KOREA

Highlight of developments since the 5th meeting of the WPMN

- MKE established KSA 6202 (Guideline to safe handling of manufactured nanomaterials in workplace/laboratories) as a national standard in 2009.
- MOE has developed the mid-term plan for The Risk management for nanomaterials (2010–2014).
- MOE organized the Nanomaterial Risk Expert Committee in order to share the expertise and experiences and establish the collaborative system for potential risk of nanomaterials.

Work completed, underway or planned

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 Korean government has not had any national regulatory development on human health and environmental safety on manufactured nanomaterials as yet. However, MOST (Ministry of Science and Technology) started the preliminary investigation of any needs in the new regulatory system and possibilities to apply the existing laws and rules to issues related to nanomaterials.

2 Developments related to voluntary or stewardship schemes

The Korean government has not had any national developments related to voluntary or stewardship schemes as yet.

3 Information on any risk assessment decisions

The Korean government initiated research projects as elaborated below in #5 this year including risk assessment part, but these are still in the initial stage.

The KATS is developing a guideline for exposure monitoring of nanomaterials such as CNTs and silver nanoparticle, and method for exposure assessment.

4 Information on any developments related to good practice documents

The further Korean government initiated projects related to good practice as elaborated below in #5.

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

The Korean government has well recognized the importance of potential risks of nanomaterials, and several projects are on progress, regarding on the human health and environmental safety issues of nanomaterials.

Ministry of Environment (MOE)

MOE has conducted the Eco-technopia 21 project to promote the development of environmental technologies since 2001. Under this umbrella, MOE started a project on human health and environmental
safety of nanomaterials, such as fullerene (C60), MWCNT, silver nanoparticles, TiO2, and SiO2, as target materials in the framework of Eco-technomia21 from April 2007, which will be continued until 2010. The ultimate goal of the research is to support the establishment of infrastructure in order to minimize potential risks possibly occurred from the manufacture, distribution and disposal of nanomaterials and nanomaterials-containing products. MOE implemented the projects such as ‘Research on the most relevant dosing metric for the ecotoxicity management system of manufactured nanomaterials (2009~2012)’ in order to find the correlation between the dosing metric and the risk assessment and ‘Genomic studies of nano-particles to bacteria, yeast and fish’ to develop alternative methods for nano-toxicity tests. Furthermore, ‘Guideline for the life cycle assessment (LCA) of nanomaterials’ and ‘Safety guideline for nano-safety management’ are under review.

MOE and NIER (National Institute of Environmental Research, a subsidiary body of MOE), have developed the Long-term Plan for the Risk Management for Nanomaterials including developing the inventory for nanomaterials, infra structures for the researches on the risk of nanomaterials, producing the data on the risk, toxicity, exposure, environmental fate, phy-chem properties of nanomaterials, etc. Furthermore, MOE and NIER take the key role on facilitating and conducting sponsorship programme under the close co-operation among ministries, academia, and industries.

NIER has been conducting 4 projects on the development of test methods and a database for risk assessment of manufactured nanomaterials (2007~2010). The prototype of the database and the environmental and mammalian toxicity tests for silver nanoparticles, MWCNT and titanium dioxide nanoparticles are on progress. NIER organized the Nanomaterial Risk Expert Committee and held the first meeting in September 2009. This committee handles the nanomaterial safety issues, which include the areas on developing test methods, evaluating the validation of the data and national planning on the nanomaterial risk assessment.

Ministry of Knowledge and Economy (MKE)

The Ministry of Knowledge Economy (MKE) in collaboration with the Ministry of Education, Science and Technology (MEST) has initiated the programme "Strategy on Nano Fusion Industry Development" to strengthen research on the safety and social impact of nanomaterials. The MKE/KATS implemented "Platform Technology on Risk management for Green Nanoproduct Development (2009-2013)" which will provide an infrastructure for certification of nano products based on a risk management system including characterization, efficacy, quality and safety assessment along with standard development.

The Korean Agency for Technology and Standards (KATS), an organization under MKE, has been developing national standards to ensure safety and support marketing of consumer products containing silver nanomaterials and CNTs. This work is due to Korea's role as an exporting country and to prepare for TBT (technical barrier to trade). KATS has published "Nanoparticle diameter measurement using TEM" (KSD 2716, 2008), and published KSA 6202(Guideline to safe handling of manufactured nanomaterials in workplace/laboratories as a national standard in 2009. KATS further proposed an international standard on "Preparation of MSDS (material safety data sheet) for nanomaterials", and is simultaneously developing a Korean standard for the preparation of MSDS in 2009. Guidelines for exposure monitoring, characterization, and safety assessment of nanomaterials such as CNTs and silver nanoparticles are in development. Accordingly, a guideline for exposure monitoring of nanomaterials has already been launched.

Korea Food & Drug Administration (KFDA)

KFDA has been operating the Nanotoxicology Project since 2007. The Nanotoxicology Project focuses mainly on preparing guidelines to evaluate safety and effectiveness in newly-developed foods,
drugs, medical devices and cosmetics using nanoscale materials. Research areas in the Nanotoxicology Project encompass a wide range of safety issues related to manufactured nanomaterials including toxicological evaluation, risk assessment, reduction of potential health risk, toxico/pharmaco-kinetics (TK/PK) and physico-chemical characterization.

Silica, silver, gold, iron oxide, quantum-dot, zinc oxide, titanium dioxide, carbon nanotube and chitosan nanoparticles have been used as test materials for preparation of guidelines to evaluate safety and effectiveness. Effects of size, shape and surface character of nanomaterials on general toxicity, genotoxicity, immune response, developmental and reproductive toxicity, PK profile, uptake mechanism, interaction with biomaterials were mainly investigated. We plan to conduct in-depth studies on the nanomaterials mentioned above to understand the mechanism of toxicity and to identify physico-chemical characterizations.

**KRISS (Korea Research Institute of Standard Science)**

KRISS has been developing the National Measurement Standards of (nano) materials. In connection with this topic, the research projects on the physico-chemical properties in line with *in vivo* toxicity testing and the development of reference materials for silver, gold, titanium dioxide, polystyrene, silicon dioxide, CNTs and quantum dot are ongoing. Surface structures and its compositions are studied using XPS, MALDI-ToF, ToF-SIMS etc... The size measurement of nano particles is also executed out with SMPS, DLS, PBMS, TEM, BET and AFM as a part of OECD-WPMN and VAMAS (TWA34) projects. Nanoparticle trace technology using ToF-SIMS and Raman spectroscopy is under developing. Regarding ADME, studies on the transport and potential transformation of nanomaterials is under investigation.