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**COMMITTEE OF EXPERTS ON THE TRANSPORT OF
DANGEROUS GOODS AND ON THE GLOBALLY
HARMONIZED SYSTEM OF CLASSIFICATION
AND LABELLING OF CHEMICALS**

Sub-Committee of Experts on the Globally Harmonized
System of Classification and Labelling of Chemicals

Seventeenth session
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Item 8 of the provisional agenda

OTHER BUSINESS

Ongoing work on the safety of nanomaterials

Transmitted by the expert from France

1. At the last session of the Sub-Committee, the expert from France was invited to provide further information related to nanomaterials (see ST/SG/AC.10/C.4/32, para. 83). This document contains information about nanotechnology and current work about nanomaterials.

Introduction

2. Nanotechnology is a collective term for a range of technologies, techniques and processes involving the manipulation of matter at the molecular level, systems that typically possess at least one physical dimension in the range 1-100 nanometres. Such systems may possess entirely new physical and chemical characteristics, resulting in properties that are neither well described by those of a single molecule of the substance, nor by those of the bulk material. These new characteristics can generate a vast array of novel products. Nanotechnology promises significant social benefits, including enhancements in medical diagnosis and treatment, more efficient energy sources, lighter, stronger and cheaper materials and electronic products and cleaner, cheaper water.

3. The market is growing very quickly and presence of nanotechnology becomes a reality in our daily life. Indeed, more than 800 products have been referenced in an international data base (<http://www.nanotechproject.org>). More than 2000 nanomaterials were put on the market (<http://www.nanowerk.com>). Chemical substances manufactured at a nanoscale are an actual breakthrough in chemistry. Such substances may have new properties regarding the same chemical composition at another scale (conventional form) or between different nanoforms with high level of innovation.

4. However, it appears important to reassure the public, taking into account the uncertainties emerging from the rapidly growing number of new nanotechnologies which involve dissemination of nanoparticles during all the cycle of life. Moreover, it would be better to have a coherent approach at the international level and to encourage synergies and cooperation between all the stakeholders in order to be successful in building adequate governance, in ensuring an adequate implementation of existing regulation, and, when needed, amending regulation or completing it.

5. There is a crucial and urgent need for research on health, safety and environment, bearing in mind the behaviours of particles at a nanoscale and the associated difficulty to characterize their physical and chemical properties. In addition, the development of relevant, validated methods becomes a priority in order to correctly identify nanomaterials before carrying out any toxicity study. To achieve all these goals, it becomes strictly necessary that the European and international work is supported and that, if possibly and appropriate, discussions in other fora such as the United Nations and the World Health Organization starts.

A. WORK IN THE EUROPEAN UNION

1. European Commission Communication

6. A communication on the regulatory aspects of nanomaterials to the European Parliament, the Council and the European Economic and Social Council was made by the European Commission on 17 June 2008 (COM(2008)366 final of 17.6.2008¹)

7. The conclusions were that the current legislation covers in principle the potential health, safety and environmental risks in relation to nanomaterials. The protection of health, safety and the environment needs mostly to be enhanced by improving implementation of current legislation. Knowledge on essential questions such as characterisation of nanomaterials, their hazards, exposure, risk assessment and risk management should be improved.

8. As knowledge becomes the critical factor for implementation and, eventually, regulation, targeted actions in a number of areas and at different levels, particularly in the field of research and development, were launched as a matter of priority. Activities are coordinated with international partners and stakeholders in the appropriate fora, such as the Organisation for the Economic Co-operation and Development (OECD) and the International Standardisation Organization (ISO).

9. Commission working groups in charge of coordinating implementation of legislation are examining, on an ongoing basis, whether a regulatory change on specific aspects is necessary,

¹ <http://eur-lex.europa.eu>

taking into account the continuously generated information linked with the identified knowledge gaps. They will take into consideration work that has been carried out in this respect at national and international level.

10. Authorities and agencies in charge of implementing regulation should continue to carefully monitor the market.

11. The Commission intends to report on progress in these areas three years after the presentation of this Communication.

2. Regulation (EC) No. 1907/2006: Regulation concerning the registration, evaluation, authorisation and restriction of chemicals (REACH)

12. An ad-hoc group “nanomaterials and REACH” started in July 2008 and is planned to work until December 2012 which corresponds to the deadline for the regulation of chemicals.

13. A first document entitled “Nanomaterials in REACH”² was endorsed by the Competent Authorities on 16 December 2008 and published on the European Commission’s website.

14. This document describes how REACH applies to nanomaterials focusing on definitions, registration and assessment, communication down the supply chain, evaluation, authorisations and restrictions. It states in particular that REACH is applicable to substances in whatever size or form and for all their identified uses. Nanomaterials having specific properties may require a different classification and labelling compared to the bulk material, also when the nanoform is derived from a bulk substance. Questions have been raised especially how nanomaterials with different kind of surface modifications should be seen as belonging to the same substance or whether they should be considered as separate substances, and also in which respect a nanomaterial consisting of layers should be considered as a substance or a mixture.

15. Regardless of quantities produced, suppliers of a dangerous substance or mixture must provide a safety data sheet (SDS) (article 31 of REACH). It is also a common practice for suppliers of chemicals and nanotechnology to provide SDS also for other substances. As a consequence, SDS has become a standard means of providing information on substances down the supply chain. The European Commission’s document mentions also that nanoform information (composition and information on ingredients, handling and storage, exposure controls: personal protection, physical and chemical properties, toxicological and ecotoxicological informations) has to be included in SDS and clearly recognisable in it, e.g: by using specific headings.

16. Further work of the working group is planned on other aspects of the application of REACH to nanomaterials including substance identification.

3. Scientific Committee on Emerging and newly Identified Health Risks (SCENIHR)

17. SCENIHR adopted an opinion about Risk assessment of nanotechnologies³ at its 28th plenary held on 19 January 2009. This opinion deals with the recent developments in the risk assessment of nanomaterials for both humans and the environment. Currently, the procedure for

² <http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf>

³ <http://ec.europa.eu/health/>

assessing the potential risks of manufactured nanomaterials is still under development. Indeed, the knowledge on the methodology for both exposure estimation and hazard identification needs to be further developed, validated and standardised. As already detailed in previous SCENIHR opinions (SCENIHR 2006, SCENIHR 2007a), free and low solubility nanoparticles (nanomaterials) are a priority concern in the context of human and environmental risk.

18. The nanomaterial should be characterised as it is produced by a manufacturer, resulting in information that may be used for safety evaluation and the Safety Data Sheet (SDS) of the nanomaterial (nanoparticle) itself. In addition, the nanomaterial should be characterised as it is used in biological systems for safety evaluation (possible coating with proteins). The preparation of nanomaterials for use in biological systems may considerably change nanomaterial properties, notably the size distribution due to agglomeration/aggregation of the particles. A consensus is now emerging regarding the physico-chemical properties that need to be determined in the characterisation of nanomaterials and which properties may be important in the risk assessment of nanomaterials. There is also a need for reference nanomaterials.

19. Currently, the definition of what is “nano” is still under debate. Generally nanomaterials are defined as being smaller than about 100 nm in at least one dimension. However, when a nanomaterial is in particulate form, the particles may be present as single particles but might also be present as agglomerates/aggregates. When describing a nanomaterial it is important to describe not only the mean particle size but also the size of the primary particles. In addition, information on the presence of agglomerates/aggregates should be presented. In addition to size, the specific surface area as determined by Brunauer, Emmett, and Teller (BET) method⁴ is a good metric to describe particulates, as this metric is independent of the primary versus the agglomerated state.

20. There is a need to further establish reliable and standardised measurement techniques, to develop measurement strategies, and to further implement screening/monitoring of nanoscale particles in sensitive work areas. Challenges are currently seen, especially in the detection and assessment of manufactured nanoparticles in the environment. Similarly, exposure estimates for consumers from food and consumer products remains difficult. Key issues are raised concerning the toxicokinetics, genotoxicity and environmental fate. Additional Research is urgently needed. As there is not yet a generally applicable paradigm for nanomaterial hazard identification, a case by case approach for the risk assessment of nanomaterials is recommended.

4. Joint action for safety of nanomaterials under the Public Health Program 2009

21. The European Commission has adopted a work plan for 2009 for the implementation of the second programme of Community action in the field of health (2008-2013) and the selection, award and other criteria for financial contribution to the actions of this programme, following an initial proposal from France.

22. This work plan calls, under section 3.2 “Improve citizens’ health security”, for a 3 year joint action about the safety of nanomaterials, paragraph 3.2.2.3 “Safety of nanomaterials”⁵. This program has been published as Commission Decision 2009/158/EC of 23 February 2009. In

⁴ http://en.wikipedia.org/wiki/BET_theory.

⁵ <http://eur-lex.europa.eu/>

support of the safe, integrated, and responsible development path chosen by Europe for nanoscience and nanotechnologies, the purpose of this Joint Action is:

- “(i) to strengthen, expand, and share the knowledge required for the assessment of the hazard, exposure, and overall risk of nanomaterials, (ii) to accelerate the exploitation of existing data and the exchange of best practices in risk assessment and management, and (iii) to promote the establishment of robust methodologies throughout the EU.”

23. A consensus has been reached in order to comply with the aim of the joint action as drafted: “genotoxicity and kinetics ring testing”. It has been decided that the major aim is addressing “Gaps for Risk Assessment of nanomaterials”: generation data for risk assessment on nanomaterials available on the market and likely to be used in consumers products with a potential of large exposure for consumers and workers. The other aim is to elaborate robust methodologies or to optimize existing methodologies in order to improve risk assessment. The following types of nanomaterials used for testing have been selected:

- (a) Silicon dioxide: high volume of production, different type of applications including food usages;
- (b) Titanium dioxide: high volume of production, different type of applications including cosmetics usages;
- (c) Carbon nanotubes: high risk of toxicity, different types of usages including leisure and sport clothes.

B. INTERNATIONAL ACTIVITIES

1. Standardisation: ISO Technical Committee on nanotechnologies (ISO TC 229 “nanotechnologies”)⁶ (33 participating countries, 7 observing countries)

24. The lack of scientific knowledge on the effects of specific nanomaterials (particularly nanoparticles) on human health and the environment, has led to concern over the environmental, health and safety risks potentially associated with nanotechnology and its products. International standardization will play a critical role in ensuring that the full potential of nanotechnology is reached and that nanotechnology is safely integrated into society. Standards are expected to help create a smooth transition from the laboratory to the marketplace, promote progress along the nanotechnology value chain (from nanoscale materials that form the building blocks for components and devices to the integration of these devices into functional systems) and facilitate global trade.

25. Four categories of standards are proposed:

- (a) Terminology and nomenclature standards (Working Group 1) provide a common language for scientific, technical, commercial and regulatory processes;

⁶ http://www.iso.org/iso/standards_development/technical_committees

- (b) Measurement and characterisation standards (Working Group 2) provide an internationally accepted basis for quantitative scientific, commercial and regulatory activities;
- (c) Health, safety and environmental standards (Working Group 3) improve occupational safety, and consumer and environmental protection, promoting good practice in the production, use and disposal of nano-materials, nanotechnology products and nanotechnology-enabled systems and products;
- (d) Specific applications of nanomaterials (Working Group 4) which lead to harmonised specifications.

26. Since the beginning of the work in 2005, two documents have been published in 2008:

- (a) One technical report (ISO/TR 12885/2008) describes health and safety practices in occupational settings relevant to nanotechnologies, focusing on the occupational manufacture and use of engineered nanomaterials.
- (b) The other one (ISO/TS 27687/2008 “Terminology and definitions for nano-objects - Nanoparticle, nanofibre and nanoplate”) lists unambiguous terms and definitions related to particles in the field of nanotechnologies with the aim to facilitate communications between organizations and individuals in industry and those who interact with them.

27. Some projects deserve particular attention as explained below.

Working group 1 “terminology and nomenclature”: Task Group for the development of a Nomenclature Model for nanomaterials (leader: representative of Canada)

28. The idea is to build, in cooperation with the International Union of Pure and Applied Chemistry (IUPAC), a nomenclature for naming unambiguously nanomaterials taking into account, at least the specific physical and chemical parameters:

- (a) size of the particles and their granulometric distribution;
- (b) surface chemical reactivity;
- (c) core and/or shell composition;
- (d) crystalline structure;
- (e) functionalisation (coating);

Working Group 3 “Health Safety and the Environment”: Guidance on Physico-chemical parameters of engineered nano-objects for toxicological assessment (leader: representative of the United States of America).

29. The following criteria have been selected at the last meeting in Shanghai (November 2008):

- (a) Particle size and size distribution;
- (b) Agglomeration state and aggregation;
- (c) Shape;
- (d) Composition including chemical composition, crystal structure, purity/impurity;
- (e) Surface area;
- (f) Surface chemistry including catalytic activity, chirality, special considerations where particle is all surface such as dendrimers;
- (g) Surface charge;
- (h) Solubility/Dispersibility;

30. In a view to work on measurements and associated methods, a task group with experts from Working Group 2 (“measurements and metrology”) and Working group 3 has been created and will report to the next plenary in Seattle in June 2009.

Material Safety Data Sheets for nanomaterials

31. A proposal from a representative of the Republic of Korea about preparation of Safety Data Sheets (SDS) for nanomaterials is under ballot closing on 29 April 2009. Regulations require preparation of a SDS for hazardous chemicals, including those containing nanoscale materials, for use in manufacture, storage, transport or other handling activities. Yet, there remain few nanomaterial specific SDSs. Those that exist generally provide insufficient information. Nanoparticle characteristics predictive of potential safety hazards or toxicity for engineered nano-scale materials need to be identified and interpreted for SDS end-users, and this document will enable that process. The second revised edition of the “Globally Harmonized System of classification and labelling of chemicals” is mentioned as a document to be considered the relationship of the project with the activities of other international bodies especially the United Nations, the OECD and the European Commission is also mentioned.

2. Organisation for Economic Co-operation and Development (OECD)

32. The OECD Working Party on Manufactured Nanomaterials⁷ (WPMN) was established in September 2006. 30 OECD members, and some observers (6 countries, WHO, and NGOs such as ISO and BIAC participate. The objective is to promote international co-operation in human health and environmental safety aspects of manufactured nanomaterials. There are eight projects covered under “steering groups” on the following subjects: overview of ongoing and planned research; legislation and voluntary schemes; test data on substances; nanomaterials and OECD tests methods; alternative methods; risk assessment and exposure.

33. The third project concerns safety testing of a representative set of manufactured nanomaterials⁸. The aim is to understand which kind of information on intrinsic properties may

⁷ <http://www.oecd.org/>

⁸ <http://www.olis.oecd.org>

be relevant for exposure and effect assessment of nanomaterials by testing representative nanomaterials. 59 endpoints have been defined in the following different areas:

- (a) Nanomaterial information/Identification;
- (b) Physical and chemical properties and material characterisation;
- (c) Environmental toxicology;
- (d) Mammalian toxicology;
- (e) Material safety.

34. A sponsorship programme has been put in place for the testing of manufactured nanomaterials. 14 nanomaterials have been selected for inclusion in a priority list for testing, and the testing of 9 out of 14 is already sponsored. The outcome will provide a world-wide “base-line” for nanomaterials. The applicability of accepted methodologies for non nanonose scale substances to nanomaterials will be better understood, leading to possible revisions of those methodologies. This program will provide a basis for evaluating adequacy of current legislation.

C. QUESTIONS

- 35. Can it be considered, for the same chemical (same CAS and purity) that nanomaterials with new properties have the same hazards as conventional form?
 - 36. Is it possible to distinguish for a same chemical, the properties of its different nanoforms?
 - 37. How can this be done? Should new endpoints be determined?
 - 38. To which extent information about nanomaterials need be provided?
 - 39. What kind of information is needed?
 - 40. What kind of communication tool is needed for this purpose?
 - 41. What kind of collaboration can be suggested in order to contribute to clarification of nanomaterials hazard classification and indeed to health safety and environmental issues of nanomaterials?
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