

## Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)

### Request for a Scientific Opinion via Accelerated Procedure (see Rules of Procedure<sup>1</sup>): Scientific basis for the definition of the term “nanomaterial”

#### 1. Background

The services of the European Commission urgently need to elaborate a working definition of the term “nanomaterials” to ensure the consistency of forthcoming regulatory developments to guide, as appropriate, the effective implementation of existing regulation, and to contribute to international work and dialogue on nanotechnology definitions.

The SCENIHR adopted a Scientific Opinion on “The scientific aspects of the existing and proposed definitions relating to products of nanoscience and nanotechnologies” at the 21st plenary meeting on 29 November 2007.<sup>2</sup> Moreover, both SCENIHR<sup>3</sup> and the predecessor to the Scientific Committee on Consumer Safety (SCCS)<sup>4</sup> have provided further advice on the definitions of the term nanomaterial and other related terms in their opinions. Moreover, the European Food Safety Authority used the terms and definitions suggested by the SCENIHR in the opinion on “The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety” on 10 February 2009.<sup>5</sup>

In order to prepare a science-based definition of nanomaterials, the services of the European Commission need clarification on the size ranges and other relevant characteristics and corresponding metrics reported in the scientific literature, the types of physical and chemical properties particular to nanomaterials, the relevant thresholds, as well as the most appropriate metrics to express such thresholds.

The development of the policy and regulatory activities on nanotechnologies requires the establishment of a working definition of nanomaterials as a matter of urgency. Therefore, SCENIHR is requested to provide a scientific opinion on the issues mentioned below in accordance with the accelerated procedure referred to in Article 9.13 of the Rules of Procedure, in co-operation with other Scientific Committees of the European Community and, as appropriate, with external experts.

#### 2. Terms of reference

Advice on the essential elements of a science-based working definition: Based on current knowledge, the Committee is invited to provide advice on the essential elements of a science-based working definition of “nanomaterials” and, specifically, to identify the most appropriate metrics to define materials at nanoscale, taking into account:

- (i) Reported size ranges and other relevant characteristics and corresponding metrics: The size ranges and other relevant characteristics (e.g., specific surface area, shape, density, spatial arrangements, aggregation, agglomeration, etc.) and corresponding metrics of materials reported as “nanomaterials” in the scientific literature;
- (ii) Characteristics: A first indication of possible characteristics and associated mechanisms that alone or in various combinations may lead to different properties;
- (iii) Physico-chemical properties: The physical and chemical properties that materials may show as a result of being at nanoscale or having a nanoscale structure;
- (iv) Threshold(s): The threshold(s) at which properties identified in (iii) above may be expected to occur (the threshold(s) may be “below” or “above” depending on the relevant characteristic(s) and associated metric(s)).

#### 3. Deadline: May 2010

---

<sup>1</sup> [http://ec.europa.eu/health/archive/ph\\_risk/documents/rules\\_procedure\\_en.pdf](http://ec.europa.eu/health/archive/ph_risk/documents/rules_procedure_en.pdf)

<sup>2</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_012.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_012.pdf)

<sup>3</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_023.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf)

<sup>4</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/docs/sccp\\_o\\_099.pdf](http://ec.europa.eu/health/ph_risk/committees/04_sccp/docs/sccp_o_099.pdf)

<sup>5</sup> <http://www.efsa.europa.eu/en/scdocs/scdoc/958.htm>