

## ***UNITED STATES***

### **Highlights**

- EPA issues draft inventory document relevant to determining whether nanomaterials are “new” or “existing” chemicals under TSCA
- EPA issues draft stewardship program concept paper
- FDA issues task force report
- NEHI issues interim report on prioritizing EHS research needs for engineered nanomaterials
- NIEHS and NIBIB/NIH jointly propose NanoHealth Enterprise
- EPA is developing a nanomaterial research strategy
- NTP initiates nanomaterial testing program
- EPA begins nanomaterial risk assessment case studies
- EPA holds public meetings on stewardship program, on materials characterization and on pollution prevention through nanotechnology

### **1. Any national regulatory developments on human health and environmental safety including recommendations or discussions related to adapting existing regulatory systems or the drafting of laws/ regulations/ guidance materials;**

The Environmental Protection Agency (EPA) released for public comment guidance under the Toxic Substances Control Act (TSCA) in order for manufacturers of nanoscale materials to make the distinction between “new” and “existing” chemicals on the TSCA Inventory. EPA is reviewing comments and will announce a final version in early 2008.

EPA has received and reviewed a number of new chemical notices for potential nanoscale materials under TSCA. EPA has permitted manufacture of these nanoscale materials under limited conditions.

### **2. Developments related to voluntary or stewardship schemes;**

For new products using nanotechnology, USG agencies have encouraged manufacturers to enter into discussions with the appropriate review authority early in the product development process, prior to submitting an application or notice for regulatory decision, so that potential issues of regulatory uncertainty or information needs can be identified and where possible addressed. These discussions are ongoing for a number of products that use manufactured nanomaterials.

On July 12 EPA announced in the Federal Register the availability of the documents for public review and comment. These documents included a Concept Paper for the Nanoscale Materials Stewardship Program, a TSCA Inventory Status of Nanoscale Materials - General Approach, and an Information Collection Request for the program

that included a proposed optional reporting form. EPA is developing the final program based on public input and expects to announce the program early in 2008. Key goals of the Program are to assemble and encourage the development of scientific information on hazards, exposure, risks, and risk mitigation practices to provide a sound scientific foundation to inform industry and EPA. The program would complement EPA's regulatory authorities and ensure the responsible development and commercial use of nanoscale materials.

### **3. Information on any risk assessment decisions;**

EPA has assessed a number of new chemical notices for potential nanoscale materials under TSCA.

### **4. Information on any developments related to good practice documents**

None.

### **5. Research programmes or strategies designed to address human health and/ or environmental safety aspects of nanomaterials;**

On August 16, 2007 the Nanotechnology Environmental and Health Implications Working Group of the National Science and Technology Council released an interim report for comment entitled "Prioritization of Environmental, Health and Safety Research Needs for Engineered Nanoscale Materials" ([http://www.nano.gov/Prioritization\\_EHS\\_Research\\_Needs\\_Engineered\\_Nanoscale\\_Materials.pdf](http://www.nano.gov/Prioritization_EHS_Research_Needs_Engineered_Nanoscale_Materials.pdf))

The National Institutes of Environmental Health Sciences and the National Institute of Biomedical Imaging and Bioengineering at the National Institutes of Health are proposing an integrated, interdisciplinary initiative that will employ state-of-the-art technologies to examine the fundamental physical and chemical interactions of engineered nanomaterials with biological systems at the molecular, cellular, and organ level. This initiative, called the NanoHealth Enterprise, proposes a partnership with private industry, other federal agencies, international partners, public health advocates, and academia to address critical research needs for the safe development of nanoscale materials and devices.

The US Food and Drug Administration (FDA) issued a Nanotechnology Task Force Report dated July 25, 2007. The report offers the Task Force's initial findings and recommendations to the FDA Commissioner and includes:

- A synopsis of the state of the science for biological interactions of nanoscale materials;
- Analysis and recommendations for science issues; and,
- Analysis and recommendations for regulatory policy issues.

US EPA is developing a Nanomaterial Research Strategy (NRS) that identifies a research program that will be coordinated with research conducted by other US agencies. The NRS will undergo external peer review in November 2007 and will be published in the *Federal Register* for comment. The NRS covers fiscal years 2007-2012 and is focused on addressing EPA's programmatic needs within four research themes:

- Sources, Fate, Transport, and Exposure
- Human Health and Ecological Research to Inform Risk Assessment and Test Methods
- Risk Assessment Methods and Case Studies
- Preventing and Mitigating Risks

The National Toxicology Program (NTP) is designing and/or conducting studies on the following nanomaterials:

- Cadmium selenide based Quantum dots
- Titanium dioxide
- Fullerene-C60
- Multiwalled carbon nanotubes
- Ceric oxide
- Gold
- Silver

EPA is developing a series of case studies of selected nanomaterials as a means to identify what is known and what needs to be known to be able to assess the potential environmental and health implications of these materials. In the present context, the term case study should be understood to mean an illustration of issues, rather than a fully developed assessment. The draft case studies will be developed and released for invited review in 2007 and 2008. We intend to have a number of cases, each being a type of application from two classes of nanomaterials: nanoscale titanium dioxide and single-walled carbon nanotubes.

## **6. Information on any public/ stakeholder consultation.**

On August 2 EPA held a general public meeting to receive further public input and comment on the stewardship program.

EPA's Office of Pollution Prevention and Toxics (OPPT) held a scientific peer consultation September 6-7, 2007 on material characterization pertaining to nanoscale materials to support development of the stewardship program it is considering.

On September 25-26, 2007 EPA sponsored a conference on pollution prevention through nanotechnology. The purpose of the P2 conference was to exchange information and ideas on the potential environmental and pollution prevention benefits of innovative nanotechnologies and nanomaterials. A second area of concentration was to identify and promote stewardship opportunities associated with applications of nanotechnology.