano particles, in-vivo and in-vitro imaging and diagnostic techniques, biodegradation of nanoscale particles, life cycle analysis and risk assessment

http://www.spp1313.de/website/program/general/programm_82/en/en_programm_univer_1.php

NANOCON 2011

September 21-23, 2011, Brno, Czech Republic

- Two sessions on biotechnology, nanomaterials in medicine, and health, safety and environmental challenges

<http://www.nanocon.cz/>

Nanoscale Bioceramics in Healthcare and High Performance Ceramics

October 12-13, 2011, Stoke-on-Trent, Staffordshire, UK

- Hosted by Institute of Nanotechnology and CERAM
- Focus on application of bioactive glass and ceramics to orthopaedics, regenerative medicine, dentistry, biosensing, controlled drug release, high performance coatings, and functionalized biomaterials.

<http://www.nano.org.uk/events/ion-events>

NanoMedicine – 2011

November 3 – 5, 2011, Shenzhen, China

- Breaking Research of Nanomedicines
- Versatile Nanotech and Nanomaterials in Biomedicine
- Nanodevices and Diagnostic
- Nanomedicine Targeting Major Diseases
- Regenerative Nanomedicine
- Culturing Public Environment for Healthy Growth

<http://www.bitconferences.com/NanoMedicine2011/>

BioNanoTox and Applications International Research Conference

November 10-14, 2011, Mobile, AL

- Multidisciplinary focus on biology, nanotechnology, and toxicology
- Joint research between nanomaterials and biological systems

<http://sites.google.com/site/bntconference/>

Nano Health

January 15-16, 2012, Egypt, Cairo

- To address the future of nanotechnology, as well as potential risks and regulatory issues
- New frontiers in drug delivery and therapeutics
- New frontiers in imaging and diagnosis

- Nanotechnology and the developing world
- Roadmapping new technologies
- Novel medical materials and products

<http://www.clocate.com/conference/Nano-Health-2012/13170>

REFERENCE SECTION

Nano Organizations

- National Center for Toxicological Research (NCTR): <http://www.fda.gov/AboutFDA/CentersOffices/NCTR/default.htm>
- National Nanotechnology Initiative (NNI): <http://www.nano.gov/>
- Nano Science and Technology Consortium (NSTC): <http://www.nstc.in/>
- Nano Science and Technology Institute (NSTI): <http://www.nsti.org/>
- The Nanotechnology Institute (NTI): <http://nanotechinstitute.org/>

Nano Journals

- American Chemical Society -- Nano Letters: <http://pubs.acs.org/journal/nalefd>
- Institute of Physics – Nanotechnology: <http://iopscience.iop.org/0957-4484/>
- Journal of Nanoscience and Nanotechnology: <http://www.aspbs.com/jnn/>
- NanoTrends - A Journal of Nanotechnology and its Applications: <http://www.nstc.in/journal/default.aspx>
- BCC Research -- Nanotechnology Reports: <http://www.bccresearch.com/index/category/code/nanotechnology>

CONTACT

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