

## Questions and answers on risk assessment of nanotechnology products

### 1) What are nanotechnologies?

Nanotechnologies involve the controlled production at molecular level of new materials, structures and devices, which have at least one dimension in the range 0.2-100 nanometres. To put this into context, the diameter of a human hair is 80 000 nanometres. Nanotechnologies encompass the many techniques used to create structures at a size scale below 100 nanometres, which exploit the very large surface-to-volume ratios of nanoparticles, as well as special (“quantum-mechanical”) physical effects.

### 2) What is the importance of nanotechnologies for Europeans?

Nanotechnologies are expected to bring significant improvements to the quality of life of European citizens. Current and expected areas of application include information and communication technology, health care, environmental remediation, energy capture and storage, cosmetics, house-cleaning products, paints, vanishes, chemistry (e.g., tailor-made catalysts), agriculture, food technology, textiles, surface finishing and lubrication agents. Public investment in nanotechnologies has reached over 3 billion euros worldwide, and private investment is expected to exceed government spending in 2005.

### 3) What are the safety concerns related to nanotechnologies?

Nanotechnology products are not generally considered to be inherently harmful to human health and the environment. However, due to their small size, nanoparticles may enter the body more readily than larger particles and could therefore potentially reach and affect vulnerable organs. The novel characteristics of nanotechnology products also need to be assessed in relation to possible environmental impact.

### 4) What has been the EU approach to nanotechnologies so far?

The Strategy<sup>1</sup> and the Action Plan for Nanotechnologies<sup>2</sup> underline the importance of a safe and responsible approach to nanotechnologies, and the integration of risk assessment throughout the life-cycle of nanotechnology-based products. This reflects the first priority of the Commission when it comes to new technologies and novel substances – ensuring consumer safety. In doing so, science-based safety assessments are an essential part of achieving consumer confidence and acceptance of major technological innovations.

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<sup>1</sup> [Towards a European strategy for nanotechnology](#), COM(2004) 338 Final adopted on 12 May 2004 and approved by the [Council of European Union on 24 September 2005](#)

<sup>2</sup> [Nanosciences and nanotechnologies: An action plan for Europe 2005-2009](#) (COM(2005) 243) adopted on 7 June 2005

With regard to R&D, the Commission also gave high priority to research and development on nanotechnologies in its Sixth Framework Programme for Research and Technological Development, in recognition of the huge potential of nanotechnologies and their potential contribution to European competitiveness. An even higher profile has been proposed for these technologies under the Seventh Framework Programme.

### **5) Why did the Commission seek a scientific opinion on risk assessment methods for nanotechnology products?**

The protection and safety of human health and the environment relies on integrated and adequate risk assessment of products throughout their life-cycle. Therefore it is essential to know whether existing risk assessment methodologies are appropriate for testing and monitoring nanoparticles, and whether they are available for routine use. The sound risk assessment methods are vital for the practical implementation of many aspects of Community legislation which may eventually be affected by nanotechnologies e.g. on chemicals, pharmaceuticals, cosmetics, medical devices, food and feed products, workers' health and safety, environmental protection and general product safety.

The Commission therefore asked the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) for an opinion on the appropriateness of the current risk assessment methods for the products of nanotechnologies. SCENIHR is one of the three independent scientific committees<sup>3</sup> established by the Commission to provide advice in the fields of consumer safety, public health and the environment.

The SCENIHR opinion<sup>4</sup> offers an authoritative insight into where amendments are needed to procedures for assessing risk of the products of nanotechnologies, and identifies areas where major gaps in knowledge exist. It can also be used as a reference by industry and by the research community when looking at areas where additional research and development should be undertaken to support risk assessment.

### **6) Why is the Commission launching a public consultation?**

The public consultation on is being launched by the Commission to gather feedback from stakeholders on the SCENIHR opinion. Following the consultation, the SCENIHR and Commission services will carefully examine all the comments, in order to further refine approaches to risk assessment of the products of nanotechnologies.

The public consultation will run until **16 December 2005**, and can be accessed at: [http://europa.eu.int/comm/health/ph\\_risk/committees/04\\_scenihr/scenihr\\_cons\\_01\\_en.htm](http://europa.eu.int/comm/health/ph_risk/committees/04_scenihr/scenihr_cons_01_en.htm) the outcome of the consultation will be published on the same site.

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<sup>3</sup> [http://europa.eu.int/comm/health/ph\\_risk/risk\\_02\\_en.htm](http://europa.eu.int/comm/health/ph_risk/risk_02_en.htm)

<sup>4</sup> [http://europa.eu.int/comm/health/ph\\_risk/committees/04\\_scenihr/scenihr\\_opinions\\_en.htm](http://europa.eu.int/comm/health/ph_risk/committees/04_scenihr/scenihr_opinions_en.htm)