Background document

FachDialog 2
Traceability of nanomaterials
Nano-databases, notification and nano-labelling

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Imprint

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Content

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1 The Series of Dialogues

The FachDialog „Traceability of nanomaterials – nano-databases, notification and nano-labelling“ is the second of four stakeholder workshops organized by the German Ministry of the Environment, Nature Conservation and Nuclear Safety (BMU). Approximately 25 representatives of different stakeholder groups, ministries and authorities are invited to each of the events. The minutes are agreed among the participants and the results of the discussion will be published as part of a thematic report by BMU.

In contrast to the concept of the German NanoCommission, no continuous and overarching debate is planned between the different dialogue workshops. The discussion is therefore focused on a few relevant aspects and will be finalized at the end of the meeting. The emphasis of the dialogue workshops is on the societal context of the respective topics and the main aim is to facilitate the exchange of views among the stakeholders.

This document aims at preparing and focusing the discussion at the stakeholder dialogue but will not be discussed at the meeting. It is made available in German and English and the discussion at the meeting will be in English because several international guests will participate.

This background document gives a brief introduction to the topic (Section 2) and a short overview of the planned proceedings (Section 3). Section 4.1and 4.2review information and mechanisms to generate and provide information on nanomaterials under REACH and the CLP-regulation. The results of discussions of the working group on regulation of the German NanoCommission are summarized in Section 4.3and a summary of a feasibility study on a German product register is provided in Section 4.4. Some background on the current activities in France and Denmark and on the Nordic Product Registers as well as activities of the EU-Commission, which will be further elaborated at the FachDialoge is presented in Sections 5.1 to 5.3.

2 Topics and objectives

The FachDialog 2 deals with the (potential) implementation of nano-databases, notification requirements for nanomaterials and nanoproducts and the relation between these with (potential additional) labelling provisions.

The aim of the dialogue is to promote an exchange of opinions among the stakeholders on these topics with view to the on-going activities in some of the EU Member States and at EU-level.

The discussion will focus on the questions:

- at which level could nano-databases be implemented best – at EU-level or in national responsibility of the Member States?
- which (types of) products should be covered – should a general nano-database be established or one with a scope limited to specific products (sectoral approach)?
- how should nano-databases be interlined with provisions for labelling nanomaterials or nanoproducts[1]?
- the degree of detail the information in the database should have,
- the rights of access for different actors to specific information.

3 Planned proceedings

On the first day of the FachDialog core concerns and requests of the German stakeholders related to nano-databases and labelling will be introduced and discussed. In the light of this range of interests, the French and Danish activities regarding notification of nanomaterials and nanoproducts, the establishment of a nano-database will be introduced and debated. Furthermore, experience from the Nordic Product registers on information collection and dissemination for chemical products will be presented. Activities at the EU-level will be presented at the end of the day.

On the second day, the core aspects of a nano-database, notification requirements and potentially related labelling provisions will be discussed more in-depth with the aim of identifying common views on possible ways forward for the German government and other actors.

4 Information on the legal context

It is not intended to have a detailed discussion on the current legal situation at the dialogue workshop. Therefore, interlinkages of core EU-chemicals legislation (REACH and CLP-Regulation) with potential future nano-databases, notification requirements and labelling provisions are summarised in the following. Furthermore, existing substance lists or databases in other legislation are indicated and the conclusions of a feasibility study on a German nano product register are provided.

[1] This discussion may also touch the question how labelling could be implemented; i.e. if only „nano“ should be on the products or if additional information should be included and communicated.

4.1 REACH

REACH[2] stipulates requirements for the manufacture, import and use of chemicals in the EU. It covers nanomaterials as they are chemical substances. Neither the legal text nor the guidance documents currently differentiate approaches and requirements for nanomaterials from those of bulk substances.

4.1.1 Information collection

A technical dossier has to be provided for substances manufactured or imported in amounts above1 t/a per manufacturer or importer to the European Chemicals Agency (ECHA) containing the following information:

- identity[3]of the substance, amongst others including information on impurities and analytical methods,
- hazardous properties[4]; the requirements on the amount and type of data increase with increasing registration volumes,
- uses of the substance, including an assessment of potential exposures and risks, if the registration volume exceeds 10 t/a and the substance is classified as hazardous or fulfils the criteria for PBTs/vPvBs[5].

Some substances, such as biocide active substances are exempted from REACH or from specific titles. For some substances modified requirements apply, e.g. related to research and development (PPORD) or intermediates.

Formulators don't have to register whereas importers of mixtures must register contained substances, if the threshold of 1 t/a is exceeded. Article producers and importers are to register substances intended to be released from these articles (if the total amount exceeds 1 t/a). They are to notify the content of SVHC on the candidate list above 0.1% in the article under certain conditions and must inform the recipients of the article of the SVHC content (Article 33).

It can be concluded that for registered substances[6] at least basic information on their identity and properties will be available at ECHA. It is not yet clear in how far this information will be differentiated for nanomaterials and the bulk form of the substances. No information is collected on the specific mixtures or articles[7] these nanomaterials are contained in.

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[2] Regulation No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

[3] The type of information necessary to identify a nanomaterial was explored in the project RIPoN 1. Up to now, there is no common understanding on the type of identifiers and information that should be provided if a nanomaterial is registered. The report is available at: http://ec.europa.eu/environment/chemicals/nanotech/index.htm.

[4] The RIPoN 2 project generated recommendations for the update of ECHA guidance on information requirements for nanomaterials. The report is available at: http://ec.europa.eu/environment/chemicals/nanotech/index.htm.

[5] The requirements and specific aspects related to the safety assessment of nanomaterials under REACH were explored in the project RIPoN 3, available at http://ec.europa.eu/environment/chemicals/nanotech/index.htm.

[6] Due to the Phase-In Scheme, lower volume substances are registered later than those in higher volumes. Therefore, the information situation improves over time until the last registration deadline has elapsed in 2018.

[7] In the chemical safety report general information on the type of mixtures and the article categories the substance may be included in is provided but not on specific products.

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4.1.2 ECHA database on registered substances

Art. 118 specifies that the following information should always be regarded as confidential and is hence never published:

- full composition of a mixture,
- the precise use, function or application of a substance or mixture, including information about precise uses as an intermediate,
- the precise tonnage of the substance or mixture,
- commercial links between manufacturers, importers, distributors and downstream users.

Art. 119specifies that the following substance information shall always be published[8]:

- IUPAC (and EINECS, if available) name for substances fulfilling the criteria for specific hazard classes,
- classification and labelling,
- physicochemical data and data on pathways and environmental fate,
- results of each toxicological and ecotoxicological studies,
- any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I,
- guidance on safe use according to Sections 4 and 5 of Annex VI,
- analytical methods to detect a dangerous substance (after discharge to the environment or exposure of humans).

Amongst other, the following information should be made available, unless confidentiality is claimed:

- degree of purity and identity of dangerous impurities and/or additives, if essential to classification,
- tonnage band of registration,
- study summaries or robust study summaries,
- information in the safety data sheet (SDS), other than listed before,
- trade name(s) of the substance,

The ECHA data base provides information on the registered identified uses by title of use and specific use descriptors.

It can be concluded that the information needed to ensure safe use of substances as well as the basic information on properties of substances will be made available to the authorities and the general public, as far as it is provided through registration. The Member State CAs (CAs) have access also to information that is claimed confidential.

4.1.3 Information in the supply chain

REACH Art. 31 requires the placers on the market of substances to provide safety data sheets (SDS), if they meet the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008; if they fulfil the PBT/vPvB criteria

[8] http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

or if they are listed on the candidate list for authorisation. SDS for mixtures are required if they are classified according to Directive 99/45/EC[9]. If a chemical safety report (CSR) including an exposure and risk assessment was prepared, the relevant exposure scenarios (ESs) have to be attached to the SDSs of substances. All information received has to be taken into account by formulators in preparing the SDSs for their mixtures.

The classified ingredients of a mixture and substances on the candidate list have to be identified in Section 3 of the mixture's SDS, if their concentrations exceed the lowest applicable limit value[10]. Information on physico-chemical, toxicological and ecotoxicological properties of a mixture's ingredients may be provided in the SDS in addition to information on the mixture as such.

The information flow in the supply chain normally stops when chemicals are included in an article. An exception is the communication on SVHC on the candidate list for authorization: if they are present in an article above 0.1% w/w, their name has to be forwarded to the recipient of the article as well as information needed to ensure safe use of the article.

It can be concluded that the actors in the supply chain will receive information on the content of nanomaterials in mixtures, as long as their concentration in mixtures exceeds the relevant concentration limits. Information on nanomaterials in articles will only be passed on if these are included in the candidate list and are present in articles in concentrations above 0.1% w/w.

4.2 CLP - Regulation

The CLP-regulation[11] defines rules for the classification, labelling and packaging of chemicals in the EU. The physical form of a substance is to be taken into account; hence the classifier is to distinguish between the nanoform and the bulkform of a substance.

The classifier of substances is to use the harmonised classification in the annexes of the Regulation, if available, or carry out a self-classification based on the property information he has available, e.g. from registration. There is no requirement in the CLP-Regulation to generate data if there is no or insufficient information to classify a substance (for a specific end-point).

The classifier of a mixture has various options to derive its classification. Depending on the classification endpoint, he may use calculation methods, conclude by analogy or conduct tests for the mixture as such. He is to take the information he receives from his supplier into account.

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[9] Under certain conditions a safety data sheet has to be supplied on request.

[10] The concentration limits to consider are: Directive 1999/45/EC the Table in Article 3(3); Part 3 of Annex VI to the CLP-Regulation; adjusted values in Table 1.1 of Annex I of the CLP-Regulation if M-factors are assigned in Part 3 of Annex VI; Directive 1999/45/EC, Part B of Annex II, Part B of Annex III and Annex V; specific concentration limits (considering M-factors if assigned) in the classification and labelling inventory.

[11] Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)

The classification of substances and mixtures is to be communicated using hazard pictograms and statements.

It can be concluded that the classification process should be specific for nanomaterials. In practice the specific classification of nanomaterials depends on the availability of respective hazard data. The labelling information does not indicate if a substance is present in a product in its nanoform.

4.3 The NanoCommission's discussion on nano-databases

The NanoCommission, more specifically its working group on regulation, amongst others collected information and discussed their opinions on a register for nanoproducts. The current section summarizes[12] the descriptions of existing registers, lists or databases, which may (also) contain information on nanomaterials in different legislation that was compiled in the report of the working group.

4.3.1 Cosmetics Regulation

According to the EU Cosmetics Regulation[13] manufacturers, importers and distributors of cosmetic products containing nanomaterials must notify the Commission six months prior to placing on the market (Article 16 (3)), providing the following information on contained nanomaterials:

- identification, including IUPAC name and other descriptors,
- specification including particle size, physical and chemical properties,
- estimate of the quantity contained in cosmetic products intended to be placed on the market per year,
- toxicological profile,
- safety data relating to the use category of the cosmetic product and
- reasonably foreseeable exposure conditions.

4.3.2 Novel foods

Before the first placing a food on the market an application for authorisation is to be submitted to the CA in the respective Member State (MS)[14]. Amongst others, the application should include all necessary information to demonstrate that the food does not pose any risks to consumers. The Directive does not explicitly differentiate the nanoform from the bulkform of foodstuff and their ingredients.

[12] The full report can be obtained at http://www.bmu.de/files/english/pdf/application/pdf/nano_abschlussbericht3_en_bf.pdf; German version: http://www.bmu.de/files/pdfs/allgemein/application/pdf/nano_abschlussbericht3_bf.pdf.

[13] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on Cosmetic Products, OJ L 342 of 22.12.2009, p. 59.

[14] This information is also made available to the Commission and the competent authorities in the other Member States (by means of an official internal database).

The application documents are available to the CAs via a Commission database. The database is not published but some MS make the non-confidential parts of application documents and their initial assessment reports available on the internet. Any opinion delivered by the European Food Safety Authority (EFSA) is published on its website. Authorisation decisions by the Commission are published in the Official Journal of the European Union

The Novel Food Directive was under revision but no agreement was reached.

4.3.3 Food additives

An application for authorisation for placing food additives on the market must contain information required for safety assessment of the food additive, including the substance's specification and studies that have been carried out. For substances at the nanoscale separate authorisations have to be applied for and granted. Authorised food additives are included in a Community list of permitted food additives and published in the Official Journal. EFSA opinions are publicly accessible via the authority's website.

4.3.4 Food contact materials

Substance-specific authorisation procedures exist for certain components in food contact materials made from plastics and regenerated cellulose film. So-called active and intelligent materials and articles will also require authorisation in the future[15].

Information in an authorisation application to be submitted via the MS CAs to EFSA should enable a safety evaluation of the food contact materials. Substance data are entered into an EFSA database to which the national authorities and the Commission have access. The evaluations by EFSA are published on the Internet.

Authorised substances are listed in the annexes of the respective legislative acts. No separate lists exist for nanomaterials; however it is expected that after the revision of the directive on materials used in plastics details on the use of the nanoform of a substance will be required. The lists include the following information on the authorized substances:

- identity and reference number,
- function,
- if necessary, the conditions of use,
- if necessary, restrictions and/or specifications of use,
- if necessary, conditions of use of the material or article to which it is added or into which it is incorporated.

[15]Directive 2002/72/EC (plastics), Directive 2007/42/EC (cellulose film) and Regulation (EC) No 450/2009 (active and intelligent materials)

4.3.5 Biocidal products

The existing registers/databases currently don't contain specific information as to whether or not nanomaterials are present in the listed biocidal products. In the new Biocides Regulation, a reporting requirement on the content of nanomaterials in biocidal products is included and the databases will be extended respectively. The below information relates to the registers as under the Biocidal Products Directive (98/8/EC).

The Community Register for Biocidal Products (R4BP) established at European level[16] aims to facilitate compliance and consistency in MSs submitting authorisation and registration information on biocidal products. It is not public.

In Germany, information on authorised and registered biocidal products are published[17]by the CA (Federal Institute for Occupational Safety and Health (BauA)) including the product's name and type, its registration number, active substances contained, the authorisation expiry date and information on its use. Data from the notification of biocidal products containing existing active substances is also available.

Any placer on the market of a biocidal product under a different trade name must provide the Federal Institute for Risk Assessment (BfR) with information on the product (trade name, composition, labelling) its use as well as safety precautions and emergency measures for documentation in the Poison Information Database[18]. These data are treated confidentially by the BfR and cannot be made available to the public or to other authorities.

4.3.6 Plant protection products and plant strengtheners

The EU database on pesticide residues[19] contains information on active substances assessed in the EU including data on toxicology and maximum residue levels in food and feed. EFSA publishes comprehensive peer review reports on substances assessed at EU level including information on toxicology, residue behaviour and ecotoxicology[20].

In Germany, information on authorised and registered plant protection products and plant strengtheners are announced in the Federal Gazette by the authorisation body, the Federal Office for Consumer Protection and Food Safety (BVL) including the product's name and authorisation number, contained active substances, expiry date of the authorisation and any requirements or special conditions attached to its use.

[16] https://webgate.ec.europa.eu/env/r4bp/user.login.cfm

[17] https://www.biozid-meldeverordnung.de/offen/index.php

[18] Mandatory notification applies not only to biocidal products, but to all hazardous substances and mixtures intended for consumer use.

[19] http://ec.europa.eu/sanco_pesticides/public/index.cfm

[20] http://www.efsa.europa.eu/en/scdocs.htm

Since July 2009 all authorisation and approval reports are also published on the BVL website as well as information on plant strengtheners[21]. The latter list may include indications of constituents in nanoform.

4.3.7 Other registers and information instruments

The European system RAPEX (Rapid Alert System for non-food consumer products)[22] enables market surveillance authorities to inform each other if risk management measures are to be put in place with regard to products that present a serious risk to consumer health and safety. Hazards in the workplace and environmental hazards are not covered. It also does not enable the CAs to obtain a market overview of nanoproducts. A similar system is in place for the food and feed sector – RASFF (Rapid Alert System for Food and Feed).

4.4 Feasibility study on a register of nanoproducts

In May 2010 the final report[23] of a legal feasibility study on a register for nanoproducts, commissioned by the BMU was published.

According to the study, a register of nanoproducts (nanomaterials, mixtures and articles) produced or placed on the market in Germany is legally viable and is workable in practice. Nevertheless, it should be the first priority to establish a register at EU-level as this would lead to a higher level of protection for human health and the environment and cause less limitation to the free movement of goods.

The aim of such a nanoproduct register and corresponding notification requirements would be to provide the authorities with an overview of nanoproducts on the German market. Furthermore it should enable the nanoproducts' producers to take risk management measures (e.g. to trace nanoproducts and remove them if necessary from the market) in order to prevent risks to human health or the environment. The nanoproduct register is hence seen as a means of implementing the precautionary principle.

The register of nanoproducts is regarded as justified by the authors of the study, because based on existing legislation the German authorities lack important information on nanomaterials in consumer products. Some of this information is expected for specific products, such as cosmetics and foods, in the near future.

[21] http://www.bvl.bund.de/cln_007/nn_492710/DE/04__Pflanzenschutzmittel/00__doks__downloads/PflStM__liste,templateId=raw,property=publicationFile.pdf/PflStM_liste.pdf

[22] http://ec.europa.eu/consumers/dyna/rapex/create_rapex_search.cfm

[23] Öko-Institut e.V.: Rechtliche Machbarkeitsstudie zu einem Nanoproduktregister, Berlin, Freiburg, Mai 2010, availableat: www.bmu.de/gesundheit_und_umwelt/downloads/doc/46240.php

The authors of the study recommend that for the purpose of the register the term “nanoproduct” should include the following:

- nanomaterials according to the definition used in the product register;
- mixtures as defined in Art. 3 (2) REACH containing nanomaterials;
- articles as defined in Art. 3 (3) REACH containing nanomaterials.

The authors of the study recommend that consideration should be given to introducing mandatory reporting in stages. For example, in the first phase manufacturers and importers could be required to report on production and placing on the market of nanomaterials as such. In the second stage producers of semi-finished products and modified nanomaterials (formulators and importers) and in the final phase producers and importers of finished products could be included.

5 Activities in other Member States and at EU-level

5.1 French reporting scheme on nano-substances[24]

The French government plans to implement a mandatory reporting scheme on nanomaterials. By means of a basic report and sustainable data collection tools, it will ensure a better market knowledge and traceability of nanomaterials in the EU market and permit a rapid and adequate response if ever a specific risk from a nanomaterial emerges.

More information on nanomaterials will be provided to consumers and to workers (nanomaterial identity and its uses). However, information that is commercially sensitive will not be disclosed.

The mandatory reporting scheme is a French initiative, but it is undertaken with other Member States and with a willingness to contribute to the improvement of the legislative framework at the EU level.

In 2007, a national brainstorming about sustainable development was organised by the French government. It was called the “Grenelle de l’environnement” and involved all concerned stakeholders: state and regional administration, industry, employees, NGOs, elected representatives and scientific experts. It was

[24] Clarisse Durand, Ministry of Ecology, sustainable Development, Transports and Housing, Clarisse.DURAND@developpement-durable.gouv.fr

concluded in form of a commitment[25] that the risks linked to the production and the use of manufactured nanomaterials need to be anticipated.

This commitment was implemented through two articles in the Grenelle Laws[26]. These articles define the legal requirement to organise a national public debate on nanotechnology, which was performed between October 2009 and February 2010. Furthermore, they provide details on the mandatory reporting scheme.

The following information will have to be reported:

- identity of nanomaterials,
- uses of the nanomaterials,
- quantities that are produced, imported or distributed and
- identity of downstream users.

The information on identity and uses of nanomaterials will be made available to the general public. The Grenelle Laws also specifies:

- the need to develop a methodology for assessing risks and benefits associated with nanomaterials and nanoproducts and to improve information on risks and protection measures,
- that available data on hazards and exposures could be requested by the authority in order to gather a minimum information (not a risk management measure).

The conditions of execution have to be specified in a decree. The following clarifications are given:

- the terms “substance at the nanoscale” and “substance at the nanoscale contained in a mixture without being linked to it” are defined. The definition of “substance at the nanoscale” is derived from the EU Commission Recommendation on nanomaterials,
- the reporting requirement will apply to manufacturers, importers into France and distributors. Reporting will be done each year,
- the threshold for reporting is set at 100 grams,
- some exemptions and adaptations are specific to research and development,
- the decree allows the reporters to require the confidentiality of their data.

The decree was submitted to a wide consultation by regular mails and on the internet. The main remarks received regarded the definition, the reporting threshold, research and development specificities and issues of confidentiality.

On June 23, 2011, the decree was notified in accordance with the 98/34/EC Directive. Observations from Germany, UK and the European Commission were received. After this step, the decree was forwarded to the Conseild’Etat (highest administrative jurisdiction in France), in order to be published as soon as possible.

[25] Commitment n°159

[26] Article 42 of Grenelle Law I of August 3, 2009 and Article 185 of Grenelle Law II of July 12, 2010.

The reporting scheme will start in 2013 and will relate to nanomaterials that were produced, imported to France or distributed in 2012. 2012 can be devoted to the preparation of the first reports.

5.2 Registration of nanoproducts in Denmark – planned activities[27]

In November 2011, the new Danish government decided to establish a national nanoproduct database. The objective of the database is to provide an overview of what nanomaterials are on the Danish market and further in which amounts, how, and where they are used. The database is part of the four year programme to strengthen the Danish efforts to get better knowledge about use and exposure of nanomaterials.

The Danish Environmental Protection Agency is working on establishing this database. The initial planning includes considerations in relation to scoping of the database e.g.:

- which regulatory sectors should be covered?
- which legal entities should provide information?
- what changes in the national regulation are needed?
- what technical solutions are possible?

It is a preferred that the database should be established in collaboration with other EU-countries and that the data could be used in an EU-context, if similar systems are established on the European level. Furthermore, the possibilities of making the database mandatory are explored. The database should cover a broad range of (mixtures/articles) products containing nanomaterials put on the Danish market intended for professional as well as consumer use and presumably only those with an intended release of nanomaterials.

Data should preferably be submitted to the database by industry, importers and other professionals in a way that is as simple as possible and data should be available in a format that fits into the existing EU-formats.

5.3 Registers on chemical products in the Nordic countries[28]

The national product registers in Denmark, Finland, Norway and Sweden are unique and very valuable sources of data concerning the downstream uses of chemical substances in products on the national markets.

The Nordic product registers are central registers that keep information on chemical substances and products. National legislation requires manufacturers and importers to declare chemical substances and products to the product

[27] Flemming Ingerslev; The Danish Environmental Protection Agency; fling@mst.dk

[28] Poul Erik Andersen, National Working Environment Authority, Product Register department: pea@at.dk

registers. Data in the registers includes information on function, industrial category, classification, composition, quantity etc.

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The registers are useful tools for the national authorities and poison information centres in efforts to prevent injury to health and environmental damage resulting from chemicals. Data in the registers is used as support for risk and exposure assessments, statistical calculations, substance flow analyses and supervision activities. Aggregated data on potential exposure and use of substances are publicly available in the database SPIN.

Links:

Denmark: http://arbejdstilsynet.dk/en/engelsk/produktregistret.aspx

Finland: http://www.tukes.fi/en/Branches/Chemicals-biocides-plant-protection-products/Submitting-information-on-chemicals-/

Norway: http://www.klif.no/no/english/english/The-Product-Register/

Sweden: http://www.kemi.se/en/Start/The-Products-Register/

6 EU Activities and information sources[29]

The Commission is currently conducting a second regulatory review on nanomaterials. This is a follow-up to the first regulatory review on nanomaterials and a subsequent Parliament Resolution of 24 April 2009[30]. In this framework, the Parliament also called "*on the Commission to compile before June 2011 an inventory of the different types and uses of nanomaterials on the European market, while respecting justified commercial secrets such as recipes, and to make this inventory publicly available; furthermore calls on the Commission to report on the safety of these nanomaterials at the same time*".

In its response[31] of 14 July 2009 the Commission stated in relation to paragraph 16 of the above resolution that "*the Commission intends to present information on types and uses of nanomaterials, including safety aspects, in 2011.*" This formulation was chosen because at the time of the resolution the implications of an "inventory" were unclear and required further analysis, including an analysis of registration dossiers under the first registration deadline of the REACH Regulation and of notification dossiers under the CLP Regulation.

[29] Otto Linher, European Commission, Otto.Linher@cec.eu.int

[30] http://www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2009-0328&language=EN

[31] Follow-up to the European Parliament resolution on regulatory aspects of nanomaterials, adopted by the Commission on 14 July 2009

In addition, the Environment Council of December 2010[32] invited the Commission to "*evaluate the need for the development of specific measures for nanomaterials relating to risk assessment and management, information and monitoring, including the further development of a harmonized database for nanomaterials, while considering potential impacts*".

As part of the regulatory review it is planned to issue a Communication outlining the Commission's view on the way nanomaterials are addressed in European Union regulation and setting out priorities for future work in the context of regulation. The Communication will be accompanied by a Staff Working Paper on types and uses of nanomaterials, including safety aspects. This Staff Working Paper will give an overview of current knowledge of nanomaterials on the market, their application and available safety information. It is also planned to address the question of obligatory registries for nanomaterials in products in both documents. Adoption of both documents is likely to take place around March 2012.

Background information can be found on the following websites:

http://ec.europa.eu/nanotechnology/index_en.html
http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index_en.htm
http://ec.europa.eu/environment/chemicals/nanotech/index.htm
http://ec.europa.eu/environment/chemicals/nanotech/questions_answers.htm (definition of nanomaterial)
http://www.nanohub.eu

[32] http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/118646.pdf