EUROPEAN COMMISSION

Highlight of developments since the 3rd meeting of the WPMN


- On 1 June 2008 REACH (Registration, Evaluation, Authorisation of Chemicals) became operational and the six month pre-registration period for phase-in substances commenced. For further information consult the website of the European Chemicals Agency (ECHA); http://echa.europa.eu/home_en.asp.

- On 30 May 2008, the Commission Regulation (EC) No 440/2008, laying down test methods pursuant to the REACH Regulation (EC) No 1907/2006, was adopted. The regulation reinforces the 3R approach to animal testing and aim at an adoption of new alternative methods in a more expedient way than in the past. The Commission is preparing a proposal for the first adaptation to technical progress of this Regulation by the end of 2008.

- The European Commission organised on 17 – 18 April 2008 in Brussels a "Workshop on research projects on the safety of nanomaterials: reviewing the knowledge gaps", The agenda, proceedings and presentations, please consult: http://cordis.europa.eu/nanotechnology/src/publication_events.htm

- The REACH Competent Authorities Group established on 27 March 2008 a sub-group on Nanomaterials to exchange views on existing and arising implementation issues and other matters in relation to nanomaterials under REACH. It is composed of experts from the Competent Authorities in the EU Member States, ECHA and from stakeholders from industry and NGOs. On this basis, the CASG-Nano will provide recommendations to the REACH CAs and the Commission. The group is planned to meet at twice yearly intervals starting on 1-2 July 2008.

- The European Commission adopted on 7 February 2008 a "Recommendation to the Member States on a Code of Conduct for Responsible Nanosciences and Nanotechnology Research", in line with the objective of the Community's Nanotechnology Action Plan. Based on seven principles; i) meaning (activities should be comprehensible); ii) sustainability; iii) precaution; iv) inclusiveness (with regard to stakeholders); v) excellence; vi) innovation; and vii) accountability (with regard to social and other impacts). The Code of Conduct contains suggestions for actions to be taken on good governance and due respects for precaution for responsible nanosciences and nanotechnology research. For further information see: ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/nanocode-recommendation-pe0894c08424_en.pdf
The EU Scientific Committee on Consumer Products has adopted an opinion on "Safety of Nanomaterials in Cosmetic Products" in December 2007, the EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) adopted in June 2007 an opinion on "the appropriateness of the risk assessment methodology in accordance with the Technical Guidance Documents for new and existing substances for assessing the risks of nanomaterials" and in November 2007 an opinion a Scientific review of definitions related to the products of nanotechnology.

A draft Regulation proposal on the classification and labelling of chemicals based on the Global Harmonised System, adopted by the Commission on 27 June 2007 repealing the EU Directives 67/548/EEC and 1990/45/EC on classification and labelling of substances and preparations. The proposal is now examined by the Council and Parliament, see http://ec.europa.eu/enterprise/reach/ghs_en.htm

The first call for proposals in the 7th EU Research Framework Programme (FP7) was published on 22 December 2006. The proposals received on these topics have been evaluated and the research projects begin this year. Of particular interest is the coordination action "NanoImpactNet" (http://www.nanoimpactnet.eu/). The objective of the NanoImpactNet is to create a scientific basis to ensure the safe and responsible development of engineered nanoparticles and nanotechnology-based materials and products, and to support the definition of regulatory measures and implementation of legislation in Europe. The following basic forms of activities are planned:

- Promotion of coordination on test strategies and methods; screening tools; risk assessment tools; and risk assessment methodologies.
- Sharing and discussing existing knowledge in order to identify knowledge gaps; define strategies to address these gaps; and train staff and students.

The second call for proposals in the 7th EU Research Framework Programme (FP7) was published on 30 November 2007. The proposals received will be evaluated in autumn. Updates on research projects open in 2008 funded by the European Commission can be found at:


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

According to the new regulatory review, existing EU 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. The Commission and EU Agencies will therefore in the first place review current documents that support implementation, such as implementing legislation, standards and technical guidance with regard to their applicability and appropriateness to nanomaterials.

Knowledge on essential questions such as characterisation of nanomaterials, their hazards, exposure, risk assessment and risk management should be improved. As knowledge becomes the critical factor for implementation and, eventually, legislation, 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, particularly through FP 6 and 7, and the European Commission’s Joint Research Centre. Activities are coordinated with international partners and stakeholders in the appropriate fora, such as the OECD and ISO.

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

Authorities and Agencies in charge of implementing legislation should continue to carefully monitor the market, and use Community market intervention mechanisms in case risks are identified for products already on the market.

A new sub-group under REACH (CASG Nano) focussing on nanomaterials has been set-up with a view to discuss how REACH applies to nanomaterials. The objective is to exchange views on existing and arising implementation issues and other matters in relation to nanomaterials under REACH. On this basis, the group will provide recommendations to the REACH Competent Authorities advising the Commission.

2. Developments related to voluntary or stewardship schemes

The European Commission has not developed any voluntary programmes or stewardship schemes. These and general issues regarding information on nanomaterials will be discussed in the CASG Nano.

3. Information on any risk assessment decisions

The European Commission has not taken any risk assessment decisions since the last Tour de Table document issued in November 2007 (ENV/CHEM/NANO(2007)16) of relevance in the context of nanomaterials. However, the European Commission has requested the Scientific Committee on Emerging and Newly Identified Human health Risks (SCENIHR) to identify and assess new information and update the opinions on potential risks of products of nanotechnologies, in particular, with respect to characterisation, eco-toxicology and toxicology as well as exposure assessments. The update should:

1. Provide, on the basis of the results obtained, recommendations on:
   - improvements of existing test methods and/or on the development of new ones, including in vitro and in vivo methods, to address aspects specific to nano in characterization and hazard assessment.
   - improvements in exposure assessment (including, amongst others, also relevant information on sampling, detection tests, instrumentation, modelling) to address aspects specific to nano and provide a list of specific nanomaterials/particles with possible substantial exposure noting current activities within the OECD Working Party on Manufactured Nanomaterials.
   - improvements in risk assessment in general including specifically information linked to mechanistic information to address aspects specific to nano.
2. Recommend further prioritised needs for short, medium and long-term research in areas related to the possible risks of products of nanotechnologies based on a knowledge gap closure analysis.

3. Identify, as much as possible scientific evidence permits, direct or indirect health risks with regard to current and foreseeable applications of nanomaterials based on information related to volume of production in different sectors. For the sector of cosmetics and medical devices indications from patents should also specifically be taken into account. Risks and specificities of different nanomaterials serving the same purpose shall, in as much as possible, be compared.

The opinion should be delivered in November 2008. For more information, please see http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_q_015.pdf

4. Information on any developments related to good practice documents

The European Commission's Code of Conduct (CoC) adopted on 7 February 2008 provides EU Member States, employers, research funders, researchers and more generally all individuals and civil society organisations involved or interested in nanosciences and nanotechnologies (N&N) research ("all stakeholders") with guidelines favouring a responsible and open approach to N&N research in the Community. The CoC:

- invites all stakeholders to act responsibly and cooperate with each other, in line with the N&N Strategy and Action Plan of the Commission, in order to ensure that N&N research is undertaken in the Community in a safe, ethical and effective framework, supporting sustainable economic, social and environmental development;

- covers all N&N research activities undertaken in the European Research Area;

- is voluntary. It offers a set of general principles and guidelines for actions to be taken by all N&N stakeholders. It should facilitate and underpin the regulatory and non-regulatory approaches outlined in the 2005-2009 N&N Action Plan for Europe, improving the implementation of current regulation and coping with scientific uncertainties;

- should also be a European basis for dialogue with third countries and international organisations.

The CoC is complementary to existing regulations. It does not limit or otherwise affect the possibilities of Member States to grant a wider measure of protection with regard to N&N research than is stipulated in this Code of Conduct.

Stakeholders who adhere to the CoC should also be inspired, where applicable, by the principles set out in the Charter of Fundamental Rights of the European Union. The CoC will be regularly monitored and revised every two years by the Commission in order to take into account developments in N&N worldwide and their integration in European society.


5. Research programmes or strategies designed to address human health and/or environmental safety aspects of nanomaterials
Also in the second year of FP7 several topics were launched specifically addressing the safety of nanomaterials. The proposals received for these topics have not yet been fully evaluated.

| NMP-2008-1.3-1 | Validation, adaptation and/or development of risk assessment methodology for engineered nano-particles |
| Large scale integrating projects |

| NMP-2008-1.3-2 | Impact of engineered nanoparticles on health and environment |
| Small or medium-scale focused research projects |

The European Commission has released a publication on nanotechnology research funding addressing potential health and environmental impacts of nanoparticles: EU nanotechnology R&D in the field of health and environmental impact of nanoparticles <ftp://ftp.cordis.europa.eu/pub/nanotechnology/docs/final-version.pdf>. The compilation aims at gathering the most complete overview of past and ongoing research projects funded by the Framework Programmes, EU Member States, Candidate Countries and Countries associated to FP6 or FP7 in the area of possible impacts in health, environment and safety of nanoparticles. It will be updated in the autumn to include new projects and additional information.

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

The Commission considers that dialogue is indispensable for emerging technologies such as nanotechnologies. Public trust in and acceptance of nanotechnologies are crucial for the long-term development. The Commission and a number of the Member States have also actively promoted multi-stakeholder dialogues on nanotechnologies, and numerous other outreach activities. These events have involved, depending on the special themes of the conferences, participation of public authorities, scientists, industry associations, consumers, environment and other non-governmental organisations. Furthermore these activities complement and are coordinated with various other activities at Member State level and by international organisations. Nevertheless, surveys have indicated that European public is not yet sufficiently aware of nanosciences and nanotechnologies. However, these surveys also show that public confidence in European public authorities’ ability to ensure good governance for nanotechnology is higher in Europe than elsewhere.

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

In the second year of FP7 several topics were launched specifically addressing outreach activities and public engagement. The proposals received for these topics have just been evaluated in June.

**NMP-2008-1.1-2** Support to outreach and communication in nanotechnology
SiS-2008-3.0.3.1 Encouraging co-operation and networking between scientific events organisers on public engagement with science

7. Additional Information

The Commission passed a mandate (M/409) to CEN, CENELEC and ETSI for the elaboration of a programme of standards to take into account the specific properties of nanotechnology and nanomaterials in 2007 and received in May 2008 the final report, which includes information on:

- the programme of standardization items relevant to nanotechnologies;
- the legal status of foreseen standardization documents;
- an assessment of the feasibility of standardization work carried out at the international level;
- a draft roadmap of the progress of standardization activities considered necessary.

This report will now be discussed within the Commission with a view to decide on possible further action.