

# **SCENIHR Risk Analysis Approach and Overview of Opinions on Nanotechnologies**

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# What is SCENIHR?

- Scientific Committee on Emerging and Newly Identified Health Risks
- One of three independent non-food scientific committees at DG SANCO
- First mandate period 2004-2008
- New mandate period 2009-2011
- Presently 17 members covering many areas of expertise

# SCENIHR Mandate

Emerging or newly identified risks, broad, complex or multi-disciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health

(NB! Risk management issues specifically excluded)

## Examples

- new technologies (e.g. nanotechnologies)
- medical devices, tissue engineering, blood products
- physical hazards (e.g. noise and electromagnetic fields)
- antimicrobial resistance
- fertility reduction, cancer of endocrine organs
- interaction of risk factors, synergic or cumulative effects
- methodologies for assessing new risks

# SCENIHR –mode of working

- Question(s) framed by one or more Commission Services
- Question discussed in a SCENIHR Plenary Meeting. Chairman of a Working Group (WG) is appointed
- External experts are identified and invited for the WG. NB! all members must declare any relevant interests at each meeting.
- WG produces a preliminary report (6-18 months)
- Report is discussed at SCENIHR and a preliminary opinion / final opinion is agreed upon
- Final Opinion, belonging to EC DG SANCO and/or other DG, is published

# Risk assessment – A weight of evidence approach

- The primary objectives of health risk assessment are:
  - to identify and characterise any hazardous properties of a given agent
  - to examine the relationship between exposure and these hazards (dose response relationship)
  - to highlight uncertainties in the determination of hazards and dose response relationships
  - to evaluate the possible modes/mechanisms for each hazard of concern.
- A health risk assessment evaluates the evidence within several areas of studies (human epidemiological studies, human volunteers studies, animal studies, in vitro studies)
- The evidence from across the areas are **weighed** to produce a combined assessment.
- The combined assessment should address the question of cause and effect. The answer to this question is not necessarily a definitive yes or no, but may express the weight of the evidence for the existence of a hazard.
- If such a hazard is judged to be present, the risk assessment should also address the magnitude of the effect and the shape of the dose-response function,
- A full risk assessment also includes exposure characterisation in the population and estimates of the impact of exposure on burden of disease.

# Since risk assessment is using the scientific literature, relevant publications have to be found

- Published scientific papers obtained via electronic literature searches, papers known to assessing experts
- Published governmental reports and opinions of other relevant scientific committees
- Requested from stakeholders

# Criteria for weighting

## High priority papers:

1. Peer reviewed
2. Well established highly rated journal
3. Full experimental details provided in the paper
4. Findings agree with other published work and/or findings compatible with known science
5. Established methodology used (e.g. OECD), valid statistical methods, valid control groups included
6. Work performed to GLP/GCP
7. Work from an organisation /scientist with a good reputation in the area of the publication
8. No obvious information gaps

## Low priority papers:

1. Not peer reviewed
2. Journal not well known
3. Limited or no experimental details provided
4. Unexpected findings not supported by other high quality papers on the same topic
5. Methodology not well established or unclear. Statistical evaluation not significant. Suitable control groups not used.
6. Work not audited
7. Organisation/author not well known in area or considered to be prejudiced
8. Data provided appears to be incomplete, selective, or unreferenced

## Risk assessment based on evidence from several lines of investigation

- Exposure assessment
- Animal studies
- In vitro studies
- Human epidemiological studies
- Human volunteers studies

# Four SCENIHR Opinions on nanotechnologies

- SCENIHR has so far produced four opinions on Nanotechnologies.
- Appropriateness of existing methodologies for risk assessment of nanotechnology products (two opinions, 2006 and 2007)
- Scientific aspects of definitions relating to products of nanoscience and nanotechnologies (2007)
- Risk assessment of products of nanotechnologies (2009).

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

- Although the existing toxicological and eco-toxicological methods are appropriate to assess many of the hazards associated with the products and processes involving nanoparticles, they may not be sufficient to address all the hazards.
- In general, there is insufficient knowledge and data concerning
  - nanoparticle characterisation
  - their detection and measurements
  - the fate (and especially the persistence) of nanoparticles in humans and in the environment
  - all aspects of toxicology and environmental toxicology related to nanoparticles
- Satisfactory risk assessments for humans and ecosystems can at present not be performed.

## 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

- Technical Guidance Documents currently make very little reference to substances in particulate form.
- With respect to human health, the current methodologies described in Technical Guidance Documents are generally likely to be able to identify the hazards associated with the use of nanoparticles.
- With respect to environmental exposure, the validity and appropriateness of existing technologies are not always clear.
- In the absence of sufficient data on the fate and the effects of nanoparticles on the environment, it is neither feasible nor appropriate to propose firm rules on how substances in nanoparticulate form should be evaluated.

## The scientific aspects of the existing and proposed definitions relating to products of nanoscience and nanotechnologies

- The opinion deals with the development of a conceptual framework for definitions in the areas of nanoscience and nanotechnologies.
- This opinion stresses that there is a need for an overarching framework for such definitions.
- Such a framework is established for relevant definitions concerned with nanoscience, nanotechnologies and the products of nanotechnology, based on a sound scientific rationale that emphasises the specific needs for clarity of terminology in relation to risk assessment.

# Risk assessment of products of nanotechnologies

- The opinion deals with the recent developments in the risk assessment of nanomaterials for both man and the environment.
- As there is not yet a generally applicable paradigm for nanomaterials hazard identification, a case by case approach for the risk assessment of nanomaterials is warranted.

# Concluding remarks

- Risk identification and assessment performed by SCENIHR is based on scientific evidence and several lines of investigation
- The various evidence lines are weighted, and thus contribute to different extents to the final conclusion
- There is a vast body of scientific literature dealing with physical, chemical and biological/medical properties of engineered nanoparticles
- Despite the amount of scientific publications, in most cases it is not appropriate for risk assessment
- At present a case by case approach for the risk assessment of nanomaterials is warranted.