Scientific Committee on Emerging and Newly Identified Health Risks
Request for a scientific opinion:

on the appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies

1 Background

1.1 General characteristics of nanotechnologies

The term "nanotechnologies" refers to technologies of the very small, with dimensions in the range of nanometers. Nanotechnologies exploit the specific properties that arise from structuring matter at a (meso-) scale characterized by the interplay of classical physics and quantum mechanics. Today, these properties are often unpredictable *a priori*. Nanotechnologies enable other technologies. Thus, they will mostly result in the production of intermediate goods. Because nanotechnologies connect disciplines as diverse as physics, chemistry, genetics, information and communication technologies (ICTs), and cognitive sciences amongst others, they offer the foundation of the so-called nano-bio-info-cogno (NBIC) "convergence".

1.2 Expected benefits from nanotechnologies

Technology analysts highlight nanotechnologies as benefiting today or likely to benefit in the foreseeable future:

- materials sciences (esp., ceramics; more generally, lighter and stronger materials);
- cosmetics (e.g., non-ghosting sunscreen, nano-liposome-based skin care products);
- house-cleaning products (e.g., window-washing sprays);
- paints, vanishes, and other coatings;
- chemistry (e.g., tailor-made catalysts);
- information and communication technology (e.g., nano-electronics);
- biomedical applications (e.g., "lab-on-a-chip", biosensors, medical imaging, prostheses and implants, drug delivery devices);
- environmental remediation technology;
- energy capture and storage technology (e.g., solar cells, batteries, fuel cells, fuels and catalysts);
- agriculture (e.g., sensors, seed improvement);
- food (ranging from non-permeable membranes and, national legislation permitting, antibacterial powders to pathogen and contaminant sensors, environmental monitors, and remote sensing and tracking devices);
- military technology.

The market for nanotechnologies is estimated at $700 billion by 2008 and more than $1 trillion by 2015 by the US National Science Foundation (NSF).

1.3 Community interest

The high expectations raised by nanotechnologies have led the Community to manifest its interest in boosting nanotechnologies in its Communication of 12 May 2004 entitled "Towards a European strategy for nanotechnology" [COM(2004) 338 final]. Council endorsed "the main message of this Communication, namely the need to develop an integrated and responsible strategy" for nanotechnologies [12487/04 (Presse 269), Point 4, p. 25].

1.4 Potential areas for concern

Some nanoparticles, nanospheres, nanotubes, and nanofibers produced via nanotechnologies including adventitious by-products have the potential to raise concerns for humans (public health, consumer safety, and the health and safety of workers) and the environment. The concerns that nanoparticles, nanotubes, and nanofibers raise constitute the most significant ones relating to nanotechnologies within the next 3–5 years. They require further studies. In this respect, more often than not, the toxicological, ecotoxicological, and exposure data needed to perform a complete risk analysis are lacking.

Experts are of the unanimous opinion that the adverse effects of nanoparticles cannot be predicted (or derived) from the known toxicity of material of macroscopic size, which obey the laws of classical physics. This has led the UK Royal Society and the Royal Academy of Engineering to recommend "that chemicals in the form of nanoparticles or nanotubes be treated as new substances under the existing Notification of New Substances (NONS) regulations and in the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)" (Chapter 8 "Regulatory issues", Point 18, p. 71).

1.5 European Council recommendations

The European Council highlighted "the need to pay special attention to integrating societal, environmental and health considerations into the R&D process and assessment of potential risks throughout the life cycle of nanotechnology-based products" [12487/04 (Presse 269), Point 6, p. 26] and welcomed "the Commission's intention to engage in a dialogue at international level, with a view to establishing a framework of shared principles for the safe, sustainable, responsible and socially acceptable development and use of nanotechnologies" [12487/04 (Presse 269), Point 8, p. 26; emphasis added].

In view of the Council's call for a "safe, sustainable, responsible and socially acceptable development and use of nanotechnologies", it is therefore timely to undertake a general reflection on the adequacy of existing risk assessment methodologies as concern nanotechnologies and their engineered and adventitious products and to identify any gaps in current knowledge which may be an impediment to the demonstration of their safety.

2 Terms of reference

The scientific committee is requested to answer the following questions, in each case, considering the different kinds of nanotechnologies separately:

1. Are existing methodologies appropriate to assess potential and plausible risks associated with different kinds of nanotechnologies and processes associated with nano-sized materials as well as the engineered and adventitious products of nanotechnologies?
2. If existing methodologies are not appropriate to assess the hypothetical and potential risks associated with certain kinds of nanotechnologies and their engineered and adventitious products, how should existing methodologies be adapted and/or completed?
3. In general terms, what are the major gaps in knowledge necessary to underpin risk assessment in the areas of concern?

In making its report, the Committee is asked to include considerations of both engineered and adventitious products and potential risks related to public health, to consumer safety, to the health and safety of workers, and to the environment.

3 Deadlines

Autumn 2005 (indicative deadline)

Supporting Documents:

Aitken, R.J., K.S. Creely, and C.L. Tran (2004) *Nanoparticles: An occupational hygiene review*. [A report of the Institute of Occupational Medicine (IOM) on behalf of the UK's Health and Safety Executive (HSE)]
URL: http://www.hse.gov.uk/research/rrhtm/rr274.htm

Arnall, A.U. (2003) *Future Technologies, Today's Choices: Nanotechnology, Artificial Intelligence and Robotics; A technical, political and institutional map of emerging technologies*. (A report commissioned to the Imperial College London by the Greenpeace Environmental Trust)
URL: http://www.greenpeace.org.uk/MultimediaFiles/Live/FullReport/5886.pdf

Dürrenberger, F., J. Höck, and K. Höhner (2004) *Overview: Inherent risks of different nanotechnological fields* (see, in particular, summary table p. 35, which proposes a typology of different kinds of nanotechnologies and their inherent risk)
URL:
http://www.temas.ch/WWWTEMAS/TEMAS_Homepage.nsf/vwAllByKey/Overview_TT%7Cde

ETC Group (2003) *The Big Down*
URL: http://www.etcgroup.org/documents/TheBigDown.pdf

European Commission, Directorate-General for Health and Consumer Protection (2004) *Nanotechnologies: A Preliminary Risk Analysis*

URL: http://europa.eu.int/comm/health/ph_risk/events_risk_en.htm

European Commission (2004) "Towards a European strategy for nanotechnology" [COM (2004) 338]
URL: http://www.cordis.lu/nanotechnology/src/communication.htm

European Council (2004) Conclusions of the 2605th European Council Meeting on "Competitiveness (Internal Market, Industry and Research)" [12487/04 (Presse 269)]
URL: http://ue.eu.int/ueDocs/cms_Data/docs/pressData/en/intm/82067.pdf

European Parliament, Scientific Technology Options Assessment (2004) *Nanotechnology* web page
URL: http://www.europarl.eu.int/stoa/ta/nanotechnology/nanotechnology.htm

Luther, W. (2004) Industrial application of nanomaterials - chances and risks (Band 54) Hrsg.: VDI-Technologiezentrum
URL:
http://www.vdi.de/vdi/organisation/schnellauswahl/techno/arbeitsgebiete/zukunft/sub/10803/index.php
Swiss Re: *Nanotechnology*
URL: http://www.swissre.com/INTERNET/pwswpspr.nsf/fmBookMarkFrameSet?ReadForm&BM=../vwAllbyIDKeyLu/FSTN-5YXLL2?OpenDocument

UK Royal Society and the Royal Academy of Engineering (2004) *Nanoscience and nanotechnologies: opportunities and uncertainties*
URL: http://www.nanotec.org.uk/finalReport.htm

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