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Nanomaterials: Commission proposes case by case approach to assessment

Why a second regulatory review for Nanomaterials?

Both the potential of nanomaterials to create major new technological breakthroughs[1] as well as concerns about their safety have attracted considerable attention. The regulatory review is a systematic analysis of all relevant EU legislation to determine whether current legislation is appropriate to ensure the safe use of nanomaterials, whether and what regulatory gaps need to be filled, and how this can be done without jeopardizing their contribution to innovation, growth and job creation for the European economy.

The Commission Communication on the Second Regulatory Review is an update of the 2008 Regulatory Review[2] and responds to a 2009 European Parliament Resolution, which criticised the 2008 review on a number of aspects and called for further information and analysis; as well as to a 2010 call by the Council to evaluate the need to develop specific nanomaterials measures relating to risk assessment and management, information and monitoring.

The Communication is accompanied by a Staff Working Paper on nanomaterial types and uses, including safety aspects, which gives a detailed overview of available information on nanomaterials on the market.

[1] Nanotechnology has been identified as one of six key enabling technologies (KETs) by the High Level Expert Group on Key Enabling Technologies;
http://ec.europa.eu/enterprise/sectors/ict/key_technologies/kets_high_level_group_en.htm.

[2] For more details and an overview of Commission action since its first Communication in 2004, see
http://ec.europa.eu/nanotechnology/index_en.html

The Review's main conclusions: Nanomaterials are similar to normal chemicals/substances

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. Important challenges relate primarily to establishing **validated methods and instrumentation for detection, characterization, and analysis**, completing information on nanomaterial hazards and developing methods to assess exposure to nanomaterials:

- **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.
- Overall the Commission remains convinced that the Registration, Evaluation, Authorisation and Restriction of Chemical substances **(REACH) Regulation is the best possible framework for the risk management of nanomaterials** when they occur as substances or mixtures, but within this framework more specific requirements for nanomaterials have proven necessary. The Commission envisages modifications in some of the REACH Annexes and encourages ECHA to further develop guidance for registrations after 2013.
- In order to improve the availability of information on nanomaterials, 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). In parallel, the Commission will launch an impact assessment to identify and develop the best means to increase transparency and ensure regulatory oversight, including an in-depth analysis of consequent data gathering needs. This analysis will include those nanomaterials currently falling outside existing notification, registration or authorisation schemes.

What are nanomaterials and which definition is applied?

Nanomaterials are materials which **often have specific properties due to their small particle size**. The 2011 Commission Recommendation on the definition of nanomaterials[3] defines 'nanomaterial' as *"a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50% may be replaced by a threshold between 1 and 50%. […]*"

[3] Commission Recommendation 2011/696/EU, OJ L 275, 20.10.2011

There are **no changes to the definition envisaged** at this stage, although a review is planned for 2014 in the light of experience and of scientific and technological developments. At present, the Commission aims to integrate the definition into existing and future EU legislation, to develop detection, measurement and monitoring methods for nanomaterials and to validate those methods to ensure the proper implementation of the definition. This follows on from a recently published report by the Commission's Joint Research Centre on requirements for measurements for the implementation of the Commission definition of the term 'nanomaterial'[4].

Today's report gives detailed explanations of the main elements of the definition and the reasoning of the choices made. The different types of nanomaterials are described in appendix 1 to the Staff Working Paper, including a comparison between the EU and International Organization for Standardization (ISO) definitions and terminology.

Three groups of nanomaterials

The total annual quantity of nanomaterials on the global market is around 11 million tonnes, with a market value of roughly 20bn €. The Staff Working Paper, in particular Appendix 2, gives a detailed overview of nanomaterials currently on the market, as well as their uses.

1. "Traditional" high volume nanomaterials

Contrary to what is suggested in public debate, more than 99.9% of all nanomaterials on the market in terms of production volumes and sales are produced in **quantities above 1 tonne per year**. Many of the highest volume nanomaterials on the market are widespread in application and have been on the markets for decades, if not more than a century. Examples of such **"traditional" high volume nanomaterials** include carbon black (a filler in tyres, rubber and polymer materials) and synthetic amorphous silica: used in a wide variety of applications, including as a filler in tyres and polymers, to provide anti-slip properties in paper, in paints and adhesives, in the food industry as a widely used anti-coagulant in food powders, as an aid to clear beer, wine, and fruit juices, in tooth paste, in the construction industry as an insulation material.

2. Nanomaterials currently attracting most attention in the public debate

Examples include nano-titanium dioxide, nano-zinc oxide, fullerenes, carbon nanotubes and nanosilver. Those materials are marketed in clearly **smaller quantities** than the traditional nanomaterials. Many of those have been developed more recently and the use of some of those materials is increasing fast, although not necessarily at the pace of some earlier projections.

- **Nano-titanium dioxide and nano-zinc dioxide** can be used as a UV-filter in sunscreens (currently subject to an evaluation by the Scientific Committee on Consumer Safety), in paints and varnishes and in self-cleaning surfaces in the construction industry.
- **Carbon nanotubes** are mainly used to impart electrical conductivity to plastic materials, e.g. in disk drive components or automotive plastic fuel lines and fenders. Other uses include polymer additives, paints and coatings, fuel cells, electrodes, electrolytes and membranes in batteries, especially lithium batteries.

[4] http://ec.europa.eu/dgs/jrc/index.cfm?id=2540

- **Fullerenes** are very often confused with carbon nanotubes and are used in high market applications requiring particular strength such as tennis rackets and golf balls, but also in cosmetics, fuel and solar cells. However due to their high cost, their market is rather limited.
- **Nanosilver** can be used as a disinfectant and anti-odour substance in textiles. However, its use seems relatively limited (estimated at roughly 20 tonnes worldwide).

3. Different nanomaterial substances and new uses

This group of nanomaterials covers a wide range of different nanomaterial substances and new uses which are being developed rapidly, mainly in specialised technical applications. Examples of such applications include catalysts, electronics, solar panels, batteries and biomedical applications including diagnostics and tumour therapies. This group of nanomaterials has a very high innovation potential and rarely includes applications with high potential for direct exposure to consumers.

There are also new applications such as graphene or quantum dots for which some give very high market projections. However, the Commission currently does not have substantiated information on the size of their current market presence.

Why do we need nanomaterials, and what are their benefits?

The use values and benefits of nanomaterials vary widely, depending on the substance and its uses. In certain cases such as **tumour therapies**, nanomaterials can directly save lives. In others they improve everyday commodity products, such as paints and varnishes, anti-slip paper, improved toner inks for better printing, or simply make tooth paste clean teeth better and faster. In again others, they improve industrial processes e.g. by better catalysis.

In other cases, they can **create major technological breakthroughs** such as in batteries, fuel cells, or electronics. Some of those innovations will be crucial to resolve environmental problems such as energy generation and storage from renewable sources. The importance of nanomaterials is not only determined by their own value but also by the value added to products in which they are incorporated. For example, cars increasingly incorporate nanomaterial based components (antistatic fuel lines, anti-scratch paints etc.) which will be essential to keep their market value and competitive edge on the world market. Products underpinned by nanotechnology are forecast to grow from a volume of 200 bn € in 2009 to 2 trn € by 2015.

In particular in the high-innovation segment of nanomaterials, there are many newly founded SMEs and spin-off companies. Currently, direct employment in nanotechnology is estimated at 300 000 to 400 000 jobs in the EU, with a growth tendency.

Europe is still competitive, but China is catching up

Most nanomaterials are produced in all industrialised countries, and it is difficult to give a general and conclusive picture whether Europe, the US or the industrialised countries in East Asia are market leaders. Industrialising countries such as China also have a rapidly increasing production of nanomaterials but overall seem to still somewhat lag behind the industrialised world regions.

In general, Europe seems to be quite strong in research and development on nanotechnologies but less strong in transforming research results swiftly into cutting edge goods and services. The European Commission’s work on key enabling technologies, which include nanotechnologies aims at bridging this gap.

Should we be concerned about nanomaterials? Are they hazardous? Should we apply the precautionary principle?

Research on nanomaterials and knowledge on their hazard properties has significantly improved. There are no indications that nanomaterials as a group of materials are toxic to a degree which would require immediate responses without awaiting scientific assessments. The independent Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) concluded that nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. Like for most other chemicals, toxic responses can be found at high or very high doses (the thresholds vary significantly from nanomaterial to nanomaterial). There is a significant discussion among scientists whether the doses at question are realistic compared to normal exposure situations for consumers or workers handling nanomaterials.

Contrary to hazard patterns, information on exposure to nanomaterials is scarce. This is because there are few methods or models to detect their presence in complex materials and the environment. Also, it is difficult to distinguish manufactured nanomaterials from natural (e.g. fine dust) or incidental nanomaterials (e.g. diesel exhaust). Therefore, also little is known about their fate at the waste stage and in the environment.

Overall, notwithstanding a number of uncertainties, there is no reason for alarm about nanomaterials. The applicable instruments of science-based policy making, including risk assessment, scientific opinions and risk management are in principle working and should be fully used to deal with potential risks related to nanomaterials. This does not exclude that certain adaptations of regulation and guidance may be necessary and that in certain cases a precautionary approach on the basis of available scientific results might be the best policy response.

Existing methods to assess the risks of nanomaterials are adequate: In 2006 the OECD launched a work programme to ensure that the approaches for hazard, exposure and risk assessment for manufactured nanomaterials are of a high quality, science-based and internationally harmonised. The OECD recently confirmed that *"approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials. As with other chemicals, it is clear that each nanomaterial may pose specific challenges, but in most instances, they can be addressed with existing test methods and assessment approaches."*[5]

Position of the European Scientific Committees/agencies

In its opinion of 19 January 2009, the SCENIHR concluded: "*The health and environmental hazards were demonstrated for a variety of manufactured nanomaterials. The identified hazards indicate potential toxic effects of nanomaterials for man and environment. However, it should be noted that not all nanomaterials induce toxic effects. Arguably, some manufactured nanomaterials have been in use for a long time (carbon black, TiO_2) and show low toxicity. The hypothesis that smaller means more reactive and thus more toxic cannot be substantiated by the published data. In this respect nanomaterials are similar to normal substances in that some may be toxic and some may not. 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 recommended*."

[5] http://www.oecd.org/env/chemicalsafetyandbiosafety/safetyofmanufacturednanomaterials/

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. This will remain so until there is sufficient scientific information available to characterise the harmful effects of nanomaterials on humans and the environment*."

The guidance provided by the **European Food Safety Authority** (EFSA) in 2011 offers a strategy for risk assessment in food and feed. It concerns (i) characterisation requirements of engineered nanomaterials used in food and feed and (ii) testing approaches to identify and characterise hazards to human health during use. The guidance lowers information requirements in the absence of exposure, i.e., no migration from a food contact material, or of absorption of engineered nanomaterials as such because of complete degradation/dissolution. The guidance also flags uncertainties.

In the medicinal products area, the **European Medicines Agency** (EMA) has been examining applications of nanotechnologies to medicinal products since 2006. To date, recommendations from the EMA Committee for Medicinal Products for Human Use (CHMP) has led to the approval of about twenty medicines based on nanotechnology.

Do nanomaterials fall below the tonnage thresholds so that they will not be registered in REACH?

Like any chemical, the safety of nanomaterials is regulated by the REACH Regulation. Manufacturers and importers of nanomaterials at quantities of 1 tonne or more per year must register the substance and ensure its safe use throughout the supply chain. For substances in the tonnage band 1-100 tonnes, the deadline for registrations is 2018, for substances between 100 and 1000 tonnes, the deadline is in May 2013, except where the nanomaterial is a new substance, which is not on the European Inventory of Existing Commercial chemical Substances (EINECS) list of substances established in the 1980s. These deadlines were put in place because gathering the necessary data is a major exercise, and because lower tonnage substances are more likely to be produced by SMEs who should be able to benefit from the experiences of the first registration deadline. Therefore, it was decided to start with high production volume and the most dangerous substances. Nanomaterials were not treated differently than any other substances. The Commission cannot see a reason why this should be changed because the general hazard and risk patterns do not differ from other chemical substances.

The most prevalent of nanomaterials in terms of tonnage and sales have already been registered, as they are produced in the high tonnage band. However, the Commission has found that many of the existing registration dossiers for nanomaterials do not specify clearly how specific risks of nanomaterials are addressed (for substances which can occur both in nanomaterial and non-nanomaterial forms) and. Therefore, the Commission envisages **modifying one or several REACH Annexes** to require clarity on these aspects. Moreover, despite the general applicability of existing risk assessment methods, specific aspects of testing requirements may need to be adapted. A number of options will be assessed in an impact assessment.

In addition, the **European Chemicals Agency (ECHA) has updated guidance** for nanomaterials and has set up a group assessing previously registered nanomaterials (GAARN), to gather experiences from existing registration dossiers and a Nanomaterials working group to give advice on scientific and technical issues in relation to nanomaterials under REACH.

Most nanomaterials on the market in terms of quantities on the market but also - a few exceptions apart - most of the nanomaterials which are currently publicly debated are produced in quantities clearly above 1 tonne per year and manufacturer. Small volume nanomaterials are mostly used in technical applications such as catalysts or in applications where the nanomaterials are bound in a matrix or enclosed in equipment. Consumer and environmental exposure to those nanomaterials is likely to be limited.

In line with SCENIHR's conclusion that nanomaterials are similar to normal substances in that some may be toxic and some may not, the Commission does not consider appropriate at present to change the rules for when a chemicals safety assessment is required.

How many nanomaterials are on the European market and how many have been registered under REACH?

There are roughly 20-30 nanomaterial substances on the European market which are produced in significant quantities and many of those have been registered. However, there are a number of factors which make it difficult to give exact figures. One of those factors is the absence of an obligation under REACH to indicate whether a registration dossier concerns a nanoform (although this is possible on a voluntary basis through a tickbox in REACH-IT). Another factor is that, especially for substances with both nano and non-nano forms, it is often unclear whether and how the nanoform has been covered by the registration dossier.

In addition, there is a high number (in the rough range of several hundreds to a few thousand) of substances which are produced as nanoparticles in low quantities, mostly for very technical applications with little direct consumer exposure. However, for those it is often unclear whether they are used in products placed on the market, or still mainly used for research and development.

In close collaboration with ECHA, the Commission has assessed how nanomaterials have been addressed in REACH registration and Classification, labelling and packaging of substances and mixtures Regulation (CLP) notification dossiers. At the end of February 2012, seven substances had selected "nanomaterial" as the form of the substance in voluntary fields in their registration dossiers. Further assessment of registrations identified additional substances relating to nanomaterials. In some cases, substances occur only or mainly as nanomaterial. Therefore, there is little doubt that those registrations concern nanomaterials, even though the voluntary tickbox has not been ticked. In other cases, registration dossiers for substances with both nano and non-nano forms contain information (such as particle size distribution) suggesting that the nanoform is covered by the registration dossier. More details on this are explained in the Staff Working Paper section 5.2.

As part of the REACH registration dossier, registrants must also indicate whether their substances meet criteria to be classified as hazardous substances. Most of the substances with known nanoforms have not been classified as hazardous. Where they have been classified as hazardous, both the nano- and bulk forms are normally hazardous. This information should however be taken with the caveat that this is self-classification by registrants and that often it is unclear from the registration dossier whether the classification or absence thereof concerns the non-nano and/or nanoform.

Where this is not already covered by the REACH registration dossier, all hazardous substances, including nanomaterials must be notified to the European Chemicals Agency (ECHA), independently of their tonnage (thus also covering very small amounts). There is also the possibility for notifiers to indicate that the notification concerns nanomaterials. Among the dossiers received by ECHA, 18 CLP notifications had selected nanomaterial as the form of the substance

Appendix 2 of the Staff Working Paper gives relevant information per substance such as whether it has been registered under REACH and whether it has been classified as hazardous under the CLP Regulation. Appendix 3 presents an ECHA analysis on the coverage of nanomaterials in registration and notification dossiers.

What other legislation is in place to ensure safety of nanomaterials? Are there gaps?

A range of other pieces of legislation apply to specific uses of nanomaterials — mainly **consumer products** where the exposure to nanomaterials may be particularly high. This includes the **Cosmetics and Biocides Regulations**, as well as legislation on food and food contact materials. Further legislative work is envisaged, in particular for **novel foods**. The Commission also takes a **positive view on ingredient labelling**, i.e. risk independent information on the presence of nanoforms in products where ingredients lists exist (already included in the Cosmetics, Biocide and Food Labelling Regulations). Nanomaterials are also covered by **medical regulations**, and a number of nanomedicines (e.g. for tumour treatment) have already been authorised. Those regulations have been found to adequately address risks from nanomedicines.

Workplace legislation currently does not contain specific provisions on nanomaterials. However, the Commission has launched a study on nanomaterials in the workplace. In addition to this study, a Nano subgroup of the Chemicals working party set up under the Advisory Committee on Safety and Health at Work is working on a draft opinion on risk assessment and management of nanomaterials at the workplace, to be subsequently endorsed by the Advisory Committee. A final assessment on whether a revision of occupational health and safety legislation is necessary will be made by 2014 in the light of these activities and respective conclusions.

The Commission has also assessed the coverage of nanomaterials in **environmental legislation** such as waste, water and air legislation. Although those pieces of legislation in principle allow measures to limit the presence of nanomaterials in these media, in practice this is found to be difficult. This is because of lack of ways to measure the presence of nanoparticles in the environment and to eliminate them from materials once they are integrated. Therefore, the **Commission favours measures at source** (e.g. through risk management measures under REACH) to limit potential emissions to the environment.

Does the Commission envisage creating a nanomaterial registry, as in France?

The Commission's objective is to give as much transparent information on nanomaterials, their risks and on products containing nanomaterials as possible. The Communication, and in particular the attached Staff Working Paper give a good overview of available information. Current knowledge about nanomaterials does not suggest risks which would require information about all products in which nanomaterials are used. Experience so far shows that, if risks were to be identified, they could be handled with the existing tools such as the General Product Safety Regulation and its RAPEX system, or more specific instruments under EU product legislation. Currently available information (such as the information presented in the attached Staff Working Paper and the information generated by existing legislative tools such as REACH and the Cosmetics Regulation) is considered a good basis for policy making.

As a **first step, 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. In parallel, the Commission 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.

See also:

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