

Commission's activities around nanomaterials and preparation for REACH Review

*Nano and REACH Workshop
23 June 2011, Brussels, Belgium*



European Commission
Enterprise and Industry

Maila Puolamaa

Contents

- EU approach to Nanotechnologies
- Commission Communication on Regulatory aspects of Nanomaterials
- REACH Review

EU Approach to Nanotechnologies

- *'Safe, integrated and responsible'*, Towards a European Strategy for Nanotechnology, 2004
- European Nanotechnology Action Plan 2005-2009; *Implementation Reports of the AP in 2007 and 2009*
- Framework Programmes for R&D; NS&NT since late 90s
- Code of Conduct for nanotechnology research, 2008
- *Communication on Regulatory Aspects, 2008*
- Nanotechnologies - Safety for Success Dialogue, 2006
- *REACH CASG Nano, 2008*

1st Regulatory Review, 2008

- **No legal void**; in principle covered; legislative change will be proposed as necessary
- **Implementation remains a challenge**, as instruments of implementation are still lacking, although they are gradually being built up
- **Lack of knowledge** impedes us for the time being to elaborate general guidance, measures, standards, methods (Special Annex on the R&D needs)
- **A new review in 2011**;

REACH

Environment

Regulation

Implementing regulation

Standards

Guidance

Science, literature

Worker

Protection

Pharmaceuticals Food

Cosmetics Biocides

Sports Equipment

Plant protection

Consumer goods,etc



2nd Regulatory Review, 2011

- Task Force on the 2nd Commission Communication on Regulatory Aspects of Nanomaterials, with an Annex on information on nanomaterial types and uses, including safety aspects
- On-going evaluation of need to review legislations (e.g. REACH, Air-Water-Waste, Worker Safety)
- Definition of Nanomaterial
- Other relevant aspects

=>Inputs to legislative reviews, incl. REACH

2nd Regulatory Review - REACH

- COM actions on REACH implementation for NMs:
 - CASG Nano Work Programme 2008-2012:
 - / Advice on NMs in REACH and CLP, 2008-2010
 - / Studies on RiPoNs on Substance Identification, Information Requirements and Chemical Safety Assessment, under finalisation
 - / Makes use of FP7 research, OECD-WPMN & ISO/CEN etc.
- Request of Parliament to evaluate the need to review REACH, inter alia:
 - Simplified registration for nanomaterials manufactured or imported <1 tonne/year
 - Consideration of all nanomaterials new substances
 - Chemical safety report with exposure assessment for all registered nanomaterials
 - Notification requirements for all nanomaterials placed on the market on their own, in preparations or in articles
- DG ENTR: REACH and Emerging Technologies, on-going
- ENV-JRC: Assessment of the REACH registration dossiers and adequacy of available information, on-going.

REACH Review and reporting obligations for 2012

- On-going evaluation of need to review legislations (e.g
- REACH requires specifically **3 reviews** to be conducted by 1 June 2012:
 - Review of ECHA (Article 75.2),
 - Low tonnage review (Article 138.3)
 - Review of the scope of REACH (Article 138.6)
- Commission has to publish by **1 June 2012 a general report** on the operation of REACH, and the funding of alternative test methods (Article 117.4)
- The general report will have to consider information reported:
 - **By MS** (June 2010 – including evaluation and enforcement)
 - **By ECHA** (June 2011 – including non-animal test methods)

Assessment whether or not to amend the scope of REACH to avoid overlaps with other relevant Community provisions.

Experience acquired with the operation of REACH

Nanomaterials in REACH registration dossiers and adequacy of available information.

Inspections requirements for REACH and CLP

The (nominal) risk caused by chemicals in 2012 compared to the 2007 (a follow-up of the baseline study of REACH)

Functioning of the European Chemical market after the introduction of REACH regulation

Impact of the REACH regulation on the innovativeness of EU chemical industry

Health and environmental benefits of REACH

Registration requirements for 1 to 10 tonnes substances and polymers

Review of the European Chemicals Agency (ECHA) based on Article 75 of Regulation (EC) N° 1907/2006

The REACH contribution to the development, commercialisation and uptake of products of emerging technologies

Implementation and enforcement of restrictions in Member States

Follow-up to the 2012 Review

- The Commission **may, if appropriate, present a legislative proposal** based on the review outcomes
- The Commission will consider proposing **practical approaches to better implement** the current legislation (e.g. guidance)
- After 1 June 2012, the Commission services will also conclude **whether or not a legislative revision is needed** and necessary, bearing also in mind potential impacts on the next registration deadlines (2013 and 2018).

Thank you!

- Further info:

http://ec.europa.eu/nanotechnology/index_en.html

http://ec.europa.eu/enterprise/sectors/chemicals/index_en.htm

- <http://ec.europa.eu/environment/chemicals/nanotech/index.htm>