



# **Nanotechnology risk assessment: knowns and unknowns**

Herman B.W.M.Koëter,  
Deputy Executive Director and Director of Science

# Nanotechnology: what about it?

- Nanotechnology, nanoparticles, nanomaterials, nanolayers, nanoscience...
- Is there more talking than doing?
- Is industry heavily investing and as silent about it as some say they are?
- Are regulatory authorities as nervous about this as some believe they are?
- Are we too late or too early?
- Should somebody take the lead?

# Nanotechnology – Questions received

- EFSA was asked to evaluate the safety of a silicon dioxide coating in situ on the inner surface of PET articles. The coating is intended to provide gas barrier properties and the max thickness is 100 nm. EFSA (AFC Panel) published its opinion in February 2007;
- Recent request for a safety evaluation for a titanium nitride based nanoparticle to be used as a food contact material additive;
- Feed additive authorization dossier involving nanotechnology may be submitted soon.

- Since 2005 EFSA (Dr Anne Theobald) is following developments of nanotechnology in the area of its remit;
- Since 2006 developments are followed more closely, data and information are collected;
- In early 2007 an internal EFSA working group was set up which prepared an internal report giving a synopsis of current knowledge, trends and developments in the food and feed area.

- In Spring 2007 the EFSA Advisory Forum (AF) requested EFSA to take the initiative and provide the platform to EU Member States active in the area of risk assessment of nanomaterials to discuss approaches in order to avoid diverging developments;
- **Harmonizing risk assessment approaches**

- On 29 June 2007 a request for an opinion was received from the Commission related to the risks arising from nanotechnologies on food and feed safety and the environment. The mandate was divided into:
  - Needs for Risk Assessment
  - Appropriateness of Methods for Risk Assessment
  - Risk Assessment

- Mandate briefly discussed at July SC Plenary and EFSA sent an initial reply to EC on 13 July 2007;
- Mandate re-discussed at September SC Plenary suggested to EFSA that:
  - a generic risk assessment would be very difficult as it depends on physical and chemical properties and toxicokinetics of nanomaterials in question;
  - Focus should be on the nature of hazards associated with actual/foreseen applications, rather than on their relative magnitude.

# Nanotechnology – Revised mandate

## Proposed revised mandate sent to Commission on 8 October 2007:

- EFSA to produce an **initial** scientific opinion on the need for specific risk assessment approaches of **applications of nanotechnology** in the food and feed area;
- Opinion to identify **nature of possible hazards** associated with **actual/foreseeable applications**;
- Member States to be involved to learn from their experience and to ensure **harmonised approaches**;
- Already **published opinions** by EU scientific advisory bodies, and third countries to serve as a basis.



- EFSA is currently asking Member States to propose leading scientific experts by 2 November 2007;
- Working group to be established including members of SC and relevant Panels and experts from MS to prepare draft opinion;
- Opinion to be adopted by the SC by summer 2008.
- **Point-counter-point discussion on nanotechnology in food at EFSA's Scientific Forum, 20-21 November 2007**

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