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**COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN  
PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL  
COMMITTEE**

**Second Regulatory Review on Nanomaterials**

(Text with EEA relevance)

{SWD(2012) 288 final}

# COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

## Second Regulatory Review on Nanomaterials

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### 1. INTRODUCTION

This Communication constitutes the follow-up to the 2008 Commission Communication on regulatory aspects of nanomaterials<sup>1</sup>.

It assesses the adequacy and implementation of EU legislation for nanomaterials, indicates follow-up actions and responds to issues raised by the European Parliament<sup>2</sup>, the Council<sup>3</sup> and the European Economic and Social Committee<sup>4</sup>.

It is accompanied by a Commission Staff Working Paper (SWP) on Nanomaterial Types and Uses, including Safety Aspects<sup>5</sup> 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. The SWP provides detailed information on the definition of nanomaterials, nanomaterial markets, uses, benefits, health and safety aspects, risk assessment, and information and databases on nanomaterials. Its main conclusions are reflected in sections 3 and 4.

### 2. DEFINITION OF NANOMATERIALS

The 2011 Commission Recommendation on the definition of nanomaterials<sup>6</sup> 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 %. [...]*"

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

<sup>1</sup> COM (2008) 366, 17.6.2008

<sup>2</sup> Resolution European Parliament on Regulatory Aspects of Nanomaterials (2008/2208(INI), 24.4.2009

<sup>3</sup> Conclusions on "improving environmental policy instruments" of 20 December 2010

<sup>4</sup> Opinion European Economic and Social Committee; INT/456 of 25.2.2009, Nanomaterials

<sup>5</sup> SWD(2012) 288 final

<sup>6</sup> Commission Recommendation 2011/696/EU, OJ L 275, 20.10.2011

remain necessary. The Commission will review this definition in 2014.

### **3. BENEFITS OF NANOMATERIALS AND THEIR CONTRIBUTION TO GROWTH AND JOBS; INNOVATION AND COMPETITIVENESS**

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 20bn €. Carbon black and amorphous silica represent by far the largest volume of nanomaterials currently on the market<sup>8</sup>. Together with a few other nanomaterials, they have been on the market for decades and are used in a wide variety of applications.

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

International collaboration in particular with our trade partners can stimulate the development and commercialization of nanotechnology-enabled applications and industries.

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.

## **4. SAFETY ASPECTS**

### **4.1. Nanomaterials in the workplace, in consumer products and in the environment**

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 to monitor their presence, including those pertaining to their small size and low concentration levels and to 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.

### **4.2. Safety, risk assessment, and risk/benefit assessment**

Since 2004, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and the Scientific Committee on Consumer Safety (SCCS), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA) have been working on the risk assessment of nanomaterials.

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

*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. However, it should be noted that not all nanomaterials induce toxic effects. Some manufactured nanomaterials have already been in use for a long time (e.g., carbon black, TiO<sub>2</sub>) showing low toxicity. Therefore, 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 chemicals/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 still warranted.”<sup>13</sup>*

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<sup>13</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_023.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf), p. 52 and p. 56.

EFSA in its 2011 scientific opinion<sup>14</sup> confirmed that the risk assessment paradigm used for the evaluation of standard food products is also appropriate for nanomaterial applications in the food and feed chain and the need for a case by case approach. Such a case-by-case approach is in place through the pre-market approval system in food and feed legislation (such as novel foods, food additives, feed additives, plastic food contact materials). A similar approach was adopted by the EMA for medicinal products.<sup>15</sup>

Despite certain limitations as mentioned by the Scientific Committees and Agencies, in particular the need for a case-by-case scientific approach when assessing differences between bulk and various nanofoms of the same chemical substance, it is possible to perform risk assessments of nanomaterials today.

Several risk assessments and risk/benefit assessments have been completed and various products in different sectors have been authorised (such as 20 medicines and three food contact materials<sup>16</sup>). The SCCS has assessed and approved the safety of one nanomaterial used as a UV filter and is completing the assessment of three other nanomaterials. Other substances will be assessed as the case arises (e.g. UV filters, food and feed ingredients).

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.<sup>17</sup>

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.

## 5. REACH AND CLP

Pursuant to REACH<sup>18</sup>, 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

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<sup>14</sup> Scientific opinion on "Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain" (2011), 9(5):2140.

<sup>15</sup> [http://www.ema.europa.eu/ema/index.jsp?curl=pages/special\\_topics/general/general\\_content\\_000345.jsp&mid=WC0b01ac05800baed9](http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000345.jsp&mid=WC0b01ac05800baed9)

<sup>16</sup> Namely silicon dioxide, carbon black and titanium nitride. Silicon dioxide has also been authorised as food additive.

<sup>17</sup> M/461 EN of 2.2.2010

<sup>18</sup> Regulation (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). OJ L 136, 29.5.2007, p.3. Unofficial consolidated version see:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20110505:en:PDF>

be subject to authorisation or restrictions. REACH applies equally to substances for which all or some forms are nanomaterials.<sup>19</sup>

The CLP Regulation<sup>20</sup> 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.

### **5.1. Coverage of nanomaterials in REACH registrations and CLP notifications**

Many substances exist in different forms (solids, suspensions, powders, nanomaterials, etc.). Under REACH, different forms can be considered within a single registration of a substance. However, the registrant must ensure the safety of all included forms and provide adequate information to address the different forms in the registrations, including the chemical safety assessment and its conclusions (e.g. through different classifications where appropriate).

The information requirements of REACH registration apply to the total tonnage of substance, including all forms. There is no prescription to undertake specific tests for each different form, or to spell out the way in which the different forms have been addressed in the registrations, although the REACH dossier structure allows this and the technical advice from ECHA encourages it.

In close collaboration with ECHA, the Commission has assessed how nanomaterials have been addressed in REACH registrations and CLP notifications. As of February 2012, 7 substance registrations and 18 CLP notifications had selected "nanomaterial" as the form of the substance in voluntary fields. A further assessment identified additional substances with nanoforms.<sup>21</sup>

Many 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. These findings can partly be explained by the absence of detailed guidance to registrants on registration for nanomaterials and the general wording of the REACH annexes.

The Commission Recommendation on a definition of nanomaterial will clarify terminology, but will in itself not provide the necessary clarity to the registrants on how to address nanomaterials in REACH registrations.

The Commission will therefore, based on available information on technical progress, including the REACH Implementation Projects

particular possible amendments of REACH annexes, to ensure clarity on how nanomaterials are addressed and safety demonstrated in registrations.

## 5.2. Substance identification and registration timelines

Many substances exist as bulk and nanoforms. The nanoforms can be seen as forms of the same substance or as distinct substances. In the latter case, the question arises whether they are treated as “new” substances and whether they would be subject to immediate registration.<sup>22</sup>

When more experience from the evaluation of registrations is available, ECHA will provide guidance on treating nanomaterials as forms of a bulk substance or as distinct substances with the aim of enabling effective data sharing. The results of the REACH Implementation Project on Nanomaterials on Substance Identification (RIPoN1) suggest, however, that some flexibility will be needed. 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.

## 5.3. Chemical safety assessment

RIPoN on Information Requirements (RIPoN2) and the RIPoN on Chemical Safety Assessment (RIPoN3)<sup>23</sup> address – inter alia - the question whether the existing REACH requirements and the relevant guidance are appropriate to assess nanomaterials. They contain a number of specific proposals.

RIPoN 2 concluded that, with a few caveats, the guidance at the time of the project and the information requirements were considered applicable for the assessment of nanomaterials. RIPoN3 concluded that known exposure assessment methods were generally applicable but may still experience methodological challenges.

The REACH approach to hazard assessment and risk characterisation, with its built-in flexibility, makes it overall suitable for nanomaterials. 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. In a case-by-case scientific approach:

- 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

<sup>22</sup> Any immediate registration requirement for nanomaterials treated as new substance could reasonably only apply from the moment that the interpretation of the REACH provisions was clear enough for registrants to exclude the interpretation that the nanomaterial is a form of an existing substance.

<sup>23</sup> <http://ec.europa.eu/environment/chemicals/nanotech/index.htm#ripon>

grouping and read-across<sup>24</sup>, 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.

ECHA has updated guidance to take into account the final RiPoN Reports. ECHA 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.

#### **5.4. Extension of REACH obligations to small volume nanomaterials**

Most nanomaterials which are subject to a scientific debate are manufactured or imported in volumes of 1 tonne per year or more. 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. As regards registration thresholds and timelines for registration based on volume, the Commission considers REACH appropriate, subject to actions outlined in chapter 7.

### **6. HEALTH, SAFETY AND ENVIRONMENT PROTECTION IN EU LEGISLATION**

The Parliament called on the Commission to evaluate the need to review a number of areas of legislation, including air, water, waste, industrial emissions and worker protection legislation.

- As regards safety and health at work, the ongoing work can be summarized as follows:

In addition to the study on nanomaterials in the workplace<sup>25</sup>, 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 a review of occupational health and safety legislation will be made by 2014 in the light of these activities and respective conclusions.

- As regards consumer product safety legislation, work is under way on adapting the relevant legislation in order to transpose the horizontal definition and to introduce specific provisions on nanomaterials; on updating the relevant risk assessment processes; on strengthening market surveillance; and on improving information and labelling requirements:

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<sup>24</sup> REACH, Annex XI, section 1.5

<sup>25</sup> See section 4.2



The Commission is committed to implement the definition of nanomaterials in consumer product safety legislation, when appropriate. Specific provisions on nanomaterials have been introduced for biocides, cosmetics, food additives, food labelling and materials in contact with foodstuff.

At the same time, the Commission undertook a detailed analysis of how consumer product legislation is being implemented with reference to nanomaterials. The main challenge remains the implementation of a proper risk assessment, also in those areas where legislative change has been implemented.

Therefore, for instance, EFSA has at the request of the Commission adopted a guidance document<sup>26</sup> clarifying the data to be provided when submitting an application dossier for a nanomaterial to be incorporated in food and feed.

Similarly, guidance has recently been developed by the Scientific Committee on Consumer Safety for cosmetic products.

The Commission takes the view that current legislation on medicinal products allows an appropriate risk/benefit analysis and risk management of nanomaterials.

For legislation on medical devices, actions under consideration include a labelling requirement in a proposal foreseen for 2012. In addition, the Commission is considering to reclassify devices containing free nanomaterials under Class III, making them subject to the

CLP and exposure information. There is still a considerable lack of data on exposure to nanomaterials via the environment. Consequently, no specific provisions for nanomaterials have yet been established in EU environmental legislation, triggering measures to control such pollutants through monitoring, separate treatment or environmental quality standards. This applies also to the risk management responses explicitly identified by the European Parliament: new environmental quality standards, revision of emission limit values, a separate entry for nanomaterials in the list of waste and the revision of waste acceptance criteria in landfills. As risk characterisation may depend on particle size or surface functionalization, it is anticipated that setting the precise scope, dose metrics and value of any thresholds employed under environmental legislation, if necessary, would be more challenging than for conventional pollutants. REACH should generate relevant data in this respect.

Even when it is possible to show the presence of specific nanoparticles in environmental media or waste, it would be technically difficult to separate or eliminate them. Therefore 'end-of-pipe' measures would not be effective to prevent potential negative impacts on the environment or health, nor would they allow addressing any emerging recycling challenges or need for remediation in a cost-effective manner.

Although the Commission does not exclude specific provisions in downstream environmental legislation, potential risks are normally best addressed "upstream" by REACH and product legislation. Any CLP classification of a nanomaterial will automatically unlock some operative provisions across a range of environmental legislation that serve to control releases of hazardous substances into the environment.

The Commission is also taking steps to ensure that remaining implementation gaps of the legislation are addressed. For example, revisions of the selection process for priority substances under the water legislation and the relevant BREF<sup>28</sup> documents under industrial emissions legislation, incorporating various nanomaterial aspects, are already being pursued.

Developing capacity to monitor and model nanomaterials, e.g. in the environment is necessary. This will facilitate the evaluation of the efficiency of different tools of the environmental legislation and inform appropriate risk management strategies. Where necessary, this will be supported by targeted implementing environmental legislation.

## 7. NEED FOR BETTER ACCESSIBLE INFORMATION

Transparency of information on nanomaterials and products containing nanomaterials is essential. This has been recognised by the Parliament which has called on the Commission to evaluate the need for notification requirements for all nanomaterials, including in mixtures and articles, and the Council, which invited the Commission to evaluate the need for the further development of a harmonized database for nanomaterials, while considering potential impacts.

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

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<sup>28</sup> BREFs - Best available technique REFERENCE Documents define Best Available Technique (BAT) for individual industrial sectors under the Industrial Emission Directive

Product Safety Directive<sup>29</sup> and its RAPEX system<sup>30</sup>, 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. 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, the Commission will be launching an impact assessment to identify and develop

## ANNEX

Action	Content	Timeline
Nanomaterial Definition	Implementation of definition into European Union legislation and use in Union Agencies	Done for biocides; adaptation of the definition for cosmetics is in progress
	Report on existing measurement methods, possible update of Q&A	2012
	Proposal for a first set of detection, measurement and monitoring methods	2014
	Review of definition	2014
REACH and CLP	Possible amendment of REACH Annexes	Planning and Timelines will be addressed in REACH Review
	CASG(Nano) – Subgroup of REACH and CLP Competent Authorities (CARACAL), advising the Commission on regulatory issues relating to REACH and CLP	Set up in 2008
	Evaluation of REACH registration dossiers concerning nanomaterials	Nanomaterials prioritised by ECHA for compliance check; substance evaluation according to the “CoRAP” list (currently including silicon dioxide (NL 2012), silver (NL 2013) and titanium dioxide (F 2014))
	ECHA assessment of nanomaterials in REACH registration and CLP notification dossiers	Done (see Appendix 3 of Staff Working Paper)

	Nano Support Project (JRC in cooperation with ECHA)	Part 1 (identification of registration dossiers covering nanomaterials, scientific assessment and proposals to address shortcomings) – done and available on <a href="http://ec.europa.eu/environment/chemicals/nanotech/pdf/jrc_report.pdf">http://ec.europa.eu/environment/chemicals/nanotech/pdf/jrc_report.pdf</a> , part 2 (assessment of potential economic and environmental consequences of the technical proposals made in Task I) expected in October 2013
	GAARN (Group on Assessing Already Registered Nanomaterials) – Informal group to assess three selected registration dossiers on nanomaterials	Set up in 2012, end of work foreseen in 2013
	ECHA Nanomaterial Working Group – Permanent Group to advise ECHA on scientific and technical aspects relating to nanomaterials	Set up in 2012
	ECHA Guidance Update for Registration	Done, further updates possible after the end of the next registration round
	Update of IUCLID to facilitate submission of structured information on NM	Initial solutions provided already in 2010 (IUCLID 5.2) and recently in 2012 (IUCLID 5.4); further relevant updates expected after the REACH 2013 deadline
Cosmetics	Assessment of individual substances	ETH-50: concluded; titanium dioxide, zinc oxide, HAA299: foreseen for 2012
	Joint market surveillance pilot project on nanomaterials in cosmetics	2013
Medicines	Authorisation of individual medicines	20 medicines authorised so far, further assessments as the case arises

Food	Mandatory labelling for nano-ingredients in food introduced in labelling Regulation	Labelling applicable from December 2014
	Definition of "engineered nanomaterial" in labelling Regulation	Definition to be updated to Commission Recommendation
	Pre-market approval under Novel Food Regulation for food under nano form	To be addressed in the Novel Food Proposal foreseen for 2013
	Requirement for risk assessment for food additives and food contact materials	For additives and food contact materials risk assessment as the case arises (with authorisation where appropriate)
Food contact materials	Authorisation of individual food contact materials	Two nanomaterials authorised; further assessments as the case arises
Worker Protection Legislation	Study on occupational risks of nanomaterials	2013
	Final assessment on review of occupational health and safety legislation	2014
OECD Working Party on Manufactured Nanomaterials	Eight subgroups, including one on safety testing of a set of representative manufactured nanomaterials which should provide data on 13 selected nanomaterials	Current Programme started in 2009, with work towards completion of Phase1 well progressed
Mandate M/461 to CEN	Development of methods for nanomaterial characterisation, sampling, measurement and exposure simulation	Work started in 2010, will take several more years

Research, Development and Innovation activities under Horizon 2020	The proposal for the Regulation establishing Horizon2020 (COM(2011)809) identifies Nanotechnologies as one of the six Key Enabling Technologies (KETs) under the Industrial Leadership pillar. Ensuring the safe development and application of nanotechnologies is one of the main lines of activity.	Final calls under 7th Framework Programme for Research to bridge gap towards Horizon 2020
Nano-ingredient labelling		Implemented in the Cosmetics and Biocides Regulations
Information on Nanomaterials	Information on Nanomaterial Types and Uses, including Safety Aspects (overview of available information as well as information sources, databases, etc.)	Done (Annexed Staff Working Document)
	Web-platform	2013
	Study on nanomaterials falling outside the scope of existing notification or registration requirements and options for getting information	2013