Second Regulatory Review on Nanomaterials Brussels, 3.10.2012 COM(2012) 572 final

This Communication constitutes the follow-up to the 2008 Commission Communication on regulatory aspects of nanomaterials1.

It assesses the adequacy and implementation of EU legislation for nanomaterials, indicates follow-up actions and responds to issues raised by the European Parliament2, the Council3 and the European Economic and Social Committee4.

It is accompanied by a Commission Staff Working Paper (SWP) on Nanomaterial Types and Uses, including Safety Aspects5 which responds to the European Parliament's concern that the Commission's approach to nanomaterials is jeopardised by the lack of information on the use and on the safety of nanomaterials that are already on the market.

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The 2011 Commission Recommendation on the definition of nanomaterials6 defines ‘nanomaterial’. The definition is intended to be used by Member States, European Union agencies and companies. The Commission will use it in EU legislation and instruments of implementation where appropriate.

Where other definitions are used in EU legislation, provisions will be adapted in order to ensure a consistent approach, although sector specific solutions may remain necessary. The Commission will review this definition in 2014.

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The annual quantity of nanomaterials on the gobal market is estimated at 11 million tonnes, with a value of roughly 20bn €.
Carbon black and amorphous silica are by far the largest volume of nanomaterials currently on the market.

Products underpinned by nanotechnology are forecast to grow from a volume of 200 bn € in 2009 to 2 trn € by 2015. There are many newly founded SMEs and spin-off companies in this high technology area. Currently, the direct employment in nanotechnology in EU is estimated at 300.000 to 400.000 jobs ang growing.

Nanotechnology has been identified as a key enabling technology (KET) providing the basis for further innovation and new products.

The Commission **has outlined a single strategy for KETs**, including nanotechnology, built upon three pillars: technological research, product demonstration and competitive manufacturing activities

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The applicable legislation must ensure a high level of health, safety and environmental protection. At the same time, it should permit access to innovative products and promote innovation and competitiveness. The regulatory environment affects time to market, marginal cost structure and allocation of resources, especially for SMEs. It also creates new business opportunities and contributes to consumer and investor confidence in the technology.

In addition to cooperation such as in the OECD or at UN-level, the Commission has started a regular dialogue with the United States in the context of the Transatlantic Economic Council (TEC), with a view to avoiding unnecessary divergences.

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In **2009, SCENIHR** concluded that *"while risk assessment methodologies for the evaluation of potential risks of substances and conventional materials to man and the environment are widely used and are generally applicable to nanomaterials, specific aspects related to nanomaterials still require further development.*

It further asserted that "*health and environmental hazards have been demonstrated for a variety of manufactured nanomaterials.* ***The identified hazards indicate potential toxic effects of nanomaterials for man and the environment****.*

As there is not yet a generally applicable paradigm for nanomaterial hazard identification, a case-by-case approach for the risk assessment of nanomaterials is still warranted."

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The key remaining question is: to what extent data for one form of a substance can be used to demonstrate the safety of another form, due to still developing understanding of e.g. drivers of toxicity.

- Clarity is required whether and which nanoforms of a substance are covered by a registration. These nanoforms should be adequately characterised, and the user should be able to identify which operational conditions and risk management measures apply to them.
- Information should be provided on which forms of a substance have been tested, with the test conditions adequately documented.
- Conclusions of a chemical safety assessment should cover all forms in a registration. *Where data from one form of a substance are used in demonstration of the safe use of other forms, a scientific justification should be given on how, applying the rules for grouping and read-across, the data from a specific test or other information can be used for the other forms of the substance***.** Similar considerations apply to exposure scenarios and the risk management measures.

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Harmonization and standardization of measurement and test methods in support of risk assessment of nanomaterials is being promoted through the OECD and by a Commission Mandate to the European Standards Organisations.

A study launched by the Commission in 2011 on occupational risks of nanomaterials, and other relevant research, including on the fate of nanomaterials in the environment and in waste, will provide more insight for further legislative guidance and risk assessment work.

Research concerning safety and the development of reliable test methods will also remain a key priority under the EU Framework Programmes and for the Commission's Joint Research Centre.

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Reach registrations for substances known to have nanomaterial forms do not mention clearly which forms are covered or how information relates to the nanoform. Only little information is specifically addressing safe use of the specific nanomaterials supposed to be covered by the registration dossiers.

The Commission will therefore, based on available information on technical progress,including the REACH Implementation Projects on Nanomaterials and experience with the current registrations, in the upcoming REACH review assess relevant regulatory options, in particular possible amendments of REACH annexes, to ensure clarity on how nanomaterials are addressed and safety demonstrated in registrations.

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Whether nanoforms have been addressed in one or several registrations, for the Commission the key issue remains whether the registration provides clear information on the safe use for all forms of the substance.

ECHA has updated guidance to take into account the final RIPoN Reports and has set up a Group Assessing Already Registered Nanomaterials (GAARN), who considers in co-operation with the Commission, Member States experts and stakeholders, a few key nanomaterial registrations. The purpose is to identify best practices for assessment and reporting of nanomaterials in REACH registrations and to develop recommendations on how to fill potential information gaps. In addition, ECHA has set up a Nanomaterials Working Group to give advice on scientific and technical issues in relation to nanomaterials under REACH.