Current developments in China on the safety of manufactured nanomaterials

Abstract

In our report we collected information on the following initiatives related to the safety of nanomaterials in China after the first meeting of the WPMN:

1. *Concerning nanometer biological material class medical devices product classification adjustment notice;*
2. *Published and implemented China Standards of nanotechnologies;*
3. *Research on the social implications of nanotechnology.*

Institute of Physics, Chinese Academy of Sciences
Notional Center for NanoSviences and Tecnology
National Technical Committee 279 on Nanotechnology of Standardization
Administration of China
04-17-2007

1. The adjustment of government regulation concerning product classification for medical devices made with nanometer biological materials

The State Food and Drug Administration of China (SFDA) announced a notice (document number 146, 2006) for all of its sub national bureaus to inform of the issue on the adjustment of product classification for medical devices made with nanometer biological materials, as follows:

In 2004, the National Bureau of the State Food and Drug Administration (SFDA) issued the regulation to classify the "nanometer silver antibiotic device for women's use" - a product produced using nanometer level metal silver material – as a Class II medical device. Currently, there are some 10 products made with nanometer level metal materials that have been registered and sold in the market as Class II medical devices. In view of the special characteristics of the nanometer level materials, it is decided, from the date of issuance of this regulation, that medical devices made with nanometer biological materials (for example medical instruments made with nanometer metal silver material) will be classified as Class III medical devices, and be subject to the administration of the relevant regulations of Class III medical devices. Nanometer biological material products that have been granted product license as Class II medical devices before the issuance of this regulation can continue their production within the validity of their product licenses. The production of these registered products may be sold within the validity of the produced products. When

the validity of the current product license has expired, the product should be re-registered as a Class III medical device in accordance with this regulation. For products that the SFDA has accepted the applications for license, but has not yet granted the license, they will be treated as Class III medical devices in the continued process of examination and registration. http://www.casmed.net/htm/apa/35.htm

2. Published and implemented China Standards of nanotechnologies

Up to date China standards for nanotechnologies as following:

(1) GB/T 18735-2002 General specification of nanometer thin standard specimen for analytical transmission electron microscopy (AEM/EDS) (Published: 2002-5-22; implemented: 2002-12-1)

(2) GB/T 19345-2003 Amorphous and nanocrystalline soft magnetic alloy strips (Published: 2003-01-01; implemented: 2004-05-01)

(3) GB/T 19619-2004Terminology for nanomaterials (Published: 2004-12-27; implemented: 2005-04-01)

(4) GB/T 13221-2004 Nanometer power-Determination of particle size distribution-Small angle X-ray scattering method(ISO/TS 13762:2001,MOD) (Published: 2004-12-27; implemented: 2005-04-01)

(5) GB/T 19587-2004 Determination of the specific surface area of solids by gas adsorption using the BET method(ISO 9277:1995,NEQ)(Published: 2004-12-27; implemented: 2005-04-01)

(6) GB/T 19588-2004 Nano-nickel powder (Published: 2004-12-27; implemented: 2005-04-01)

(7) GB/T 19589-2004 Nano-zinc powder (Published: 2004-12-27; implemented: 2005-04-01)

(8) GB/T 19590-2004 Nano-calcium carbonate (Published: 2004-12-27; implemented: 2005-04-01)

(9) GB/T 19591-2004 Nano-titanium dioxide (Published: 2004-12-27; implemented: 2005-04-01)

(10) GB/T 19627-2005 Particle size analysis-Photon correlation spectroscopy (ISO 13321:1996,IDT) (Published:2005-01-13; implemented: 2005-08-01)

(11) GB/T 15445.4-2006 Representation of results of particle size analysis—Part 2:Characterization of a classification process（ISO 9276－4：2001,IDT） (Published: 2006-02-05; implemented: 2006-08-01)

(12) GB/T 20307-2006 General rules for nanometer-scale length measurement by SEM (Published: 2006-07-19; implemented: 2007-02-01)

(13) GB/T 20099-2006 Sample preparation dispersing procedures for powders in liquids ISO 14887：2000,IDT）(Published: 2006-2-5 implemented: 2006-8-1)

Other Chinese Standards related to Nanotechnology as following:

1. GB 11847-1989 Determination of specific surface area of uranium dioxide

powder by multipoint BET method

(Published: 1989-10-21 implemented: 1990-08-01)

2. GB/T 13390-1992 Metallic powder — Determination of the specific surface area—Method of nitrogen adsorption

(Published: 1992-02-19 implemented: 1992-10-01)

3. GB/T 17507-1998 General specification of thin biological standards for X-ray EDS microanalysis in electron microscope

(Published: 1998-10-16 implemented: 1999-07-01)

4. GB/T 12334-2001 Metallic and other inorganic coatings--Definitions and conventions concerning the measurement of thickness idt ISO 2064：1996

(Published: 2001-01-02 implemented: 2002-06-01)

5. GB/T 18873-2002 General specification of transmission electron microscope(TEM)-X-ray energy dispersive spectrum(EDS) quantitative microanalysis for thin biological specimens 100nm-300nm

(Published: 2001-01-02 implemented: 2002-06-01)

6. GB/T 18907-2002 Method of selected area electron diffraction for transmission electron microscopes

(Published: 2001-01-02 implemented: 2002-06-01)

7. GB/T 10722-2003 Carbon black—Determination of total and external surface area by nitrogen adsorption

(Published: 2003-10-11implemented: 2004-05-01)

8. GB/T 19077.1-2003 Particle size analysis-Laser diffraction method ISO 13320-1:1999,MOD

9. GB/T 19921-2005 Test method of particles on silicon wafer surfaces

(Published: 2005-09-19implemented: 2006-04-01)

10. GB/T 19922-2005 Standard test methods for measuring site flatness on silicon wafers by noncontact scanning

(Published: 2005-09-19implemented: 2006-04-01)

(Published: 2003-04-01implemented: 2003-09-01)

11. GB/T 20725-2006 Electron probe microanalysis guidelines for qualitative point analysis by wavelength dispersive X-ray spectrometry ISO 17470:2004, IDT

(Published: 2007-03-26implemented: 2007-08-01)

12. GB/T 6524-2003 Metallic powders — Determination of particle size distribution by gravitational sedimentation in a liquid and attenuation measurement (ISO 10076:1991,IDT)

(Published: 1986-06-021implemented: 2004-05-01) (Substitute GB/T 6524-1986 Determination of particle size distribution of metallic powders by method of photosedimentation, ASTM B430-1979 NEQ)

13. GB/T 20170.1-2006 Test methods for physical characters of rare earth metals and their compounds--Determination for particle size distribution of rare earth compounds

(Published: 2006-04-131implemented: 2006-10-01)

14. GB/T 20170.2-2006 Test method of physiical characters of rare earth metals and compounds—Determination on specific surface area of rare earth compounds

(Published: 2006-04-13implemented: 2006-10-01)

Recently, the Ministry of Science and Technology (MOST) started to support standardization activities in nanotechnology including health, safety and environment.

3. Research on the social implications of nanotechnology

In China, about 1000 enterprises are involved in nanotechnology, the commercialization of which is gradually increasing. The main nano products in China are still nanoscale powders of oxides, metals, carbon nanotubes, fullerenes, their diverse derivatives, and applications of them such as those for coatings, fibers, fabric, papers, ceramics, catalysts, and nanomedicine, etc. But, most of the enterprises are still small. With the rapid development of application fields of nanotechnology, as has happened in many other countries, the issue of nanotechnology safety has given rise to serious public and governmental concern. Researchers from the Chinese Academy of Sciences (CAS) initiated activities to study the environmental and toxicological impacts of manufactured nanomaterials in 2001, including recognition, identification and quantification of the biological and environmental hazards resulting from exposure to diverse nanomaterials/ nanoparticles. In 2003, a formal research "Lab for Bio-Environmental Health Sciences of Nanoscale Materials" was established at the Institute of High Energy Physics, CAS. In this laboratory, researchers from nanoscience, biological, toxicological, environmental sciences and chemical fields work together to explore the biological and environmental (including both the positive and negative) effects of nanoscale materials. The research activities include not only ways to identify the possibly adverse effects of nanomaterials, but also ways to recover or reduce the release of nanoparticles in manufacturing processes, how to eliminate nanotoxicity, how to reverse-utilize nanotoxicity in clinical diagnoses and therapy by assimilating knowledge and techniques of nanoscience, toxicology, medicine, life sciences, chemistry and physics, etc.

In 2004, the highest-level scientific meeting organized by Chinese government, (a joint symposium organized by the Ministry of Science and Technology (MOST), the National Natural Science Foundation of China (NSFC), the Ministry of Education

(MOE) and CAS etc) was held in Beijing Fragrant Hill, focusing on the issues of "Nanosafety: Biological, Environmental and Toxicological Effects of Nanoscale Materials/Particles". Researchers from more than 20 universities and institutes, government officials and policy makers attended the symposium, presented their research data and exchanged ideas. Currently, more than 30 research organizations in China have initiated their research activities studying the toxicological and environmental effects of nanomaterials/ nanoparticles, and techniques of recovering nanoparticles from manufacturing processes.

Educational activities aiming at introducing nanotechnology to the public in China have thus far been few. Recently, China's Science Press established an editorial board to edit and publish a series of Nano-books for the public. Prof. Chunli Bai, the most famous nano-scientist in China, and the Executive President of CAS, has been invited to be the Editor-in-Chief. They plan to publish at least two books per year, and this publication plan will continue into the future. Every year, a "science week" is held in local areas in different parts of China, where introductory lectures on nanotechnology are given to a public audience.

In 2006, NCNST decided to establish the Nanosafety Lab focusing on the economic, environmental and social aspects of the research, standardization, regulations, etc. being done in connection with nanotechnology, and then signed an agreement with the Institute of High Energy Physics (IHEP), CAS, to co-build the China "Lab for the Bio-Environmental Effects of Nanomaterials & Nanosafety". This Lab was opened in August 2006, and includes two branches, one located at IHEP, CAS, and the other at NCNST. The missions of the China Nanosafety Lab mainly include, (1) Doing methodological and metrological studies of nanoparticle detection; (2) Identification and quantification of nano-hazards to humans and the environment; (3) Exploring the behaviors of nanoparticles in the environment (air, water, soil, and other parts including foods and nanodrugs, etc.), and their health impacts; (4) Accumulating experimental data on nanotoxicology and nano-ecology; (5) Drafting regulatory frameworks for research and industrial activities on nanotechnology; (6) Establishing standard procedures for safety assessment of nanoproducts for

nano-industries/ enterprises including assessment methods, and identifying the toxicity classes of nanomaterials.