European Commission
Enterprise & Industry Directorate General

Safety For Success

2 – 3 October 2008

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Nanotechnology in Europe,

a “Safe, Integrated and Responsible” Approach

Outlined in the following Commission Communications:

- Towards a European Strategy for Nanotechnology (2004)
- Nanotechnology Action Plan for Europe 2005-2009 (2005)
- Nanosciences and Nanotechnologies: An action plan for Europe 2005- 2009. First Implementation Report 2005-2007 (2007)

- Scheduled 2009 : Second Implementation Report

"Action Plan for Europe 2005 – 2009" as part of "Safe, Integrated and Responsible" approach:

Regulatory Review

Communication "Regulatory aspects of nanomaterials", 17 June 2008

- Legislation
- Documents, adopted with the framework of legislation, that implement or support implementation of legislation
- Implementation and enforcement

European Parliament has announced an "own initiative report" on regulatory review

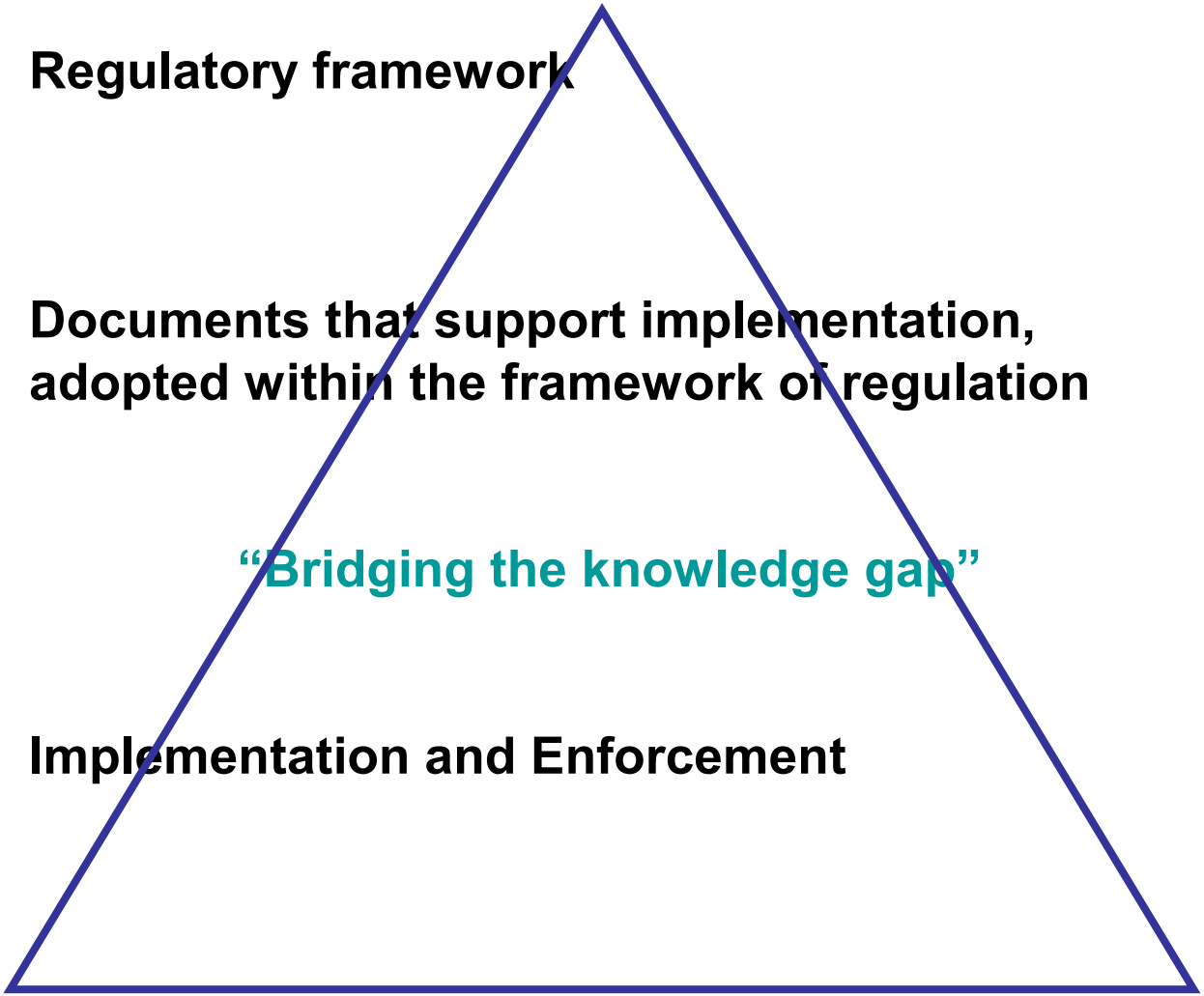
Commission Communication, accompanied by Commission Staff Working Document (CSWD)

CSWD contains

- Summary of main elements of EU legislation
- Research priorities for regulatory purposes
- Measures undertaken to address the knowledge gap and related action

Regulatory framework

- Risk assessment and risk management
- Technology neutral
- “No data, no market”
- Obligation to update on permanent basis technical file, authorisations…
- Premarket intervention or direct market access
- Information and access to information; labelling
- “Tools” for Member States and regulators; market intervention mechanisms
- Simultaneous application of different regulations, directives in different areas
- Smooth implementation ensured by documents adopted within regulatory framework, e.g. guidance, standards, “comitology”…..



Covers in principle HSE risks

Great amount of work to be done on developing implementing rules, standards, guidance, testing methods, risk assessment models, data gathering ……..

-/- "regulatory gaps"

Case-by-case

"No data no market"

Constant update on technical documentation, authorisations, approvals, etc.

An ongoing task

- Ensure that appropriate regulation is in place and is properly implemented and enforced
- Contribute to that essential knowledge gaps in relation to implementation of regulation are filled
- New report on review regulatory framework within 3 years

How are orientations in Communication, Commission Staff Working Document being implemented?

Some examples in relation to Cosmetics, Pharmaceuticals, Medical Devices, REACH, Food.

Second Implementation Report, 2009, will give overall view on actions implementing the 2005 Action Plan

Bridging the knowledge gap
Regulatory priorities for R&D

- Nomenclature, definitions
- Data on human health and environmental effects and test methods to generate data
- Data on exposures throughout the lifecycle, exposure assessment methods
- Measurement, characterisation and analytical tools

Work on Cosmetics

- EU Scientific Committees: SCCP and SCENIHR
- Increased dialogue Commission, Scientific Committees, Industry
- Cooperation under the ICCR
- Fact-finding as a basis for transparency and trust
- Recast of Directive on Cosmetic Products

Recast of Directive on Cosmetic Products
Proposal February 5, 2008

- Obligation to notify presence of substances in the form of “micronised particles”…
- Product Safety Report to pay particular consideration to any possible impacts on the toxicological profile due to inter alia particle sizes
- No provisions on “nano-labelling”
- Currently under discussion with Parliament and Council.

Medical Devices
Work on implementation and supporting documents

- MDEG WG New and emerging technologies on medical devices (N&ET); report on devices containing nano materials (2007)
  i. Reclassification of devices ‘Free nanoparticles’ (class III)
  ii. Voluntary Reporting Scheme
  iii. Regulatory guidance
  iv. Review of standards

- Mandate to CEN, CENELEC for review of standards, in cooperation with ISO/IEC

Public Consultation
Recast of the Directives on Medical Devices

- Are the Directives' "essential requirements" robust enough to cover risks in relation to the use of nanomaterials ?

- Are current conformity assessment procedures appropriate to cover highest risk category devices ?

Work on Medicinal Products
EMEA

Reflection paper on nanotechnology-based medicinal products for human use

- *The existing regulatory framework is flexible enough to accommodate products arising from new technologies*
- *Nanomedicine to be evaluated on a case by case basis using established principles of benefit/risk analysis.*
- *No specific guidance documents on nanomedicinal products at present. Once sufficient scientific experience has been gained for specifically identified sub-technologies within the field of nanomedicines additional guidance maybe developed.*

Work on Medicinal Products
EMEA

- A dedicated 'nano group' has been set up within the Innovation Task Force

- ITF nano group to provide a “forum for early dialogue with applicants on regulatory, scientific or other issues that may arise from the development of nanomedicinal products”

Work on Food

- Risk assessment of nanoparticles qualified by EFSA as a priority action for EFSA Advisory Forum and Scientific Committee

- June 2007, Commission request to EFSA to provide an initial scientific opinion on the risks arising from nanomaterials and nanotechnologies in the food and feed area

- Draft Opinion for public comments to be published recently (Session 7)

Work on Chemicals – REACH

- Dedicated expert group has been set up (Commission, Competent Authorities, Stakeholders) to discuss all specific aspects related to nanomaterials.

- Specific presentation in Session 7

European-wide dialogue with citizens and stakeholders at large

- Trust and transparency acknowledged as essential to the introduction of products on the market
- Various countries and sectors have set up platforms for dialogue
- Commission committed to creating a platform for citizens to voice their concerns in a dialogue with the Commission, Member States and nanotechnology professionals in relation to new products arriving on the market in the light of regulatory background
- Currently discussions Commission services on manageable and meaningful set-up