Scientific Committees on Emerging and Newly Identified Health Risks (SCENIHR)
Request for Scientific Opinion

on Risk Assessment of Products of Nanotechnologies

1. BACKGROUND

Products of nanotechnologies are considered to bring benefits to everyday life of citizens and to offer challenges for better optimisation of use of natural resources and protection of the environment. They are already being marketed in sectors such as e.g. healthcare (targeted drug delivery, regenerative medicine, and diagnostics – as indicated by patent analysis[1]), electronics, cosmetics, textiles, information technology, and environmental protection. With the rapidly evolving process technologies, mass productions of nanomaterials will take place implying also potential wide scale exposure of workers and consumers as well as the environment.

The European Union has in its Strategy and Action Plan for nanosciences and nanotechnologies provided for developing the means to benefit from the potential of nanotechnologies, but also to do this in a "safe, integrated, and responsible" way. A review of the Community legislation in relation to nanomaterials is under finalisation. The objective of safe, integrated and responsible development of nanotechnologies is also pursued in the 7th Framework Programme for Research and Technological development for 2007-2013, activities of the Joint Research Centres, national research programmes, in the European Technology Platforms (ETPs) and research by industry and other stakeholders. Internationally, the co-operation for the safety of nanotechnologies is also taking place, especially with respect to activities in OECD, standardisation in ISO/CEN, pharmaceutical products between in Trans-Atlantic co-operation and for medical devices in the Global Harmonisation Task Force.

In its opinion of 2006, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concluded that nanomaterials may have different toxicological and (eco)toxicological properties than the substances in bulk form. Therefore their risks need to be assessed on a case-by-case basis and the risk assessment methods and instruments may require further development.

A second SCENIHR opinion, adopted on 21-22 June 2007, on the nanomaterials in Technical Guidance Documents (TGDs) of chemicals legislation concluded that the current methodologies described in the TGDs are generally likely to be able to identify the hazards, but modifications are required for the guidance on 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/materials. Depending on the regulatory environment, the roles and involvement of different parties and stakeholders, the scope and responsibilities for development and implementation of risk assessment of nanomaterials vary across sectors/areas. It is therefore useful to substantially contribute to a thorough exchange of scientific information across sectors/areas. Consequently, it is envisaged to either make use of existing or organising, on a case-by-case basis, events or other suitable exchange mechanisms with all interested parties to enhance exchange of the evolving scientific information from various sources in the area of risk assessment of nanomaterials.

Hence, the Commission considers it important that this process benefits from and is supported by the expertise that the Scientific Committees have built up in their opinions over recent years. Therefore the SCENIHR is expected to update and provide scientific advice on the risk assessment of nanomaterials in the light of new and upcoming scientific information, including the outputs of various events on the Safety of Nanomaterials and the opinions of other Community Scientific Committees and groups, including EGE (here especially: Opinion on Ethics of Nanomedicine), on substances by the European Chemicals Agency (ECHA), on food and feed by the European Food Safety Authority (EFSA) and on pharmaceuticals by the European Medicines Agency (EMEA). The

[1] See recent OECD-Document entitled "*New patent analysis captures nanotechnology's current state of development 15-Jun-2007*". This new STI Working Paper (2007/4) aims to capture current inventive activities in nanotechnologies based on the analysis of patent applications to the European Patent Office (EPO) - http://www.oecd.org/dataoecd/6/9/38780655.pdf.

scientific opinions will also provide inputs to various Commission activities. Based on these Commission activities a further contribution to various activities at European and international level (i.e. in OECD, ISO/CEN, and the EU-US Partnership activities) in the area of risk assessment of nanomaterials is envisaged.

2. TERMS OF REFERENCE

The SCENIHR is asked:

To identify and assess new information and update the opinions of the SCENIHR on potential risks of products of nanotechnologies, in particular, with respect to characterisation, eco-toxicology and toxicology as well as exposure assessments. This update should be done in a step-wise manner taking into account the upcoming risk assessment demands related to specific nanomaterials and the evolving scientific information from various sources, including results from scientific research projects and activities of the European Technology Platforms related to the safety of nanomaterials. The update should:

i) 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.*

ii) 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.

iii) 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[2] 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.

It should be noted that the Commission may ask the SCENIHR and the SCCP to prepare ad hoc opinions on specific applications of nanomaterials in the field of cosmetics and medical devices and handle these as a matter of priority.

3. DEADLINES

End of November 2008.

[2] See recent OECD-Document entitled "New patent analysis captures nanotechnology's current state of development 15-Jun-2007". This new STI Working Paper (2007/4) aims to capture current inventive activities in nanotechnologies based on the analysis of patent applications to the European Patent Office (EPO) - http://www.oecd.org/dataoecd/6/9/38780655.pdf.