

Regulatory aspects of nanomaterials

2008/2208(INI) - 03/10/2012 - Follow-up document

The Commission presents a Communication on regulatory aspects of nanomaterials, which constitutes the follow-up to the [2008 Commission Communication](#). It assesses the adequacy and implementation of EU legislation for nanomaterials, indicates follow-up actions and responds to issues raised by the European Parliament, the Council and the European Economic and Social Committee.

This communication is accompanied by a Commission Staff Working Paper on Nanomaterial Types and Uses, including safety aspects 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.

Benefits of nanotechnology: the total annual quantity of nanomaterials on the market at the global level is estimated at around **11 million tonnes, with a market value of roughly EUR 20 billion**. Carbon black and amorphous silica, which have been on the market for decades, represent by far the largest volume of nanomaterials currently on the market. The group of materials currently attracting most attention are nano-titanium dioxide, nano-zinc oxide, fullerenes, carbon nanotubes and nanosilver. Those materials are marketed in clearly smaller quantities than the traditional nanomaterials, but the use of some of these materials is increasing fast.

Other new nanomaterials and new uses are being developed rapidly. Many are used in innovative applications such as catalysts, electronics, solar panels, batteries and biomedical applications including diagnostics and tumour therapies.

1) The benefits of nanomaterials: these range from saving lives, breakthroughs enabling new applications or reducing the environmental impacts to improving the function of everyday commodity products.

Products underpinned by nanotechnology are **forecast to grow from a volume of EUR 200 billion in 2009 to EUR 2 trillion by 2015**. These applications will be essential for the competitiveness of a wide area of EU products in the global market. Currently, the direct employment in nanotechnology is estimated at 300 000 to 400 000 jobs in the EU, with an increasing tendency.

Nanotechnology has been identified as a key enabling technology (KET) and the Commission has outlined a single strategy for KETs, built upon three pillars: technological research, product demonstration and competitive manufacturing activities.

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.

2) Definition: Commission Recommendation 2011/696/EU contains the definition of nanomaterials which is intended to be used by Member States, EU agencies and companies. The Commission will use it in EU legislation. Where other definitions are used, 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.

3) Safety-related aspects: natural and incidental man-made nanoparticles are ubiquitous in the human environment and their presence and behaviour is generally known and understood. However, **limited data**

exist on manufactured nanoparticles in the workplace and the environment. There are major technical challenges in monitoring their presence, including those pertaining to their small size and low concentration levels and in distinguishing particles of manufactured nanomaterials from natural or incidental nanoparticles. Detecting nanomaterials in complex matrices such as cosmetics, food, waste, soil, water or sludge is even more challenging. While some monitoring methods exist, these often remain to be validated, which hampers comparability of data.

In the light of current knowledge and opinions of the EU Scientific and Advisory Committees and independent risk assessors, nanomaterials are similar to normal chemicals/substances in that **some may be toxic and some may not.** Possible risks are related to specific nanomaterials and specific uses. Therefore, nanomaterials require a **risk assessment, which should be performed on a case-by-case basis,** using pertinent information. Current risk assessment methods are applicable, even if work on particular aspects of risk assessment is still required.

Important challenges relate primarily to establishing validated methods and instrumentation for detection, characterisation, and analysis, completing information on hazards of nanomaterials and developing methods to assess exposure to nanomaterials.

4) REACH and CLP: pursuant to the [REACH Regulation](#), chemical substances imported or manufactured in the EU must in most cases be registered with ECHA, demonstrating their safe use. The registration dossier or substance may be subject to evaluation. Depending on its characteristics, any substance may be subject to authorisation or restrictions. REACH applies equally to substances for which all or some forms are nanomaterials.

Regulation (EC) No 1272/2008 (the CLP Regulation) provides an obligation to notify to ECHA substances in the forms as placed on the market, including nanomaterials, which meet the criteria for classification as hazardous, independent of their tonnage.

The European Parliament called on the Commission **to evaluate the need to review REACH** concerning simplified registration for nanomaterials manufactured or imported below one tonne, consideration of all nanomaterials as new substances, and a chemical safety report with exposure assessment for all registered nanomaterials.

The Commission looks in detail at the assessments conducted, including the chemical safety assessments, as well as at the guidance available and studies planned. It is also taking steps to ensure that remaining implementation gaps in legislation – relating, for example to water or industrial emissions - are addressed.

It states that **overall it remains convinced that REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures but more specific requirements for nanomaterials within the framework have proven necessary.**

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

5) Access to information: lastly, with a view to **improving transparency**, the Commission will create a **web platform** with references to all relevant information sources, including registries on a national or sector level, where they exist. A first version mainly based on links to available information will be put on line as soon as possible. The Commission will assist in the elaboration of harmonised data formats, to improve exchange of information. In parallel, it will be launching an **impact assessment** to identify and

develop the most adequate means to increase transparency and ensure regulatory oversight, including an in-depth analysis of the data gathering needs for such purpose. This analysis will include those nanomaterials currently falling outside existing notification, registration or authorisation schemes.

The Commission will follow closely the evolution of the dossier and will present a **report** to the European Parliament, the Council and the European Economic and Social Committee within a period of three years.