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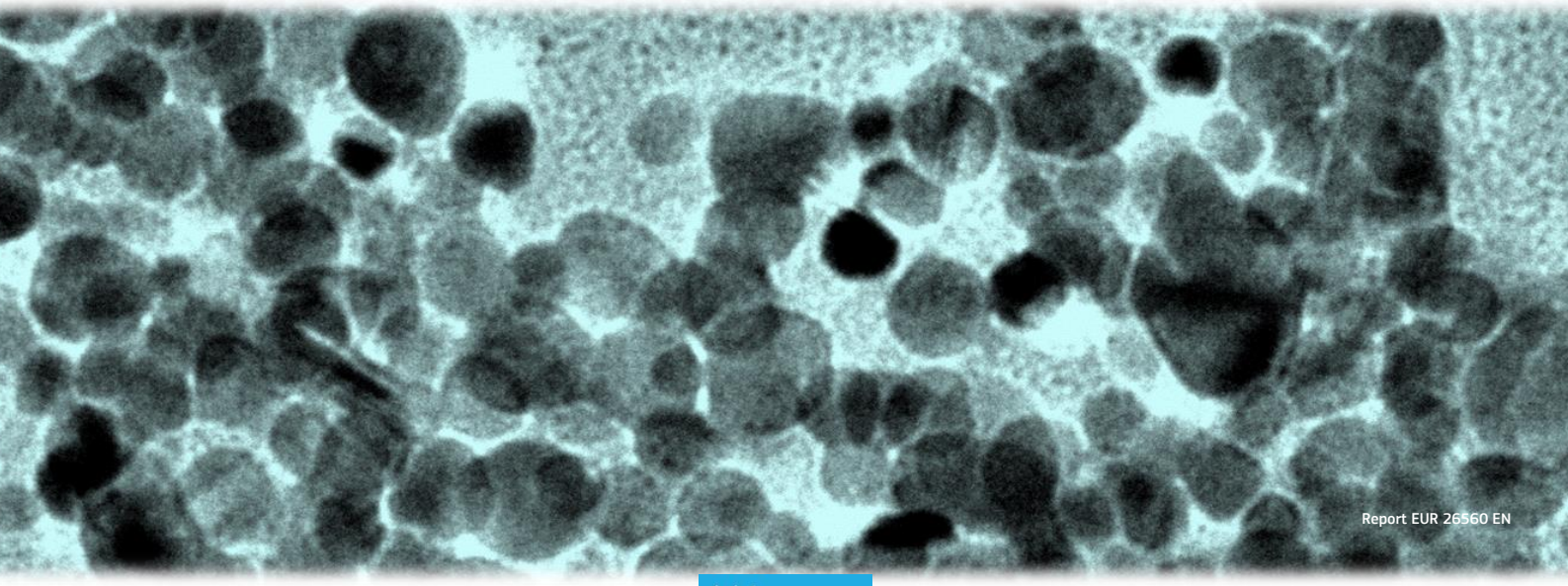

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Considerations on information needs for nanomaterials in consumer products

Discussion of a labelling and reporting scheme for nanomaterials in consumer products in the EU

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Executive Summary

This report recapitulates issues relevant for the on-going discussion on transparency and requests for more information regarding the use of nanomaterials (NMs) in consumer products. It reviews content related labelling of products containing NMs and the establishment of product registers for such products and contributes to the debate on the need for such measures and their possible impact. The addressees of the report include policy makers, EU Member State authorities, industry, NGOs, research institutes and consumers.

The number and amount of consumer products and applications using nanotechnology on the market are rapidly increasing. Technological innovations at the nanoscale are exploited in novel products, but may at the same time involve unknown risks. The safety of products containing NMs is regulated by several EU legal acts that address chemicals and products in general including the Chemicals Regulation REACH, the Classification and Labelling of Products Regulation, General Products Safety Directive and others. In addition, NMs are explicitly addressed in a number of recently revised sector specific legislations (e.g. the Regulations for Biocidal Products, Cosmetic Products, Provision of Food Information to Consumers, Active and Intelligent Materials and Articles, and Plastic Food Contact Materials). However, several stakeholders, for example the European Parliament, some EU Member States and non-governmental organisations, have requested more transparency and traceability concerning the use of NMs in consumer products on the market. The report summarises EU legislation and how it addresses NMs.

Labelling consumer products containing NMs and/or making information on NM content available in product registers or inventories are measures to provide information and traceability of their use. Labelling provides information to the consumer at the time of purchase, while a product register may give a better overview of the overall application of NMs and potential exposure of humans and the environment. Mandatory labelling requirements regarding the content of NMs (in an ingredients list) are already part of EU legislation on food, cosmetics and biocides. Mandatory reporting to the European Commission (EC) is required for cosmetic products containing NMs and some EU Member States are introducing mandatory reporting schemes for a wider range of consumer products (France, Belgium and Denmark). Labelling and/or registration of NMs in consumer products should be understood as a "risk-independent" description of the composition of the product, since the presence of NMs does not automatically imply a risk. Any information provided needs to be adequate and proportionate to the knowledge of the consumers and should not lead to any discrimination of products. Any means to increase information and transparency should preferably be harmonised at least within the EU or even at an international level to avoid trade barriers and unfair commercial practices. The report discusses the different options and their influence both on labelling and creation of registers.

Identification of products containing NMs and market transparency requires a harmonised definition of the term "nanomaterial". Several definitions are available, including a Recommendation by the European Commission. A claim of the presence (or absence) of NMs in products should be enforceable and possible to monitor. Currently available methods allow in principle the detection and quantification of NMs, also when they are embedded in simple matrices, but these methods are not yet standardised nor generally agreed upon. Routine application of detection methods in complex matrices, such as in cosmetics or food, still needs considerable development. The report gives an overview of the state of the art of verification methods.

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1 Introduction

Specific physical and chemical properties of nanomaterials (NMs) can make them attractive to a wide range of applications in different fields. On the other hand, such properties may also give reasons for concern regarding their safety for human health and the environment. Humans and the environment can potentially be exposed to engineered nanomaterials (ENMs) during the entire life cycle, from production, over use to disposal. Potential risks associated with the use of nanomaterial are not yet fully understood. Furthermore, the general public may not be aware of possible exposure as there are currently few requirements to convey this information.

The safety of substances and products placed on the market within the European Union (EU) is regulated by several different pieces of legislation and any nanomaterial (NM) in a product is also covered by these legal instruments, even if the legislation does not mention NMs explicitly. In addition, new or recently revised legislation on Cosmetic Products (European Parliament and Council 2009a), Food Information for Consumers (European Parliament and Council 2011a), Active and Intelligent Materials and Articles (European Commission 2009a), Plastic Food Contact Materials (European Commission 2011b) and Biocidal Products (European Parliament and Council 2012c) explicitly address NMs. These legal acts introduce specific provisions for NMs, and some require labelling (listing) of ingredients which are in the nanoform and for cosmetic products a register of products containing NMs.

The European Parliament (EP) (European Parliament 2009b), several EU countries (e.g. in a note sent by The Netherlands to the European Commission (EC) on behalf of Austria, the Czech Republic, Denmark, France, Italy, Luxembourg, Spain, Sweden and Croatia) (Ministry of Infrastructure and the Environment of the Netherlands 2012) and non-governmental organisations (NGO) consider the current regulatory framework to be inadequate for NMs. They have called, among others, for more transparency, traceability and information regarding the use and possible exposure to NMs by the introduction of registers for products containing NMs or making use of nanotechnology (sometimes called "nanoproducts") and/or by labelling of such consumer products.

This report summarises issues and problems concerning traceability, market transparency and the safety of NMs which have to be taken into account in any political decision-making process. It aims at contributing to on-going discussions on labelling of products containing NMs and their reporting to product registers. The addressees of this report include policy makers, EU Member State authorities, industry, NGOs, research institutes and consumers. The report starts by giving a short review of the EC NM definition, which is needed as a basis for regulatory labelling or reporting on NMs. After illustrating the use of NMs and their general safety aspects, the legal framework within the EU relevant for NMs is reviewed, as well as other activities aiming at increasing the information on NMs and ensuring their safety. Thereafter different labelling and reporting requirements, already available practices and possible implications are presented and discussed. The report also provides an overview of the scientific challenges to verify the presence (identity and concentration) of NMs in products in view of the implementation of the definition. Nanomaterials

2 Nanomaterial

2.1 What is a nanomaterial?

Nanomaterials are typically materials with external dimensions or internal/surface features at the nanoscale; the latter comprising a size range between 1 and 100 nm (Figure 1). This size range has been proposed by several definitions, e.g. ISO/TS 12805:2011 by the International Organization for Standardization or EC Definition 2011/696/EU. Such materials often display chemical, physical, and biological characteristics which are different from macroscale counterparts, even if the elemental or molecular composition is the same. This may apply to optical properties, chemical and biological reactivity, permeability through membranes, magnetic properties, etc. Some of the NM properties can be extrapolated from their macroscale counterparts, whereas others change drastically below a certain size. The latter can be considered as "true" nanoscale features. Although a material may not necessarily show such true nanoscale features, it can nevertheless have properties that are clearly different from those of the macroscale just because of its reduced size. For example, smaller particles have an increased surface to volume ratio compared to their larger counterparts and therefore the specific surface area of a NM can be extremely high. As chemical reaction rates often relate to surface area, a NM can be much more reactive than the same quantity of the same substance in non-nanoform. Consequently the same chemical formula of the material may give raise to many different forms with differences in e.g. size and/or crystal structure and consequently physico-chemical and/or biological properties.

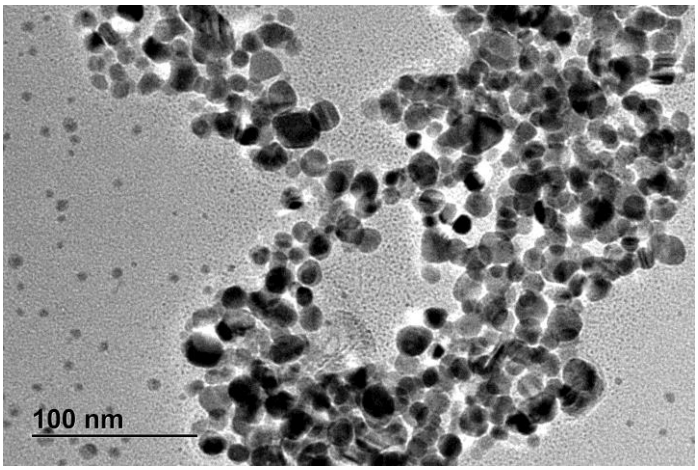


Figure 1: Transmission Electron Microscope (TEM) image of silver nanoparticles.

There is no general relationship between size and physico-chemical properties valid for all materials, and therefore the only feature common to all NMs is the nanoscale dimension (Lövestam *et al.* 2010). The properties of a NM can be affected by its environment. The agglomeration state, the stability of a colloidal dispersion, or the surface charge does not only depend on the properties of the NM but is largely determined by the matrix in which nanoparticles are embedded. Molecules that adsorb onto the surface of nanoparticles can in turn affect the NM interaction with the surroundings. Hence in order to understand the behaviour of a NM in a specific environment, it is often necessary to consider the NM and the matrix in which it is embedded as a whole. This has an important impact on the safety, as well as on the traceability of NMs (see Chapter 5).

2.2 Definition of nanomaterials

Several formal definitions of the term "nanomaterial" are available, proposed by different international and national bodies. The majority of the proposed definitions agree that the most suitable and universally applicable measurand for NMs is their size. These definitions have been reviewed in 2010 in a Reference Report of the Joint Research Centre (JRC) (Lövestam *et al.* 2010).

In 2011 the EC adopted a Recommendation (2011/696/EU) on the definition of the term "nanomaterial" for legislative and policy purposes in the EU, which in the following will be termed the "EC Definition" (European Commission 2011a). This definition is broadly applicable across different regulatory sectors and its use is recommended to promote consistency in the interpretation of the term "nanomaterial" for legislative and policy purposes in the EU. The EC Definition uses size (size range 1 nm-100 nm) as the most important defining property of the material (alternatively also the specific surface area can be used) and applies to materials in a particulate form. The size refers to the constituent particles which may form agglomerates and aggregates that have larger sizes (outside the nanoscale), but are still considered as NMs according to the EC Definition. The EC Definition applies to all particulate NMs regardless of their origin, i.e. natural, incidental or manufactured (also called engineered or intentionally produced). It also establishes a threshold of 50 % or more particles <100 nm in the number size distribution which in specific cases can be lowered to 1 % (for more details see Annex I).

The Biocidal Products Regulation (EU) 528/2012/EC (European Parliament and Council 2012c) is the first legal act that contains a definition of NM which is based on the EC Definition. Other EU provisions on NMs were adopted before the EC Definition and therefore use different definitions (Annex I).

The use of different definitions allows addressing a group of materials tailored to the needs of specific application areas, e.g. cosmetics or food. However, as the same (nano)material might be used in various areas of application and therefore possibly be subject to more than one specific regulation, different definitions of the term "nanomaterial" could lead to the situation that the same substance is regarded as NM under one legislation but not under another.

The Cosmetics Regulation (EC) 1223/2009 (European Parliament and Council 2009a) and Regulation (EU) 1169/2011 on Provision of Food Information to the Consumers (FIC Regulation) refer to size ranges compatible with the EC Definition: from 1 to 100 nm, or less than 100 nm, respectively. However, and this is a relevant difference, these definitions only refer to "intentionally manufactured (or produced) materials". In addition, the Cosmetic Products definition, in accordance with the International Collaboration on Cosmetics Regulation (ICCR) (Ansell et al. 2010) further restricts the definition to insoluble or biopersistent material and consequently excludes soluble and/or naturally occurring materials with nanoscale dimensions. An alignment of the definitions in the Cosmetic Products Regulation and the FIC Regulation with the EC Definition is currently (early 2014) being discussed.

For any legal definition (EC Definition or definition tailored to a specific legislation), it is important to have a clear guidance on its implementation, including for example guidance on how to decide whether a certain substance is a NM or not according to that specific definition. The guidance should include information on experimental methods as well as standard operation procedures for sample preparation and measurement protocols (see Chapter 5). These issues have been summarised in a

JRC report on: "*Requirements on measurements for the implementation of the European Commission definition of the term "nanomaterial"*" (Linsinger et al. 2012).

2.3 General use of nanomaterials

Nanomaterials cover a broad range of materials of different chemical composition. Because of their diverse properties, they are used in a wide range of applications and product areas. Rather than being a technology on its own, nanotechnology is considered a technology that uses materials and manipulation at the nanoscale and which has a potential influence on almost any other technology area. NMs are utilised in a wide range of products, for example medical devices (diagnostics, drug delivery), medicinal products, cosmetic products (e. g. UV absorbers in sunscreens), food (enhanced flavour and texture, encapsulation of micronutrients), electronics (data storage, displays), energy and environmental applications (catalysts, photovoltaics, fuel cells), automotive (coatings, tyres), construction (thermal insulation) and advanced materials in general. Types and uses of NMs including health and safety aspects have been discussed for example in a Staff Working Paper (SWP) of the EC (European Commission 2012a). With their widespread use and diverse applications there is a large, developing and valuable global market for nanotechnology. This has recently been analysed in detail by SRI Consulting (Schlag et al. 2010), the results of which were used when drafting the SWP.

2.4 Safety aspects

Nanomaterials and products containing them are entering the market at a steady rate. The SWP has noted that some NMs have been used in considerable quantities for many years, e.g. carbon black (e.g. in car tyres) and silicon dioxide (e.g. as food additive) (European Commission 2012a).

Potential risk to human health and the environment depends on possible hazards of NMs and exposure of workers, consumers and the environment. It may be linked to their physico-chemical differences compared to macroscale materials and their greater ability to pass biological barriers and possibility to bioaccumulate. Toxicity studies suggest that many NMs have the potential to induce oxidative stress and inflammation and some may even induce granulomas, fibroses and tumours (EU-OSHA 2009; Stone et al. 2010). However little is known whether effects seen in laboratory experiments are relevant at exposure levels applicable to human exposure. There are also uncertainties as regards the NM's environmental fate and behaviour, which are mainly related to the difficulty to measure them in environmental media (see also section 5.4).

The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), concluded in its opinion from 2009 (SCENIHR 2009) that *"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] recommended."*

Several expert bodies dealing with risk assessment of NMs (including the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), the Scientific Committee on Consumer Safety (SCCS), the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Agency for Safety and Health at Work (EU-OSHA), the OECD Working Party on Manufactured Nanomaterials (WPMN)) agree that existing risk assessment methods and test

methods are to a large extent applicable to NMs. Some aspects, including sample preparation and characterisation, dosimetry, exposure data and models require further development of standardised and validated methods.

The European Academies Science Advisory Council (EASAC) and the JRC conclude in their joint report on NMs (JRC-EASAC 2011) that "*currently there is only a limited amount of scientific evidence to suggest that nanomaterials present a ("additional") risk for human health*". Safety of NMs, and the underlying metrological challenges, remain a key priority under the EU Framework Programmes and for the JRC (JRC-EASAC 2011). In addition, the EC has invited the European standardisation bodies to develop tools to support risk assessment by a mandate given in February 2010 (European Commission 2010).

The EC has adopted a Recommendation for a definition of the term "nanomaterial" with a broad scope. Different sector-specific definitions are currently used in current EU legislation. All these definitions refer to mutually compatible size ranges (on the scale 1-100 nm). The main difference is that some definitions use additional descriptors for defining a nanomaterial, such as the origin or the persistence.

Different physico-chemical properties may influence the nanomaterials biological and environmental behaviour. Until now however, there are no indications that nanomaterials, on average, are more hazardous than other chemicals.

3 EU regulatory basis to provide information on nanomaterials

Nanomaterials must comply with the existing provisions of Community law addressing labelling of products, risk/safety assessment, warnings to consumers and other users based on the properties of products, instructions for use, or any other information or assessment requirements. NMs are covered by the substance definition of REACH (Regulation (EC) No 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals) and are thereby covered by its provisions. As a consequence, and depending on the annual tonnage of production or import, NMs have to be registered with ECHA (European Chemicals Agency), demonstrating their safe use. Depending on their properties, NMs may also become subject to authorisation or restrictions. For products containing NMs, different EU sectorial product legislations apply, which aim to ensure that products placed on the marked do not pose a risk to the consumer. This is achieved for example by introducing provisions for placing those products on the market which may pose a risk (e.g. sale restrictions for quantities or only to professional/trained users) or by hazard-labelling them as a risk reduction measure.

Currently, EU legislation dealing specifically with NMs include the Cosmetic Products Regulation 1223/2009 (European Parliament and Council 2009a), the Regulation on the Provision of Food Information to Consumers 1169/2011 (European Parliament and Council 2011a), the Regulation on Plastic Food Contact Materials 10/2011 (European Commission 2011b), Regulation on Active and Intelligent Materials and Articles (European Commission 2009a), and the Regulation on Biocidal Products 528/2012 (European Parliament and Council 2012c).

In October 2012 the EC published the Second Regulatory Review on Nanomaterials (European Commission 2012b), which provides an assessment of the adequacy and implementation of EU legislation for NMs and indicates follow-up actions. It concludes that REACH (see Section 3.1) and the General Product Safety Directive (see Section 3.7) with its RAPEX system set the best possible framework for the risk management of nanomaterials; however more specific requirements for NMs within the framework have proven necessary, including modifications in some of the REACH Annexes and further guidance for registration. The EC is currently carrying out an Impact Assessment of relevant regulatory options, in particular possible amendments of REACH Annexes, to ensure further clarity on how nanomaterials are addressed and safety is demonstrated in registration dossiers.

Concerning consumer information and labelling of NMs, similar provisions for nano-ingredient labelling as the ones introduced in food and cosmetics could be envisaged for other regulatory schemes already having ingredient labelling. In addition, the Commission has created a web platform with references to all relevant information sources on NMs (see Section 4.6) and a first version of this platform was published in December 2013 (JRC 2013). The second regulatory review is accompanied by a Commission Staff Working Paper that provides detailed information on the definition of NMs, NM markets, uses, benefits, health and safety aspects, risk assessment, and information and databases on NMs (European Commission 2012a). In addition, the EC has contracted a "*Study to assess the impact of possible legislation to increase transparency on nanomaterials on the market*" to which this report may provide useful background information. The results of the impact assessment are expected by autumn 2014 (RPA and BiPRO 2014).

An overview of EU legislation with regard to consumer products relevant for NMs is given in Annex II.

Provisions of EU law apply to nanomaterials, even if nanomaterials are not explicitly mentioned. Recent sector-specific EU legislations include specific provisions for nanomaterials.

In a regulatory review the European Commission has assessed the adequacy and implementation of EU legislation for nanomaterials and provided a staff working paper on nanomaterial types and uses including safety aspects.

3.1 REACH

The European chemicals legislation REACH (European Parliament and Council 2006a) is based on the principle that manufacturers, importers and downstream users must ensure that the substances they manufacture, place on the market or use do not adversely affect human health or the environment.

Under REACH, reporting to the European Chemicals Agency (ECHA) is mandatory for chemical substances manufactured or imported above 1 tonne/year (tpa). The information (on different forms) needs to be adequate for classification and labelling and if required (> 10 tpa total quantity of the substance) for Chemical Safety Assessment.

There are no provisions in REACH referring explicitly to NMs. However, NMs are covered by the "substance definition" as REACH addresses chemicals of any size, shape or physical state and thus all REACH provisions apply to NMs (European Commission 2008). A NM can be registered as a "form" of a substance, or as a distinct substance. NMs that are distinct substances, but are not reaching the tonnage threshold for registration (< 1 tpa) are not captured by the registration system. As most known NMs are currently registered as the form of a substance together with a bulk substance, they are likely to reach a total tonnage level triggering mandatory registration under REACH. Specific guidance for the "Information requirements and safety assessment" of NMs was published by ECHA in May 2012 (ECHA 2012). It is relevant to note here that chemicals including nanomaterials are also addressed by the Classification, Labelling and Packaging (CLP) Regulation (European Parliament and Council 2008a), and may be addressed by sector specific legislation (e.g. Cosmetic Products) requiring a safety assessment which do not have a tonnage threshold (see more information below).

Substances of very high concern (SVHC) which are either CMRs (carcinogenic, mutagenic or reproductive toxic), PBTs (persistent, bioaccumulative, and toxic), vPvBs (very persistent and very bioaccumulative), endocrine disrupters or which give rise to an equivalent level of concern are listed in Annex XIV of REACH and are subject to authorisation (according to Article 57) for a concentration above 0.1 % (European Parliament and Council 2006a). There are currently (February 2014) no NMs or nanoforms in Annex XIV or its candidate list (http://echa.europa.eu/web/guest/candidate-list-table).

A safety data sheet (SDS) needs to be compiled for all substances or mixtures that meet the criteria for hazard classification, PBTs, vPvBs or are included on the candidate list for authorisation according

to Article 59(1). A SDS also needs to be provided for substances where a Community workplace exposure limit exists. These information duties apply to NMs accordingly. The new guidance by ECHA for SDSs specifically addresses NMs by requiring an indication under the physical state, additional characterisation information and appropriate and available safety information on redox potential, radical formation potential and photocatalytic properties (ECHA 2011).

Nanomaterials are covered by the substance definition of REACH, and the REACH provisions apply to them. NMs can be registered as nanoform(s) in the dossier of the corresponding non-nanoform of a substance or as distinct substance.

Specific guidance for NM registration under REACH has been issued by ECHA.

A safety data sheet needs to be prepared for all substances, including nanomaterials classified as hazardous.

3.2 Globally Harmonised System for Classification and Labelling

Regulation 1272/2008 on Classification, Labelling and Packaging (CLP) (European Parliament and Council 2008a) is complimentary to REACH. It implements the Globally Harmonised System (GHS), and provides the general framework for hazard classification and labelling of substances and mixtures. Its provisions apply independently of the volume of the substance placed on the market. Through the labelling of the substance or mixture, the hazardous properties (including physico-chemical hazards, hazards to human health and to the environment) are communicated through the supply chain, i.e. downstream to users including consumers (see Figure 2 and Figure 8).

There are general or substance specific concentration limits for labelling mixtures containing classified substances. As for any other hazardous chemical, a mixture containing a hazardous nanomaterial above such a concentration limit must be labelled for its hazardous properties. In addition, regardless of labelling, there is an obligation to provide the "recipient of the product" with sufficient information to allow safe use if an article contains SVHCs (see section 3.1).

When evaluating the available information for the purpose of classification, the forms or physical states of the substance or mixture shall be considered (Art. 9(5)). Different particle sizes or forms of a substance may have different properties. Thus, substances in the nanoform may require classification and labelling different from their bulk counterpart (European Commission 2009b).

As required in the legislation, ECHA has established a CLP inventory, parts of which are publicly available. The public CLP Inventory on notified and registered substances that have, so far, been received from manufacturers and importers was launched in February 2012 and is available at: http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database.

Figure 2: Hazard Classes and Pictograms for dangerous substances (CLP Regulation 1272/2008/Globally Harmonised System, CLP/GHS).
Products containing dangerous substances (above a general or specific concentration limit) must mention the name of the substance(s) and be labelled with pictograms, signal words and hazard and precautionary statements.

The CLP Regulation requires that hazardous properties of nanomaterials (as for any other substance or mixture) have to be communicated through the supply chain (any user or consumer). Those properties have to be indicated on the product label (above certain concentration limits).

3.3 Cosmetic products

The Cosmetic Products Regulation EC No 1223/2009 (European Parliament and Council 2009a) was the first legal instrument containing specific provisions for NMs including a definition (different from the EC Definition, see also Annex I).

The Regulation includes an obligation (Art. 13) to notify any cosmetic product placed on the EU market to the EC. The notification is done via the Cosmetic Products Notification Portal (CPNP) of the EC. If a cosmetic product contains NMs, certain specific information has to be provided - including identification of the NM, the quantity of the NM contained in cosmetic products intended to be placed on the market per year, the specification of the NM including size of particles, physical and chemical properties, toxicological profile, safety data and reasonably foreseeable exposure conditions - six months prior to being placed on the market (Art. 16) (European Parliament and Council 2009a). The EC is required to make available a catalogue of all NMs used in cosmetic products placed on the market, "including those used as colorants, UV-filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonable foreseeable exposure conditions" (Art. 16(3)), and to submit to the EP, an "Annual Status Report" on the developments in the use of NMs in cosmetic products.

Furthermore, the Regulation includes a labelling obligation for products that contain NMs in the sense of the applied definition (Art. 19; see Annex I). This means that all ingredients present in the form of NMs shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word "nano" in brackets, e.g. "titanium dioxide (nano)" (Figure 3). This information may be indicated on the packaging alone. The list shall be preceded by the term "ingredients". The list of ingredients shall be established in descending order of relative weight of the ingredients at the time they are added to the cosmetic product. Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations above 1 %.

Figure 3 also shows that, given the length of the ingredient list, it could be printed in small font size and difficult to read even on a normal container.

Most of the Regulation's provisions, including those on labelling for NMs, entered into force on 11 July 2013.

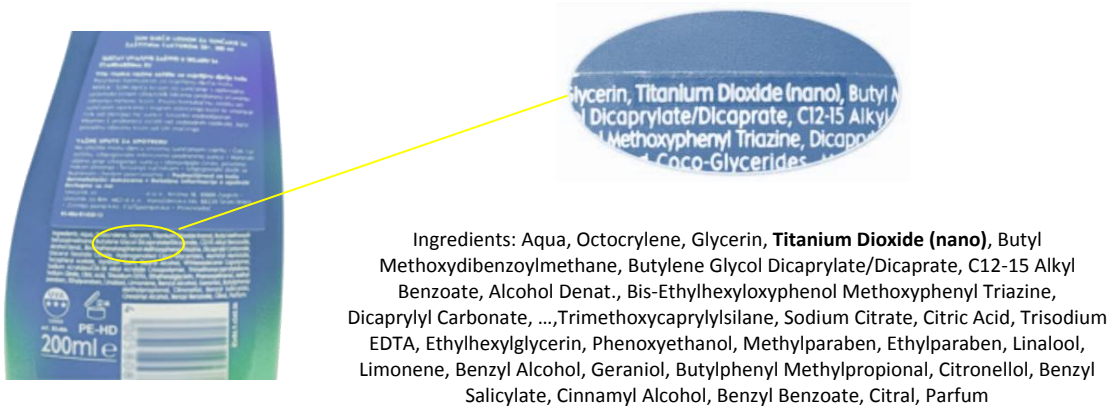


Figure 3: The back of a sunscreen bottle provides information to the consumer on general properties of the product ("advertising"), "important usage instructions" and the "ingredients list". It also offers the UVA logo, sun protection factor (SPF) and the period after opening (PAO) sign. Since July 2013 cosmetic products must be labelled for their content of nanomaterials by adding "(nano)" after the substance name (see example of an ingredients list). The nanomaterial may appear as one of many substances in the list. The amount of the information and the small font size can sometimes make it difficult to read and to understand for the consumer.

Cosmetic products containing nanomaterials need to be labelled (since July 2013 onwards) and notified to the European Commission before being placed on the market. The notification is done via the Cosmetic Products Notification Portal of the EC.

3.4 Food and Food Contact Materials

The "General Principles and Requirements of Food Law", including procedures in matters of food safety are laid down by Regulation 178/2002 (European Parliament and Council 2002b). It applies horizontally to all food and feed.

EU Regulation 1169/2011 "on the Provision of Food Information to Consumers" establishes the principles, requirements and responsibilities governing food information to consumers, and in particular food labelling (European Parliament and Council 2011a). It contains specific provisions for nanomaterials, including a definition of "engineered nanomaterial" (different from the EC Definition, see Annex I). It specifies that besides information such as nutrition values, allergens or country of origin, all ingredients present in the form of ENMs shall be clearly indicated in the list of ingredients. As for cosmetic products, the names of such ingredients shall be followed by the word "nano" in brackets. This mandatory labelling enters into force in December 2014.

Certain ENMs are exempted and they are not required to be included in the list of ingredients (Art. 20 of the Regulation on the Provision of Food Information to Consumers) when they are:

- Food additives or food enzymes contained in one or more ingredients of that food (carry-over principle) and if they serve no technological function in the finished product or are used as processing aids;
- Carriers and substances which are not food additives;
- Substances used as processing aids which are not food additives and which are still present in the finished product, even if in an altered form.

Although not explicitly mentioned, the use of nanotechnology in food production is currently covered by Regulation No 258/97 concerning "novel foods" and "novel food ingredients" (European Parliament and Council 1997). "Novel food" is food not consumed to any significant degree in the EU prior to May 1997 (when the first Novel Foods legislation entered into force). It comprises newly developed, innovative food, or food produced using new technologies and production processes or food which has been traditionally consumed outside of the EU. Novel food and food ingredients have to undergo a safety assessment by EFSA (European Food Safety Authority) and an authorisation procedure before being placed on the market. Authorisations granted for bulk forms do not cover nanoforms and therefore a separate authorisation including a risk assessment has to be performed for the nanoform. The proposal for a revision of the novel food Regulation (European Commission 2013a) provides a firmer basis for covering foods modified by new production processes such as nanotechnology and nanoscience and food or vitamins, minerals and other substances containing or consisting of "engineered nanomaterials". The definition for "nanomaterial" is applied as in Regulation 1169/2011.

Substances added to food for a technological purpose or to improve their solubility or bioavailability are covered by Regulation EC 1333/2008 on food additives (European Parliament and Council 2008b) or Framework Directive 2002/46/EC on food supplements (European Parliament and Council 2002a) respectively. Food additives, enzymes and flavourings as well as food supplements must, prior to be placed on the market, undergo an EU-wide (Community) assessment and authorisation procedure. Some of the particulate food additives, which have been in use for years such as anticaking powders (SiO_2, $CaCO_3$), may contain a fraction of particles at nanoscale (see example in Figure 3). Previously authorised food additives are considered as new additives if there is a significant change in production methods or in the starting materials used, or if there is a change in particle size, for example through nanotechnology. They therefore need to be (re-)evaluated and authorised. Concerning calcium carbonate (E170) EFSA concluded that "*the available data are sufficient to conclude that the current levels of adventitious nanoscale material within macroscale calcium carbonate would not be an additional toxicological concern*" (EFSA Panel on Food Additives and

Nutrient Sources added to Food 2011). The re-evaluation of silicon dioxide (E551) is expected to be completed by 2016 (European Commission (DG SANCO) 2013). Food additives already included in the Union lists by Regulation 1129/2011 and which could be in the form of "engineered nanomaterial" in the final food are being discussed to be excluded from mandatory qualifying as "nano" in the list of ingredients.

Food contact materials (FCM) and articles are covered by Regulation (EC) No. 1935/2004, however, there are special measures for specific FCMs. The revised EU "Plastic Food Contact Materials" Regulation 10/2011 (amended and corrected by Regulation 1183/2012) (European Parliament and Council 2011a) refers specifically to NMs, stating that substances in nanoform shall only be used if explicitly authorised and mentioned in the specifications of Annex I of the regulation. Authorisations that are based on the risk assessment of the conventional particle size of a substance do not cover engineered nanoparticles. So far there is only one material listed as "nanoparticle" in Annex I specifying its use (Titanium nitride for use as additive or polymer production aid only). In addition, Carbon black (primary particles of 10 – 300 nm, aggregated to a size of 100 – 1200 nm) and amorphous silicon dioxide (primary particles of 1 – 100 nm, aggregated to a size of 0,1 – 1 µm which may form agglomerates within the size distribution of 0,3 µm to the mm size) have been listed without specifically mentioning them as NM or nanoparticle. The "Active and Intelligent Materials and Articles" Regulation 450/2009 (European Commission 2009a)specifies that the risk of nanoparticles in intelligent packaging systems should be assessed on a case-by case basis as regards their risk until more information is known. Nanoparticles in food contact materials are not covered by the functional barrier concept. This concept allows the use of certain non-authorised substances behind a functional barrier, provided they fulfil certain criteria and their migration remains below a given detection limit.

For addressing the potential risks of substances in non-plastic FCMs, such as inks, coatings and adhesives, the EC plans to issue a consultation on policy options early 2014.

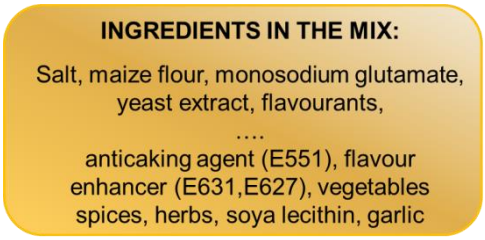


Figure 4: Example of an ingredients list of food containing silicon dioxide (E551) as anticaking agent.

The use of nanotechnology in food production is covered by the Novel Food Regulation.

Nanomaterials used as novel food, food additives, food supplements or in food contact materials have to undergo an EU-wide authorisation which is based on a risk assessment. Risk assessment and authorisation for the macromaterial do not cover nanoforms.

Engineered nanomaterials in food have to be indicated in the list of ingredients with the word "nano" in brackets (from the end of 2014).

3.5 Biocidal Products

The Biocidal Products Regulation (BPR) (EU) No 528/2012 (European Parliament and Council 2012c) includes specific provisions for nanomaterials and incorporates most of the criteria of the EC Definition of a NM. A biocidal product is an active substance or mixture containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy, deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

Biocidal active substances and biocidal products have to undergo an authorisation procedure (European Parliament and Council 2009b). The approval of an active substance for biocidal use does not cover NMs, except where explicitly mentioned. Biocidal products containing NMs are not eligible for a simplified authorisation procedure. To approve nanomaterials as active substances and for subsequent product authorisation, the test methods applied to the NMs shall be accompanied by an explanation addressing their scientific appropriateness taking into consideration the specific characteristics of each NM. Every five years, Member States are required to submit to the EC a report on the implementation of the BPR in their respective territories. The report must address several topics, including information on the use of NMs in biocidal products and the potential risks.

The BPR applies to biocidal products and treated articles and considers a treated article that has a primary biocidal function as a biocidal product; this is especially relevant where the treatment takes place outside the EU. Furthermore, the BPR includes specific requirements for treated articles that are not biocidal products. Pursuant to Art. 58 (applicable from 1 September 2013), treated articles can only be placed on the EU market if they are treated with active substances approved in the EU. This applies regardless of whether or not the active substances are intended to be released from the article, i.e. regardless of whether they have an internal or external function. Examples for treated articles include "odourless" socks containing nano-silver. For articles placed on the market that are treated with a non-approved active substance, Art. 94 of the BPR grants the possibility to maintain those articles on the market during a transitional period expiring on 1 September 2016, by submitting an application for approval of the active substance before that date. There are currently no transitional measures for the labelling rules of treated articles set in Article 58(3).

Labelling requirements apply to biocidal products (Art. 69) and treated articles (Art. 58) where a claim (see Figure 5) is made that the treated article has a biocidal property. In case of a treated article containing biocidal active substances the label should provide the following information: the words "treated with biocidal products", followed by the name of all active substances that were used to treat the article or materials or that were incorporated in the articles or materials and, where relevant, of all active substances which are intended to be released under normal or foreseeable conditions of use from the treated article or material. From 1 September 2013 the name of all (not only "active") NMs contained in biocidal products is required to be followed by the word "nano" in brackets.

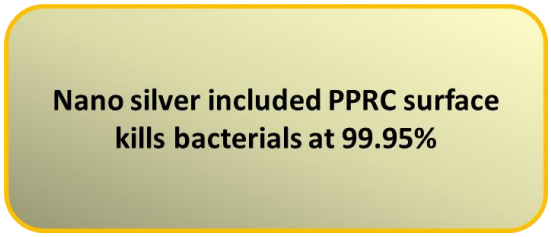


Figure 5: Example of a "nano silver" and "biocidal" claim on a food contact material (plastic food container for vegetables and fruits).

Nanomaterials used as active biocidal substances have to be approved and biocidal products containing them have to be authorised. Nanomaterials are assessed and approved separately from bulk materials. Specific product authorisation is needed if the biocidal product contains a NM and products containing NMs are a priori excluded from the simplified authorisation procedure. Biocidal products and articles treated with biocides need to be labelled with regard to the active substance(s), and specifically mention any nanomaterial.

3.6 Medical Devices

The European Commission adopted a Proposal (COM(2012)542 final) for a Regulation of the European Parliament and of the Council on medical devices (European Parliament and Council 2012a). This proposal includes specific provisions for nanomaterials. It contains a definition of nanomaterial which is identical to the current EC Definition. The proposal provides no exception from the 50% threshold for the size distribution based on particle numbers, but the Commission is empowered to adapt the definition of nanomaterial by delegated act in view of technical and scientific progress and taking into account definitions agreed at Union and international level.

It proposes that the label of the device shall have an indication that the device incorporates or consists of nanomaterial and all devices incorporating or consisting of nanomaterial are in class III (the highest risk class) unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose.

The Commission has adopted a proposal for a new Regulation on medical devices which explicitly addresses nanomaterials. It required a labelling of all medical devices which incorporate or consist of nanomaterials. Those devices are in class III, the highest risk class for medical devices.

3.7 General Products Safety

The General Products Safety Directive 2001/95 (GPSD) (European Commission 2001) is intended to ensure a high level of product safety throughout the EU for consumer products that are not covered by specific sector legislation; sector specific legislation exists e.g. for toys, chemicals, cosmetics and machinery, whereas there is no sector specific legislation for e.g. textiles. The Directive also complements the provisions of sector legislation that do not cover certain matters, for instance in relation to producers' obligations and the authorities' powers and tasks. The framework of the GPSD should assure that only safe consumer products are placed on the EU market. In addition, producers must inform consumers of the risks associated with the products they supply and must take appropriate measures to prevent such risks and be able to trace dangerous products. As well as making provision for market surveillance and enforcement, the Directive provides for an alert system, known as the Community Rapid Information System (RAPEX), which ensures that the relevant authorities are rapidly informed about dangerous products.

The current GSDP makes no reference to nanomaterials, but its modification into a Regulation is planned. GPSD covers also textiles which may contain or be coated with NMs to render the fabric water and dirt repellent (e.g. CNTs, nanoTiO_2 or nanoZnO), antimicrobiotic (nano silver), or provide UV-protection (nanoTiO_2 or nanoZnO) (ÖAW-ITA 2010a). Textiles shall have a composition label which lists the name and mass percentage of fibres in the product. The composition labelling rules are laid down by the EU Textile Labelling Regulation 1007/2011 (European Parliament and Council 2011c). This Regulation contains an invitation to the Commission to submit a report to the European Parliament and to the Council regarding possible new labelling requirements (on origin, care, size, and allergenic substances and electronic labelling) with a view to facilitating the free movement of textile products and to achieving a high level of consumer protection throughout the Union. The Regulation currently makes no reference to NMs.

Only safe consumer products shall be placed on the EU market. Consumers have to be informed about risks associated with products and (dangerous) products have to be traceable.

Currently there is no requirement in EU legislation to label consumer products in general (including textiles) for their content of nanomaterials.

3.8 Waste Electrical and Electronic Equipment and Restriction of Hazardous Substances

Electrical and electronic equipment (EEE) increasingly make use of nanotechnology, and nanomaterials are a key component in the manufacturing of computers and new compact energy sources, such as lithium-ion batteries. The EP had previously called for notification of all applications of NMs in EEE to the EC and proposed to include an agreed definition of NM, the labelling of EEE containing NMs and the prohibition of the use of nanosilver and long multi-walled carbon nanotubes in EEE (European Parliament 2010). Eventually, the scientific evidence for such rigorous measures was found to be insufficient. Thus, the treatment requirements for Waste Electrical and Electronic Equipment (WEEE) according to Directive 2012/19/EU (European Parliament and Council 2012b) do not specifically address NMs, nor is the removal of specific NMs from WEEE required. Still, the WEEE

directive acknowledges that exposure to nanomaterials that are firmly embedded in large structures, for example in electronic circuits, may occur in the waste phase and during recycling. To control possible risks from the treatment of WEEE containing nanomaterials, the Commission should assess whether specific treatment may be necessary. Electronic circuits and components with structures at the nanoscale are not included in the EC Definition of NMs, as the latter refers to particulate NMs only. No NM is yet specifically mentioned in Annex II (restricted substances) of the Directive on the Restriction of Hazardous Substances in electrical and electronic equipment (RoHS) 2011/65/EU (European Parliament and Council 2011b) however the restriction of a substance (e.g. lead) also covers its nanoforms.

There are no specific provisions such as labelling requirements in EU legislation for nanomaterials in electrical and electronic equipment (EEE), neither does the Waste Electrical and Electronic Equipment Directive contain any reference to nanomaterials.

Nanomaterials are not listed as restricted (hazardous) substances (needing substitution) in the RoHS Directive.

3.9 The European Ecolabel

The EU Ecolabel Regulation No. 66/2010 (European Parliament and Council 2010) lays down rules for the establishment and application of the voluntary EU Ecolabel award scheme to encourage businesses to market products and services with lower impact on the environment throughout their life cycle, from the extraction of raw material through to production, use and disposal. The EU Ecolabel (see Ecolabel logo in Figure 6) covers a wide range of (non-food and non-medical) products and services, including cleaning products, appliances, paper products, textiles, home and garden products, lubricants and services such as tourist accommodation. The criteria are developed for each product group to address the unique characteristics of each product type. Every four years on average, the criteria are revised to reflect technical innovation.

Consumer associations, such as the European Consumers' Organisation (BEUC) and the European Environmental Bureau (EEB) (EEB and BEUC 2011) and some EU Member States have pushed not to grant the EU Ecolabel to certain products containing nanomaterials (e.g. textiles, soaps, shampoos and hair conditioners or detergents containing nanosilver). The EU's Ecolabel Board (EUEB), however, has so far decided against such exclusion (RSC 2011). The exclusion of goods being awarded the EU Ecolabel depends (amongst other criteria) on their content of certain dangerous substances, i.e. classification of their constituents (nanoform or non-nanoform) under the CLP Regulation. Thus substances (including NMs) and preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction under the CLP Regulation are excluded (European Parliament and Council 2010). To address the potential differences in the toxicological profile of NMs and their non-nano counterparts, a text requiring information relating to the form or state of a substance has been added to the verification requirements of the standard Ecolabel hazardous substance criteria.

Silver, and thus also nanosilver, is classified as very toxic to the environment and would be excluded from being awarded the EU Ecolabel. There are however exemptions for substances classified as toxic to the environment under certain conditions, if substitutes are not available on the market and if there are other environmental benefits (e.g. paints for which silver/clay biocides can be used).

Figure 6: The award of the Ecolabel to products depends on the absence of dangerous ingredients (based on CLP, SVHC or other criteria). There are currently no provisions for nanomaterials.

There are no provisions in the EU Ecolabel Regulation which are specific to nanomaterials.

The exclusion of goods being awarded the EU Ecolabel depends (among others) on the classification of their constituents (nanoform or non-nanoform) under the CLP Regulation.

4 Measures to trace nanomaterials in consumer products

Transparency and traceability of the use and possible exposure to substances in consumer products on the market may in general be required for substances of concern, as well as for substances of special interest to the public, although not necessarily representing a specific risk. Labelling for genetically modified organisms (GMOs) used in the production of food and feed is an example that was discussed extensively in the past. Since 2003 (European Parliament and Council 2003) all food products that make direct use of GMOs at any point in their production have to be labelled, regardless of whether or not the genetically modified (GM) content is detectable in the end product. All products having GM content are listed in a publicly available EU register for authorised GMOs (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm).

The EP resolution of 2009 called on the EC to compile an inventory of the different types and uses of NMs on the European market and to make it publicly available (European Parliament 2009a). In response to this, the EC prepared in a SWP an overview of types and uses of NMs on the market, which also considered safety aspects (European Commission 2012a). In addition, the EP (European Parliament 2009b; European Parliament 2013) re-iterated its call for the provision of information to consumers on the use of NMs in consumer products: all ingredients present in the form of NMs in substances, mixtures and articles should be clearly indicated in the labelling of the product. The EP also called for the full enforcement of Directive 2006/114/EC referring to misleading advertising to ensure that there is no such practice related to NMs (European Parliament and Council 2006b).

Providing information and ensuring traceability of nanomaterials on the market can be implemented by two different means:

- Labelling of products containing nanomaterials,
- Notification to an inventory or a product register.

The options for development of different reporting systems for NMs were evaluated by different institutes for example in Belgium, Germany and the Netherlands (Milieu Ltd and RPA Ltd 2010; Öko-Institut 2010; Wijnhoven *et al.* 2011; BiPRO and Öko-Institut 2013) and are presented in more detail in the text below.

4.1 "Labelling"

"Label" can be defined as any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to the packaging or container of a product or on a separate but associated label (European Parliament and Council 2011a). Labelling is the action of putting a label on a product, for which the manufacturer, importer or distributor (i.e. all those that place a product on a market) is responsible.

The objective of product labelling is to guarantee that consumers have access to certain information to exercise a choice and/or to protect their health or the environment. The extent and content of information provided depend on the type of product and can for example include:

- The content and composition of products,
- The origin of a product,
- The content of dangerous substances (classified according to CLP),
- Specific information on the proper and safe use of a product.

In the case of food, labelling should provide complete information on the content and composition of products and the date of minimum durability or the "use by" date in order to protect the consumers' health and interests (see Figure 7) (European Parliament and Council 2011a). Substances causing allergies or intolerances (nuts, milk, mustard, fish, grains containing gluten, etc.), quantity of certain ingredients or categories of ingredients and the alcoholic strength (by volume) of beverages containing more than 1.2 % by volume of alcohol, belong to the mandatory particulars. In addition, details on particular aspects of the product, such as its origin or production method may be provided (see also the EU legislation information for consumers on product labelling http://europa.eu/legislation_summaries/consumers/product_labelling_and_packaging/index_en.htm).

Figure 7: The ingredients list on food packaging informs consumers on the composition of the food product. Substances or products causing allergies or intolerances (as listed in Annex II of Regulation 1196/2011) have to be emphasised through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example by means of the font, style or background colour.

Labelling of certain non-food products must also contain particular information e.g. to guarantee safe and proper use or for consumers to make an informed choice. Such labelling can include information on product energy consumption, energy efficiency, CO_2 emission, textile fibre names, composition of lining and sole of footwear, ecolabels (see Section 3.8), the price of a product, etc. (Caswell 1998). Ingredients lists for non-food stuff have to be provided for e.g. cosmetic products, biocidal product and detergents.

For consumer products containing dangerous substances classified according to CLP (Section 3.2) in concentrations above the general or specific concentration limit, the label must mention the substance name (see Figure 8). If applicable, it shall include hazard pictograms, the signal words "Danger" or "Warning", hazard statements (e.g. "Fire or projection hazard", "Fatal if swallowed"), precautionary statements (e.g. "Keep out of reach of children") and supplementary information, for example about physical properties or health hazards.

Ingredients: … Zinc oxide …

Warning
Hazard Statements:
H400 "Very toxic to aquatic life"
H410 "Very toxic to aquatic life with long lasting effects"
Precautionary Statement:
P273: Avoid release to the environment.
P391: Collect spillage.
P501: Dispose of contents/container to …

Figure 8: Consumer products containing dangerous substances (according to CLP) must mention the name of such substances and, if applicable, include hazard pictograms, signal words, hazard statements and/or precautionary statements. For example, zinc oxide is classified as hazardous to the aquatic environment. Therefore products containing zinc oxide (macro and nanoform) above the generic concentration limit (25%) have to be labelled for environmental hazard.

In order to avoid confusion and misuse of products, labels should be easily understandable and preferably has to take into consideration the perceived level of knowledge and understanding of those meant to read the label. Reader-friendliness is an important element in maximising the influence of labels on the audience (European Commission 2012c).

Product-specific information should be available (on the product itself or its packaging) at the time a purchase decision is made, and/or full technical specifications of the product should be available through catalogues, web sites or other reference sources.

Labelling is a means to convey information to consumers relating to the content, use and safety of products. It may help the consumer in making an informed choice for product purchase and use. The label has to be clear, readable and understandable and has to take into consideration the perceived level of knowledge of the consumer. The European Union legislation provides for information for consumers in a wide range of products.

4.2 Labelling for content of nanomaterials ("Nanolabelling")

A clear identification of products containing nanomaterials gives the consumer/user the possibility to select or avoid such products. This can be done either by ingredients labelling, or by positive or negative nanoclaims (see below). None of these labels should be misunderstood as a safety statement or warning, and the labelling specification should not lead the consumer/user to such a misinterpretation. In 2013 ISO (ISO 2013)published a guidance document (ISO/TS 13830:2013) on voluntary labelling for consumer products containing manufactured nano-objects (PCMNOs) with the aim to provide a framework to facilitate a harmonised approach for the voluntary provision of nanolabelling. It applies to PCMNOs that may or may not exhibit or impart nanoscale phenomena,

but does not apply to products that contain naturally occurring nano-objects or those incidentally present.

Ingredients labelling

Provisions for labelling of certain consumer products for their content of NMs do already exist (Chapter 3). The EC has pointed out that similar provisions can be envisaged for other regulatory schemes where ingredient labelling already exists, allowing consumers to make an informed choice (European Commission 2012b). Current legal provisions for "nanolabelling" or "nanolabels" require that all ingredients present in the form of NMs (according to the criteria in the relevant regulation) are to be clearly indicated in the list of ingredients by adding the word "nano" in brackets after the substance name. The ingredients for food and cosmetics products are listed in descending order of relative weight. Ingredients in concentrations of less than 1 % may be listed in any order after those in concentrations above 1 %. The ingredients list is usually provided "back of pack" and can for certain products be quite extensive and therefore be written in small letters to fit on the package (see example Figure 3). It may thus be challenging to read the list and identify nano-ingredients or other substances of interest in a certain product.

The nanolabelling used for food and cosmetics has primarily an information purpose and must be clearly distinguished from requirements for the hazard-related labelling of products containing NMs classified according to the CLP Regulation. By indicating the size of a material there is no intention to indicate any differences in the hazard profile compared to the larger size.

Labelling of other product groups is being discussed by several stakeholders. For consumer products without ingredient labelling requirements, e.g. electronic equipment or car tyres, nanolabelling could only be done with a stand-alone "NANO" label ("nanoclaim") as described below. A further challenge is the labelling of products that do not contain NMs, but where NMs can be formed *in situ* during the use of the product (e.g. spraying).

Nanoclaim

Products carrying "nanoclaims" have been marketed for several years. A "nanoclaim" is a statement that a product contains NMs or has been manufactured using nanotechnology (the exact meaning is not well defined), without necessarily providing proof of such a statement. It appears that the term "NANO" – just as other claims like "NANOtec" or "with nanoparticles" (see examples in Figure 9) – is sometimes placed by producers on the product label or on the product website mainly for marketing reasons. An internet search by RIVM in 2012 for the project "How do producers justify the nano claims they place on consumer products" (Wijnhoven *et al.* 2012) identified 33 products with nanoclaims either on a website (32) or on the product label (24). The products include: electronics and computers, household products and home improvements, personal care and cosmetics, motor vehicles, sporting goods, textiles and shoes. The interpretation of the term "nano" varied from one manufacturer to another, with some referring to materials of size ranges up to 1000 nm and others referring to a nanostructured or very thin layer/coating.

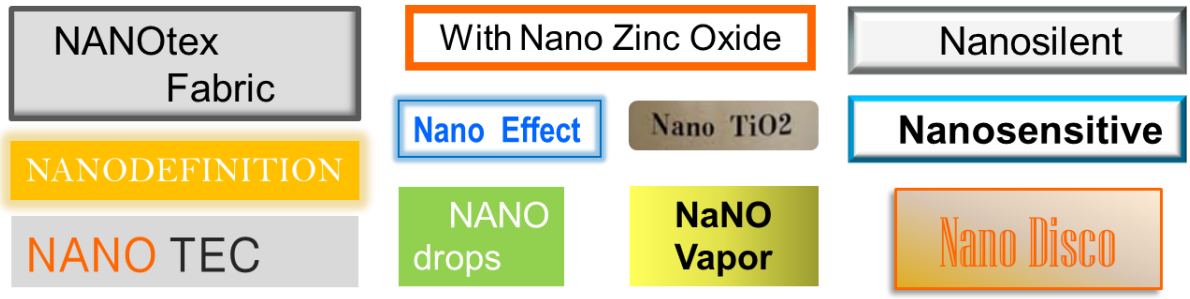


Figure 9: Examples of (positive) nanoclaims found on products on the market (non exhaustive). In most cases the claim refers to the content of a nanomaterial or the use of nanotechnology. In other cases "Nano" is used as name of a product with no obvious link to a nanomaterial or nanotechnology.

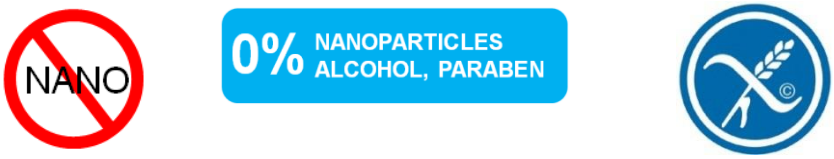
Clearly visible nanoclaims or nanolabels (e.g. "NANO" written in capital letters, optionally also in combination with a circle or picture or in combination with other words (Figure 9) at a prominent place on the product ("front of pack") are already widely used in some consumer products. Such labels can help consumers in immediately identifying products containing at least one material in the nanoform, without having to consult the list of ingredients. Such a label could however give the impression of a specific property, e.g. hazard associated with the NM ingredient in the labelled product, and would change the currently purely informational purpose of ingredient labelling (as in cosmetic products, food or biocides). This type of label is not required by any legislation in the EU, but has been proposed as industrial standard certification in some Asian countries like Thailand Taiwan and Iran (Figure 10). Compared to ingredient labelling, it would be "less neutral", since it could more likely serve as advertising or lead to discrimination of a product. It should be noted that the graphical design of such a label can considerably affect how it is perceived (positive or negative). Therefore, in the absence of known specific NM-associated risks, a compulsory generic "NANO" label is of little benefit and can lead to confusion. On the other hand, a voluntary (verifiable) "NANO" label attached by the producer for marketing purposes is, in principle, acceptable if it additionally specifies which NM is present in the product ("*contains substance xyz (nano)*").

Figure 10: Nanoproducts certification system as introduced by industrial standards committees in Taiwan (∞Nano) and Thailand (NanoQ).

Absence of nanomaterials (negative labelling/claim)

Besides a labelling for the presence of nanomaterials (positive labelling), also a labelling for the absence (negative labelling) of NMs is in principle conceivable. This could be either clearly exposed, for example as a *"NANO free"* label, a crossed out "NANO" or as text added after the list of ingredients: e.g. *"this product does not contain nanomaterials*" (see example in Figure 11). So far this option has not been proposed in any context.

It could in principle be used on a voluntary basis similarly to what is done by manufacturers for other substances/techniques which attract public attention, such as "BPA (Bisphenol A) free" in plastic ware, "paraben free" in cosmetic products or "gluten free" in food (see Figure 11). In that context it may be noted that several different negative claims can be found on consumer products and it can become quite difficult for a non-expert to interpret the significance of such labels.



(a) (b) (c)

Figure 11: Examples of claims for the absence of "nano", nanoparticles or other chemical substances (a, b) in a cosmetic product or for certain food ingredients (c), e.g. crossed grain for gluten free food.

A non-specific negative labelling for nano would be very difficult to apply universally, since it would imply deciding for a huge number of products whether they contain NMs or whether they are free of any material in the nanorange (e.g. 1 – 100 nm). Moreover, the EC Definition includes also incidental and naturally occurring NMs, for which it is difficult to guarantee their absence. The situation would be different if such a negative label would apply only to engineered or manufactured, intentionally added NMs. In such a case, the producer of a product could apply a label based on the knowledge of the manufacturing process. Unfortunately, it is still a major problem to distinguish natural or incidental from intentionally added NMs in a product using currently available analytical methods (see Chapter 5), thus making verification challenging. If such a "NANO-free" label is introduced, the conditions for applying it must be clearly defined; for instance there must be precise thresholds for the presence of NMs, below which a product can be considered nano-free for the purposes of such a label.

The labelling of products for their content of nanomaterials should be risk-independent.

Current EU legislation on food, cosmetics and biocides requires nanomaterials to be reported in the list of ingredients with "nano" added in brackets after the substances name.

Voluntary "nanoclaims" (positive and negative) put on products by manufacturers are mainly marketing-related. Such claims can lead to either positive advertising but also to discrimination of a product.

4.3 Inventory / product register on nanomaterials

There are initiatives and suggestions from the European Parliament (European Parliament 2009b), several EU Member States and non-governmental organisations to collect information on nanomaterials used in products in a database, which could be either an inventory or a product register. A nano-inventory is considered to be a detailed, itemised list, report, or record of NM types and uses. Inventories have been created by different institutions, listing nanotechnology-based consumer products, based on nano-claims or other information (some examples are described in Annex III). A nanoproduct register is considered a more formal or official recording of nanotechnology-based consumer products, for example based on notification requirements for producers and those who place the products on the market. (European Parliament 2009b). In the following sections we refer to both inventories and registers that are currently being created for specific purposes at European level or at national level, at the initiative of EU Member States.

The main objective of a nanoproduct register is to increase transparency and traceability of NMs with regard to uses, volumes and markets. The main potential users of information are public authorities and policy makers, downstream user industries and workers, consumer and environmental associations as well as consumers. It is discussed that a product register could capture nanomaterials at quantities below one tonne, which are not registered under REACH or those for which there are no reporting obligations under current legislation. However this is currently not supported by the Commission as NMs on average do not seem to be produced generally at lower quantities nor do they seem generally more hazardous than other chemical substances (European Commission 2013b). In addition, the Commission understands that the need for traceability is based on the assumption that serious risks might occur requiring immediate action to withdraw products from the market. There are so far no indications on the seriousness and likelihood of such events.

Reporting to a product register can provide stakeholders with a comprehensive overview of nanoproducts on the market and enables effective intervention by relevant authorities in case a hazard to the general public, workers and/or the environment is identified. If such a register is publicly available (as requested by the EP or some NGOs) all citizens could get that overview and could make nano-related purchase decisions before buying or ordering a product. Furthermore, such product registers could reduce possible misleading claims, as they could be checked against the register. A nanoproduct register facilitates the estimation of potential exposure to and fate of NMs that might arise from the production, use or disposal of NMs or products containing NMs, both for humans and the environment. It also contributes to setting up a general knowledge database that may be relevant for national or European regulatory purposes. Nanoproduct registers can also contribute to ensuring sustainability and market acceptance of innovative nanotechnology (BiPRO and Öko-Institut 2013).

Extent of the information in an inventory / product register

A product register can collect and store basic information on the applicant, substance identification, type of product and target users. Depending on the type and extent of information to be reported, it can also collect and deliver useful information on toxicological and eco-toxicological effects of NMs and their possible fate after use (i.e. where they end up in the course of their life cycle), as proposed for example in a report by Milieu Ltd (Belgium) (Milieu Ltd and RPA Ltd 2010). In the case that a NM

is identified as potentially hazardous, in addition to hazards already identified through REACH and CLP (see Chapter 3), a registry would allow immediate identification of products on the market containing this NM, thus increasing the speed and effectiveness of appropriate risk management measures. A product register could also contain additional information about the measurement method to be used to prove the NM content. If required, the method should be suitable, robust, standardised and of reasonable cost (VCI 2011) (see Chapter 5). In general, it is important that product registers are regularly updated to contain the relevant information and to observe trends.

In principle, a product register could cover all types of products containing NMs; it could however also be restricted to products for which a nanolabelling requirement exists. The report "Legal feasibility on the introduction of a nanoproducts register" (Öko-Institut 2010) proposes that all NMs and nanoproducts should be covered by a product register, irrespective of their product group, the type of NM they contain, and irrespective of who places, or intends to place, the product on the market.

In contrast, a recent study on the scope of a Belgian national register for NMs and products containing NMs (BiPRO and Öko-Institut 2013) concluded that declaring all of the products, and tracking them through their lifecycle, would be prohibitively expensive. Having assessed six different options, the authors recommend one that includes various exemptions from reporting – such as selected product groups, for example pigments and fillers, or supply chain actors (e.g. retailers). A range of exemptions is also planned in a future Danish national nanomaterial product register for certain activities (sold between businesses) or products (already regulated, such as in food) (http://hoeringsportalen.dk/Hearing/Details/16910).

Based on the introduced mandatory labelling requirements for food, cosmetic products and biocidal products, or the explicit authorisation of NMs in plastic food contact materials, registration of NMs present in these products could be an option, though it is currently not required.

Access rights to the inventory / product register data

The conditions of product registers need to be assessed and defined with regard to the type of information the database provides and who are the stakeholders. The access to a product register could be organised as restricted (e.g. only policy makers), semi-public (including specific organisations) or public (including the general public). Restricted access to the register or to certain types of information could be important if companies claim confidentiality, as the publication of the information could adversely impact their business (VCI 2011). The above mentioned report by Milieu Ltd (Milieu Ltd and RPA Ltd 2010) recommends that any information, other than that specifically mentioned as confidential under REACH, should be made publicly available, ensuring the balance between the public's right to know and the need to protect commercial interests in a very competitive and innovative market. The legislative framework for the French notification scheme established that the information about the identity (chemical name) and the uses of the NMs have to be made available to the public. All other information on the identity is considered confidential, as is the information on quantities, the commercial name of the NMs or mixture and the identity of the professional users. Notifiers could also claim confidentiality for certain information, if its public availability could affect business confidentiality or intellectual property of research and innovation results (Art. R523-18) (Ministère de l'Écologie du Développement durable et de l'Énergie 2012b).

Interested citizens or consumer organisations have in principle already the possibility to create lists of nanomaterials on their own initiative by using the eChemPortal (www.echemportal.org), which provides free public access to information on physical-chemical properties, environmental fate and behaviour, ecotoxicity and toxicity of chemicals. The eChemPortal is an effort of the Organisation for Economic Co-operation and Development (OECD) in collaboration with the European Commission, the European Chemicals Agency (ECHA), the United States, Canada, Japan, the International Council of Chemical Associations (ICCA), the Business and Industry Advisory Committee (BIAC), the World Health Organization's (WHO) International Program on Chemical Safety (IPCS), the United Nations Environment Programme (UNEP) and environmental non-governmental organisations. eChemPortal allows simultaneous searching of reports and datasets by chemical name and number and by chemical property. Direct links to collections of chemical hazard and risk information prepared for government chemical review programmes at national, regional and international levels are obtained. Classification results according to national/regional hazard classification schemes or to the Globally Harmonized System of Classification and Labelling of Chemicals are provided when available. Currently 28 data sources participate in Chemical Substance Search, and 4 databases, including ECHA's dissemination portal ECHA CHEM, participate in Chemical Property Data Search. Thus, information on chemical properties of REACH registered substances is directly accessible via the eChemPortal. By querying for granulometry data in an appropriate way the user can create his own inventory of nanomaterials from the databases providing this information to eChemPortal.

Nano-product registers can provide an overview of available nanomaterials and nanoproducts on the market. They can also deliver useful information about the fate of nanomaterials during the life cycle and the potential human and/or environmental exposure. Registers can also include data on human and environmental hazard if so desired.

Information requirements for a nanoproduct register as well as access rules need to be defined.

4.4 Voluntary or compulsory traceability measures?

The labelling or reporting of products containing nanomaterials could be either on voluntary or compulsory basis. The required information for mandatory reporting would have to be provided by producers, distributers or importers, but could also include "professional users" and research laboratories, as requested for example by a French decree (Ministère de l'Écologie du Développement durable et de l'Énergie 2012c). Currently, the EU Cosmetic Products Regulation (European Parliament and Council 2009a) and the French decree mandates the notification of information on NMs contained in products, and non-public inventories are to be created as a consequence.

Publicly available information about products on the market containing NMs or produced using nanotechnology ("nanoproducts") currently builds on voluntary reporting (see examples in Annex III). Voluntary reporting can be based on a commitment of (certain) industry (branches) to provide information on their products. Information could also be received from different stakeholders, including NGOs and consumers (see examples below in Section 4.5 and Annex III).

Voluntary reporting may imply a reduced reliability of the information in the product register, since the accuracy and the comprehensiveness may be influenced by the public perception of "nano" (Oomen *et al.* 2011). It has been observed that some years ago the word "nano" had generally a positive attribute for new technologies and new exciting product properties (Federal Institute for Risk Assessment 2008) and was therefore more generously applied to advertise/promote products, even if in some cases the product actually did not contain NMs (Federal Institute for Risk Assessment 2010; Wijnhoven *et al.* 2012). Due to perceiving a growing scepticism from consumers towards NMs, producers and retailers seem increasingly to refrain from making "nanoclaims", especially for products which consumers expect to be "natural" and healthy, or which are "closer" to the human body, such as food or cosmetics (Bieberstein *et al.* 2013).

Trial voluntary reporting schemes for NMs have been experimented in the UK and the USA, with limited results as only a small fraction of the products under development or on the market were reported (DEFRA 2008; Milieu Ltd and RPA Ltd 2010; ÖAW-ITA 2010b). Voluntary surveys have been carried out in Germany, Ireland, Denmark, and Japan (Milieu Ltd and RPA Ltd 2010; Öko-Institut 2010) and Australia (CIE 2011). Although response rates were in general rather low some of the provided information was quite detailed. The views of some EU Member States on reporting schemes for NMs were presented at a workshop on the regulatory framework for the traceability of NMs in September 2010 under the Belgian EU Presidency (Milieu Ltd and RPA Ltd 2010; Trio.be 2010). A recommendation from the report and the workshop is that an EU-level reporting system for NMs on the market should be mandatory. This was also emphasised in a note of a group of EU Member States including Croatia to the EC (Ministry of Infrastructure and the Environment of the Netherlands 2012).

Labelling/registration on a voluntary basis is not legally binding and there are no sanctions for not adhering to it. Not all distributors of nanoproducts receive the relevant information and are thus not able to apply it. This may lead to gaps in coverage of nanoproducts (Öko-Institut 2010). A resulting discrimination of those who apply it cannot be excluded (if "nano" is considered to be negatively associated). The only way to regulate false claims and avoid unfair commercial practices thus seems to be compulsory labelling and/or registration of products containing NMs.

Only mandatory reporting/labelling of products containing nanomaterials can assure accurate and comprehensive information and avoid unfair commercial practices.

4.5 Available inventories/registers

A number of EU Member States and other countries have put forward proposals to gather information and to improve the public's knowledge about products containing nanomaterials (Öko-Institut 2010; Trio.be 2010). International organisations are active in this area as well. The approaches taken include voluntary or mandatory reporting systems and (one-time) voluntary surveys.

ECHA has compiled (2011-2012) a non-public inventory of substances identified as NMs included in REACH registration dossiers and CLP notifications submitted so far (European Commission 2012a).

This action was requested by the EC in response to the EP's 2009 communication on NMs (European Parliament 2009b).

The European Cosmetic Products Regulation (European Parliament and Council 2009a) requires compulsory pre-market notification of cosmetic products from 11 July 2013 onwards, using the Cosmetic Products Notification Portal (CPNP) maintained by DG Health and Consumers. The Regulation specifically requires also the notification of NMs and certain specific properties of those NMs, which shall be registered through CPNP. In this way a non-public inventory of NMs used in cosmetic products and of cosmetic products containing NMs, will be continuously populated. DG Health and Consumers shall report annually certain information to the EP, as required by the Regulation.

National product register

In France, article 185 of Law No 2010-788 of 12 July 2010 (Grenelle 2 law) on the national environmental commitment has put in place a compulsory declaration scheme (Articles L. 523-1 to 5 of the environmental code) for the identity, quantities and usage of nanoparticle substances or NMs, distributed or imported in France. The conditions for application of these articles are defined by a decree (Ministère de l'Écologie du Développement durable et de l'Énergie 2012a).

In particular, the decree specifies the definitions, the minimum threshold and the reporting frequency, the provisions concerning the protection and confidentiality of the data and penalties. Based on this, France has become the first European country requiring companies to report the production, distribution and import of NMs in quantities of/above 100 g/year (gpa) from January 2013. The information has to be submitted to the French Agency for Food Safety, Environment and Labour (ANSES) and is used to create an annually updated, non-public inventory (Ministère de l'Écologie du Développement durable et de l'Énergie 2012a).

A first analysis based on public data was presented in November 2013 by the French Ministry of the Environment (Ministère de l'Écologie du Développement durable et de l'Énergie 2013). 3,409 notifications referring to an estimated number between 243 and 422 different substances were received. 41% of the registrations did not provide a CAS number, but the substances were identified by a chemical name. An aggregated amount of 504,104 tonnes (282,014 tonnes manufactured and 222,090 tonnes imported) of NM was reported with the highest tonnages for carbon black (274,837 tonnes), silicon dioxide (SAS) (155,072 tonnes), calcium carbonate (34,502 tonnes), titanium dioxide (14,321 tonnes), Aluminium oxide (2,193 tonnes) and copolymer of vinylidene chloride (1,560 tonnes).

National compulsory declaration measures are also being considered by Denmark (Miljoministeriet and Miljostyrelsen 2013) and Belgium (BiPRO and Öko-Institut 2013).

In July 2013 the Danish Environmental Protection Agency launched a public consultation on a draft order for a NMs register. The draft order would impose annual reporting requirements on manufacturers and importers concerning mixtures and articles sold to consumers and containing or releasing NMs. The order provides also a number of exemptions for which the duty to notify does not apply, including nanoproducts sold between business or manufactures or imported by companies for their own use, for products regulated by other legislation (e.g. food, cosmetic products), nanoproducts containing NM not intentionally manufactured or where the NMs are included in a solid matrix and nanoproducts for research and development. The executive order will

enter into force 18 March 2014. The first reporting must be made by 30 June 2015 for the period of 1 May 2014 to 1 May 2015.

The Belgian Federal Public Service (FPS) Health, Food Chain Safety and Environment developed and notified to the EC in July 2013 a draft decree to establish a notification scheme of products containing NMs, which was based on a study in which different options and their direct costs to industry were compared (BiPRO and Öko-Institut 2013). This draft decree includes a declaration duty for substances manufactured at the nanoscale if placed on the market for professional users more than 100 g per year or incorporated into articles and complex objects is their release cannot be excluded. It also includes exemptions from notification obligations, for example for pigments and widely used filling materials or products that are subject to other regulatory provisions (e.g. biocides, food etc.). The draft decree would apply respectively from January 2016 for NMs and from January 2017 for mixtures containing NMs. No date has been set yet for articles and complex objects containing NMs.

Both notification schemes make reference to the EC Definition recommendation with certain exemptions as for example listed above or the Belgium draft decree also excluding chemically unmodified natural substances and substances whose nanosized fraction is a by-product of human activity.

The German Federal Environment Agency (UBA) supports the establishment of a central nanoproduct register at European level and has published a "Concept for a European Register of Products Containing Nanomaterials" (Umweltbundesamt 2014). A European register is preferred over national product registers, as they would lead to different duties and regulation in the Member States and increased costs for authorities and notifiers.

In Norway, chemical products must be registered in the Norwegian Product Register of Chemicals at the Norwegian Environment Agency, which includes chemicals that are classified as dangerous, and whose quantity produced in/imported to Norway and/or placed on the market each year is 100 kg or more. If the chemical contains nanomaterials this must be declared in the registration, and information on any substance in nano form must be given for all mandatory declared chemicals, including the identity of the constituent that is in nano form. Only intentionally added nanomaterials need to be registered in the Norwegian Product Register of Chemicals, and the definition of nanomaterials follows the EC Recommendation 2011/696/EU.

Publicly accessible inventories of nanoproducts

Several NGOs have called for a public inventory of all NMs on the market and their uses, the labelling of (some) products, a national register of exposed workers and/or regulation of misleading advertising. Currently available nano-product registers (e.g. Woodrow Wilson) are mostly based on a voluntary reporting and nanoclaims (for more details see Annex III). These databases are not necessarily reliable since they lack independent verification mechanisms. Extracting quality-checked information from diverse sources based on common information requirements is a first step towards the reliability and comparability of available information that can also be used for regulatory decision making.

The Danish Nanodatabase nandb.dk (http://nanodb.dk/) maintained and updated daily by DTU Environment of the Technical University of Denmark and two Danish NGOs, i.e. “The Danish Eco

Council" and the "Danish Consumer Council ". Nanodb.dk is an on-line inventory of products that either contain NMs or are marketed with the word "nano" (Figure 12). Besides providing a short description of the use of the NMs it includes also a NanoRiskCat colour code, which refers to exposure potential and potential hazards for humans and the environment, deviating from giving information only on NM content of products (Hansen *et al.* 2014).

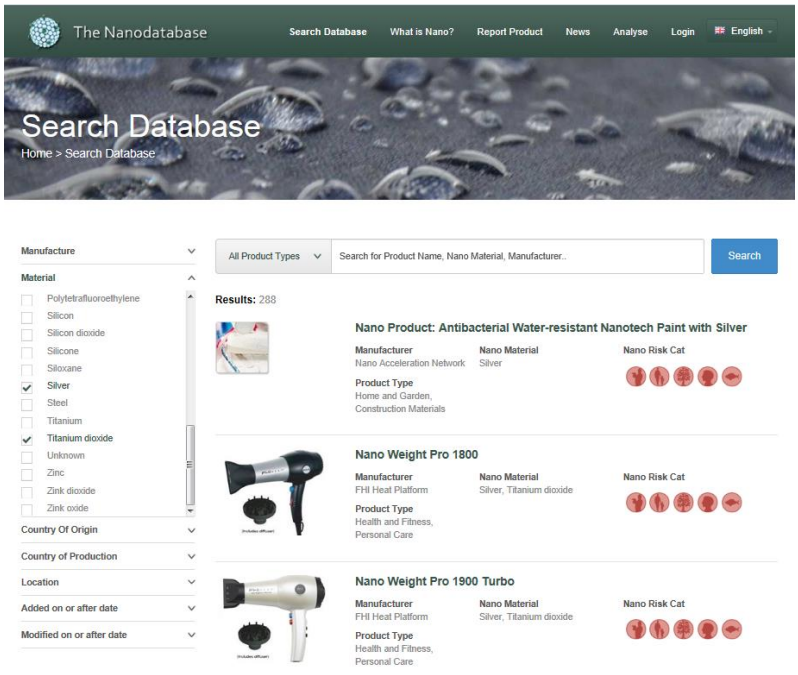


Figure 12: Danish Nanodatabase (http://nanodb.dk/) can be searched for products, manufacturers, nanomaterial or country of origin. The colour codes have been assigned to signify whether the risk of exposure or potential effects are high (red), medium (yellow), low (green), or unknown (grey) (Hansen *et al.* 2014).

A harmonisation of the obligations in different EU Member States is needed to avoid different registration or labelling requirements in different member states, which may hamper free movement of goods and work against fair market competition. Several EU Member States, including the Netherlands, Austria, the Czech Republic, Denmark, France, Italy, Luxembourg, Spain, Sweden and Croatia agree that an EU-registration on NMs is preferred over a series of varying national databases for improving a harmonised European policy on NMs (Ministry of Infrastructur and Environment of the Netherlands 2013). Preferably an EU product register should be managed centrally, since national product registers would result in overlaps with various EU legislation and in varying obligations and regulations in individual EU Member States. This would increase the costs for authorities and stakeholders obliged to notify.

Non-public nano-inventories/registers have been created for REACH registered substances (ECHA), cosmetic products and ingredients (DG Health and Consumers) and nanoproducts/nanomaterials in France.

Public inventories are currently based on voluntary reporting and nanoclaims and are not necessarily reliable, since they lack independent verification mechanisms.

Several EU Member States have started national initiatives to establish reporting schemes for nanomaterials and/or nanoproducts. Other Member States would prefer a harmonised central EU nanomaterials register.

4.6 A web platform on nanomaterials at EU level

The wide use of nanomaterials, the increasing amount of NM-related information and the growing number of regulatory provisions for NMs have triggered requests for better and accessible relevant information. It has been realised that available information is widely scattered among very different sources of various scope and non-uniform information quality. Furthermore, information needs are diverse regarding the type and depth of information.

As mentioned in the introductory part of Chapter 3, the EC adopted a Communication on a Second Regulatory Review on NMs, with an attached SWP (European Commission 2012a). The two documents show in their sections "Need for better accessible information" and "Information and databases" that transparency of information on NMs and products containing NMs is essential. Following the calls from the EP and the Council, the EC services, led by the JRC, have developed a web platform for NMs.

The web platform is aimed at improving the transparency and accessibility of information on NMs and products containing NMs, through a single-entry point, thus providing an overview, as complete as possible, of the information generated and gathered on NMs within the EU and beyond. In its present initial version, the platform is based on web links to available information relevant to NMs. Relevant information on NMs includes some basic knowledge, information on materials type and use (e. g. in products), policy issues, regulatory provisions, environment, health and safety aspects, ethical issues and information initiatives to the general public. The current structure with general categories of web links is reproduced in Figure 13 below (front page of the web platform). The platform was launched by the end of 2013 and is available at the following website: http://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials/. It enables an online visitor to easily retrieve available facts on NMs from the main information sources and databases available online in the EU and beyond.

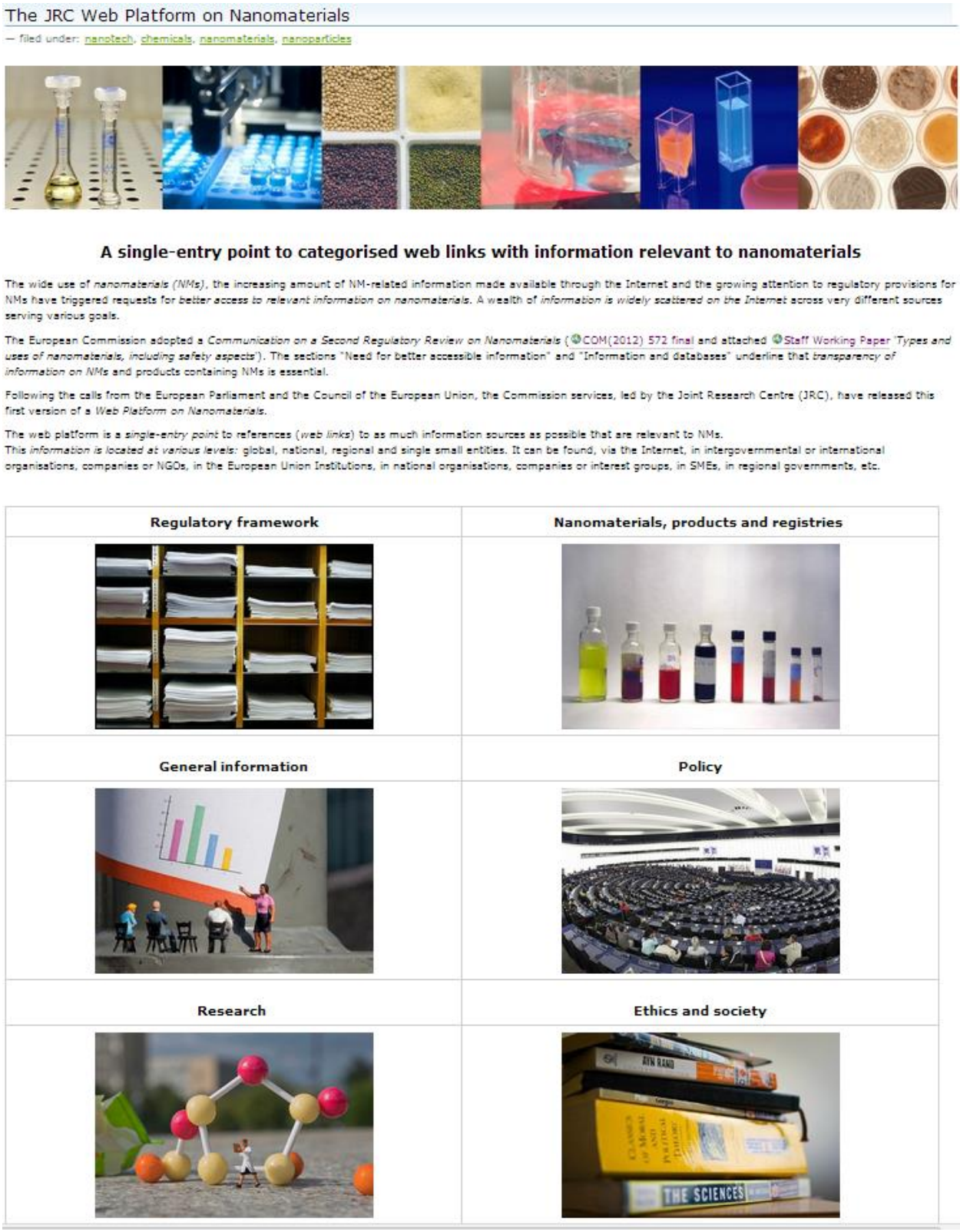


Figure 13: Structure of the EU web platform on nanomaterials http://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials/.

The categorised information gathered via the web platform facilitates to some extent the policy-making processes, also in the field of labelling and registers. The future evolution of the web platform, beyond the first step of web links collection and categorising, depends, among others, on the conclusions of an impact assessment. It was launched by the EC 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 (RPA and BiPRO 2014). This analysis will include those NMs currently falling outside existing notification, registration or authorisation schemes.

Easy access to transparent information on nanomaterials for all users (consumers, downstream/workplace users, regulators, researchers) is of high importance. The EC, under the leadership of its Joint Research Centre, has developed a web platform on nanomaterials as a first step to provide relevant information via a single-entry point.

4.7 Considerations on transparency and traceability measures for nanoproducts

Labelling

Labelling products regarding the content of nanomaterials allows the consumer to make an informed choice of purchasing or not without consultation of e.g. a database or other sources of information. Nanolabelling enables consumers to immediately react to information he receives (from any source) about specific properties of NMs, be it related to specific beneficial properties (for instance higher effect and thus requiring lower dosages of a certain product, e.g. nano-TiO_2 in sunscreens) or to a specific risk (e.g. increased allergic reactions). Nanolabelling can thereby contribute to strengthening the position of the consumers in the market place.

Although more information empowers the consumer, a plethora of symbols, images, logos and text can lead to information overload. While the producer has the responsibility to place only safe products on the market, the decision to purchase (or not) products containing NMs are made by a "non-expert", who may not have the adequate knowledge to make an informed choice (Throne-Holst and Rip 2011). Nanolabelling may therefore influence the perception of advantages or possible risks of a certain product. Therefore, depending on the consumers' perception and attitude, nanolabelling could function as advertising for persons that have a positive mind-set towards products containing NMs, or as warning in the opposite case. Nanolabelling could hence lead to a better market acceptance or to a discrimination of products containing NMs. If nanotechnology-based products are perceived negatively by consumers, this could be an impediment for innovation and a missing opportunity to exploit the benefits offered by NMs. Although innovation is impeded by the negative perception and not necessarily the fact that the label is placed on the product for information, the presence of a label will draw the attention of consumers and consumer organisations to certain types of materials/products. Therefore communication is very important to inform stakeholders about the significance of the label.

So far, existing labelling requirements for nanomaterials are regulated via the ingredients list. For consumer products without ingredient labelling requirements, e.g. electronic equipment or car tyres, the only possibility would be a stand-alone "NANO" label that could draw disproportionate attention to one of the (sometimes many) components of a product.

Product register

Reporting to a register of products containing nanomaterials is applicable to all product types and not dependent on an ingredient list. It is better suited to provide authorities, researchers, or other stakeholders with an overview of nanoproducts produced or placed on the market. Nanolabelling could facilitate the notification to a product register by the manufacturer, downstream user or retailer, but also provide for collecting information on nanoproducts on the market by third parties. Both labelling and registers can be complementary and allow fast and easy monitoring of NMs on the market.

Product registers can provide useful information on potential exposure of humans and the environment to NMs and contribute to ensure a high level of protection of the environment and human health in manufacture, use and disposal of NMs (Nel *et al.* 2013). Product registers can allow searches and statistics on the overall market volume, product types, potential exposure and trends. They can support authorities in setting priorities in the surveillance, in risk communication and risk management, in case a hazard of a certain NM would be discovered (Umweltbundesamt 2014). Registers would also provide a traceable record of the use of NMs and products in case long-term adverse or positive effects would appear later on. The access to (certain information in) product registers would usually require access to the internet and may be restricted to authorised persons. The information may therefore not be available for everyone, as would be the label directly on the product.

General considerations

Any kind of measures to increase transparency and traceability probably creates additional costs to notifiers/retailers and authorities which may eventually be passed on to the consumers. They may also influence the perception of possible risks or benefits of products and could lead to unexpected market reactions. A current study for the Commission is assessing the "impact of possible legislation to increase the transparency on NM on the market" (RPA and BiPRO 2014). The study will utilise experiences from already implemented transparency measures such as the French Notification Scheme and the Cosmetics Products Notification Portal.

A fundamental requirement to enforce transparency measures is the agreement on a definition of the term "nanomaterial" to allow discrimination between NMs and other materials. Currently, different definitions for NMs exist (e.g. cosmetics, food, biocides, EC Definition, see Section 2.2), which are applicable in specific sectors. Applying these definitions strictly could lead to a labelling requirement for a NM under one legislation but not under another one. There are efforts to harmonise existing definitions in current legislations (cosmetics, food) with the EC Definition, while recognising that there might always be different needs for sector-specific considerations. In addition, it might be difficult to decide whether a material used in one sector is the same as one used for another purpose in a different sector, because the definitions of terms such as substance, ingredient, or formulation are not necessarily the same across sectors.

Strict application of a broad nanomaterial definition could also lead to a labelling requirement for products that have been produced and used in the same way for many years, and which contain materials that, owing to the EC Definition, have become NMs. This may give the impression of having a new product, or of using new processes and possibly conveying the feeling of facing new risks or benefits. An example is the use of amorphous silicon dioxide that has been used as anti-caking agent (E551) in food for decades. The exemption from adding "nano" to certain food additives already included on the FIC Regulation Union list is currently under discussion.

Moreover, it should be noted that any legal definition of "nano" is a compromise (with some arbitrary measures), which is not based on a unique relationship between particle size and NM properties, such as a specific hazard. Nanolabelling can therefore just convey risk-independent information, a fact that might be difficult to communicate to the layman. Nanolabelling does not contain any information on the presence or absence of a hazard/risk of a product, but it could be (mis)understood as such. The requirement to specifically label ingredients in the nanorange could potentially lead to reformulation of products (e.g. ingredients in powder form in cosmetic products) to avoid the use of such materials.

Concerning thresholds (> x%) for nanolabelling/reporting for the presence or absence of NMs in final products the following scenarios could be considered:

1. Compulsory labelling for nanomaterials if a nanomaterial is added as ingredient, independently of the concentration. In that case, no threshold would be applicable. This would be analogous to ingredient labelling in the Cosmetics Regulation.
2. Introduction of a legal threshold for NM content in a product (based on particle number or mass content per gramme or ml of the final product) below which products would not need to be labelled.

The rationale behind a NM content threshold in the final product would be that it is practically impossible to rigorously exclude the presence of any nanoparticle in a product. Even if products have been manufactured without the deliberate use of nanotechnology, NMs could be present incidentally, for instance through the use of grinding processes, as in flour. Thus, the introduction of a generic nanolabel ("contains nanomaterials") is not favoured as this could lead to labelling virtually all products.

Labelling and registration of products containing nanomaterials can be complementary means to increase the transparency of the use of nanomaterials and may serve towards gaining an overview of potential human and environmental exposure.

Labelling empowers the consumer, but could also lead to information overload. Labelling and registration of products containing nanomaterials could lead to promotion or discrimination of certain products, depending on the mind-set of consumers.

5 Verification of nanospecific information

5.1 Information on the label

Collection and dissemination of information on nanomaterials for purposes such as product labelling or registration in databases is only meaningful,

- if the information is reliable and/or
- if the information can be verified independently (e.g. particle size) and/or
- if as a minimum the level of confidence of the information is known.

Enforcement of labelling requirements for nanomaterial ingredients requires among others standardised and agreed procedures and analytical methods to be used by the producers as well as the regulatory control laboratories, which ensure that labelling or reporting is applied correctly, independent from whether it is mandatory or voluntary.

The present state of technology is still far away from what would be required for direct characterisation and quantification of nanomaterials in complex matrices such as final formulations or products (e.g. food, cosmetic products) (Calzolai et al. 2012; Linsinger et al. 2012). At the moment the only way seems to transmit the information that at some point of the production process a nanomaterial was added or used, regardless of whether or not the nanoparticle is detectable in the end product. Determination of size, size distribution and other relevant properties of nanoparticles could be part of an inspection process during the production, analogously to current inspection systems in the food industry. Figure 14 shows some stages between the production of the nanomaterial and its use in the product. According to the current state of technology verification of the presence of a nanomaterial and its quantification is conceivable at the pure ingredient level, i.e. in the first five stages up to the processing stage at the user. This approach seems at present more feasible than verification of the material in the final product and would in general considerably improve the traceability of nanomaterials as ingredients in products. Clarification and guidance are still required to decide on the relevant steps of the production the information refers to.

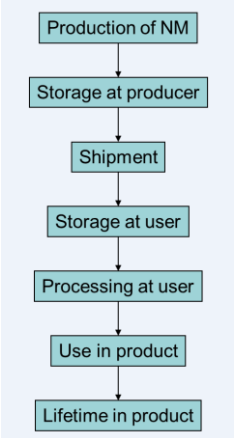


Figure 14: Stages in the use cycle of a nanomaterial for possible verification of material-related information.

The acceptability of this approach for regulators, industry and consumers remains to be discussed, in particular how far information obtained at a specific stage allows extrapolation of the material

properties to a later stage of use. Nanolabelling of a product based on information from an earlier stage of production should however not diminish the confidence in the correctness of the label. Depending on future scientific and technological progress, verification of the information on the label or reporting could also be extended to the final product.

A further complication is that the presence of NMs during the use of a product may either be due to the addition of the ingredient by the manufacturer, or due to formation of NMs in situ during the use of a product (e.g. in spraying), without any addition of NMs to the original product. Depending on the conditions for labelling or registration, such a product may or may not be captured by these measures. The order for the Danish product register for example provides for both, products containing or releasing NMs.

Verification of the provided information strongly depends on the kind and extent of information to be included on the label or in a register/inventory. Labelling will include at minimum the chemical composition of nanomaterials in particulate form. Labelling or registration may be based upon the EC Definition (2011/696/EU) or other definition(s) that include also non-particulate forms of nanomaterials (e.g. nanoporous materials). Therefore appropriate methods to detect, identify and quantify all these forms of nanomaterials are required.

A complete size characterisation including distribution and agglomeration state may not be feasible for technical and/or economic reasons. Instead, it could be limited to the median of a size distribution or another reasonable measurand, such as the fraction of particles which fall into a certain size range (e.g. 1-100 nm). If labelling or reporting of nanomaterials above a certain content threshold is required, the concentration of the nanomaterial in a product has to be determined. This could be either threshold detection - concentration more or less than X – or an exact analysis. This implies deciding on a suitable measurand, as the most frequent measurand "mass" does not always seem to be appropriate for nanomaterials. Often surface and/or particle number are proposed.

Labelling and reporting of nanomaterials and products containing them require the possibility to validate the information given. Verification of the NMs presence, identity and quantity is conceivable at different stages of the production and use.

Information requirements depend on the legal context, e. g. the definition of nanomaterial or on voluntary agreements.

5.2 Confidence level of information

The information collected in an inventory or register of nanomaterials or products containing them needs to be adapted to the purpose of the register. It may contain fundamental information on the NM, such as chemical identity, particulate nature and information on size. Additionally it may contain information on further physico-chemical properties, market data, coverage by specific regulation and/or information on effects related to health, safety and the environment. Custom-tailored information, depending on interest and access rights can be provided by specific filters. The correctness of information included in such a database and independent verification of it are still

major issues. In case of legal obligations (French Decree, Cosmetics Regulation), measures need to be taken to enable independent verification, e. g. by accepting only information that can be confirmed by generally agreed and standardised methods (if such methods exist), or by requiring the registrant to report the used methods and procedures in detail (French Decree) (Ministère de l'Écologie du Développement durable et de l'Énergie 2012a).

Users of a nanomaterial NM inventory, product register or a nanotechnology web platform should be informed about the reliability of the information presented. This could be achieved by developing and maintaining a system of confidence levels, as already suggested by RIVM for the purposes of a register of products containing nanomaterials (Wijnhoven et al. 2011). The EC impact assessment on ' transparency measures' (see Section 4.6) considers the suitability and the possibility to implement such a system (RPA and BiPRO 2014).

The reliability of information in nanomaterial inventories, product registers and web platforms should be communicated to users, possibly using an independent system of confidence levels.

5.3 Detection and quantification of raw nanomaterials

The characterisation of raw nanomaterials is at present a very active field of research and development and methodologies for detection and quantification of nanomaterials at "raw" stage are currently more advanced than for NM in complex media (Ansell and Rauscher 2011). A nanomaterial is considered “raw” if it has not been in contact with media other than those required for its production or storage. This refers to the first four stages of use in Figure 14. The material can still be considered “raw” for part of the fifth stage (processing at user), e.g. if the processing includes some simple refining steps.

Approaches for NM characterisation and quantification need to be further developed for verification of legally required or voluntary transparency measures. Requirements to measurements for the implementation of the EC Definition have been discussed by the JRC report "Requirements on measurements for the implementation of the European Commission definition of the term "nanomaterial"" (Linsinger et al. 2012). This report includes a critical review of currently available methods for the determination of the number-based size distribution of particulate materials, including recommendations for further development to meet the needs for implementation of the EC Definition of nanomaterial. The EC has dedicated considerable funds for practical implementation of that definition, which includes selection and – if necessary - further development of suitable methods and guidance on how to apply them.

These efforts and the current progress of the state of technology render it likely that in the near future a decision can be taken for a large variety of raw materials about their nanomaterial status. However, much more work needs to be done for the harmonisation of test methods and the development of test guidelines.

There are a number of test guidelines which may be used for size characterisation under certain conditions, but it has to be noted that currently these test guidelines are not well established in the

scientific community. Test guidelines are also available for measurement of other parameters, such as solubility or analysis of chemical composition. Currently studies are on-going, e.g. within the OECD on whether and how far existing test guidelines for the characterisation of chemicals in general are applicable to nanomaterials and appropriate revisions, as well as identification of the need for new test guidelines and specific requirements for sample preparation methods for nanomaterials (OECD 2009; OECD 2012).

There are some standards on testing the composition (ISO), size (ISO, ASTM (American Society for Testing and Materials), CEN (European Committee for Standardisation)) and length, if applicable (ISO, ASTM), but these must be revised or modified for nanomaterials. No ISO, CEN, ASTM or CEN standard exists for measuring the concentration of a nanomaterial.

Detection and characterisation of nanomaterials also require benchmark materials, i.e. representative test materials, reference materials or certified reference materials, for the assessment of the applicability of existing methods, their modification, development of new methods, validation of methods, and quality control of routinely used methods (Roebben et al. 2013). This applies to all measurands including especially particle size at the nanoscale. Some reference nanomaterials with a defined particle size are available, but those refer to specific methods of size measurement. The development of reference materials or at least representative test materials for the measurement of size at the nanoscale and other parameters is therefore urgently needed (Roebben et al. 2013).

Detection and quantification of nanomaterials in their raw state (e.g, as produced) is currently an active field of research and development and the technology is about to reach an acceptable level for that purpose. There is a particular need for reference materials, standardisation of methods for nanomaterial characterisation and for test guidelines.

5.4 Nanomaterials in complex matrices

Nanomaterials which are part of a product (cosmetics, food, etc.) are in "contact" with a vast variety of substances. For example, cosmetics and food products can be complex compositions of different components and particles with a similar or different chemical composition as the NM. In addition, the NM may interact with the other ingredients of a certain product, and may change properties (e.g. agglomeration state, macromolecule corona, surface charge). It therefore becomes a challenging task to separate and to analyse the nanomaterial in certain products (Calzolai et al. 2012; von der Kammer et al. 2012). Moreover, food has a natural or unintentionally formed content of several nanosized components (e.g. proteins, micelles) that may need to be distinguished from the intentionally added (engineered) nanomaterials.

The characterisation of nanomaterials in complex media and especially the quantification (e.g. the nanoparticle concentration by number, mass or volume) therefore pose much greater problems than characterising the pristine or raw nanomaterial.

Systematic approaches and reliable methods for the detection and characterisation of nanoparticles in complex matrices, such as biological environments, soil or food, as well as final formulations and/or consumer products, are currently in the development or proto-type stage and cannot yet routinely be applied. Hence, in case it would be required to characterise and quantify a NM in a final or intermediate product the versatility of potentially suitable methods needs to be identified and their further development promoted.

At present, only in exceptional cases it is possible to specifically detect and quantify NMs in matrices, as shown in Figure 15 (example from the EU FP7 project SMART-NANO). In such cases a number of analytical techniques are often used in combination (Blasco and Picó 2011; Calzolai et al. 2012). Such combinative or stepwise approaches, sometimes called "hyphenated techniques", appear currently most promising. The methodologies used generally require some preparation of the test item which can include dilution of the analyte or one or more separation steps to extract the nanomaterial to be analysed from a complex formulation.

There have been first efforts to develop new methods that aim at detecting nanoparticles in (diluted) complex matrices (e.g. environmental, biological or food samples) without previous separation (Farkas et al. 2011; Gallego-Urrea et al. 2011). However, at present, such methods are far from being routine or even accepted by the scientific or regulatory communities.

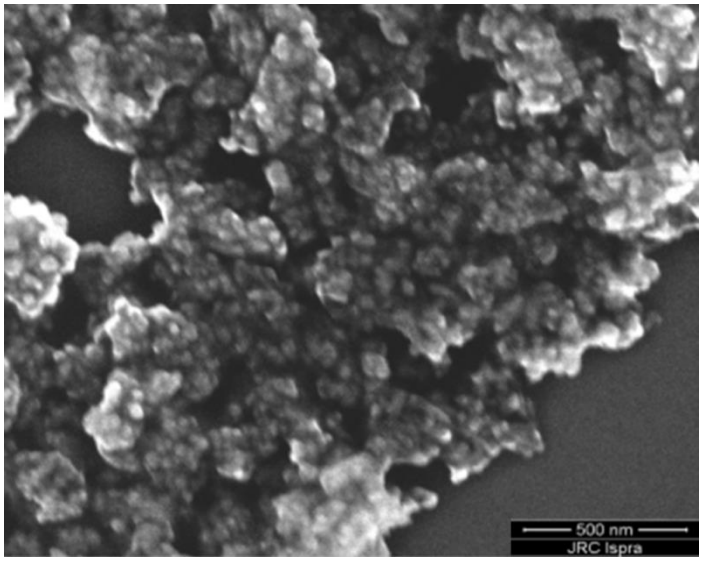


Figure 15: Electron Microscope image of TiO_2-NP in a commercial sunscreen lotion.

Depending on the product that is subject to nanolabelling, the technical demands may be significant, but still less complex compared to a complete characterisation, which may primarily be needed in a study aimed at safety assessment. The EU Regulation on Cosmetic Products requires that characterisation follows methods which are in accordance with the relevant harmonized standards, the references of which have been published in the Official Journal of the European Union. As a second example, according to the definition used by the International Collaboration on Cosmetics Regulation (ICCR) (Ansell et al. 2010), the properties insolubility, size in the final formula and stability and persistence in biological media are criteria for nanomaterials. Interestingly, the latter definition refers to size in the final formulation (the product), which usually is a complex mixture (e.g. body

lotion). These examples show that the requirements for characterisation can vary considerably, depending on the definition that nanolabelling is based upon.

Currently there are a number of challenges to achieve a reliable and reproducible characterisation of nanomaterials in complex matrices, which can be summarised as follows:

- Sample(s) have to be representative for the entire formulation;
- Standard operating procedures (SOPs) for sample preparation and measurement need to be developed to provide for reproducibility of test items preparation and test results;
- The separation and/or extraction process itself can change the nanomaterial and may lead to analytical artefacts (aggregation, de-aggregation, …);
- Depending on the applicable definition of nanomaterial in a specific regulatory context, it may be required to distinguish between natural and engineered nanoparticles;
- There is a need for reference or representative test materials;
- There is a lack of validated methods for the analysis of nanomaterials in complex matrices.

Presently methods to detect and characterise nanomaterials in an arbitrary complex matrix such as food or cosmetic products are under development. There are several challenges that need to be overcome towards the establishment of such methods for reliable and reproducible routine characterisation of nanomaterials in complex matrices.

6 Conclusions

The EU legislative framework regulating the safety of substances and products and the communication of information, including possible hazards apply to nanomaterials even if these are not specifically mentioned. Some recent legislative acts address NMs specifically (cosmetic products, biocidal products and part of the food legislation) and additional ones are in preparation. Due to an increased interest in NMs and their potential risks, several parties have requested more transparency and traceability regarding the use of NMs in consumer products.

Transparency and traceability of NMs on the market can in principle be provided by two different means, by labelling of products containing NMs and by collecting information in a product register or inventory. While nanolabelling provides information to the consumer at the time of purchase, product registers can give a better overview of the overall production and use of NMs, on trends and on potential exposure of humans and the environment. Both measures complement each other and should generally be understood as independent from risk.

Some current legislative acts foresee a labelling for the content of NMs, via the mandatory ingredients list, by adding, "nano" in brackets after the substance name of the nano-ingredients in cosmetic products, biocides and food. The labelling of other kinds of products, for example household products, textiles or consumer products in general is suggested by some stakeholders. A labelling of products without an ingredients list would most likely be conducted via an isolated NANO label. A generic label or claim displayed on a product signalling the presence or absence of NMs without any other specific information (e.g. the substance name) can potentially lead to misuse and/or confusion, e.g. giving the impression of the presence or absence of a specific NM-related risk. For a proper use of the provided information, and to avoid misuse, it is important that labelling takes into consideration the perceived level of knowledge and understanding of those meant to read the label.

Any kind of information requirement and transparency measure (labelling/product register) should be based on a (internationally) harmonised definition of nanomaterial for legal clarity and enforceability. It also needs to be verifiable, however, based on the current technical capabilities, this is still challenging – especially on an affordable routine basis.

Reporting should also take into consideration the uncertainties related to the origin (natural or engineered/manufactured) of the NM, the intention of adding them and whether they are used in final or semi-finished products. It should be considered whether the NMs are still present in the original nanoform, since they may change shape and properties due to aggregation/agglomeration, ageing, reaction with other molecules or embedding in complex matrices or they are formed *in situ* during the use of a product (e.g. in spraying). All these facts render an accurate nanolabelling and (affordable) monitoring complicated. Therefore further developments and standardisation in nanomaterials detection and characterisation methods are needed and reference materials for reliable metrology at the nanoscale are necessary.

Any decision on nanolabelling or reporting in a product register should comply with the general principles of decision management, i.e. proportionality, subsidiarity (for EU-level legislation), non-discrimination, consistency, examination of the benefits and costs of action and inaction, and examination of the evolving scientific evidence (Öko-Institut 2010).

National regulations of traceability measures may lead to different information requirements and could create cross-border trade barriers by influencing free market interplay at various levels (manufacturers, distributors/importers and downstream users) between the EU Member States.

Several EU Member States agree that a (centralised) EU-registration of NMs is preferred over a series of varying national databases for improving a harmonised European policy on NMs. National product registers would result in overlaps with various EU legislation and in varying obligations and regulations between EU Member States. This could increase the costs for stakeholders obliged to notify and for authorities.

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7 References

Ansell, J., Bronaugh, R., Carter, L. K., Chaudhry, Q., Lafranconi, M., Nishimura, T., Schellauf, F., Swei, H. and Tooley, I. (2010). Report of the ICCR Joint Ad Hoc Working Group on Nanotechnology in Cosmetic Products: Criteria and Methods of Detection. Toronto, International Cooperation on Cosmetics Regulation (ICCR-4), from http://www.fda.gov/downloads/InternationalPrograms/HarmonizationInitiatives/UCM235485.pdf.

Ansell, J. and Rauscher, H. (2011). Report of the Joint Regulator - Industry Ad Hoc Working Group: Currently Available Methods for Characterization of Nanomaterials. Paris, International Cooperation on Cosmetics Regulation (ICCR-5), from http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/iccr5_char_nano_en.pdf.

Bieberstein, A., Roosen, J., Marette, S., Blanchemanche, S. and Vandermoere, F. (2013). "Consumer choices for nano-food and nano-packaging in France and Germany." *European Review of Agricultural Economics* **40**(1): 73-94.

BiPRO and Öko-Institut (2013). Study of the scope of a Belgian national register for nanomaterials and products containing nanomaterials. Munich, Federal Public Service health, Food Chain Safety and Environment, Brussels, from www.health.belgium.be/.../BE%20Nano%20Register%20Report_final.pdf.

Blasco, C. and Picó, Y. (2011). "Determining nanomaterials in food." *TrAC - Trends in Analytical Chemistry* **30**(1): 84-99.

Calzolai, L., Gilliland, D. and Rossi, F. (2012). "Measuring nanoparticles size distribution in food and consumer products: a review." *Food Addit Contam Part A Chem Anal Control Expo Risk Assess* **29**(8): 1183-1193.

Caswell, J. A. (1998). "How Labeling of Safety and Process Attributes Affects Markets for Food." *Agricultural and Resource Economics Review* **27**(2): 8.

CIE (2011). Feasibility of Implementing a Mandatory Nanotechnology Product Registry. Canberra, Sydney, Centre for International Economics.

DEFRA (2008). UK Voluntary Reporting Scheme for engineered nanoscale materials. London, Department for Environment Food and Rural Affairs, from http://archive.defra.gov.uk/environment/quality/nanotech/documents/vrs-nanoscale.pdf.

ECHA (2011, December 2011). "Guidance on the compilation of safety data sheets." from http://echa.europa.eu/documents/10162/13643/sds_en.pdf.

ECHA (2012). "Updated Guidance on Information Requirements and Chemical Safety Assessment for Nanomaterials." from http://echa.europa.eu/en/view-article/-/journal_content/3df5b7b9-a36d-4e74-811b-3aeee23366f8.

EEB and BEUC (2011). Ecolabel board meeting in February 2011 - EEB and BEUC position on all purpose cleaners and hand dishwashing detergents. Brussels, EEB, European Environmental Bureau; BEUC, the European Consumers' Organisation, from http://www.eeb.org/?LinkServID=E1CB8662-DC17-D929-D735094F2D4440BE&showMeta=0.

EFSA Panel on Food Additives and Nutrient Sources added to Food (2011). "Scientific Opinion on re-evaluation of calcium carbonate (E 170) as a food additive." *EFSA Journal 2011* **9**(7): 2318.

EU-OSHA (2009). Workplace exposure to nanoparticles. Luxembourg, EU-OSHA - European Agency for Safety and Health at Work, from.

European Commission (2001). "Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety." *Publications Office of the European Union* **L11**(4): 4-17.

European Commission (2008). Nanomaterials in REACH. Follow-up to the 6th Meeting of the REACH Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH). Brussels 2008, European Commission**:** 21.

European Commission (2009a). "Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food." *Official Journal of the European Union* **L135**: 3-11.

European Commission (2009b). Classification. labelling and packaging of nanomaterials in REACH and CLP. Brussels, European Commission, from http://ec.europa.eu/environment/chemicals/reach/pdf/classif_nano.pdf.

European Commission (2010). Mandate addressed to CEN, CENELEC and ETSI for standardization activities regarding nanotechnologies and nanomaterials. Brussels.

European Commission (2011a). Commission Recommendation of 18 October 2011 on the definition of nanomaterial. Official Journal of the European Union. **2011/696/EU:** 38-40.

European Commission (2011b). "Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food." *Official Journal of the European Union* **L12**(1): 1-89.

European Commission (2012a). Commission Staff working paper: Types and uses of nanomaterials, including safety aspects accompanying the Commission Communication on the Second Regulatory Review on Nanomaterials.

European Commission (2012b). Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Second Regulatory Review on Nanomaterials. E. Commission.

European Commission (2012c). Commission staff working document on knowledge enhancing aspects of consumer empowerment 2012-2014. Brussels.

European Commission (2013a). Proposal for a Regulation of the European Parliament and of the Council on novel foods. COM(2013) 894 final.

European Commission (2013b). Additional measures to increase transparency and ensure regulatory oversight on nanomaterials; 13th Meeting of Competent Authorities for REACH and CLP; 26 – 28 November 2013. Bruxelles.

European Commission (DG SANCO) (2013). Assessment of nanomaterials in food, health and consumer products. Workshop on the Second Regulatory Review on Nanomaterials. D. H. a. Consumers. Brussels.

European Parliament and Council (2006a). "Regulation (EC) 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC." *Official Journal of the European Union* **L396/1**: 1-849.

European Parliament and Council (2008a). "Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and

1999/45/EC, and amending Regulation (EC) No 1907/2006." *Official Journal of the European Union* **L 353**: 1-1355.

European Parliament (2009a). Report on regulatory aspects of nanomaterials (2008/2208(INI)) Motion for a European Parliament Resolution. A6-0255/2009**:** 1-21.

European Parliament (2009b). European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials. Brussels and Strassbourg.

European Parliament and Council (2009a). "Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products." *Official Journal of the European Union* **L342**: 59-209.

European Parliament (2010). Report on the proposal for a directive of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) (COM(2008)0809 – C6-0471/2008 – 2008/0240(COD)) http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A7-2010-0196+0+DOC+PDF+V0//EN.

European Parliament and Council (2011a). Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004. Official Journal of the European Union. **L 304:** 18-63.

European Parliament and Council (2012a). "Proposal for a Regulation of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009." **COM(2012) 542 final**.

European Parliament (2013). "Letter to the Vice-President of the European Commission Mr Antonio Tajani, Commissioner Janez Ptotcnik, Tonio Borg, Neven Mimica and Maire Geoghegan-Quinn." **312467**(IPOL-COM-ENVI D(2013) 36547): 1-4.

European Parliament and Council (1997). Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. Official Journal of the European Communities. E. Union. **L43:** 1-6.

European Parliament and Council (2002a). Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements. Official Journal of the European Union. **L 183:** 7.

European Parliament and Council (2002b). Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Official Journal of the European Union. E. Union, Publications Office of the European Union. **L 31:** 1-24.

European Parliament and Council (2003). Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Official Journal of the European Union. **L268:** 23.

European Parliament and Council (2006b). "Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising." *Official Journal of the European Union* **L376**: 7.

European Parliament and Council (2008b). "Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings." *Official Journal of the European Union* **354**: 16-33.

European Parliament and Council (2009b). Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. Official Journal of the European Union. Luxembourg, Publications Office of the European Union. **L 309:** 1-50.

European Parliament and Council (2010). "Regulation (EC) No 66/2010of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel." *Official Journal of the European Union* **L27**: 1-19.

European Parliament and Council (2011b). "Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment." *Official Journal of the European Union* **L 174**(88): 1-23.

European Parliament and Council (2011c). "Regulation (EU) No 1007/2011 of the European Parliament and of the Council of 27 September 2011 on textile fibre names and related labelling and marking of the fibre composition of textile products and repealing Council Directive 73/44/EEC and Directives 96/73/EC and 2008/121/EC of the European Parliament and of the Council." *Official Journal of the European Union* **L272**: 1-64.

European Parliament and Council (2012b). "Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE)." *Official Journal of the European Union* **L197**: 38-71.

European Parliament and Council (2012c). "Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products." *Official Journal of the European Union* **L 167**: 1-123.

Farkas, J., Peter, H., Christian, P., Gallego Urrea, J. A., Hassellöv, M., Tuoriniemi, J., Gustafsson, S., Olsson, E., Hylland, K. and Thomas, K. V. (2011). "Characterization of the effluent from a nanosilver producing washing machine." *Environment International* **37**(6): 1057-1062.

Federal Institute for Risk Assessment (2008). Public Perceptions about Nanotechnology; Representative survey and basic morphological-psychological study. 14195 Berlin, Federal Institute for Risk Assessment, from http://www.bfr.bund.de/cm/350/public_perceptions_about_nanotechnology.pdf.

Federal Institute for Risk Assessment (2010). Risk Perception of Nanotechnology – Analysis of Media Coverage. 14195 Berlin, Federal Institute for Risk Assessment, from http://www.bfr.bund.de/cm/350/risk_perception_of_nanotechnology_analysis_of_media_coverage.pdf.

Gallego-Urrea, J. A., Tuoriniemi, J. and Hassellöv, M. (2011). "Applications of particle-tracking analysis to the determination of size distributions and concentrations of nanoparticles in environmental, biological and food samples." *TrAC Trends in Analytical Chemistry* **30**(3): 473-483.

Hansen, S. F., Jensen, K. A. and Baun, A. (2014). "NanoRiskCat – A Conceptual Tool for Categorization and Communication of Exposure Potentials and Hazards of Nanomaterials in Consumer Products. ." *Journal of Nanoparticle Research.* **16**(2195): 1-25.

ISO (2013). ISO/TS 13830:2013: Nanotechnologies - Guidance on voluntary labelling for consumer products containing manufactured nano-objects. Geneva**:** 1-6.

JRC-EASAC (2011). Impact of Engineered Nanomaterials on Health: Considerations for Benefit-Risk Assessment. Brussels, European Commission Joint Research Centre; European Academies Science Advisory Council, from.

JRC (2013). "The JRC Web Platform on Nanomaterials ", from http://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials.

Linsinger, T. P. J., Roebben, G., Gilliland, D., Calzolai, L., Rossi, F., Gibson, N. and Klein, C. (2012). Requirements on measurements for the implementation of the European Commission definition of the term "nanomaterial". Luxembourg, European Commission Joint Research Centre, from http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/26399/2/irmm_nanomaterials%20%28online%29.pdf.

Lövestam, G., Rauscher, H., Roebben, G., Sokull-Klüttgen, B., Gibson, N., Putaud, J.-P. and Stamm, H. (2010). Considerations on a definition of nanomaterial for regulatory purposes. Luxemburg, European Commission Joint Research Centre, from http://ec.europa.eu/dgs/jrc/downloads/jrc_reference_report_201007_nanomaterials.pdf.

Milieu Ltd and RPA Ltd (2010). Proposal for an EU Reporting System for Nanomaterials. Brussels, London, Milieu Ltd. (Belgium), RPA Ltd. (United Kingdom), from http://www.nanomaterialsconf.eu/further-information.html.

Miljoministeriet and Miljostyrelsen (2013). Draft Order on a register of mixtures and articles that contain nanomaterials as well as the requirement for producers and importers to report to the register (submitted to European Commission - DG Enterprise and Industry). 2013/603/DK

Ministère de l'Écologie du Développement durable et de l'Énergie (2012a). "Arrêté du 6 août 2012 relatif au contenu et aux conditions de présentation de la déclaration annuelle des substances à l'état nanoparticulaire, pris en application des articles R. 523-12 et R. 523-13 du code de l'environnement." *Journal Officiel de la République Française* **Texte 18 sur 112**.

Ministère de l'Écologie du Développement durable et de l'Énergie (2012b). Code de l'environnement. Legifrance.gouv.fr.

Ministère de l'Écologie du Développement durable et de l'Énergie (2012c). Décret n° 2012-232 du 17 février 2012 relatif à la déclaration annuelle des substances à l'état nanoparticulaire pris en application de l'article L. 523-4 du code de l'environnement JORF n°0043 - texte n° 4 Legifrance.

Ministère de l'Écologie du Développement durable et de l'Énergie (2013). Éléments issus des déclarations des substances à l'état nanoparticulairehttp://www.developpement-durable.gouv.fr/IMG/pdf/Rapport_public_format_final_20131125.pdf.

Ministry of Infrastructur and Environment of the Netherlands (2013). Pragmatic steps towards a more effective EU nano policy. Building Blocks for Completing EU Regulation of Nanomaterials (Conference). Den Haag, Ministerie van Infrastructuur en Milieu.

Ministry of Infrastructure and the Environment of the Netherlands (2012). Note on the safety of nanomaterials. Den Haag, Ministry of Infrastructure and the Environment of the Netherlands. **IENM/BSK-2012/126104**.

Nel, A., Malloy, T., Avery, D., Nasser, E. and Beryt, E. (2013). "Implications of the French Registry for Engineered Nanomaterials." *ACS Nano* **7**(6): 4694-4696.

ÖAW-ITA (2010a). "Nano-Textiles." Nanotrust dossier 15 (en), from http://epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier015en.pdf.

ÖAW-ITA (2010b, December 2010). "Vountary approaches by industry in the field of nanomaterials." Nanotrust dossier, 16, from http://epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier016en.pdf.

OECD (2009). Preliminary Review of OECD Test Guidelines for their Applicability to Manufactured Nanomaterials. Paris http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2009)21&doclanguage=en.

OECD (2012). Guidance on sample preparation and dosimetry for the safety testing of manufactured nanomaterials http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono(2012)40&doclanguage=en.

Öko-Institut (2010). Legal feasibility study on the introduction of a nanoproduct register. Freiburg, Institute for Applied Ecology, from http://www.bmu.de/files/pdfs/allgemein/application/pdf/bericht_nanoproduktregister_en_bf.pdf.

Oomen, A. G., Bennink, M., van Engelen, J. G. M. and Sips, A. J. A. M. (2011). Nanomaterials in consumer products - Detection characterization and interpretation. Bilthoven, National Institute for Public Health and the Environment, from http://www.rivm.nl/bibliotheek/rapporten/320029001.pdf.

Roebben, G., Rasmussen, K., Kestens, V., Linsinger, T. P. J., Rauscher, H., Emons, H. and Stamm, H. (2013). "Reference materials and representative test materials: the nanotechnology case." *Journal of Nanoparticle Research* **15**: 1455 -1468.

RPA and BiPRO (2014). Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market - Inception Report prepared for DG Enterprise and Industry. Loddon.

RSC (2011). "Eco-credentials of nanomaterials in question." Chemistry World, from http://www.rsc.org/chemistryworld/News/2011/February/15021102.asp.

SCENIHR (2009). Risk assessment of products of nanotechnologies. Brussels, Scientific Committee on Emerging and Newly Identified Health Risks, from http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf.

Schlag, S., Suresh, B., Yoneyama, M. and Yang, V. (2010). Nanoscale chemicals and materials, SRI Consulting, from http://www.ihs.com/products/chemical/planning/scup/nanoscale-chemicals.aspx.

Stone, V., Hankin, S., Aitken, R., Aschberger, K., Baun, A., Christensen, F., Fernandes, T., Hansen, S., Hartmann, N., Hutchison, G., Johnston, H., Peters, S., Micheletti, C., Ross, B., Sokull-Kluettgen, B., Stark, D. and Tran, C. (2010). Engineered Nanoparticles: Review of Health and Environmental Safety (ENRHES), European Commission, from http://ihcp.jrc.ec.europa.eu/whats-new/enhres-final-report.

Throne-Holst, H. and Rip, A. (2011). "Complexities of labelling of nanoproducts on the consumer markets." *European Journal of Law and Technology* **2**(3): 12.

Trio.be (2010, 14.09.2010). "Workshop “Towards a regulatory framework for the traceability of nanomaterials”." from http://www.health.belgium.be/eportal/Aboutus/eutrio/environment/Nanomaterials/index.htm?fodnlang=en.

Umweltbundesamt (2014). Concept for a European Register of Products Containing Nanomaterials. Berlin

http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/information_concept_nanoregister_npr_e_0.pdf.

VCI (2011). VCI position on how to create more transparency on "nano products" on the market by meqans of databases, German Chemical Industry Association**:** 1-2.

von der Kammer, F., Ferguson, P. L., Holden, P. A., Masion, A., Rogers, K. R., Klaine, S. J., Koelmans, A. A., Horne, N. and Unrine, J. M. (2012). "Analysis of engineered nanomaterials in complex matrices (environment and biota): General considerations and conceptual case studies." *Environmental Toxicology and Chemistry* **31**(1): 32-49.

Wijnhoven, S. W. P., Oomen, A. G., A.J.A.M., S., Bourgeois, F. C., G.J., t. D., M.W., K. and M.I., B. (2011). Development of an inventory for consumer products containing nanomaterials.

Wijnhoven, S. W. P., Kooi, M., vanEngelen, J. G. M. and Oomen, A. G. (2012). How do producers justify the use of nano claims on consumer products; Presence and rationale of nanoclaims on consumer products, RIVM Report, from http://ec.europa.eu/consumers/safety/docs/110912_Nano-Rreport_Laymans-summary.pdf.

8 Abbreviations and Glossary

8.1 List of Abbreviations

ANEC	European Association for the Co-ordination of Consumer Representation in Standardisation (European consumer voice in standardisation)
ASTM	American Society for Testing and Materials
BEUC	Bureau Européen des Unions de Consommateurs (The European Consumers' Organisation)
BPR	Biocidal Products Regulation (Regulation (EU) No 528/2012)
CLP	Classification, Labelling and Packaging ((EU Regulation 1272/2008))
CPNP	Cosmetic Products Notification Portal
CSR	Chemical Safety Report
DG SANCO	Directorate-General for Health and Consumers
EASAC	European Academies Science Advisory Council
EC	European Commission
ECHA	European Chemicals Agency
EEB	European Environmental Bureau
EEE	Electrical and electronic equipment
EFSA	European Food Safety Authority
ENM(s)	Engineered Nanomaterials
EP	European Parliament
EU-OSHA	European Agency for Safety and Health at Work
FCM	Food Contact Material
GHS	Globally Harmonised System for Classification and Labelling
GM	Genetically Modified
GMO	Genetically Modified Organism
gpa	Grammes per year

GPSD	General Products Safety Directive
ICCR	International Cooperation on Cosmetic Regulation
ISO	International Organization for Standardization
JRC	Joint Research Centre
NGO	Non-governmental organisation
NM(s)	Nanomaterial(s)
ÖAW	Österreichische Akademie der Wissenschaften (Austrian Academy of Science)
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent, Bioaccumulative and Toxic
PEN	Project on Emerging Nanotechnologies
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)
RIVM	Rijksinstituut voor Volksgezondheid en Milieu (Dutch National Institute for Public Health and the Environment)
RoHS	Restriction of Hazardous Substances
SCCS	Scientific Committee on Consumer Safety
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SDS	Safety Data Sheet
SOP	Standard operating procedure
SVHC	Substance of very high concern
SWP	Staff Working Paper
tpa	Tonnes per year
UV	Ultra Violet
VCI	Verband der Chemischen Industrie (German Chemical Industry Association)
vPvB	Very Persistent and very Bioaccumulative
WEEE	Waste electrical and electronic equipment (Directive 2002/96/EC)

WPMN Working Party on Manufactured Nanomaterials (OECD)

8.2 Glossary

Note: this list explains words which are sometimes used in order to coin more concise terms instead of using more precise, but longish expressions. The use of these terms is not recommended in official EU texts, but they can often be found in less informal texts.

Nanoclaim	Claim that a product contains nanomaterials
Nano-database	Database which contains information on nanomaterials and/or nanoproducts
Nano-free	Claim, that a product does not contain any ENM
Nanoinventory	Record of nanomaterials and their uses in products
Nanolabelling	Labelling of a product for its content of nanomaterials
Nanoproduct	A product containing at least one material in the nanoscale
Nanorange, nanoscale	Size range between 1 – 100 nm (as recommended in current EU definitions)
Nanoregister	Register of products which contain nanomaterials

9 List of Figures

10 Annexes

10.1 Annex I - Definitions for "Nanomaterial" in EU legislation

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products

"nanomaterial" means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm;

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers

"engineered nanomaterial" means any intentionally produced material that has one or more dimensions of the order of 100 nm or less or that is composed of discrete functional parts, either internally or at the surface, many of which have one or more dimensions of the order of 100 nm or less, including structures, agglomerates or aggregates, which may have a size above the order of 100 nm but retain properties that are characteristic of the nanoscale.

Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU)

"Nanomaterial" means 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 %.

By derogation […], fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

[…], "particle", "agglomerate" and "aggregate" are defined as follows:

"particle" means a minute piece of matter with defined physical boundaries;

"agglomerate" means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;

"aggregate" means a particle comprising of strongly bound or fused particles.

Where technically feasible and requested in specific legislation, compliance with the definition […]- may be determined on the basis of the specific surface area by volume. A material should be considered as falling under the definition […] where the specific surface area by volume of the material is greater than 60 m^2 /cm^3. However, a material which, based on its number size distribution, is a nanomaterial should be considered as complying with the definition […] even if the material has a specific surface area lower than 60 m^2 /cm^3.

The EC Definition includes a revision clause which allows taking into account new scientific and technical insights by the time the definition is reviewed in 2014.

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products

"nanomaterial" means a natural or manufactured active substance or non-active substance 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 1-100 nm.

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials.

For the purposes of the definition of nanomaterial, "particle", "agglomerate" and "aggregate" are defined as follows:

- "particle" means a minute piece of matter with defined physical boundaries,

- "agglomerate" means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components,

- "aggregate" means a particle comprising strongly bound or fused particles;

Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm shall be considered as nanomaterials.

10.2 Annex II - European Union legislation

Overview of European Union legislation with regard to specific reporting or labelling requirements for nanomaterials.

Subject/ application	Regulatory framework	Are NMs specifically addressed	Remarks
Chemical substances	REACH Regulation 1907/2006	No[3]	• Nanomaterials are covered by the substance definition • Registration ≥ 1 tpa • CSR: ≥ 10 tpa • Information of safe use for SVHC > 0.1 % in articles[4] • SDS for hazardous substances (CLP), PBT, vPVB or substances on candidate list[5] (Art. 59(1))
Substances and mixtures	Classification, Labelling and Packaging Regulation 1272/2008	No	• Classification/Labelling for hazardous properties • Different forms of a substance (nanoform) can have different classification when relevant • General and specific concentration limits for hazard labelling • No tonnage threshold • CLP inventory of notified and registered substances
Cosmetics	Cosmetic Products Regulation 1223/2009	Yes	• Definition of NM • Pre-market notification of NM in cosmetic products • Cosmetic products register for NM • non-public inventory of nanomaterials • Labelling of NM in ingredients list (since July 2013)
Food	General Food Law: Regulation 178/2002	No	
	Food additives 1333/2008	Yes	• Nanotechnology as significantly different production method requiring separate evaluation
	Novel Food Regulation 258/97 Draft regulation (COM/2013/0435)	No, but proposal for revision addresses NM	• Use of nanotechnology = Novel Food/additive • Separate evaluation of NM • Definition: as in Reg. 1169/2011

[3] Nanomaterials are not specifically addressed but considered to be covered implicitly; European Commission (2008). Nanomaterials in REACH. http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf

[4] Article 3(3) of REACH defines an *article* as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition".

[5] This list includes candidate substances for inclusion in REACH Annex XIV (List of substances subject to authorisation).

Subject/ application	Regulatory framework	Are NMs specifically addressed	Remarks
	Plastic Food Contact Materials Regulation 1183/2012	Yes	• Positive list for authorised nanomaterials, Annex I • Risk assessment: authorisations based on risk assessment of conventional substance do not cover nanomaterials
	Active and Intelligent Materials and Articles Regulation 450/2009	Yes	• Risk of nanoparticles, should be assessed on a case-by-case basis • Nanoparticles are not covered by the functional barrier concept
	Food Information for Consumers Regulation 1169/2011	Yes	• Definition of NM • Labelling of NM in ingredients list (from December 2014)
Biocides	Biocidal Products Regulation 528/2012	Yes	• Definition of NM (corresponds to EC Recommendation) • Separate assessment and authorisation of NM • 5 yearly reporting on implementation (reference to NM) • Labelling of NM in biocidal products and treated articles (from September 2013) in ingredients list
Medical Devices	EC Proposal for a Regulation on medical devices COM(2012) 542 final	Yes	• Definition of NM (corresponds to EC Recommendation) • Labelling if the device contains or consists of nanomaterials • Devices incorporating or consisting of nanomaterial are in the highest risk class
Consumer products (not covered by sector directives with specific provisions)	General Products Safety Directive 2001/95/EC	No	• Ensure high level of products safety • Information on safe use
Waste of electrical and electronic equipment	Directive 2012/19/EU	No	• No specific provisions for NM
Restriction of Hazardous Substances	Directive 2011/65/EU	No	• No specific provisions for nanomaterials
European Ecolabel	Regulation 66/2010	Yes	• Ecolabel does not exclude the use of nanomaterials in general • Exclusion depends on classification as hazardous (with exemptions)

CSR: Chemical safety report
SVHC: substance of very high concern
SDS: safety data sheet
PBT: persistent, bioaccumulative and toxic
vPvB: very persistent and very bioaccumulative

10.3 Annex III – Examples of available databases and inventories on nanomaterials (non-exhaustive)

The Nanodatabase is a Danish resource. The Nanodatabase includes products which either contain NMs or are claimed to be a nano product. All products are readily available to Danish consumers either in stores or via Internet shops. In the product inventory, each product has been assigned a short title describing the use of the nanomaterial and a colour code consisting of five dots. The first three dots always refer to potential for exposure to professional end-users, consumers and the environment in that sequence and the last two colours always refer to the hazard potential for humans and the environment. The colours signify whether the indications of exposures or effects separately are high (red), medium (yellow), low (green), or unknown (grey) (Hansen *et al.* 2014). The Nanodatabase is accessible here: http://nanodb.dk/.

The industry-driven **DaNa** project (acquisition, evaluation and public-oriented presentation of society-relevant data and findings relating to NMs), led by Dechema e.V., Germany, is an umbrella project aiming at collecting and evaluating scientific results in an interdisciplinary approach with scientists from different research areas, such as human and environmental toxicology, biology, physics, chemistry, and sociology. It includes a knowledge database (http://nanopartikel.info/cms/lang/en/Wissensbasis) that contains information about products and applications of NMs.

The U.S. **Woodrow Wilson** database as part of the US Project on Emerging Nanotechnologies Products (PEN) was the first publicly available on-line inventory of nanotechnology-based consumer products. Consumer products to be included in the database are selected by systematic web-based searches. They are included when they are identified as "nano-based" by the manufacturer or by another source, the nano-based claims for the product appear reasonable and they can be readily purchased by consumers. Nanoclaims of the products are however not verified. Since the start of the project in 2005, the inventory has been updated six times. Currently the inventory includes 1628 consumer products from 30 different countries, with the biggest category being Health and Fitness with a total of 788 products, (as of October 2013). The web link to the database is: www.nanotechproject.org/inventories/consumer.

The **RTI Nanomaterial Registry** (https://www.nanomaterialregistry.org) is a US project funded by the National Institute of Biomedical Imaging and Bioengineering (NIBIB), the National Institute of Environmental Health Sciences (NIEHS) and the National Cancer Institute (NCI). Its purpose is to build a repository of NM information by compiling data from a broad collection of publicly available NM resources, into a single database. It is the first effort of a quality-checked resource for the NM community, which provides a publically available web-based tool containing NM data (physico-chemical characteristics, biological and environmental interactions) fulfilling minimal, common information standards based on parameters built with broad community acceptance that can also be used in regulatory decision-making.

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Abstract

The number and amount of consumer products and applications using nanotechnology on the market are rapidly increasing, and stakeholders have requested more transparency and traceability concerning the use of nanomaterials in consumer products on the market. This report provides an overview how EU legislation addresses nanomaterials, and recapitulates issues relevant for the on-going discussion on transparency and requests for more information regarding the use of nanomaterials in consumer products. It reviews content related labelling of products containing nanomaterials and the establishment of registers for such products and contributes to the debate on the need for such measures and their possible impact. Furthermore, the report gives an overview of the state of the art of verification methods currently available to detect and quantify nanomaterials, also when they are embedded in matrices. The addressees of the report include policy makers, EU Member State authorities, industry, NGOs, research institutes and consumers.

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