

European Commission

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 Commission is performing a regulatory inventory, covering EU regulatory frameworks that are applicable to nanomaterials (chemicals, worker protection, environmental legislation, product specific legislation etc.). The purpose of this inventory is to "examine and, where appropriate, propose adaptations of EU regulations in relevant sectors" as expressed in Action 6d) of the Commission Action Plan. Preliminary findings indicate that the regulatory frameworks in principle give a good coverage; different aspects of production and products are at the same time subject to various Community provisions. Implementation is facilitated by different types of documents, adopted within this regulatory framework, such as implementing legislation, European standards, regulatory and technical guidance documents that may have to be adapted in order to cover HSE risks in relation to nanomaterials. However, many of the knowledge gaps (toxicity thresholds, test schemes etc) will need to be addressed to ensure implementation and adaptation of 'supporting documents'. Those knowledge gaps are in line with the ones earlier identified by EC and others and reported to the OECD. The Commission's report therefore will also indicate initiatives undertaken (e.g. Research Framework Programmes, activities of Joint Research Center, cooperation within OECD, standardisation, Scientific Committees) in order to improve knowledge levels, so as to allow a proper implementation of the EU regulatory framework.

In the chemicals regulatory area, EU competent authorities (CAs) have decided that:

- a. The decisive criterion whether a nanomaterial is a new or existing substances is the same as for all other substances, i.e. whether or not the substance is on EINECS. When a nanomaterial is derived from an existing substance, article 7.1 of the Existing Substances Regulation 793/93 (ESR) on the updating of reported information applies.
- b. 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.
- c. They invite industry to provide a number of dossiers on different representative nanomaterials, to show what kind of data is available, how risk assessment is being performed and how the risks are controlled.
- d. For the longer term, a review of the applicability of testing methods and risk assessment methods should be carried out. This should be done at international level (e.g. within the OECD chemicals programme) with active input from industry and contributions from the EU.

REACH (regulation (EC) No 1907/2006) was adopted on the 18 December 2006 and published in the Official Journal of the European Union on 30.12.2006. REACH will gradually revoke and replace several of the existing EU legislation on chemicals. REACH entered into force on 1st June 2007. The European Chemical Agency ECHA in charge of following-up the registration, the evaluation and the authorisation process under REACH, was opened on the same day in Helsinki. Nanomaterials are covered by the provisions of this Regulation.

2. Developments related to voluntary or stewardship schemes

The EC has not developed any voluntary or stewardship schemes at this stage. Issues regarding information on nanomaterials will be discussed in the chemicals CAs working group, also as a follow-up to 1.c. above.

3. Information on any risk assessment decisions

In relation to nanomaterials in chemicals legislation, risk assessment and management is implemented at this moment as for other chemicals in the framework of the current legislation on new and existing chemicals (see 1.a. above). More specific guidance and information may be required in the future.

The EU Scientific Committee on Emerging and Newly Identified health Risks (SCENHIR) has produced two Opinions in relation to nanomaterials risk assessment, respectively on 10 March 2006, and on 21-22 March 2007. In its first opinion, SCENHIR concluded that the existing toxicological and ecotoxicological methods are appropriate to assess many of the hazards associated with the products and processes involving nanoparticles, but that they may not be sufficient to address all the hazards. Therefore the risk assessment needs to be done on a case-by-case basis. The assays may need to be supplemented by additional tests, or replaced by modified tests, as it cannot be assumed that current scientific knowledge has elucidated all the potential adverse effects of nanoparticles. Specifically, attention needs to be given to the mode of delivery of the nanoparticles to the test system to ensure that it reflects the relevant exposure scenarios.

For exposure, SCENIHR also expressed that the use of mass concentration data alone to express dose is insufficient, and the number concentration and/or surface area would need to be used as well. Equipment that enables routine measurements for exposure to free nanoparticles is not yet available. In particular, existing methods used for environmental exposure assessment may not necessarily be appropriate for determining the environmental fate of nanomaterials. Consequently, current risk assessment procedures may require modification for nanoparticles both regarding test methods for hazard identification and exposure assessment.

The SCENHIR suggested that there is insufficient knowledge and data concerning nanoparticle characterisation, their detection and measurement, the fate (and especially the persistence) of nanoparticles in humans and in the environment, and all aspects of

toxicology and environmental toxicology related to nanoparticles, to allow for satisfactory risk assessments for humans and ecosystems to be performed.

In its second opinion, dealing particularly with the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents (“TGD”) for new and existing (chemical) substances for assessing the risks of nanomaterials, the SCENHIR concluded that current methodologies described in the TGDs are likely to identify certain hazards, but modifications are required for the assessment of risks to human health and the environment.. Furthermore, the opinion highlights needs to determine appropriateness of current test procedures for the prediction of human health hazards and estimation of risks for all types of nanoparticles. In particular, the SCENIHR focussed on the potential of nanomaterials to reach new target organs in the body, when administered in similar ways than bulk chemicals (translocation). This observation would lead to additional requirements of test methods to demonstrate potential new hazards.

On 19 June 2007, the Scientific Committee for Consumer Products (SCCP) adopted an Opinion for public consultation in June 2007 on safety of nanomaterials in cosmetic products. For labile particles, conventional risk assessment methodologies based on mass metrics may be adequate, whereas for the insoluble and slowly soluble particles other metrics, such as the number of particles, and their surface area as well as their distribution are also required. It is crucial when assessing possible risks associated with nanoparticles to consider their uptake. It is primarily for the insoluble and slowly soluble particles that health concerns related to possible uptake arise. Should they become systemically available, translocation/ transportation and eventual accumulation in secondary target organs may occur. The Committee also identifies a number of knowledge gaps. More particularly as regards the ban on animal testing with respect to cosmetics, the Committee takes note that at present no methodology has been validated for nanomaterials. Finally, the Committee states that review of the safety of the nanomaterials presently used in cosmetics is required.

4. Information on any developments related to good practice documents

The Commission is closely following the work in ISO and CEN. Both nanotechnology related Technical Committees in ISO (TC 229) and in CEN (TC 352) are currently working on the nomenclature and hence on the definition aspects. In ISO/TC 229, the working group on Health, Safety and Environment is proposing a Technical Report on "Current Safe Practices in Occupational Settings Relevant to Nanotechnologies". In addition, in ISO/TC 146 on Air Quality, the SC2 subcommittee on Workplace atmospheres has released a technical report ISO/TR 27628:2007 "Ultrafine nanoparticles and nano-structured aerosols – Inhalation exposure characterization and assessment". In ISO/TC 24/SC4 (Sizing by methods other than sieving), the particular issue of nanoparticle size measurements and the required reference materials is considered with more care

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

As stated in Action Plan on Nanosciences and Nanotechnologies (N&N), the European Commission aims at reinforcing N&N research and development in the seventh framework programme for research, technological development and demonstration activities (FP7) and has proposed a significant increase of the budget compared to FP6.

It has also committed itself to boost support for collaborative R&D into the potential impact of N&N on human health and the environment via toxicological and ecotoxicological studies as well as developing appropriate methodologies and instrumentation for monitoring and minimising exposure in the workplace.

Activities in FP7 have been started: In the first call for proposals, several topics were launched specifically addressing the safety of nanomaterials. The proposals received in these topics have all now been evaluated and the research projects will begin by the start of 2008 (except for one that has already started).

NMP-2007-1.3- 1 (Large scale integrating projects)	Specific, easy-to-use portable devices for measurement and analysis
NMP-2007-1.3- 2 (Small or medium-scale focused research projects)	Impact of engineered nanoparticles on health and environment
NMP-2007-1.3- 3 (Coordination and support actions)	Critical review on the data and studies on the potential impact on environment and health of nanoparticles
NMP-2007-1.3- 4 (Coordination and support actions - only one database and support action will be funded)	Creation of a critical and commented database on the impact of nanoparticles
NMP-2007-1.3- 5 (Coordination and support actions)	Coordination in studying the environmental and health impact of nanoparticles and nanotechnology based materials and products
HEALTH-2007-1.3- 4 (Small or medium-scale focused research projects) Call coordinated with NMP-2007-4.1.3-2/4.4-4	Alternative testing strategies for the assessment of the toxicological profile of nanoparticles used in medical diagnostics

Dedicated calls are foreseen among the next actions of the FP7, in particular the second calls launched on 30 November 2007, with two dedicated topics:

- NMP-2008-1.3-1 Validation, adaptation and/or development of risk assessment methodology for engineered nano-particles
- NMP-2008-1.3-2 Impact of engineered nanoparticles on health and the environment

Additionally, the European Commission has supported a nano-related pilot projects under the umbrella of “Transatlantic methods for handling global challenges”. The objective of the pilot project is to fund innovative ventures between European and US policy makers that cannot be pursued under existing EU-US instruments of cooperation, and to promote mutual learning amongst EU and US policy researchers and policymakers on more effective transatlantic approaches to challenges with a global dimension.

With this background, a Call for Proposals was launched to identify eligible projects in a variety of areas, among them, in particular

- Safety of nanotechnologies. Building on experience from the EU’s 6th Research Framework Programme, promote closer international cooperation with economically advanced countries in nanoscience and nanotechnologies in order to share knowledge and reap the benefits of critical mass.

The JRC is developing a research activity in collaboration with EU partners on risk assessment of engineered nanomaterials. The activities in FP7 focus on the development and harmonization of methods for toxicity testing of nanomaterials, the in vitro test of a representative set of MN on critical cell lines and encompass related studies on nanometrology and reference materials as well as the development of databases and studies on the applicability of 'in silico' methods adapting the traditional QSAR paradigm.

The Commission is considering supporting the development of a database containing substance information specific to nanomaterials. IUCLID could serve as a basis and could be further developed and adapted to the requirements related to nanomaterials datasets.

6. Information on any public/ stakeholder consultation

On 18 July 2007, the European Commission announced a public consultation on a Recommendation on a Code of Conduct for Responsible Nanosciences and Nanotechnologies Research. The consultation, that was open until 21 September, will provide input for a Recommendation on governance of this emerging area of science, which the Commission will put forward later this year. Contributions were received from a broad cross-section of European society, including the scientific community, industry, civil society, policy-makers, media and the general public.

The European Commission also open a Open Consultation on the Strategy on communication outreach in nanotechnology; The public and other stakeholders were invited to comment on the report and results from a workshop held by the European Commission in Brussels, February 6th 2007. This paper shaped operative recommendations for future European funding on appropriate communication and innovative approaches to engage the European civil society into a dialogue on nanotechnology. Experts in the field of science communication share success, best practices and challenge stories, to give to different audiences a "voice" in the policy making process. As a result, a set of recommended activities for Europe were outlined, which could be commented

The opinions from EU Scientific Committees, SCENIHR and SCCP are always submitted to public consultations before final adoption.

Several conferences on nanotechnology have been organised by different organisations throughout the EU and by recent EU Presidencies. The Finnish Presidency of the EU organized a conference on "Nanotechnologies: Safety for Success" in September 2006. In October 2007 the European Commission organised the another stakeholder dialogue related to consumer products.

7. Additional Information

The European Group on Ethics in Science and New Technologies (EGE) is a high-level group of independent experts on ethics appointed by President Barroso. The EGE advises the Commission on ethical issues related to science and technology or other relevant EU policies. The Group adopted an Opinion on ethical aspects of Nanomedicine in January 2007 (http://ec.europa.eu/european_group_ethics/index_en.htm).

Several research projects funded by the European Commission are related to innovation, ethical aspects and societal implications of nanotechnology. Additional information can be found at <http://cordis.europa.eu/nanotechnology/>. Linked to the European Technology Platform on Sustainable Chemistry, several documents are becoming available such as a code of conduct on nanotechnology; a guide on safe manufacturing and for activities involving nanoparticles at workplaces; and detailed information on the characterisation of nanomaterials. Moreover, the recent Nanosafety Hub event organised by the European Technology Platform on Industrial Safety (ETPIS) on the 23rd March 2007 in Brussels, BE provided an overview of progress on the development of detection and monitoring technologies and the state-of-the-art in the fields of toxicity of nanoparticles, secured integrated processes as well as workplace health, safety and environmental safety all linked to nanomaterials (more information are available on <http://www.industrialsafety-tp.org/> & http://euvri.risk-technologies.com/events/event_3/default.htm).

A standardization mandate is currently in consultation with Member States to formally convey priorities to the European standards bodies and to request feedback on their

activities. The European standards bodies are invited to forward a program of activities to the European Commission and Member States that subsequently can be endorsed by Commission and national authorities. The mandate states that European standardisation efforts will preferably be elaborated in cooperation with the international standards bodies.