



Social Dialogue, 7 July 2009



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Nanotechnology



- **Considerable promise extending from business opportunities throughout various industries to broader socio-economic benefits**
 - Energy, health care, information technology, clean water, climate change
- **Nanotechnology still at an early phase of development**
- **Available forecasts suggest global market in nanotechnology products**
 - in range of 3 billion \$ in 2015
 - about 2 million new jobs (~ 10 million in 2014)

Economic crisis is not considered !



Regulatory challenges

- **Nanomaterials, by virtue of their small size, have unique properties**
- **Balancing opportunities, uncertainties and risks**
- **The EU approach « safe, integrated and responsible » is set out in a number of Commission Communications : Strategy, Action Plan, Implementation Report**

Regulatory aspects of nanomaterials



Commission Communication on Regulatory aspects of nanomaterials adopted on **17 June 2008**

Covering legislation relevant for health, safety and environmental aspects of nanomaterials:

- Industrial chemicals (new and existing → REACH)
- Worker protection
- Products (e.g. pharmaceuticals, cosmetics)
- Environment (e.g. Air, Water, IPPC, Seveso, Waste)



Main Conclusions

Environmental and health risks of nanomaterials are *in principle* covered by EU regulatory frameworks

Implementation of the legal frameworks is a challenge:

- **Scientific knowledge gaps**
- **Guidance documents need to be reviewed**

Current legislation may have to be modified as new information becomes available (e.g **tonnage thresholds**)



REACH and Nanomaterials

“REACH is based on the principle that M/I and DUs have to

- ensure that they manufacture, place on the market or
- use such substances that do not adversely affect human health or the environment.”

“REACH requirements applies to nanomaterials, even though there are **no specific provisions for nanomaterials.**”

Sector Specific Regulation: Outcome of the recast of the Cosmetic Directive



- **Not a positive list but a negative list**
 - Pre-authorisation of nanomaterials failed **but**;
 - Colorants, preservatives and UC protective nanomaterials will still have to be approved before use

- **Label with the prefix “nano” after the ingredients name.**

- **Definition which includes properties such as bio-persistent and insoluble.**

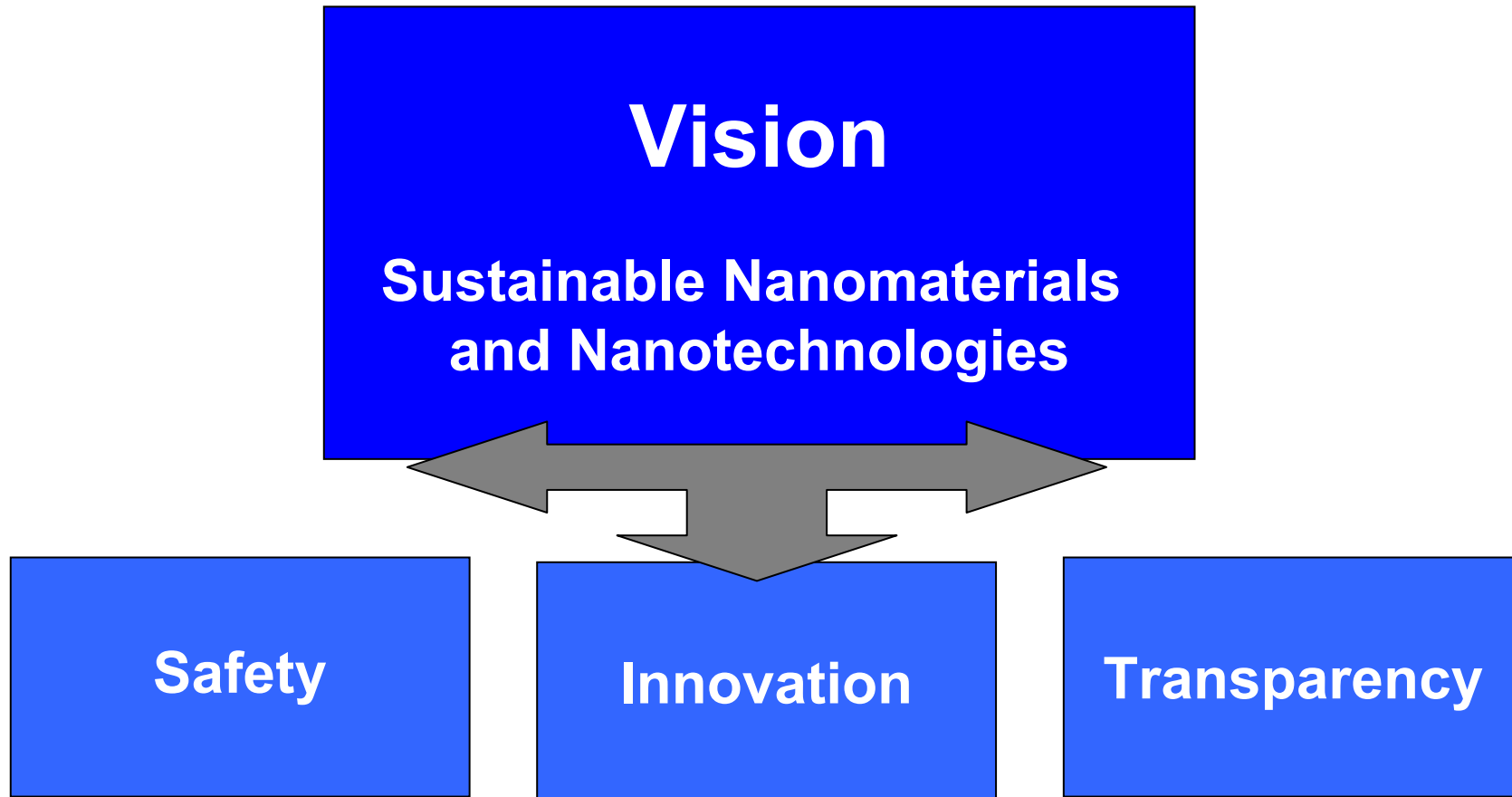
Outcome of the vote – 24 April 2009



EP Initiative Report call upon the EC to:

- **Review of the all relevant legislation**
- **Publicly available inventory of different types and uses present on the EU market by June 2011 and report on the safety of nanos**
- **No data - No market**
- **Labelling and suggest mentioning nano among products' ingredients**
- **Review of REACH:**
 - Lower tonnage trigger (below one tonne)
 - nano considered as « new substances »
 - CSR for all nanos registered, regardless of the tonnage band
 - notification requirements for all nanos placed on the market on their own, in preparations or in article
- **Protection of workers:**
 - use of nanos only in closed system
 - producer liability arising from the use of nano
 - address all exposures routes (inhalation, dermal and others)

Cefic's Strategy on Nanomaterials and Nanotechnologies



What do we want to achieve?



Safety:

- Harmonised global standards
- Ensure workplace and consumer safety and health

Innovation:

- Technology leadership

Transparency:

- Work together with policy makers as a dialogue partner
- Showing transparency and engagement in dialogues with stakeholders, authorities and NGO's.

Back up slide





Ongoing activities

- **Discussions on REACH and nano ongoing in Competent Authorities Subgroup**
- **Development of guidance**
 - Study on voluntary inventories
- **Opinions of Scientific Committees**
- **Stakeholders Dialogues (Safety for Success Dialogue, November 2009)**
- **OECD Workshop on Environmental Benefits (July 2009)**
- **OECD Workshop in Risk Assessment (US, September 2009)**