



REGULATORY AND LEGISLATIVE DEVELOPMENTS

FDA Releases Two Nanotechnology Draft Guidances

The FDA has released two draft guidances on nanotechnology, one on food safety and the other on cosmetics. They are each titled “Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives,” and “Draft Guidance for Industry: Safety of Nanomaterials in Cosmetics Products.” The draft guidance on food outlines factors that manufacturers should consider to determine whether nanotechnology affects the identity, safety, or regulatory of a food substance. The cosmetics guidance outlines FDA’s perspectives on the use and safety of nanomaterials in cosmetics. It reveals the FDA believes that current standard safety tests may need to be modified to accommodate nanomaterials.

“Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives”:

<http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm300661.htm>

“Draft Guidance for Industry: Safety of Nanomaterials in Cosmetics Products”:

<http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ucm300886.htm>

EC Releases 2012 Edition of Compendium of Projects in the European NanoSafety Cluster

The European Commission has released the 2012 edition of the Nanosafety Cluster Compendium. This document outlines projects that explore nanomaterial toxicity, exposure effects, risk management, research infrastructure and coordination funded under

Seventh Framework Programme FP7. The compendium aims to aid researchers in cross-pollinating and finding potential collaboration opportunities.

NanoSafety Cluster: <http://www.nanosafetycluster.eu>

Compendium:

http://www.nanosafetycluster.eu/uploads/files/pdf/Compendium2012_u1_web.pdf

PCAST Report Lauds NNI

The President’s Council of Advisors on Science and Technology (PCAST) released its 2012 Report to the President and Congress on the Fourth Assessment of the National Nanotechnology Initiative (NNI). The report states that “substantial progress” has been made by the NNI to expand coordination with industry, and emphasizes the importance of NNI’s environmental, health, and safety research strategy as part of the responsible development of nanotechnology.

The document can be found here:

<http://nano.gov/node/786>

OECD Documents on Nanotechnology

The OECD has organized three documents on nanomaterials and nanotechnology, which are outlined below.

1. [National Activities on Life Cycle Assessment of Nanomaterials](#)
 - Outlines OECD member countries’ initiatives exploring life cycles of nanomaterials
 - Updated regularly as new information is made available
2. [Information Gathering Schemes on Nanomaterials: Lessons Learned and Reported Information](#)
 - Aggregates information and statistics on use of nanomaterials collected from surveys in OECD countries

- Outlines most commonly used nanomaterials in OECD countries
3. [Regulated Nanomaterials: 2006-2009](#)
- Outlines nanomaterials regulated in OECD member countries from 2006-2009
 - Summarises legislation on nanomaterials in OECD member countries
- Provides information collected on nanomaterials under legislative requirements

REVIEWS AND OTHER PUBLICATIONS OF INTEREST

Gold Nanoparticles-Decorated Silicon Nanowires as Highly Efficient Near-Infrared Hyperthermia Agents for Cancer Cells Destruction. Nano Letters, 11 April 2012, Vol. 12, No. 4, pp. 1845-1850. Yuanyuan Su, Xinpan Wei, Fei Peng, Yiling Zhong, Yimei Lu, Shao Su, Tingting Xu, Shuit-Tong Lee, and Yao He. <http://pubs.acs.org/doi/pdfplus/10.1021/nl204203t>

Triple Stimulus-Responsive Polypeptide Nanoparticles that Enhance Intratumoral Spatial Distribution. Nano Letters, 11 April 2012, Vol. 12, No. 4, pp.2165-2170. Daniel J. Callahan, Wenge Liu, Xinghai Li, Matthew R. Dreher, Wafa Hassouneh, Minkyu Kim, Piotr Marszalek, and Ashutosh Chilkoti. <http://pubs.acs.org/doi/pdfplus/10.1021/nl300630c>

In Vivo Tumor Imaging Using a Novel RNAi-based Detection Mechanism. Nanomedicine: Nanotechnology, Biology, and Medicine, May 2012, Vol. 8, No. 4. Kayiu Wan, Bernd ebert, Jan Voigt, Qing Wang, et al. <http://download.journals.elsevierhealth.com/pdfs/journals/1549-9634/PIIS1549963412000226.pdf>

REVIEW: Nanoparticle in the Treatment and Diagnosis of Neurological Disorders: Untamed Dragon with Fire Power to Heal. Nanomedicine: Nanotechnology, Biology, and Medicine, May 2012, Vol. 8, No. 4. Jagat R. Kanwar, Xueying Sun, Vasu Punj, Bhasker Sriramoju, et al. <http://download.journals.elsevierhealth.com/pdfs/journals/1549-9634/PIIS1549963411003431.pdf>

Curcumin-loaded γ -cyclodextrin Liposomal Nanoparticles as Delivery Vehicles for Osteosarcoma. Nanomedicine: Nanotechnology, Biology, and Medicine, May 2012, Vol. 8, No. 4. Santosh S. Dhule, Patrice Penfornis, Trivia Frazier, Ryan Walker, et al. <http://download.journals.elsevierhealth.com/pdfs/journals/1549-9634/PIIS1549963411002887.pdf>

Effect of Novel Stabilisers – Catalonic Polymers on the Particle Size and Physical Stability of Poorly Soluble Drug Nanocrystals. Nanomedicine: Nanotechnology, Biology, and Medicine, May 2012, Vol. 8, No. 4. Wei Sun, Wei Tian, Yuyang Zhang, Jianyong He, et al. <http://download.journals.elsevierhealth.com/pdfs/journals/1549-9634/PIIS1549963411002838.pdf>

Structure and Biological Activity of Pathogen-like Synthetic Nanomedicines. Nanomedicine: Nanotechnology, Biology, and Medicine, May 2012, Vol. 8, No. 4. Orsolya Lorincz, Eniko R. Töke, Eszter Somogyi, Ference Horkay, et al. <http://download.journals.elsevierhealth.com/pdfs/journals/1549-9634/PIIS1549963411002905.pdf>

Nanomedicine Against Multidrug Resistance in Cancer Treatment. Nanomedicine, April 2012, Vol. 7, No. 4, pp.465-468. Jie Gao, Si-Shen Feng, Yajun Guo. <http://www.futuremedicine.com/doi/pdf/10.2217/nmm.12.11>

REVIEW: Understanding Nonviral Nucleic Acid Delivery with Quantum Dot-FRET Nanosensors. Nanomedicine, April 2012, Vol. 7, No. 4, pp. 565-577. Christopher L. Grigsby, Yi-Ping Ho, Kam W. Leong. <http://www.futuremedicine.com/doi/pdf/10.2217/nmm.12.28>

REVIEW: Nanoparticles and Spermatogenesis: How do Nanoparticles Affect Spermatogenesis and Penetrate the blood-Testis Barrier. Nanomedicine, April 2012, Vol. 7, No. 4, pp. 579-596. Hou Lan, Wan-Xi Yang. <http://www.futuremedicine.com/doi/pdf/10.2217/nmm.12.20>

REVIEW: Cancer Stem Cells and Drug Resistance: The Potential of Nanomedicine. Nanomedicine, April 2012, Vol. 7, No. 4, pp. 597-615. <http://www.futuremedicine.com/doi/pdf/10.2217/nmm.12.22>

Oral Exposure to Polystyrene Nanoparticles Affects Iron Absorption.

Nature Nanotechnology, April 2012, Vol. 7, No. 4, pp. 264-271. Gretchen J. Mahler, Mandy B. Esch, Elad Tako, Teresa L. Southard, Shivaun d. Archer, Raymond P. Glahn, and Michael L.

Shuler.

<http://www.nature.com/nnano/journal/v7/n4/pdf/nnano.2012.3.pdf>

CONFERENCES AND WORKSHOPS

Nanomedicine: Visions, Risks, Potential. April 19-20, 2012, Berlin, Germany

Will discuss trends in nanotechnological methods in medical applications, focusing on both scientific and technical aspects.

<http://www.nanodiara.eu/spring-conference-2012/>

Safety Issues and Regulatory Challenges of Nanomaterials, May 3-4, 2012, San Sebastian, Spain

Four EU projects: Four different ways to approach nanosafety

Regulatory testing of nanomaterials and international dimension

Challenges in nanosafety research: new materials and detection technologies

Nanomaterials interactions with living systems

Exposure and risk assessment of nanomaterials

Life cycle assessment analysis and end of life processes sustainability for nanotechnology-based products

<http://www.leitat.org/nanoLCA/>

The Joint European Summit for Clinical Nanomedicine 2012 (CLINAM 2012). May 7-9, 2012, Basel, Switzerland

Clinical trials for nanomedicines

Regulation, toxicology, ethics, sustainability

Transition from research to industrial products

Strategic instruments in nanomedicines

<http://www.clinam.org/conference.html>

ACS Middle Atlantic Regional Meeting MARM 2012, May 31-June 2, 2012, Baltimore, MD

Chemistry of renewable energy

Food and sensory chemistry

Bioanalytical chemistry

Nanotechnology environmental health and safety

Mass spectrometry and NMR of biomolecules

Computational biochemistry

Carbohydrate chemistry

Medicinal chemistry

<http://www.marmacs.org/2012>

Nanobio-Europe 2012, June 18-20, 2012, Varese, Italy

Nano-enabled drug delivery

Nanotechnology for medical applications

In vivo imaging

Biomarkers and nanoparticles

Cell analysis and manipulation

Sensors and actuators

Bioanalytics

Bio-nano materials and tissues

<http://nanobio-europe-2012.jrc.ec.europa.eu/>

3rd International NanoMedicine Conference, July 2-4, 2012, Sydney, Australia

Target delivery

Sensing

Diagnostics

Regenerative medicine

Imaging

Translational medicine

Safety

<http://www.oznanomed.org/>

9th International Conference on Nanosciences & Technologies, July 3-6, 2012, Thessaloniki, Greece

Nanotechnology in biology

Nanostructures for medical applications

Cell/Nanomaterial interactions

In-vitro and in-vivo diagnostics

Targeted drug delivery

Regenerative nanomedicine

Nanotoxicity, risk assessment, and ethics

Nanomedicine commercialization

http://www.nanotexnology.com/index.php?option=com_content&view=article&id=48&Itemid=60

Working Safely with Nanomaterials. July 6, 2012, Edinburgh, Scotland.

Nanomaterials categories

Nano toxicology/hazard banding

Nano controls/monitoring

Nano health surveillance

<http://www.bohs.org/Events/WorkingwithNanomaterials/>

77th Prague Meetings on Macromolecules: Polymers in Medicine. July 8-12, 2012, Prague, Czech Republic

Polymers for Nanomedicine
Stimuli responsive polymers
Polymers for Advanced Drug Delivery
Polymers for Biomedical Applications
Biomaterials for Tissue Engineering

<http://www.imc.cas.cz/sympo/pmm2012/>

Colloids and Nanomedicine 2012. July 15-17, 2012, Amsterdam, Netherlands.

Biomaterials
Tissue engineering and regenerative medicine
Drug delivery
Biosensors
Toxicology and risk assessment of nanomedicine systems
Proteins and peptides at interfaces
Soft matter, surfactants, polymers in biological systems
Novel phenomena and techniques

<http://www.colloidsandnanomedicine.com/index.html>

Drug Carriers in Medicine & Biology, August 12-17, 2012, Waterville Valley, NH

Vascular delivery, targets and barriers
Translational studies, clinical trials, and combination therapies
Local, pulmonary, GI, and CNS delivery
Emerging technologies, materials, carriers, and mechanisms
Carriers for vaccines and antigen delivery
Intracellular delivery, trafficking and cellular barriers
Biological response to delivered drugs and genes

<http://www.grc.org/programs.aspx?year=2012&program=dcarr>

First International Symposium on Nanomedicine in Drug Delivery and cancer Diagnostics, August 16-17, Delaware, MD

Principles of Nanomedicine
Nanotechnological advances and potential medical applications
Benefits of nanomedical tools versus traditional techniques
Therapeutic applications of nanotechnology and nanomaterials
Drug delivery using nanoparticles

<http://www.udel.edu/nanomedicine/presenters.html>

IEEE Nano 2012 Conference, August 20-23, 2012, Birmingham, UK

Nanobiomedicine
Nanosensors
Nanoplasmonics

http://www.ieee.org/conferences_events/conferences/conferencedetails/index.html?Conf_ID=19746

European Congress of Molecular Spectroscopy, August 26-31, 2012, Cluj-Napoca, Romania

Spectroscopic methods and techniques
Computational and theoretical approaches
Structure and dynamics of molecular systems

<http://www.nanowerk.com/nanotechnology-event.php?eventid=3484>

Nanosafe 2012, November 13-15, 2012, Grenoble, France

Exposure assessment
Characterisation, detection, and monitoring
Nanomaterials life cycle
Toxicology
Environmental impact
Nanoparticle release from consumer products
Personal protective equipment
Secure industrial production
Safety parameters evaluation
Standardisation, regulations

<http://www.nanosafe.org/scripts/home/publigen/content/templates/show.asp?P=121&L=EN&ITEMID=65>

REFERENCE SECTION

Nanobio- and Nanomedicine Companies

Listed alphabetically:

http://www.nanowerk.com/nanotechnology/nanomaterial/nanobiomedicine_a.php

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>

Nanomedicine: Nanotechnology, Biology,
and Medicine:

<http://www.nanomedjournal.com/home>

Nanomedicine:

<http://www.futuremedicine.com/page/about.jsp>

Nature Nanotechnology:

http://www.nature.com/nnano/focus/highlights/index.html?WT.mc_id=NM1110CT010

CONTACT

For further information, or if you have any questions about the Nanomedicines Alliance, please contact the Nanomedicines Alliance Secretariat at 1-202-230-5607 or info@nanomedicines-alliance.org

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