Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) Scientific Committee on Consumer Safety (SCCS) Scientific Committee on Health and Environmental Risks (SCHER)

Request for a scientific opinion: Addressing the new challenges for Risk Assessment

1. Background

Risk assessment must be based on the best available scientific evidence. While the data base that supports risk assessments continues to expand and despite several challenges encountered, the general procedures have not changed significantly in the last two decades. Some <u>current challenges</u> discussed in two opinions on Harmonisation of Risk Assessment Procedures by the Scientific Steering Committee (SSC) (2000¹, 2003²) include access to data, exposure assessment and the explanation/ expression of findings.

Furthermore, there are a number of <u>anticipated changes</u> concerning both the nature and the interpretation of data available for risk assessment in the near future. Possible changes include the following:

- 1. Increasing restrictions on the use of animals for testing purposes in the EU and the need to develop and use alternative in vitro and in silico testing strategies and, possibly, appropriate modelling techniques.
- 2. The availability of data from new/rapidly advancing methodologies and the associated risk of information overload and lack of an effective process for the appropriate utilisation for risk assessment purposes.
- 3. Developments in mode of action research and its future use.
- 4. Developments of novel systems that may constitute new risks and may furthermore challenge traditional approaches used in Risk Assessment (e.g. products created by synthetic biology, 4th generation nanotechnologies)

2. Terms of reference

The SCENIHR, SCCS and SCHER are requested to carry out a comprehensive review of risk assessment procedures and new challenges for RA taking into account both fundamental and practical considerations (sampling, instrumentation, cost, analysis, etc.), and to provide a scientific opinion on the issue in co-operation, as appropriate, with external experts who are specialists in relevant new methodologies.

This group should consider the above and other relevant scientific issues relevant for a future framework for risk assessment and to propose a way forward. They should also consider the need to train future risk assessors in the understanding of these methodologies and their potential applications. Finally, the group should identify and prioritize areas for possible research funding.

It is proposed that the chairs of SCENIHR, SCHER and SCCS identify a small group of experts representing the different sectors and key disciplines.

3. Deadline

December 2011

¹ http://ec.europa.eu/food/fs/sc/ssc/out82_en.html

² http://ec.europa.eu/food/fs/sc/ssc/out355 en.pdf