

**SCIENTIFIC COMMITTEE ON
EMERGING AND NEWLY IDENTIFIED HEALTH RISKS
(SCENIHR)**

Request for a scientific 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**

1. Background

The Commission Strategy¹ and Action Plan² on Nanotechnologies underline the importance of a safe and responsible approach and integration of risk assessment into every step of the life cycle of nanotechnology-based products. Due to the novel properties of the nanotechnology products, the Commission requested the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) for an opinion on the appropriateness of existing risk assessment methodologies.

The SCENIHR opinion³ concluded that nanomaterials may have different (eco-) toxicological properties than the substances in bulk form and therefore their risks need to be assessed on a case by case basis. The SCENIHR also foresaw that current risk assessment methodologies require some modification in order to deal with the hazards associated with nanotechnology. In particular, the existing toxicological and ecotoxicological methods may not be sufficient to address all of the issues arising with nanoparticles. For exposure evaluation, additional information is needed, including the number of nanoparticles and/or their surface area. Equipment for routine measurements of substances in various media may be inadequate to detect representative exposure to free nanoparticles. In addition, existing exposure assessment methods may not be fully appropriate to determine the environmental fate of nanoparticles.

The practical implementation of different areas of Community legislation dealing with chemical substances, including the legislation on new⁴ and existing⁵ substances, may be eventually affected by nanotechnologies. So far, the chemicals legislation does not have specific provisions or testing requirements for substances on a nanoscale. However, on the basis of the SCENIHR opinion, there is a need to assess the suitability of current risk assessment methods, when applied for nanomaterials, in more detail in order to guide how to deal in practice with nanomaterials in an appropriate manner.

Therefore DG Environment requests the SCENIHR to assess the current risk assessment methodology as laid down in the Technical Guidance Documents, to provide an opinion on their appropriateness and make suggestions for improvements where appropriate.

¹ COM(2004) 338 Final

² COM(2005) 243 final

³ SCENIHR/02/2005

2. Terms of reference

The SCENIHR is asked, in the light of current scientific knowledge and in relation to the general information and practices of chemicals risk assessment, to:

1. assess the appropriateness of risk assessment methodologies (effects and exposure assessment) described in the current Technical Guidance Documents of the chemicals legislation, for the risk assessment of nanomaterials;
2. where current risk assessment methodology may be improved for assessment of nanomaterials, and taking into account the practical limitations of the information available for risk assessments, provide concrete suggestions for improvement of the methodology. Distinctions should be made between improvements that can be made based on current knowledge, improvements that would require specific information on the nanomaterials, and improvements that will require scientific research before they can be implemented;
3. where possible, provide practical examples of how risk assessment of nanomaterials can be performed and of nanomaterials, forms of nanoparticles etc that may cause significantly different adverse effects or different exposure behaviour.

3. Deadline

December 2006.