National Institute for Public Health
and the Environment
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Exploring Building Blocks for Amending EU Regulation of Nanomaterials

RIVM report 601353003/2013

E.A.J. Bleeker | D. Theodori | S.W.P. Wijnhoven

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Colophon

Eric A.J. Bleeker,
Demi Theodori,
Susan W.P. Wijnhoven

Contact:
Eric A.J. Bleeker
Centre for Safety of Substances and Products (VSP)
eric.bleeker@rivm.nl

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Rapport in het kort

Verkenning van bouwstenen voor EU-wetgeving van nanomaterialen

De Nederlandse interdepartementale werkgroep voor risico's van nanotechnologie (IWR) heeft in 2013 zes bouwstenen geformuleerd om wettelijke kaders geschikt(er) te maken voor de beoordeling van risico's van nanomaterialen. Daarnaast zijn de bouwstenen erop gericht de aanwezigheid van nanomaterialen in producten bekend te maken. Het RIVM heeft onderzocht of deze bouwstenen effectief zijn en heeft de invulling ervan vorm gegeven. De zes bouwstenen zijn: (1) eenduidige definitie van nanomaterialen, (2) specifieke informatievereisten voor REACH over een stof in nanovorm, (3) verlaging van het productievolume vanaf wanneer een stof in nanovorm in REACH moet worden geregistreerd of bepaalde informatie moet worden aangeleverd, (4) aparte blootstelling- en risicobeoordeling voor werknemers die werken met nanomaterialen, en (5) registratie en/of (6) etikettering van producten die nanomaterialen bevatten. De eerste drie relateren sterk aan de Europese verordening voor chemische stoffen REACH; de overige drie relateren aan andere wettelijke kaders.

Een eenduidige **definitie** moet zich uitsluitend richten op identificatie van nanomaterialen: aangeven wanneer sprake is van een nanovorm en niet (meer) van een 'gebruikelijke' niet-nanovorm van de stof. De recent voorgestelde definitie van de Europese Commissie lijkt hiervoor zeer geschikt. De risicobeoordeling van nanomaterialen en (extra) informatie die daarvoor nodig is, volgt pas daarna in het desbetreffende beoordelingskader.

De risicobeoordeling voor nanomaterialen vereist gedetailleerdere **informatievereisten** om de materialen te karakteriseren. Daarnaast is extra informatie nodig over de mate waarin een stof giftig is, de manier waarop hij zich in mens en milieu gedraagt, en waar hij uiteindelijk terecht komt. Hetzelfde geldt voor het vaststellen van de blootstelling en welke beheersmaatregelen nodig zijn om risico's te beperken. Onder REACH zijn informatievereisten gerelateerd aan de hoeveelheid van een chemische stof die wordt geproduceerd of geïmporteerd. Dit is ontstaan vanuit de gedachte dat grotere volumes een grotere kans op blootstelling en risico's met zich meebrengen. Nanomaterialen worden doorgaans in **lagere volumes** gebruikt, zodat al bij lagere hoeveelheden informatie over de stofeigenschappen is gewenst. Als stoffen zijn uitgezonderd voor registratie in REACH, omdat ze onder specifieke wetgeving worden beoordeeld, zoals in medicijnen, moeten de bijbehorende kaders daarvoor worden aangepast. Voor **werknemers** is dat in dit onderzoek uitgewerkt in de vorm van een specifieke risicoanalyse en aparte blootstellingsgrenzen.

Om inzicht te krijgen in welke producten nanomaterialen zijn verwerkt, zou een Europese **registratie** en/of **etikettering** van nanomaterialen nuttig kunnen zijn. Wat hiervoor de beste aanpak is, is echter nog niet duidelijk en moet worden uitgezocht.

Trefwoorden:
nanomateriaal, definitie, informatievereisten, REACH, werknemers, registratie, etikettering

Abstract

Exploring building blocks for amending EU regulation of nanomaterials

In early 2013, the Netherlands Interdepartmental Working Group on Risks of Nanotechnology (IWR) defined six building blocks to amend regulatory frameworks and improve risk assessment of nanomaterials. Furthermore, the building blocks aim at improving knowledge on nanomaterials in products. RIVM has explored these building blocks for their effectiveness and provides further interpretation for them. The six building blocks are: (1) a uniform definition of nanomaterials, (2) specific information requirements under REACH for a substance in nanoform, (3) lowering the production volume for registering a substance in nanoform or requiring certain information under REACH, (4) separate assessment of exposure and risk of nanomaterials for workers, and (5) a European register and/or (6) labelling of products that contain nanomaterials. The first three building blocks are strongly related to the European REACH Regulation for chemical substances, while the other three relate to other frameworks.

A horizontal **definition** should be solely aimed at identification of nanomaterials, i.e. distinguish between a nanoform and a 'conventional' non-nanoform of the substance. The recent recommendation by the European Commission is a good starting point for such a definition. The risk assessment of nanomaterials and the necessary (additional) information should be determined as a next step in the appropriate regulatory framework.

The risk assessment of nanomaterials requires detailed information to characterise the materials. Additional information is needed on the toxic potential of the substances and on their behaviour in humans and the environment, as well as on their fate. The same holds for determining the exposure of humans and environment to nanomaterials and necessary risk management measures to limit the risk. **REACH information requirements** are related to the amount of chemical substance that is produced in or imported into the EU. This is in line with the idea that larger volumes produce a greater chance of exposure and risks. Nanomaterials are generally used in **low volumes**, thus requiring information on substance properties at low levels. In the event that substances are exempted from REACH registration because they are assessed under specific legislation, e.g. medicine, that legislation may need to be adapted accordingly. For **workers** the present study shows how such adaptation may include a specific risk analysis and separate exposure limits for each substance.

To gain insight into the products in which nanomaterials are incorporated, a European **registration** and/or **labelling** of nanomaterials may be useful. The best approach to this, however, is not yet clear and should be further explored.

Keywords:
nanomaterial, definition, information requirements, REACH, worker, registration, labelling

Contents

Summary

Discussions on the regulation of nanomaterials are being accelerated as a result of three recent publications by the European Commission (EC): the Recommendation on the Definition of Nanomaterial, the Second Regulatory Review on Nanomaterials, and the REACH[1] review. The discussions focus on how to implement the definition of nanomaterials in the different pieces of legislation, including whether adaptations of specific legislation are necessary.

Several EU Member States and NGOs have contributed to the discussion by publishing their vision of the regulation of nanomaterials or information requirements for nanomaterials. All these visions have in common that they propose additional requirements for nanomaterials and scrutinise the usefulness of the current tonnage dependence of data requirements in REACH.

Based on these current discussions and proposals, the Netherlands Interdepartmental Working Group on Risks of Nanotechnology (IWR) identified six so-called 'building blocks' for the construction of appropriate legislation for nanomaterials. In the present report the RIVM contributes to the discussions by providing advice to policy makers on these building blocks. Three of them are discussed in relation to adaption of the REACH Regulation, in line with the opinion of the EC that REACH sets out the best possible framework for the risk management of nanomaterials. The other three building blocks are discussed in line with other legislation apart from REACH in order to extend legislation on the risk management and public right to know to have information on nanomaterials.

Building block 1: Definition of nanomaterials

A definition of nanomaterials is essential for legislation on nanomaterials. The EC Recommendation is a good starting point to ensure that nanomaterials are treated in a harmonised and consistent manner in all legislations.

To guarantee uniform legal implementation of a definition, a dynamic reference to a single, legally binding definition is preferred (i.e. a horizontal definition). This would prevent further discussions on what nanomaterials are, as are now seen in the frameworks on food and cosmetics. The primary aim of the definition is to focus on identifying nanomaterials.

Determining information needs, assessing hazards and risks and performing risk management, where appropriate, should be seen as the next step, following identification, in the individual regulatory frameworks.

Building block 2: Information requirements for nanomaterials

There is a clear need for nanomaterial-specific information to enable informed decisions on the safe handling and (regulatory) risk management of nanomaterials. To generate such information, adaptation of REACH is necessary.

The most urgent information need is related to the identification and characterisation of nanomaterials in various life cycle stages (particle size distribution; specific surface area), and thus on substance identity (characterisation; appearance/morphology; aggregation and agglomeration;

1 Registration, Evaluation, Authorisation and restriction of CHemicals.

spectral data; crystalline structure/atomic structure; surface reactivity; surface charge; catalytic properties).

For risk assessment purposes further information is necessary, including:

- Information on fate and (toxico)kinetics, including dissolution kinetics, dispersibility/dispersion stability, and dustiness, both in test systems and in humans and the environment
- Ecotoxicological information, including sediment and terrestrial toxicity testing, as well as acute and particularly chronic testing
- Toxicological information, including extra genotoxicity tests, a focus on the inhalation route, and adaptation of repeated dose testing regulations
- Information on exposure, risk characterisation and risk management, including exposure and release information, identification and characterisation of nanomaterials in various life cycle stages, and nano-specific risk management measures.

Building block 3: Specific tonnage levels and registration deadlines for nanomaterials within the REACH legislation

The current tonnage levels within the REACH Regulation are considered too high for nanomaterials, based on the following two main arguments.

First, there is currently a strong need to fill the data gaps that exist in relation to the hazard and risk assessment and risk management of nanomaterials. By lowering the tonnage levels and/or the information requirements related to those tonnage levels under REACH, it is expected that more data on nanomaterials will become available sooner.

Second, the production and/or import of many of the known nanomaterials is generally below 1 tonne/year. As a result there are currently no registration obligations under REACH (unless different nanomaterials are seen as different forms of one substance).

Setting lower trigger values needs further discussion, which should cover what such values should be and on what requirements will be necessary for which trigger value.

Requiring immediate registration of nanomaterials (i.e. exempting them from extended registration deadlines) will only be effective if this can be effectuated in legislation (far) before the final extended registration deadline of 1 June 2018.

Building block 4: Exposure and risk management at the workplace

Adaptation of REACH will be beneficial to worker protection as well, as REACH provides the legal instruments for generating the information needed on the hazards, exposure and safety assessment for the majority of chemicals (including nanomaterials) and ensures communication through the supply chain.

Nevertheless, adaptation of REACH still leaves gaps in legislation, most notably where substances (including nanomaterials) fall outside the scope of REACH. To improve knowledge on nanomaterials in the workplace further adaptation of existing legislation therefore appears necessary: specifically, the creation of a definition, but also the requirement for additional information (e.g. in assessing the risk of plant protection products).

In worker legislation CAD[2] appears the most appropriate directive for adaptation to improve the safe use of nanomaterials. First, the inclusion of a definition is needed to enable a specific adaptation of the RIE[3] obligation for nanomaterials. Additionally, the introduction of a register of workers' exposure and health surveillance could be considered, although discussion on the pros and cons of such a registry (at EU level) appears necessary. Finally, the development of nano-specific health-based OELs[4] by companies or authorities will also contribute to worker protection. For now, the Netherlands has established nano reference values (NRVs). NRVs can be used as a practical, but temporary, aid to employers for as long as health-based occupational exposure limits (HBR-OELs) are not yet available.

Building block 5: A European register for products that contain nanomaterials

There is a need for information on nanomaterials used in food and non-food products to increase transparency for consumers and traceability throughout the supply chain.

The details of what type of data are needed, however, is not yet clear (e.g. do we need detailed information of each brand name, or is information on the product type sufficient?).

Along with a separate register at EU level of products that contain nanomaterials, alternative options may be considered to obtain the necessary data. An impact assessment on the need to increase transparency for consumers and traceability throughout the supply chain, and the different options open for doing so, therefore appears necessary before deciding on the best way forward. A call for tenders for such an impact assessment was issued on 23 June 2013.

Building block 6: Labelling of products that contain nanomaterials

Because of the consumer's right to know, labelling should apply to all consumer products (food and non-food) with nanomaterials that meet the EU definition. Such labels will inform consumers about the presence of nanomaterials. Legislation in certain sectors already exists (e.g. the Biocides Regulation) that requires the labelling of products that contain nanomaterials by indicating 'nano' in brackets after the name of the ingredient. As nanomaterials are not intrinsically hazardous, however, indicating nanomaterial ingredients as 'nano' on the label will provide no information on the risk, as it focuses only on the presence of nanomaterial in the product.

The CLP[5] regulation appears better suited to providing the hazard information, although for nanomaterials it may be necessary to decide on the moment in the life cycle that determines whether a nanomaterial is present in a product. In addition, hazard information on the nanomaterial should be available, as the CLP regulation does not demand information generation for hazard classification of any chemical substance.

In contrast, indicating nanomaterial ingredients as such on the label may very well be a suitable way to provide consumers with the necessary information to make an informed choice on the products they use. In addition, labelling of food

2 The Chemical Agents Directive.
3 Risk Inventory and Evaluation.
4 Occupational Exposure Limits.
5 Classification, Labelling and Packaging.

and non-food products may help in the traceability of nanomaterials in the supply chain. Nevertheless, it may still be seen by the general public as an indication that all nanomaterials are hazardous and additional information may be necessary to avoid this.

1 Introduction

Discussions on regulating nanomaterials are being accelerated as a result of three recent publications by the European Commission (EC). In October 2011 the 'Recommendation on the definition of nanomaterial' (EU, 2011a) was published, followed in October 2012 by the Second Regulatory Review on Nanomaterials (EC, 2012) and in February 2013 by the REACH review (EC, 2013b). The discussions focus on how to implement the EC recommendation on the definition of nanomaterial in the different pieces of legislation, including whether adaptations to these are necessary.

Several EU Member States have contributed to the discussion by publishing their vision of the regulation of nanomaterials (Sweden and Germany) or information requirements for nanomaterials (Denmark). A number of NGOs have shared their vision as well (e.g. Azoulay, 2012). All these visions have in common that they propose additional requirements for nanomaterials and scrutinise the usefulness of the current tonnage dependence of data requirements in REACH. In the present report, the RIVM contributes to the discussion by providing its advice for policy makers on regulating nanomaterials.

At the CASG Nano[6] meeting of 23 November 2012, Sweden tabled a draft proposal in which separate legislation for nanomaterials was proposed by KEMI[7] (KEMI, 2013) and NGOs tabled a proposal for a 'nano patch' (Azoulay et al., 2012). These proposals were strongly linked to the REACH Regulation and may also be incorporated in REACH adaptations. Separate legislation was mainly proposed to ensure harmonised implementation of the regulatory framework in Member States. Germany published a background paper outlining its views on amendments to the REACH Regulation, indicating which additional requirements are needed – not only for nanomaterials, but for ultrafine particles and fibres as well – and how the tonnage levels in REACH may need adaptation (UBA et al., 2013). Denmark discussed in detail which (additional) information requirements may be necessary for nanomaterials (Christensen and Larsen, 2013). The topic was also discussed in the Netherlands, *inter alia* at international conferences on safety issues relating to nanomaterials in March 2012 and April 2013.

As a result of the workshop in 2012, the Netherlands sent a letter to the European Commission (EC)[8], supported by Austria, Belgium, Croatia, the Czech Republic, Denmark, France, Italy, Luxembourg, Spain and Sweden, in which the EC was urged to take several measures in relation to the regulation of nanomaterials. These measures include the adaptation of current legislation (including a harmonised use of the recommended definition) to improve its application to nanomaterials, establishing a register or market surveillance of nanomaterials and products containing nanomaterials to raise awareness among consumers and workers as well as improve traceability, and adapting the REACH legislation, specifically regarding tonnage levels, registration deadlines and information requirements for nanomaterials to improve its application to nanomaterials.

6 The Competent Authorities Subgroup on Nanomaterials.

7 Kemikalieinspektionen (Swedish Chemical Agency).

8 Available at: http://www.rijksoverheid.nl/documenten-en-publicaties/brieven/2012/07/06/brief-van-het-europese-parlement-aan-de-europese-commissie-over-de-review-nanotechnologie.html.

Some of these issues were discussed in the Second Regulatory Review on Nanomaterials (EC, 2012), but further detailed discussion appears necessary to arrive at appropriate legislation for nanomaterials. Based on the current discussions and proposals indicated above, the Netherlands Interdepartmental Working Group on Risks of Nanotechnology (IWR) identified the following 'building blocks' for such legislation, which were discussed in the second Dutch conference in April 2013:

1. Further interpretation of the definition of nanomaterials, to ensure that implementation in all relevant European legislation will be as harmonised as possible
2. Specific information requirements for nanomaterials (cf. Annexes of the REACH Regulation)
3. Specific tonnage levels and registration deadlines for nanomaterials within the REACH legislation
4. Assessment of exposure and risk of nanomaterials for workers
5. A European register of products that contain nanomaterials
6. Labelling of products that contain nanomaterials.

To provide advice to policy makers, in the present report these 'building blocks' are discussed in turn in chapters 2 to 7. The focus of building block 1 is on different aspects of the definition and how to harmonise these in different pieces of legislation. Building blocks 2 and 3 are discussed in relation to the potential adaptations of the REACH legislation and its Annexes in Chapters 3 and 4. Chapter 5 focuses on additional needs (apart from the adaptation of REACH) to ensure a safe working environment. Focus on worker protection is prompted by the fact that workers are the first to be exposed to nanomaterials and exposure levels are expected to be relatively high in comparison with those of consumers, for example. Finally, Chapters 6 and 7 discuss options for providing more information (both for professionals and for consumers) on products that contain nanomaterials.

In the current report (the application of) these building blocks are discussed in relation to adaption of the REACH Regulation, in particular the adaptations proposed in building blocks 2 and 3. This is in line with the opinion of the EC that REACH sets the best possible framework for the risk management of nanomaterials, as voiced in the Second regulatory review (EC, 2012). Nevertheless, adaptation of other legislation is likely to be necessary as well, as not all substances (and thus not all nanomaterials) fall under the scope of REACH. Some of these issues are discussed in Chapter 5, namely those relating to the worker protection, but specific requirements as described in Chapter 3 may be necessary in other legislation as well, e.g. legislation on food, on pesticides and on biocides. Where appropriate this is further discussed in chapter 2 to 7. A more in-depth analysis of other regulatory frameworks is foreseen by RIVM for the near future.

2 Building block 1: Definition of nanomaterials

In its Recommendation (EU, 2011a) the EC gives the following definition for a nanomaterial:

> *'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 %.*

In addition, a material is within the definition if its specific surface area by volume is greater than 60 m^2/cm^3; fullerenes, graphene flakes and single wall carbon nanotubes are specifically indicated as compounds that should be considered as nanomaterials.

The Recommendation also includes definitions of 'particle', 'agglomerate' and 'aggregate'. A review of the definition, focusing on the appropriateness of the 50 % limit, is foreseen by December 2014.

The Commission solely aims to identify substances within a specific size range and does not aim to classify nanomaterials as intrinsically hazardous.

In 2012, the RIVM published a report in which the interpretation and implications of the definition were discussed in depth (Bleeker et al., 2012). It was concluded that the Recommendation provides a sound basis to initiate debate among stakeholders that may lead to further refinement of the definition in 2014, when it is reviewed by the EC. One topic for debate is the 50 % threshold as indicated by the EC, and the special limit between 1 and 50 % for 'specific cases'. According to the RIVM a second topic for debate may be the proposed particle size range of 1–100 nm (including the list of derogations), as this range has no scientific basis.

Table 2.1: 'Bright line' size thresholds for a selection of properties (adapted from Hassinger and Sellers, 2012)

PROPERTY	BRIGHT LINE THRESHOLD (NM)	BASIS FOR THRESHOLD
Surface morphology	None identified	N/A
Crystalline structure	11.7 to 200	Distortion of crystal lattice structure
		Different crystalline forms
Water solubility/ Dissolution	None identified	N/A
Reactivity	15 to 20	Maximum catalytic activity
Photocatalytic activity	5 to 10	Maximum photocatalytic activity

Whatever the outcome of such discussions, it should be realised that the final decision will (at least to some extent) be a political compromise. As a result, materials that show specific properties related to their size may fall outside the definition, while others that do not show such properties may fall within the

definition. A recent literature review (Hassinger and Sellers, 2012) showed that specific 'bright line' size thresholds[9] may very well depend on the type of material and the specific property, and for certain properties such a threshold does not exist at all (e.g. the property changes with size on a continuous scale; see *Table 2.1*). This clearly complicates setting a specific size threshold for nanomaterials.

2.1 Definitions in current legislation

In Europe only a few pieces of legislation currently incorporate a definition of a nanomaterial to enable specific provisions for nanomaterials. These include legislation on cosmetics, on food labelling and food contact materials, and on biocidal products. All of these regulations and directives include a provision that the European Commission shall adapt 'the definition of nanomaterials' referring to technical and scientific progress or to definitions agreed at international level.

The new Regulation for cosmetics (EC No 1223/2009; EU, 2009) was the first to include a definition of nanomaterials: '*"nanomaterial" means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm*.'

Legislation on food followed with a slightly different definition (EU, 2011b, d, e). Here, '*"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.*' Properties that are characteristic of the nanoscale include '*those related to the large specific surface area of the materials considered and/or specific physicochemical properties that are different from those of the non-nanoform of the same material*'.

On 22 May 2012, a new Regulation for biocidal products was adopted (EU, 2012). This Regulation was the first to include the new definition, but no use was made of the possibility to deviate from the 50 % threshold as provided by the Recommendation. Yet, the following sentence is included in the Biocides Regulation: '*The Commission may, at the request of a Member State, decide, by means of implementing acts, whether a substance is a nanomaterial, having regard, in particular to Recommendation 2011/696. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 81(3)*.' This may open the possibility to define specific definition criteria for certain nanomaterials used in biocidal products.

Without being exhaustive, in its 2012 report (Bleeker et al., 2012) the RIVM identified several additional regulatory frameworks that are relevant for (dealing with) nanomaterials: plant protection products, medicinal products and medical devices, REACH[10], CLP[11] and occupational health and safety. None of these, however, currently includes a definition of nanomaterial, but in several of these legislations (e.g. REACH, medicinal products and medical devices), discussions

9 A 'bright line' size threshold indicates a certain size (or small size range) where a certain property significantly changes from what can be expected from the trend on either side of that threshold.

10 Registration, Evaluation, Authorisation and restriction of CHemicals.

11 Classification, Labelling and Packaging.

are currently ongoing on how to deal with nanomaterials, including how to define them.

Clearly the definitions cited above show differences and further harmonisation of the definitions in line with the Recommendation appears preferable to ensure that nanomaterials are treated in a harmonised and consistent manner in all legislation. If different definitions were to exist for the various regulatory frameworks, this would result in materials that in one framework are defined as a nanomaterial whereas in another are not defined as a nanomaterial. This could lead to unequal treatment of producers and/or importers and will hamper transparency for workers and consumers, as well as regulators and risk assessors. This issue relates to the percentage of the number of particles smaller than 100 nm to be used as the cut-off for identification of a nanomaterial, but also to other (limiting) criteria.

2.2 Purpose of a definition

Apart from transparency for workers and consumers (and others dealing with nanomaterials), in all these legislations an important purpose of including a definition of nanomaterials is to have an instrument to request for specific or additional information on the material that is relevant to assess the risk. This purpose, however, appears to interfere with the purpose of identifying materials as being nanomaterials. This is, for instance, illustrated by the inclusion of the wording 'insoluble or biopersistent' in the current definition in the Regulation for cosmetics. This appears to be included because additional 'nano-specific' information appears unnecessary to assess the risk if a nanomaterial is not persistent, i.e. if it loses its particle character in a relatively short period[12].

The RIVM recommends clearly separating the purpose of identifying nanomaterials from the purpose of the hazard or risk assessment of nanomaterials, i.e. similar to current definitions for 'substance' or 'mixture' in the REACH legislation (EU, 2006), a definition of 'nanomaterial' could be seen as a first step to further examination of the substance. In a next step the specific requirements (e.g. to ensure safe use) could be identified for this specific group of substances, similar to specific requirements for substances or mixtures in the REACH Regulation. Such specific requirements are further discussed in Chapter 3.

In risk assessment, required data to be generated for nanomaterials can follow a tiered approach, e.g. when a nanomaterial fully dissolves in water in a relatively short period[12], no additional testing for the specific nanomaterial is needed, provided that data on the non-nanoform of that substance are sufficiently available. On the other hand, if the nanomaterial is persistent (e.g. particles in the range of 1 to 100 nm remain in the water column for a long period[12]), this could require (toxicity) testing with the nanomaterial itself. Such a tiered approach could easily be described in guidance (e.g. EFSA guidance; Antunović et al., 2011), which implies that inclusion of e.g. 'solubility' in the definition of a nanomaterial is not necessary.

12 In cases where persistency is used to include or exclude certain data requirements, a clear definition is necessary as well, i.e. there should be a definition of the period as well as of the size at which a particle is no longer considered a particle.

2.3 Definition of nanomaterial in REACH

In the Second Regulatory Review on Nanomaterials (EC, 2012) the European Commission '*remains convinced that REACH sets the best possible framework for the risk management of nanomaterials*' but envisages modifications in some of the REACH Annexes. It may be questionable, however, whether inclusion in the Annexes is suitable for incorporation in a definition of nanomaterials within REACH. As an additional option, in its recently published review on REACH (EC, 2013b) the European Commission suggests adaptation of the definitions article (Article 3 of the REACH Regulation). Several other parties, however, indicate that adaptation of REACH (Annexes) will not be sufficient and that additional legislation may be necessary (Azoulay et al., 2012; KEMI, 2013).

The REACH Regulation (EU, 2006) focuses on substances, and a substance is defined as '*a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition*'. This definition implicitly includes nanomaterials, but to make it more explicit and also to open the option to incorporate within REACH specific requirements for nanomaterials, a clear definition of nanomaterials is desirable. This would make it clear for which specific substances, defined as nanomaterials, additional information is needed.

Referring to the substance definition in the REACH Regulation, a nanomaterial could then be defined in REACH in line with the regulation for biocidal products (EU, 2012): '*nanomaterial means a 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 nm–100 nm*', followed by the further points from the Recommendation. As in the Regulation for biocidal products, a mandate for the Commission to decide on specific cases could be included (i.e. '*The Commission may, at the request of a Member State, decide […] whether a substance is a nanomaterial […]*'), rather than including the phrase on the specific cases from the Recommendation (i.e. the possibility to deviate in certain cases from the 50 % threshold).

For the inclusion of such a definition in REACH, adaptation of the definitions article (Article 3 of the REACH Regulation) appears the most suitable option. Several parties, however, hesitate to adapt the REACH Regulation for nanomaterials, as this may open the opportunity to start discussions (again) on other issues as well (e.g. voiced during the second Dutch policy conference in April 2013). It could also be argued whether incorporation of a definition is a prerequisite for adaptation of REACH. The addition of certain mandatory 'nano-specific' requirements (e.g. in Annex II or VII) for all substances (i.e. not only nanomaterials) may also yield the required result. These should at least include particle size distribution, but they could include a whole range of information requirements that are considered necessary to adequately address the potential risks of nanomaterials (see Chapter 3 for further discussion on the requirements). To avoid unnecessary testing, the possibility of waiving (some of) these requirements should then be given as well, e.g. based on the outcome

of a particle size distribution measurement with reference to a definition outside the REACH legislation[13].

2.4 Harmonising the definition of nanomaterials

As indicated above, several legislations have already incorporated definitions of nanomaterials. The publication of the Recommendation (EU, 2011a), however, initiated renewed discussions in the frameworks of cosmetics and food. These discussions suggest that the threshold levels are a main point of discussion (will 50 % suffice or are other, lower, values warranted?), potentially leading to differences between regulatory frameworks. To avoid such differences, those discussing the definition in the cosmetics framework are keeping a close eye on the discussions in the food framework and vice versa. In addition, in the discussions on the adaptation of the definition in the different food-related legislations it is realised that the same definition should be applicable in the revision of the novel food Regulation as well.

To limit further requirements in different legal frameworks specific to certain nanomaterials, such as manufactured nanomaterials, additional definitions appear necessary as well. Terms such as '(intentionally) manufactured', 'biopersistent' and 'insoluble' are also imprecise and need clearer definitions in case they are intended to be used in limiting information requirements. Similarly, in case 'old nanomaterials' (i.e. nanomaterials that have been in use for decades) are exempted from certain legal requirements, such exemptions should be clearly defined, preferably also taking into account to what extent such exemptions distort harmonisation over the different legal frameworks.

A solution that would guarantee uniform legal implementation of a definition is to make dynamic references to the Commission Recommendation. However, for such a horizontal definition to work, some of the imprecision of the present definition may need adaptation, e.g. what specific concerns are acceptable for the adaptation of the threshold of 50 %. In addition, to provide the definition with a legally more formal status, the Recommendation could be turned into either a directive or a regulation. A recommendation is not binding and can (in theory) be amended by the Commission without consent of the Member States or the European Parliament, while a directive or regulation is legally binding (or leads to legally binding legislation in Member States).

13 This option may only be feasible if the Recommendation is turned into legislation, as explained in the last paragraph of this chapter.

Summary of building block 1: Definition of nanomaterials

A definition of nanomaterials is essential for legislation on nanomaterials. The EC Recommendation is a good starting point to ensure that nanomaterials are treated in a harmonised and consistent manner in all legislations.

To guarantee uniform legal implementation of a definition a dynamic reference to one single legally binding definition is preferred (i.e. a horizontal definition). This would prevent repetition of discussions on what nanomaterials are, as is now seen in parallel discussions in the frameworks on food and cosmetics. The primary aim of the definition is to focus on identifying nanomaterials.

Determining information needs, assessing the hazards and risks and performing risk management, where appropriate, should be seen as a next step, following identification, in the individual regulatory frameworks.

3 Building block 2: Information requirements for nanomaterials

Nanomaterials have specific characteristics that may differ from non-nanomaterials. In order to assess the hazards of nanomaterials, more information needs to be generated than the set of information requirements that traditionally apply to 'conventional' non-nanomaterials. Otherwise, their safety cannot be ensured in line with the principles of the existing conventions that apply to other chemicals. This raises the question: which specific properties of nanomaterials need to be known to link them to hazards for human health and the environment not yet addressed by REACH and other regulatory frameworks covering nanomaterials?

For REACH, information requirements are dependent on the amount of substance that is produced in or imported into the EU. These so-called tonnage level triggers for nanomaterials are discussed in the next chapter.

The need to formulate nano-specific information requirements has been recognised by some European authorities and scientific institutions, and is a subject of study among several expert working groups. Within this discussion, the European Commission is of the opinion that REACH – including some additional technical adaptations – sets the best possible framework for the risk management of nanomaterials, while other actors would rather see separate legislation. Independent of how to formalise the information requirements in legislation, the question remains: which nano-specific information requirements need to be formulated?

This chapter addresses this issue in line with the principles of REACH, building both on earlier work by RIVM and on work by other authorities and institutions. Relevant in this context are the following publications:

- RIVM report 'Nanomaterials under REACH – Nanosilver as a case study' (Pronk et al., 2009);
- results of the REACH Implementation Projects on Nanomaterials (RIPoNs; Aitken et al., 2011; Hankin et al., 2011; JRC, 2011);
- 'Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain' provided by EFSA[14] (Antunović et al., 2011);
- paper 'High time to act on nanomaterials – A proposal for a "nano patch" for EU regulation' jointly issued by three NGOs (Azoulay et al., 2012);
- 'Background paper on the position of German Competent Authorities' (UBA et al., 2013);
- KEMI 'proposal regulation for nanomaterials' presented at CASG Nano on 23 November 2012 (KEMI, 2013);
- report 'Information requirements for nanomaterials – IRNANO' issued by the Danish Environmental Protection Agency (Christensen and Larsen, 2013).

14 European Food Safety Authority.

Although the focus in this chapter is on adaptations to REACH, similar adaptations could be considered in other legislation where data are required to ensure safe use, e.g. for biocidal or plant protection products, or for food safety.

A need for nano-specific data requirements is identified for the following thematic areas:

1. Substance identity and characterisation
2. Fate and kinetics
3. Toxicological information
4. Ecotoxicological information
5. Exposure, risk characterisation and risk management measures.

A thorough analysis of the different parameters in each of these thematic areas is given in the report 'Information requirements for nanomaterials – IRNANO' (Christensen and Larsen, 2013). Where appropriate in this chapter only a short summary of that analysis is given.

3.1 Substance identity and characterisation

3.1.1 Substance identity and grouping of nanomaterials

Currently, to determine the substance identity in REACH (EU, 2006) at least the parameters listed in Annex IV, Item 2 should be used (*Table 3.1*). A substance is usually identified by its chemical composition, the chemical identity and the content of each constituent in the substance. However, to identify and distinguish different forms of a substance (e.g. nanoform and non-nanoform, or different nanoforms) other parameters are necessary as well (see Section 3.1.2).

In principle, two approaches can be chosen to relate nanomaterials to the substance in its non-nanoform and to other related nanoforms.[15] One approach is that each nanomaterial with specific size, shape and surface characteristics is a substance on its own that should be seen as distinct from another material with the same molecular structure and chemical composition. The other is that each nanomaterial or non-nanomaterial is a specific form of one substance that is defined by molecular structure and chemical composition. This second approach is within the meaning of the current REACH provision that registration is based on the 'one substance, one registration' principle.

The two approaches have different consequences for the registration of nanomaterials under REACH. The first approach – where size, shape and surface characteristics are seen as 'identifiers' of different substances – implies separate REACH registrations for each nanomaterial, and would thus contribute to increased visibility of nanomaterials. However, as the REACH registration obligation applies only above a specific threshold (1 tonne/year per registrant in current REACH legislation), nanomaterials below this threshold will become 'invisible' to REACH. Therefore, several proposals have been put forward to lower this threshold. This is further discussed in Chapter 4.

15 Also when a non-nanoform does not exist, different nanoforms may need to be distinguished.

The second approach, where nanomaterials are considered as different manifestations of the same substance, and are consequently registered together with non-nanoform materials[16], yields a higher chance of nanomaterials being registered under REACH, although they may be somewhat hidden (which may result in invalid use of information, e.g. when information for the non-nanomaterial is being used for the nanomaterial as well). So, while separate REACH registrations for nanoforms may improve the visibility of nanomaterials, a registration together with non-nanomaterial[16] – where size, shape and surface characteristics are considered as so-called 'characterisers' – is likely to generate more data specific to nanomaterials as the different forms should still be properly characterised. In the case of the latter option, further information is still required for the nanoform(s) of the substances, as information for the non-nanomaterial (or another nanomaterial) may not be suitable for all forms.

Table 3.1: Substance identification parameters in REACH Annex VI Section 2

2	**IDENTIFICATION OF THE SUBSTANCE**
	For each substance the information given shall be sufficient to enable each substance to be identified. If it is not technically possible or if it does not appear scientifically necessary to give information on one or more items below, the reason shall be clearly stated.
2.1	**NAME OR OTHER IDENTIFIER OF EACH SUBSTANCE**
2.1.1	Name(s) in the IUPAC nomenclature or other international chemical name(s)*
2.1.2	Other names (usual name, trade name, abbreviation)*
2.1.3	EINECS or ELINCS number (if available and appropriate)
2.1.4	CAS name and CAS number (if available)
2.1.5	Other identity code (if available)*
2.2	**INFORMATION RELATED TO MOLECULAR AND STRUCTURAL FORMULA OF EACH SUBSTANCE**
2.2.1	Molecular and structural formula (including SMILES notation, if available)
2.2.2	Information on optical activity and typical ratio of (stereo) isomer (if applicable and appropriate)
2.2.3	Molecular weight or molecular weight range
2.3	**COMPOSITION OF EACH SUBSTANCE**
2.3.1	Degree of purity (%)
2.3.2	Nature of impurities, including isomers and by-products
2.3.3	Percentage of (significant) main impurities
2.3.4	Nature and order of magnitude (... ppm, ... %) of any additives (e.g. stabilising agents or inhibitors)*
2.3.5	Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum)
2.3.6	High-performance liquid chromatogram, gas chromatogram

* These parameters may need adaptation for nanomaterials (see main text for further details).

16 Where no non-nanoform exists, only different nanoforms of the same chemical identity will be clustered.

It is a subject of discussion which size, shape and surface characteristics are relevant in deciding on the sameness[17] of the nanoform and the non-nanoform and among different nanoforms. As the physicochemical variations for nanomaterials are so large and diverse (clearly exceeding variations in molecular and structural formulae), setting a minimal set of morphological and physicochemical properties to distinguish between the different forms presents a huge challenge, at least in the near future. Nevertheless, as nanomaterials are generally defined by their particle size distribution and/or specific surface area by volume (EU, 2011a), these parameters are obvious candidates for inclusion in such a minimal set of properties. In particular, however, where behaviour and reactivity are concerned, for the time being distinguishing different nanoforms remains a case-by-case decision, as currently data are too scarce to enable generalisations.

A further challenging issue in the sameness discussion is a decision on the most appropriate test programme for safety assessment of the different forms, which – apart from additional physicochemical properties – may require additional data on kinetics and toxicity/ecotoxicity to be considered (Pronk et al., 2009). A sameness analysis that includes such data as well is essential to conclude on whether or not the different forms are sufficiently identical to justify read-across in the safety assessment.

To conclude on the sameness issue, one should first build on insights gained by treating morphological differences *a priori* as toxicologically or ecotoxicologically relevant to improve the understanding of the specific issues pertaining to the sameness of nanomaterials. After such improvement of knowledge, a new approach to sameness can be designed based on morphological and physicochemical properties, potentially in combination with limited data on toxicity/ecotoxicity and kinetics.

In addition to decisions on the test programme, the sameness discussion will be important in deciding what information will be required for what tonnage levels. The tonnage levels are further discussed in Chapter 4.

3.1.2 Characterisation of nanomaterials

It is generally acknowledged that nanomaterials may change during their life cycle, i.e. their particle size distribution (and thereby other properties) may change, resulting in other nanomaterials or materials that are no longer considered to be nanomaterials (e.g. Environmental Defense – Du Pont Nano Partnership, 2007; Antunović et al., 2011; JRC, 2012). Similarly, non-nanomaterials may change into or release nanomaterials during their life cycle. Characterisation may, therefore, differ between the material as produced, as delivered, as used, as tested, as occurring in the environment or the human body, etc. This suggests that a material needs to be characterised both during the performance of toxicity/ecotoxicity tests and during several critical phases in the life cycle.

Currently, information on several morphological and physicochemical properties is required under REACH (*Table 3.2*). For nanomaterials, many of these properties will be just as relevant as for non-nanomaterials. Specifically for

17 A decision on sameness is necessary to decide whether data for one form can be used for another form or substance.

nanomaterials, however, the following properties are currently identified as relevant parameters for identification and understanding of their reactivity and may need adaptation or addition in the current REACH requirements.

Table 3.2: Physicochemical properties currently required in REACH

7	PHYSICOCHEMICAL PROPERTIES	TONNAGE LEVEL
7.1	State of substance at 20 °C and 101.3 kPa	≥ 1 tonne/year
7.2	Melting / freezing point	≥ 1 tonne/year
7.3	Boiling point	≥ 1 tonne/year
7.4	Relative density	≥ 1 tonne/year
7.5	Vapour pressure	≥ 1 tonne/year
7.6	Surface tension*	≥ 1 tonne/year
	Specific surface area by volume*	
	Surface charge / zeta potential / isoelectric point*	
	Other surface properties (surface structure, surface acidity, surface energy, surface reactivity – incl. surface chemistry)*	
7.7	Water solubility*	≥ 1 tonne/year
	Dissolution kinetics*	
	Dispersibility / dispersion stability*	
7.8	Partition coefficient n-octanol / water*	≥ 1 tonne/year
	Fat solubility / oleophilicity*	
7.9	Flash-point	≥ 1 tonne/year
7.10	Flammability	≥ 1 tonne/year
7.11	Explosive properties	≥ 1 tonne/year
7.12	Self-ignition temperature	≥ 1 tonne/year
7.13	Oxidising properties	≥ 1 tonne/year
	Catalytic properties / photocatalytic properties / radical formation potential*	
7.14	Granulometry*	≥ 1 tonne/year
	Particle size distribution*	
	Aggregation and agglomeration behaviour*	
	Appearance / morphology (shape, aspect ratio)*	
	Dustiness*	
7.15	Stability in organic solvents and identity of relevant degradation products	≥ 100 tonnes/year
7.16	Dissociation constant	≥ 100 tonnes/year
7.17	Viscosity	≥ 100 tonnes/year

* These parameters (may) need to be added or adapted for nanomaterials (see main text for further details). Those without a number are currently not (explicitly) mentioned in the REACH requirements.

Particle size distribution

Currently particle size distribution is a requirement under REACH, indicated as granulometry. This is an essential parameter to determine whether a material is a nanomaterial under the EC definition (EU, 2011a). For this reason, it could be

considered to explicitly indicate this requirement as particle size distribution rather than as granulometry.

Specific surface area by volume

Specific surface area by volume is indicated by the EC as an alternative method to determine whether a material is a nanomaterial conform the EC-definition (EU, 2011a). Currently it is not a requirement under REACH, but to identify nanomaterials, inclusion of this parameter in the information requirements appears essential.

Aggregation and agglomeration behaviour

According to the definition (EU, 2011a), nanomaterials are primarily identified by their primary particle size distribution. Many methods to determine such distributions, however, cannot distinguish particles from aggregates or agglomerates. Further information on how easily aggregates and agglomerates are formed by the primary particles is essential to determine to what extent a particle size distribution is influenced by aggregation and agglomeration processes. In addition there is consensus that this is key information for assessing the fate and toxicological and ecotoxicological properties of nanomaterials (e.g. Hankin et al., 2011; Christensen and Larsen, 2013). In this context it should be realised that, particularly during toxicity and ecotoxicity testing, heteroaggregation and heteroagglomeration may also occur, i.e. aggregation and agglomeration of the primary particles with other materials present in the system (e.g. Hartmann et al., 2010; Quik et al., 2012). As with the particle size distribution, information on aggregation and agglomeration is currently required in REACH under granulometry. Particularly for nanomaterials, however, this requirement could be indicated more specifically.

Appearance / morphology (shape, aspect ratio)

It is generally acknowledged that the appearance of a substance influences its behaviour. The clearest example here is the group of carbon-based nanomaterials. Although the principal constituent in all cases is a carbon atom, fullerenes, graphene and carbon nanotubes are generally considered different (forms of) substances. Similarly it can be anticipated that a silver fibre will behave differently from a silver particle or a silver ion. Aspect ratio and possibly other shape parameters are therefore needed to distinguish these different forms.

Surface charge / zeta potential / isoelectric point

Surface charge influences the interaction of a particle with its surroundings (including agglomeration/aggregation behaviour), but is also (partly) influenced by these surroundings, e.g. pH. Direct measurement, however, is difficult, so it is often estimated on the basis of zeta potential or isoelectric point. OECD (2012) notes that the zeta potential (at a specified pH and ionic strength) and/or the isoelectric point of the particles (in case the particles are stabilised by surface charges) should be determined and provided so that it can be used for the fate assessment of particles in a dispersion. For sterically stabilised particles, the zeta potential may not be a suitable parameter to estimate the fate of the particles *a priori*.

Other surface properties (surface structure, surface acidity, surface energy, surface reactivity – incl. surface chemistry)

To get an indication of the type of reactions that can take place at the surface of the material and which chemical groups are involved in these reactions, information on other surface properties may be necessary as well. This may also include specific surface treatment. How this should be incorporated in the information requirements needs further discussion.

Catalytic properties / photocatalytic properties / radical formation potential

Certain nanomaterials are specifically developed to have certain catalytic properties. As this may lead to radical formation (e.g. generation of reactive oxygen species), this has consequences for the toxicological or ecotoxicological profile of the specific nanomaterials. As the methodology for characterisation of this parameter needs further development, further discussion is needed as well on how to incorporate this in information requirements.

3.2 Fate and toxicokinetics

To understand environmental behaviour and toxicokinetics, the following additional properties are proposed.

3.2.1 Dissolution kinetics

In addition to the water solubility currently required by REACH, dissolution kinetics is considered a key parameter for environmental fate and behaviour as well as for toxicity/ecotoxicity testing. Dissolution kinetics gives information on the rate of molecules being released from the particle into the surrounding solution. By the time a nanomaterial is fully dissolved it may no longer be a particle and thus no longer a nanomaterial (e.g. nanosilver fully transformed into silver ions in solution). In this context water solubility is considered less relevant for some nanomaterials, although it remains essential information on the substance (including some nanomaterials, e.g. fullerene) and influences to some extent the dissolution kinetics.

3.2.2 Dispersibility / dispersion stability

In many toxicity and ecotoxicity tests the test substance is added in an aqueous solution. For some nanomaterials this may not be feasible as such, e.g. when it dissolves into ions that are no longer considered nanomaterials (see also previous paragraph), or when the nanomaterial is not (very) soluble in water. Nanomaterials are therefore often added to a test system in a dispersion. As particles tend to sink from a dispersion to the bottom of the vessel, the dispersibility and particularly the dispersion stability are key parameters in toxicity testing as actual exposure in the test systems is strongly influenced by these parameters. Discussions on including these parameters as information requirements should include discussions on dissolution kinetics as well.

3.2.3 Dustiness

Dustiness is seen as an essential parameter to obtain information on the potential for airborne exposure to nanomaterials (e.g. Hankin et al., 2011; JRC, 2012). Subsequently such airborne exposure influences inhalation toxicity and potential classification under the CLP Regulation (EU, 2008a). To some extent this issue is addressed under the current REACH granulometry requirement and related to the aggregation/agglomeration behaviour. Particularly for nanomaterials, however, this requirement could be indicated more specifically.

3.2.4 Fat solubility / oleophilicity

Fat solubility/oleophilicity may also be included to understand environmental behaviour and toxicokinetics, replacing the partition coefficient *n*-octanol/water (K_{OW}) currently required by REACH. K_{OW} is often used as a measure to estimate the uptake of (organic) chemicals into organisms. For nanomaterials, however, little or no information is available on uptake into organisms, although there is consensus that the K_{OW} concept is not applicable to nanomaterials.[18] Furthermore, it may be questionable whether nanomaterials in general will show oleophilic behaviour, as many have an inorganic nature. Surface modifications (e.g. with organic groups), however, may further complicate the issue. Clearly further research is needed on the uptake and fate of nanomaterials, before a simplified approach (based on physicochemical properties) can be applied.

3.3 Toxicological information

To assess the intrinsic toxicity of nanomaterials the existing REACH requirements on toxicity (*Table 3.3*) need amendments (see also Christensen and Larsen, 2013). Such adjustments may include:

- The monitoring of changes in the physical form and characteristics of nanomaterials during toxicological testing (see also Sections 3.1.2 and 3.2 above). Understanding how nanomaterials change during testing will – in the long run – allow the use of read-across to fill data gaps and is therefore instrumental in reducing the need for extra testing.
- Two extra tests for genotoxicity (using human or mammalian cells) additional to the gene mutation study in bacteria because such a bacterial test is considered to be not discriminative enough in the case of nanomaterials, i.e. it gives a large number of false negative results (Antunović et al., 2011)[19].
- Use of the inhalation route as the preferred route of exposure for testing, instead of the oral route often chosen in conventional testing schemes, because inhalation is the most likely route for (nano)particle exposure. This is also included in the nanomaterial specific appendix of the REACH Guidance

18 The n-octanol-water partitioning coefficient (K_{OW}) is often used as an indicator for (passive) transport over a lipid membrane (apart from being an indicator for accumulation in fatty tissues). For transport of bigger molecules (or particles, such as nanomaterials) other mechanisms are involved for which K_{OW} cannot be used as an indicator.

19 The Ames test uses bacterial cells, but these substantially differ from human or zoological cells (nanoparticles generally do not reach the cytosol in bacterial cells) and thus cannot directly be used to indicate hazards for humans.

on Information Requirements and Chemical Safety Assessment (ECHA, 2012; section 3.2.4).

Table 3.3: Current toxicological information requirements in REACH

8	TOXICOLOGICAL INFORMATION*	TONNAGE LEVEL
8.1	Skin irritation / corrosion – *in vitro*	≥ 1 tonne/year
8.1.1	Skin irritation – *in vivo*	≥ 10 tonnes/year
8.2	Eye irritation – *in vitro*	≥ 1 tonne/year
8.2.1	Eye irritation – *in vivo*	≥ 10 tonnes/year
8.3	Skin sensitisation	≥ 1 tonne/year
8.4.1	*In vitro* gene mutation study in bacteria**	≥ 1 tonne/year
8.4.2	*In vitro* cytogenicity study in mammalian cells or in vitro micronucleus study**	≥ 10 tonnes/year
8.4.3	*In vitro* gene mutation study in mammalian cells**	≥ 10 tonnes/year
8.4	*In vivo* mutagenicity studies**	≥ 100 tonnes/year
8.5.1	Acute oral toxicity**	≥ 1 tonne/year
8.5.2	Acute inhalation toxicity**	≥ 10 tonnes/year
8.5.3	Acute dermal toxicity	≥ 10 tonnes/year
8.6.1	Short-term repeated dose toxicity study (28 days)**	≥ 10 tonnes/year
8.6.2	Sub-chronic toxicity study (90 days)**	≥ 100 tonnes/year
8.6.3	Long term toxicity study (≥ 12 months)**	≥ 1000 tonnes/year
8.6.4	Further studies**	≥ 1000 tonnes/year
8.7.1	Screening for reproductive / developmental toxicity (OECD 421 or 422)**	≥ 10 tonnes/year
8.7.2	Pre-natal developmental toxicity study**	≥ 100 tonnes/year
8.7.3	Two-generation reproductive toxicity study**	≥ 100 tonnes/year
8.8.1	Assessment of the toxicokinetic behaviour of the substance to the extent that can be derived from the relevant available information**	≥ 10 tonnes/year
8.9.1	Carcinogenicity**	≥ 1000 tonnes/year

* In general, monitoring of changes in the physical form and characteristics of nanomaterials during toxicological testing is recommended, as this is instrumental for read-across approaches in the future.

** These parameters (may) need adaptation for nanomaterials (see main text for further details).

- Chronic/repeated dose toxicity studies are preferred above acute toxicity tests. Due to the relatively slow uptake processes of nanomaterials, acute studies are expected to be of limited value for the risk profile of nanomaterials[20] (Antunović et al., 2011). If acute toxicity testing is performed, extended pathology/histology is recommended (Hankin et al., 2011), but it may also be considered to withdraw acute toxicity testing altogether for nanomaterials and replace this by the requirement for chronic/repeated dose toxicity studies.

20 Uptake processes of nanomaterials are expected to be relatively slow, resulting in delayed manifestation of (toxic) effects. Such effects will most usually not be picked up in acute toxicity tests.

- The inclusion of additional parameters to the standard repeated dose toxicity study, such as cardiovascular and/or inflammatory parameters, and the use of sensitive species/strains for these effects. The rationale for these inclusions is the scientific evidence suggesting 'nano-specific' cardiovascular and/or inflammatory effects (SCENIHR, 2007, 2009).
- Adaptation of standard repeated dose studies to include a prolonged exposure-free follow-up phase (i.e. 'recovery phase'), as well as the inclusion of kinetic parameters in order to identify the distribution of nanomaterials in organs and potential particle persistence and associated delayed effects. As these distribution processes are generally slower for nanomaterials than for non-nanomaterials (i.e. molecules), additional time is needed to observe the effects. Furthermore, the inclusion of kinetic parameters will provide anchor points for toxicokinetic modelling.[21] This information is especially relevant in the event that the toxicological information from one nanomaterial is to be used for the assessment of several other related ('same') nanomaterials (or non-nanomaterials).
- Lowering the existing tonnage band for information requirements for nanomaterials, resulting in extra and more (nano-specific) information, also at tonnage levels below 10 tonnes/year (see Chapter 4).

3.4 Ecotoxicological information

The following adaptations/additions of the current REACH requirements on ecotoxicological information for nanomaterials (*Table 3.4*) are identified (see also Christensen and Larsen, 2013):

- Application of the extensive testing requirements to lower tonnage bands in the case of nanomaterials, resulting in extra and more (nano-specific) information, also at tonnage levels below 10 tonnes/year (see Chapter 4). This is essential in filling current knowledge gaps.
- Especially data on the stability (i.e. fate and kinetics) of nanomaterials in different environmental media is necessary in order to understand the environmental exposure and subsequent effects. For example, exposure during testing may be different from nominal exposure due to aggregation, agglomeration, dissolution, adsorption and sedimentation. Furthermore, exposure may change during the testing period as a consequences of such processes. (see Section 3.2).
- Adaptations of standard tests to reflect that sediment/soil is a particularly relevant exposure route in the case of nanomaterials, due to the water solubility/dissolution and dispersibility issues with most nanomaterials (see Sections 3.2.1 and 3.2.2).

21 Such anchor points are also beneficial in repeated dose studies with non-nanomaterials, as they improve reliability in toxicokinetic modelling in general.

Table 3.4: Current ecotoxicological information requirements in REACH

9	ECOTOXICOLOGICAL INFORMATION*	TONNAGE LEVEL
9.1.1	Short-term toxicity testing on invertebrates (preferred species Daphnia)**	≥ 1 tonne/year
9.1.2	Growth inhibition study aquatic plants (algae preferred)**	≥ 1 tonne/year
9.1.3	Short-term toxicity testing on fish**	≥ 10 tonnes/year
9.1.4	Activated sludge respiration inhibition testing	≥ 10 tonnes/year
9.1.5	Long-term toxicity testing on invertebrates (preferred species Daphnia)**	≥ 100 tonnes/year
9.1.6	Long-term toxicity testing on fish**	≥ 100 tonnes/year
9.2.1.1	Biotic degradation – ready biodegradability	≥ 1 tonne/year
9.2.1.2	Simulation testing on ultimate degradation in surface water	≥ 100 tonnes/year
9.2.1.3	Soil simulation testing	≥ 100 tonnes/year
9.2.1.4	Sediment simulation testing	≥ 100 tonnes/year
9.2.2.1	Abiotic degradation – hydrolysis as function of pH	≥ 10 tonnes/year
9.2.3	Identification of degradation products	≥ 100 tonnes/year
9.2	Further biotic degradation	≥ 1000 tonnes/year
9.3.1	Adsorption / desorption screening study	≥ 10 tonnes/year
9.3.2	Bioaccumulation in aquatic species, preferably fish**	≥ 100 tonnes/year
9.3.3	Further information on absorption / desorption**	≥ 100 tonnes/year
9.3.4	Further information on the environmental fate and behaviour and/or degradation products**	≥ 1000 tonnes/year
9.4.1	Short-term toxicity to invertebrates**	≥ 100 tonnes/year
9.4.2	Effects on soil micro-organisms	≥ 100 tonnes/year
9.4.3	Short-term toxicity to plants**	≥ 100 tonnes/year
9.4.4	Long-term toxicity testing on invertebrates	≥ 1000 tonnes/year
9.4.6	Long-term toxicity testing on plants	≥ 1000 tonnes/year
9.5.1	Long-term toxicity to sediment organisms	≥ 1000 tonnes/year
9.6.1	Long-term or reproductive toxicity to birds	≥ 1000 tonnes/year

* In general, monitoring of changes in the physical form and characteristics of nanomaterials during ecotoxicological testing is recommended, as this is instrumental for read-across approaches in the future.

** These parameters (may) need adaptation for nanomaterials (see main text for further details).

3.5 Exposure, risk characterisation and risk management measures

Exposure, risk characterisation and risk management measures are factors in determining the safe use of materials. Currently exposure data are only mandatory under REACH when a substance is classified as hazardous under the CLP regulation (EU, 2008a) or fulfilling the PBT or vPvB criteria (EU, 2011c).[22] Due to lack of data, nanomaterials are (generally) not classified as hazardous

22 The Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) criteria are described in Annex XIII of the REACH Regulation, which was revised in 2011 (EU, 2011c).

under the CLP regulation. As a result, for nanomaterials hardly any exposure data are available. The following specific adaptations are, therefore, proposed for nanomaterials:

- To require an obligatory exposure and risk characterisation for all nanomaterials subsequent to registration, including low volume levels[23] and to identify whether nano-specific risk management measures are needed during production, manufacture and use. The rationale here is that there is a need to fill the current knowledge gaps on the exposure and risk management measures of nanomaterials and that many nanomaterials are placed on the market in low quantities.
- To include in the risk characterisation the possibility that the toxicological profile and subsequent risk level of nanomaterials can change during their life cycle, because the properties of the material may change, resulting in other nanomaterials or materials that are no longer considered to be nanomaterials.

Summary of building block 2: Information requirements for nanomaterials

There is a clear need for nanomaterial-specific information to enable informed decisions on the safe handling and (regulatory) risk management of nanomaterials. To obtain such information, adaptation of REACH is necessary.

The most urgent information need is related to identifying nanomaterials (particle size distribution; specific surface area), and thus on substance identity (characterisation; appearance/morphology; aggregation and agglomeration; spectral data; crystalline structure/atomic structure; surface reactivity; surface charge; catalytic properties).

For risk assessment purposes further information is necessary, including:

- Information on fate and (toxico)kinetics, including dissolution kinetics, dispersibility/dispersion stability, and dustiness, both in test systems and in humans and the environment.
- Ecotoxicological information, including sediment and terrestrial toxicity testing, as well as acute and particularly chronic testing.
- Toxicological information, including extra genotoxicity tests, a focus on the inhalation route, and adaptation of repeated dose testing.
- Information on exposure, risk characterisation and risk management at low volume levels as well (see Chapter 4), including exposure and release information, identification and characterisation of nanomaterials in various life cycle stages, and nano-specific risk management measures.

23 Which low levels should be included, and which levels can be exempted, needs further discussion.

4 Building block 3: Specific tonnage levels and registration deadlines for nanomaterials within the REACH legislation

Within REACH the need to register a substance, as well as the information that has to be provided, are dependent on the amount of the substance that is produced in or imported into the European Union. As long as this amount remains below 1 tonne/year, no registration is needed; above 10 tonnes/year conducting a chemical safety assessment is required, but only when the amount exceeds 1000 tonnes/year must a full set of information[24] be provided. Exposure assessment under REACH is required above the 10 tonnes/year trigger, and then only when the substance is classified in the hazard classes or categories according to the CLP Regulation as specified in article 14.4 of REACH or when the substance is assessed as a PBT or vPvB. However, it should be noted that other provisions in REACH, such as the scope of authorisation and restriction, are without a threshold level. Furthermore, the CLP Regulation requires classification and labelling for every chemical, independent of production/import level.

The deadline for complying with the REACH Regulation also depends on these tonnage levels, with the latest deadline (June 2018) for the lowest tonnage levels (1–100 tonnes). Substances (≥ 1 tonne/year) known to be very hazardous[25] were subject to the earliest deadline (December 2010).

4.1 Registering nanomaterials under REACH

Nanomaterials are a heterogeneous group of materials, including some traditional high-volume commodity materials (e.g. carbon black and synthetic amorphous silica), newly developed medium-volume applications such as paints and sunscreens, and a wide range of new low-volume technical and biomedical applications (e.g. catalysts, batteries, solar panels, tumour therapies) (EC, 2013a). Nevertheless, the production and/or import of many of the known nanomaterials is generally below 1 tonne/year (e.g. BAuA, 2008), and thus under the current REACH requirements no registration under REACH is necessary. Apart from nanomaterials, many other substances will not be registered under REACH due to their low production/import levels. For nanomaterials, however, their relatively high surface area raises concerns over their potential increase in reactivity, while their low production/import levels reduce the chance that data on their physicochemical properties, toxicological information, ecotoxicological information and exposure information will become available under REACH. To some extent this depends, however, on how nanomaterials will be registered under REACH. As discussed in Section 3.1.1, each nanomaterial can be registered either as an individual substance or as a group of similar forms of a substance.

24 What comprises a full set of required data, and whether that is sufficient for nanomaterials, is further discussed in the previous chapter.

25 Those substances that are known to be carcinogenic, mutagenic or toxic to reproduction (so called CMR substances) ≥ 1 tonne/year, as well as those that are known to be very toxic to aquatic organisms that may cause long-term adverse effects in the aquatic environment (classified according to Annex I of Directive 67/548/EEC as N; R50-53) ≥ 100 tonnes/year.

Several stakeholders (NGOs, EU Member States) consider it necessary to re-examine the usefulness of the current tonnage threshold levels in REACH for nanomaterials (Azoulay et al., 2012; UBA et al., 2013). To support their proposal, Azoulay et al. (2012) refer to a German survey (BAuA, 2008) in which more than half of the companies indicated that they produce/import less than 100 kg/year of nanomaterials. The same survey also showed that some companies indicate levels of ≥ 1000 tonnes/year.

Germany proposes to incorporate an extra threshold level of 100 kg/year, specifically to gather physicochemical data on nanomaterials (UBA et al., 2013), mainly aiming at identifying the material. In addition, they propose gathering some of the information already to be required under REACH, at lower tonnage levels. A similar proposal was recently presented by Sweden as well (KEMI, 2013), which includes the obligatory registration of nanomaterials in quantities of ≥ 10 kg/year, including exposure information for nanomaterials in quantities of 10 to 100 kg/year, and a full registration for nanomaterials in quantities of ≥ 1 tonne/year. KEMI argues that the (reactive) surface area of nanomaterials is much larger than that of 'conventional' non-nanomaterial[26], and they therefore require a lower trigger value. The factor of 100 lower is based on the fact that a particle with a diameter of 100 nm has a surface area that is 100 times smaller than the total surface area of 100 particles with a diameter of 1 nm (Filipsson, 2013).[27]

Further discussion on what the exact trigger values should be for which requirements appears necessary.

4.2 Nano-specific requirements and tonnage bands

If the properties of a substance significantly differ from those of another substance, additional tests may be necessary to ensure safe use. This is one of the basic principles of REACH and applies to both non-nanomaterials and nanomaterials. Also, if nanomaterials are registered under the same substance as the non-nanoform[28], data requirements must be fulfilled for all distinct forms of the substance, both nanoforms and non-nanoforms, according to the tonnage band of the total quantity of all forms that share the same molecular and chemical identity (European Commission, 2008). The diversity of the nanoforms of a substance may lead to different testing requirements. Approaches for grouping and waiving, however, should be considered to avoid unnecessary (animal) testing and unnecessary costs, while at the same time ensuring an adequate level of protection.

To some extent this refers back to the 'sameness discussion' (see Section 3.1), but a minimum dataset could be proposed as follows. First, the data necessary for substance and form identification should be provided for each form. If none of the different forms lies within the tonnage band of the total quantity, further data requirements according to the tonnage band of the total quantity must be

26 For a certain volume the surface area increases logarithmically with the diameter of the particles that comprise that mass, e.g. a cube of 1×1×1 cm has a surface area of 6 cm^2, but if the same volume is filled with cubes of 1×1×1 nm the surface area will be 60,000,000 cm^2.

27 A particle with a diameter of 100 nm has a surface area of 4π·502 (= 4π·2500). A hundred particles with a diameter of 1 nm have a total surface area of 100·4π·0.52 (= 100·4π·0.25 = 4π·25). The difference between the two values is a factor of 100 (4π·2500/4π·25). Assuming that (toxic) interaction of a particle with its surroundings takes place only at the surface, this suggests that 100 particles of 1 nm have a 100 times more (toxic) interaction than 1 particle of 100 nm.

28 It should be realised that for some nanomaterials no non-nanoform exists.

fulfilled for the most relevant form for risk assessment (e.g. quantitatively most significant form[29], functionally most important form, form intended by manufacture, form of greatest potential toxicological relevance[30], etc.). As an example, consider the following: four different nanoforms share the same chemical and molecular identity with a total quantity of 200 tonnes/year, and are registered under the same registration dossier, while the volume in which each individual nanoform is manufactured is less than 100 tonnes/year. In this case, the requirements for ≥ 100 tonnes/year must be fulfilled for the most relevant form of the substance. The selection of the most relevant form has to be justified by the registrant. For the other three forms, the data requirements must be fulfilled according to requirements that apply for ≥ 10 tonnes/year.

As indicated in Section 3.5, it has been proposed to lower the tonnage that renders a chemical safety assessment (CSA) obligatory. Currently such a CSA is obligatory for substances produced/imported in a quantity of ≥ 10 tonnes/year. There is, however, a strong need to fill the current knowledge gaps on the exposure and risk assessment of nanomaterials, which are often placed on the market in low quantities. By lowering the tonnage level for an obligatory CSA to 1 tonne/year (being the tonnage of the total quantity of all nanoforms and non-nanoforms that fall under the same chemical and molecular identity), knowledge would be gained much faster.

Another potential way of speeding up the filling of knowledge gaps is to exempt nanomaterials from the extended registration deadlines. The usefulness of this option, however, strongly depends on how quickly the adaptation of the REACH Regulation will become effective. The last extended registration deadline (i.e. for substances produced/imported ≥ 1 tonne/year) is set for 1 June 2018. If adaptation of REACH is not effected before this date, exemption from extended registration deadlines is no longer a valid option, as by 1 June 2018 all substances that fall under REACH should be registered.[31] Nevertheless, to ensure that relevant information will be provided regarding e.g. the level, form and shape of exposure throughout the life cycle, additional 'nano-specific' requirements will be necessary as well (see Chapter 3).

29 Higher quantities may lead to higher exposure, but not necessarily also to higher risk.

30 Identifying the form of greatest toxicological relevance may be a challenge, as it requires insight into the toxicology beforehand. Only when all different forms have been tested (or proper read-across can be applied) can the most toxic form be identified. To some extent also, exposure pathways may become relevant in deciding on the most toxicologically relevant form of the substance. For the time being this may very well mean that all information is necessary for each different form of the substance.

31 Registration after this date is allowed only for those substances that are newly produced/imported in the EU.

Summary of building block 3: Specific tonnage levels and registration deadlines for nanomaterials within the REACH legislation

The current tonnage levels within the REACH Regulation are considered too high for nanomaterials, based on the following two main arguments.

First, there is currently a strong need to fill the data gaps that exist in relation to the hazard and risk assessment and risk management of nanomaterials. By lowering the tonnage levels and/or the information requirements related to those tonnage levels under REACH, it is expected that more data on nanomaterials will become available sooner.

Second, the production and/or import of many of the known nanomaterials is generally below 1 tonne/year. As a result, there are currently no registration obligations under REACH (unless different nanomaterials are seen as different forms of one substance).

Setting a lower trigger value needs further discussion, including discussion on what such a value should be, and what requirements will be necessary for which trigger value.

Requiring immediate registration of nanomaterials (i.e. exempting them from extended registration deadlines) will only be effective if this can be effected in legislation (far) before the final extended registration deadline of 1 June 2018.

5 Building block 4: Exposure and risk management at the workplace

Knowledge of the hazards and exposure of workers is necessary to ensure occupational health and safety when working with nanomaterials. This chapter investigates the gaps in legislation surrounding the protection of workers against the risks of nanomaterials and comes with proposals on bridging these gaps.

5.1 Existing legislation and the need for the safe use of chemicals in the workplace

The OSH[32] Framework Directive (EU, 1989) and the daughter Chemical Agents Directive (EU, 1998) set an obligation on employers to ensure safe use of chemicals as well as to establish rules for dealing with the risks in the workplace. Nanomaterials are not specifically mentioned in these directives, but implicitly included. In addition, REACH (EU, 2006) provides the legal instrument for generating the information needed on the hazards, exposure of workers and safety assessment for the majority of chemicals (including nanomaterials) and ensures communication through the supply chain.

5.1.1 OSH Framework Directive and the Chemical Agents Directive

The main objective of the OSH Framework Directive (89/391/EC) is to introduce measures for the improvement of the safety and health of workers. The responsibility for implementing these measures lies with the employer, who has a broadly defined duty of care, i.e. a duty '*to ensure the safety and health of workers in every aspect related to the work*'. The scope of this Framework Directive is very broad. Hazards or risks to be minimised are not further specified.

The Chemical Agents Directive (CAD; EU, 1998) sets minimum requirements for the protection of the health and safety of workers from the effects of hazardous chemical agents that are or may be present in the workplace, to '*ensure that the risk from a hazardous chemical agent to the safety and health of workers at work is eliminated or reduced to a minimum*'. More specifically, CAD requires employers to identify, assess and control – by eliminating if possible, or otherwise by minimising – such risks, considering thereby also the possibility of uncertain risks. This implies that nanomaterials should be considered as covered once they are considered as 'hazardous'.[33] For the definition of 'hazardous' the CAD relies on the CLP[34] Regulation (EU, 2008a) or any other reliable source, including additional information about physicochemical, chemical or toxicological properties of chemicals and the way chemicals are used or are present in the

32 Occupational Safety and Health.

33 Nanomaterials are not intrinsically hazardous. If a nanomaterial is hazardous, that nanomaterial is covered by the Chemical Agents Directive. If a nanomaterial is not hazardous, the introduction of measures for the improvement of the safety and health of workers appears unnecessary.

34 Classification, Labelling and Packaging.

workplace (like process-generated nanomaterials, PGNMs), which may present a risk.

Additionally, the CAD includes the provision for the Commission to propose Occupational Exposure Limits (OELs). Two types of OEL can be established at Community level: IOELs (indicative occupational exposure limits) and BOELs (binding occupational exposure limits). IOELs are health-based limits set under the CAD. The European Commission is advised on limits by its Scientific Committee on Occupational Exposure Limits (SCOEL). The SCOEL evaluates the scientific information publicly available on hazardous substances and makes recommendations for the establishment of an IOEL. IOELs are listed in Directives, which Member States are obliged to implement by introducing national limits for the substances (which can be higher or lower than the IOEL at EU level). For the establishment of the BOELs, apart from health-based factors, socio-economic and technical feasibility factors are taken into account. When a BOEL is established, Member States must establish a corresponding national BOEL, which can be stricter but cannot exceed the Community BOEL. So far the Commission has not proposed any OELs for nanomaterials.

CAD does not include any specific provisions for the risk evaluation or assessment of nanomaterials. As for non-nanomaterials, employers need to gather the following types of information for nanomaterials: 1) whether the nanomaterial used at their workplace is a hazardous substance; 2) whether hazardous nanomaterials are generated at the workplace; 3) the population at risk: who is exposed to which nanomaterials at the workplace, under what conditions and in what quantities; 4) whether exposure to the hazardous nanomaterials at the workplace poses a risk; and 5) which risk management measures need to be adopted to ensure safe working conditions. This information is necessary not only for employers to meet their CAD obligations but also for the Labour Inspectorate, which has to inspect, control and enforce safe working with (nano)materials, as well as for institutions involved in advice and practical support regarding occupational health care and safe workplace design. REACH is for many chemicals the main provider of such information, particularly on the hazards of chemicals. As indicated in Chapters 3 and 4, it is not yet clear to what extent REACH in its current state can (also) provide information for all possible nanomaterials to be encountered in the workplace.

It should be stressed here that for certain types of compound, e.g. biocides and pesticides, their specific legislations should be considered as the main (possible) supplier of information on hazards, rather than the REACH Regulation (EU, 2006).

REACH provides information for many chemicals in the workplace through two mechanisms. The major mechanism is registration. The registration obligation puts the responsibility for generating information on the registrant, the first actor in the supply chain. Registrants have access to the information on the intrinsic properties of the substance and the main foreseeable uses of their substance in the upper part of the chemicals' supply chain. However, the information on the existing uses downstream in the supply chain and on the real life conditions of use lies mainly with the downstream users. Downstream users can utilise upstream communication to inform the registrants and enable the registrants both to carry out their safety assessment required for the registration and to communicate realistic information on the safe use of chemicals back to their customers. The classification and labelling under the CLP Regulation (EU, 2008a) is very important in this process, as the REACH obligation for risk assessment (and particularly exposure assessment) applies only to chemicals classified as 'hazardous' by CLP.

The other REACH instrument for generating information is substance evaluation. In the event of a specific concern by national authorities, substance evaluation can be utilised to ask for data for registered substances, additional to the data required for registration. It is important to note that substance evaluation is only possible for substances that are already registered under REACH.

Through registration and substance evaluation, REACH is expected to deliver the basic information on nanomaterials that is needed by the employer to perform risk assessment and control, provided that REACH is adjusted to nanomaterials in the fashion discussed in Chapters 2 to 4. Defining nanomaterials and adjusting their information requirements and tonnage levels under REACH are therefore also of great importance for the protection of workers. Moreover, the additional importance of REACH for the protection of workers lies in its ability to remove substances of very high concern[35] from the market or otherwise regulate substances through the mechanisms of REACH restrictions or authorisation.

In article 2 of the CAD it is specifically indicated that '*any chemical agent which, whilst not meeting the criteria for classification as dangerous […], may present a risk to the safety and health of workers […]*'. This may suggest – based partly on case law – that, in cases where both REACH and other mechanisms of information generation fail to provide the necessary clarity on risks associated with nanomaterials, employers should treat nanomaterials posing uncertain risks as hazardous and try to prevent exposure (or generate/obtain data to show that the material is not hazardous). However, as general duty-of-care provisions allow scope for interpretation, under OSH legislation, it is not always possible to precisely indicate the measures that are or may be required of the employer.

5.2 Gaps in legislation

To identify gaps in the legislation, it is relevant to distinguish between two main categories of nanomaterials to which workers can be exposed: those that fall under the scope of REACH registration and those that fall outside that scope. Each of these categories is associated with different regulatory gaps, which require also different regulatory approaches.

5.2.1 Nanomaterials in the workplace falling under the scope of REACH registration

Nanomaterials which fall under the scope of REACH registration can be further grouped into those with relatively short and easily surveyed supply chains and those with long and complex supply chains.

It is stated above that defining nanomaterials and adjusting their information requirements and tonnage levels under REACH – as proposed in Chapters 2 to 4 – will contribute to the safe use of nanomaterials. This is most valid for the nanomaterials with relatively short and easily surveyed supply chains. For nanomaterials with long and complex supply chains, REACH registration – even after the proposed adjustments – will not always be able to provide the information needed to ensure safe use further down the supply chain, partly due

35 Under article 57f of REACH, certain substances that may have serious and often irreversible effects on human health and the environment can be identified as Substances of Very High Concern (SVHCs).

to the complexity of the supply chain – hampering the communication lines – but also due to the following issue.

REACH will fail to provide sufficient information on exposure of workers and safe use for nanomaterials that do fall under the scope of the REACH registration and which are not classified as dangerous[36] at the moment that they enter the market but can become dangerous due to changes in the form of the (nano)material through the supply chain. This is due to the fact that the obligation for exposure assessment within the REACH registration is applicable only to substances that are classified as dangerous at the moment they enter the market.

5.2.2 Nanomaterials in the workplace not falling under the scope of REACH registration

Adaptation of REACH will have no effect on the information available for the risk management of substances – including nanomaterials – that fall outside the scope of REACH. These are the nanomaterials that:

- are placed on the market in volumes lower than the registration threshold[37]
- fall under substances or categories listed in Annexes IV and V (i.e. substances explicitly excluded from REACH registration)
- are subject to other legislations, as indicated in Article 2 of the REACH Regulation (EU, 2006), e.g. those used in medicinal products for human or veterinary uses, that should be considered as registered under their respective legislations
- originate from materials that are neither classified as dangerous nor identified as nanomaterials at the moment that they enter the workplace
- are generated by equipment and specific combustion processes (PGNMs).

5.3 Bridging the gaps in legislation (some thoughts for discussion)

To address these gaps and to ensure that risk assessment can be conducted by employers, the following proposals have been put forward. These are proposals that either alone or in combination address the shortcomings in the current legislation, as identified above. They can be considered depending on their effectiveness, proportionality and acceptance by the actors affected.

5.3.1 Improve knowledge on nanomaterials in the workplace

This can be put into practice by adjusting REACH through the introduction of a definition, additional information requirements, and adjustment of tonnage levels for nanomaterials (see Chapters 2 to 4). However, adjustment of REACH will not affect the information generated for nanomaterials that fall outside the

36 Classified as dangerous includes both the substances that are classified under the CLP regulation, as well as the substances that, based on the hazard assessment, meet the criteria for classification in accordance with the CLP regulation or is assessed to be a PBT or vPvB.

37 Currently this threshold is 1 tonne/year, but even if tonnage levels are lowered, as discussed in Chapter 0, there will be substances placed on the market below the threshold, regardless of the exact value of that threshold, although the amount of those substances will be reduced by lowering the threshold value.

scope of REACH. In cases where this is a result of the nanomaterial falling under the scope of other legislation, such as the biocides or pesticides regulation, gaps can be bridged by adjustments to the respective legislation in a fashion analogous to those proposed for REACH (introduction of a definition and additional information requirements).

Additionally, REACH adjustments will affect only the information supply for substances that fall under the REACH registration obligation with relatively short and easily surveyed supply chains. Such adjustments will have little or no effect on the information for nanomaterials with long and complex supply chains or nanomaterials that are not classified as hazardous or that emerge in the workplace due to the processing of materials or due to specific equipment and combustion processes (PGNMs). To address the gaps for these nanomaterials, additional adjustments may be necessary within the OSH Framework and/or the CAD, which would include nanomaterials more explicitly in OSH legislation (similar to some of the proposals made for REACH). Options that have been put forward are:

- Introduction of the definition of nanomaterials in CAD
- Introduction in CAD of the provision that employers have the duty to check inventories and literature in order to identify whether substances in their processes are associated with a specific risk of nanomaterials
- Introduction in CAD of a risk inventory and evaluation (RIE) obligation specific to nanomaterials, explicitly applying the principle that where available data are insufficient, the most stringent risk management measures are applied
- Introduction of a register of workers' exposure and health surveillance (as advised by the Health Council of the Netherlands; Health Council of the Netherlands, 2012), preferably at European level. The registry of exposed workers is aimed at increasing knowledge on exposure at the workplace and improving the quality of the exposure scenarios and related risk management measures. Health surveillance will help employers to act swiftly in cases of individual medical disorders that may be overlooked during the risk assessment required by REACH. Nevertheless, additional discussion could be necessary on the pros and cons of such a measure, including issues of achievability, practicality and usefulness. The involvement of the European Commission is deemed necessary in order to conduct an EU-wide feasibility analysis and for funding the necessary studies
- Determine health-based occupational exposure limits for nanomaterials.

5.3.2 Improve practical knowledge at work floor level

Practical guidance (not necessarily formalised in legislation) on how employers should assess and control the risks in cases of inadequate or no information about the nanomaterials at their workplace could improve practical knowledge on the work floor. Such guidance is desirable to bridge the period until REACH starts delivering adequate information once the definition and additional information requirements (see Chapters 2 and 3) are incorporated in legislation. Such guidance should clearly specify the CAD obligations of employers for nanomaterials. Such guidance – preferably at EU level – should also contribute to the necessary harmonisation. Consideration should be given in such cases to pragmatic approaches based on the precautionary principle. Such approaches

may involve provisionally control banding methods and supporting risk management concepts like the nano-reference values (NRV; e.g. van Broekhuizen, 2011; SER, 2012). It should be stressed here that NRVs are pragmatic values, which are not health-based on a substance-specific level. NRVs are based on assumptions concerning the intrinsic characteristics of groups of substances sharing some common physicochemical characteristics and should be treated as second-best options and should only be used provisionally until substance-specific and entirely health-based limits are developed by the relevant actors. Relevant actors in this context are either companies – in their capacity as REACH registrants or employers within the meaning of the regulations on occupational health and safety (OHS) – or authorities and their responsible committees (notably SCOEL and RAC[38]). This proposal is aimed specifically at bridging the legislative gap on nanomaterials that do not fall under the scope of REACH. Similarly, guidance may also be needed in the case of PGNMs.

Summary of building block 4: Exposure and risk management at the workplace

Adaptation of REACH will be beneficial to worker protection as well, as REACH provides the legal instrument for generating the information needed on the hazards, exposure of workers and safety assessment for the majority of chemicals (including nanomaterials) and ensures communication through the supply chain.

Nevertheless, adaptation of REACH will still leave gaps in legislation, most notably where substances (including nanomaterials) fall outside the scope of REACH. To improve knowledge on nanomaterials on the work floor, further adaptation of existing legislation therefore appears necessary, specifically the inclusion of a definition, but also requirements for additional information (e.g. in assessing the risk of plant protection products).

In worker legislation, CAD appears the most appropriate directive for adaptation to improve the safe use of nanomaterials. First, the inclusion of a definition is needed to enable a specific adaptation of the RIE obligation for nanomaterials. Additionally, the introduction of a register of workers' exposure and health surveillance could be considered, although discussion on the pros and cons of such a registry (at EU level) appears necessary. Finally, the development of nano-specific health-based OELs by companies or authorities will also contribute to worker protection.

38 SCOEL: Scientific Committee on Occupational Exposure Limits; RAC: The Committee for Risk Assessment (RAC), which prepares the opinions of ECHA related to the risks of substances to human health and the environment in several REACH and CLP processes, i.e. on proposals for harmonised classification and labelling, on proposed restrictions, and assessment of authorisation applications.

6 Building block 5: A European register of products that contain nanomaterials

6.1 State of play

In recent years an increasing number of consumer products have become available that claim to contain nanomaterials. According to existing regulatory frameworks, like the General Product Safety Directive (EU, 2001), these consumer products have to be safe when they come to market. There are, however, particular uncertainties concerning evaluation of the possible risks of nanomaterials for human health and the environment. Apart from uncertainties in the hazard potential of these materials, one of the large uncertainties is prompted by the fact that there is limited insight into which consumer products contain nanomaterials. This has fuelled a growing interest in the establishment of a European register of products containing nanomaterials. As a result, the European Parliament has called on the Commission to evaluate the need for notification requirements for all nanomaterials, including in mixtures and products. In addition, the Council has invited the Commission to evaluate the need for the further development of a harmonised register of nanomaterials.

In certain product categories, such registration of products is already in place. For instance, for biocidal products (EU, 2012) it is mandatory to provide risk information on both the active ingredient (whether a nanomaterial or a non-nanomaterial) and the biocidal product the ingredient is used in, before the product is allowed on the market. This includes the proportion of active ingredient used in the biocidal product as well as information on treated articles. For other product categories, most notably consumer products, such European registers do not exist. This clearly hampers the transparency of (exposure) information on nanomaterials.

For industrial chemicals, SPIN (Substances in Preparations In the Nordic countries) is a database that contains 'non-confidential' information on substances from the product registers of Norway, Sweden, Finland and Denmark.[39] The database contains volumes in use for each substance in the four countries also divided into which industrial branch and which product type. The database also has a toolbox called the 'SPIN Exposure Toolbox' which makes it possible to search for a general indicative exposure of human beings and environment from different chemical uses and a tool indicating widespread use. For nanomaterials, the current use of this database is limited, as the substances are identified by CAS or EC number[40], which hampers identification of nanomaterials.

In the Communication on the Second Regulatory Review on Nanomaterials (EC, 2012), the Commission announced the launch of '*an impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight on nanomaterials through establishing a register for*

39 Available at http://www.spin2000.net.

40 CAS number: Chemical Abstracts Service registry number, an identifier for chemical substances assigned by the American Chemical Society; EC number: European Commission number, an identifier for chemical substances in the EU.

nanomaterials'. A call for tenders for such an impact assessment was issued on 23 June 2013.

However, some Member States have already decided to establish a register of nanomaterials at national level. France is the first country that has adopted a decree concerning a mandatory registration of products containing nanomaterials. The decree (2012-232, which is applicable from January 2013[41]), requires companies that manufacture, import or distribute nanomaterials in quantities of ≥ 100 g to submit to the authorities an annual declaration of quantity and use information. This decree applies to importers, producers and distributors of nanomaterials, as well as professional users and research laboratories located in France. The registration is focused on substances at the nanoscale that are intentionally manufactured and intentionally introduced into a product from which they are likely to be extracted or released under normal or reasonable conditions of use. By this registration procedure, France aims to obtain a better understanding of nanomaterials and their use, to improve traceability, to have better knowledge of the market and the volume of nanomaterials involved and to collect information on toxicology and ecotoxicology of nanomaterials (Paultre, 2013).

Denmark plans to introduce legislation that will establish a national database of products containing nanomaterials and requires producers and importers of such products to report information to the government. The draft legislation was presented to the Danish Parliament in November 2012. Denmark intends to register nanoproducts, i.e. mixtures and products that contain or release nanomaterials. The purpose of the registration in Denmark is to provide an overview of the nanoproducts that are on the Danish market, the extent of their use and the purposes they are used for. Additionally, it should provide information for knowledge building on exposure of nanomaterials and consequences for consumers and environment, and to inspire to an solution for the European Union for registration of nanoproducts (Ingerslev, 2013). However, because only producers and importers have to register consumer products containing nanomaterials, traceability of products in the supply chain is not feasible.

Belgium has expressed its intention to introduce a national register similar to the French system. An assessment of the scope of the draft legislation and an impact assessment will be conducted by a consultancy this year and the law could come into force by December 2013. What information has to be registered is still under discussion, as is the question of which products should be registered: only the products from which nanomaterials are released or all products that contain nanomaterials? The purpose of the registration in Belgium is to ensure sustainability of this innovative technology, to provide transparency and inspire confidence in the public and workers, and to ensure traceability. This would then enable the government to intervene in cases of hazards to public health, workers or the environment, as well as to acquire a better knowledge of the market, of the features of those materials and of their potential exposure risks. Finally, it could provide a knowledge database, which may be necessary for national or European regulatory evolutions later on (Piñeros Garcet, 2013).

41 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, http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=134C2358E0EE79CADA3A0691FB060B11.tpdjo11v_1?cidTexte=JORFTEXT000025377246&dateTexte=20130313.

Italy is working on a voluntary register. Italy intends to register mixtures, articles and consumer products that release nanomaterials. Information on the mixtures, articles and consumer products that contain nanomaterials is optional. The information registered will be used by the ministries involved (responsible for human health, environment, industry, etc.) and – on request and related to their field of expertise – by national institutes (responsible for human health, environmental protection and research, worker protection, etc.), and to inform the public on types and uses in periodic reports (Polci and Alessandrelli, 2013). However, because this is a voluntary register, completeness of the overview is uncertain, and enforcement is not possible.

In the Netherlands the Dutch Parliament has been asking for registration of consumer products containing nanomaterials preferably at European level. A motion on a mandatory notification of products containing nanomaterials was adopted by the Parliament (Besselink and Gesthuizen, 2009). In reaction to this motion, the National Institute for Public Health and the Environment (RIVM) was commissioned by the Ministry of Health, Welfare and Sports to collect opinions and needs of stakeholders to prepare for a the potential establishment of a European registration system. In principle, Dutch policy supports the establishment of a register, provided that this is initiated at European level.

6.2 Rationale for a nanomaterials register

As indicated above, there are particular uncertainties concerning evaluation of the possible risks of nanomaterials for human health and the environment, not least the limited insight into which consumer products contain nanomaterials. While this is partly covered by REACH, additional knowledge at the level of products is expected to give a more precise picture of the exposure and allow targeted policy interventions. Moreover, not all nanomaterials are covered by REACH, e.g. due to the current volume-based registration requirements in REACH (see Chapter 4).

In general, two main reasons are put forward in favour of a register for nanomaterials: transparency for consumers; and transparency and traceability in the supply chain (see Section 6.1). The latter could be beneficial for both industry and workers, as well as for regulators. Furthermore, an increase in transparency and traceability will increase knowledge on exposure to nanomaterials.

A register of consumer products containing nanomaterials can be seen as a helpful tool for consumers to make an informed choice. This assumes that nanomaterials – as distinct from other chemicals – are of specific interest to consumers.

Additionally, an overview of products containing nanomaterials could be used to improve traceability in the supply chain and may lead to better control in cases of incidents and risks.[42] What information needs to be registered for this purpose needs further discussion. It has to be noted that for traceability in the supply

42 Recently, the Swiss Federal Office for the Environment assessed whether specific approaches are needed for nanomaterials to prevent major accidents (Krug et al., 2013). It concluded that at present, insufficient fundamental data are available to draw ultimate conclusions on this question. However, currently no immediate regulations to be included in the Ordinance on Protection against Major Accidents appear necessary where nanomaterials are concerned. Part of this conclusion, however, appears to be based on the low production and processing volumes of nanomaterials in Switzerland.

chain, detailed information on all products containing nanomaterials is necessary, while for transparency for consumers a limited amount of information on consumer products may be sufficient, e.g. on whether or not the product contains nanomaterials and whether (additional) hazard labelling is necessary (see also Chapter 7).

Clear central management and the establishment of such a product register at European level are seen by the Netherlands as essential for an effective register that is able to deliver better knowledge of exposure and market overview, transparency and traceability. National product registers would result in overlaps with EU legislation and in non-harmonised obligations and regulations in individual EU member states. This in turn could lead to increased costs for authorities and for enterprises who need to register their products.

When a European register is being set up, specific attention should be paid to avoid duplicate obligations. European substance-related regulations such as REACH (EU, 2006) and CLP (EU, 2008a), as well as product-related regulations such as Cosmetics (EU, 2009), Novel Food (EU, 1997) and the Food Improvement Agent Package (FIAP)[43] should be taken into account as bases for a European product register, since both substance and product regulations contain appropriate points of departure (e.g. registration and notification requirements).

Apart from the benefits of setting up and maintaining a register of products containing nanomaterials, certain drawbacks can be identified as well. Such a register may very well be interpreted by the general public as an indication that all nanomaterials are hazardous substances, despite there being no toxicological or ecotoxicological data to support this[44], and thus creating unnecessary fear. Depending on the information that is made publicly available, a register may to a greater or lesser extent influence the competitiveness of producers of such products. Finally, setting up such a register, and especially maintaining it, may become a huge challenge that demands many resources. Among the main questions to be answered are those that relate to

- the information that the register should provide

  This relates to the (type of) products that should be registered, and what kind of product information should be included, also taking into account the information that is (or will become) available, e.g. in REACH where product type and use is required already. Additional information on the level of trade names may be beneficial.

- responsibility for setting up and maintaining the register

  Assuming that information is mainly provided by industry, industry may also be the obvious body to set up and maintain the register. However, to ensure accessibility, governmental bodies or a newly formed independent body may be better suited.

- responsibility for filling the register (including reliability of the content)

  In case required information is available in the supply chain, delivering this information should be relatively easy for industry.

43 The Food Improvement Agent Package (FIAP) is a set of four EU Regulations on the use of additives, enzymes and flavourings in food (EU, 2008b, c, d, e).

44 The Scientific Committee for Emerging and Newly Identified Health Risks (SCENIHR) stated that not all nanoforms have been found to induce a more pronounced hazard than the non-nanoform of the same substance (SCENIHR, 2009).

- responsibility for checking the (reliability of) contents of the register

  This obviously also relates to availability of data.

- benefits of the system

  This is clearly related to the aim of the register (e.g. traceability, transparency). It should also distinguish between the different groups of beneficiaries: who will profit (most), national governments, EU, industry, NGOs, consumers, workers, etc.?

Answering these questions clearly asks for a thorough cost-benefit analysis before setting up the ultimate system. Also the responsibilities and contributions of the different stakeholders (national governments, EU, industry, NGOs, consumers, workers) should be clearly defined. The impact assessment that is foreseen by the EU should provide further insight into these issues.

6.3 Alternative options to a nanomaterials register

As indicated above, transparency for consumers as well as transparency and traceability in the supply chain are the two main reasons for setting up a register of nanomaterials. Furthermore, an increase in transparency and traceability will increase knowledge on exposure to nanomaterials. Apart from a register, however, other ways of achieving these goals may be available. Some of these are discussed below.

6.3.1 Transparency to consumers

As an alternative to a mandatory register for consumer products containing nanomaterials, indicating (nanomaterial) ingredients on products may be considered. This may better fit the needs of consumers, as information on the product itself is a more straightforward system and consumers are more familiar with it than with consulting a register. It should be realised, though, that transparency is increased only if the requirements for identification and labelling of nanomaterials are straightforward. In cases of complicated regulation (e.g. differences between different regulatory frameworks), there is a chance that the confidence of the consumers in the system (and authorities) may fail. Issues of labelling are further discussed in Chapter 7.

6.3.2 Traceability in the supply chain

Rather than by a mandatory register of products containing nanomaterials in general, traceability in the supply chain could be increased by registration of necessary information by industry. Industry indicates that all necessary information is already available in the supply chain and merely needs (re)organising. The feasibility of this option needs further investigation as some doubts were expressed about the overview of trading products, for example. To ensure feasibility of the system, the European Commission should set up a framework that relies on the timely delivery of information by industry in the event of incidents. Consensus between supplier (industry parties) and receiver (government, workers and their representatives, and ultimately consumers) about the information needed should be achieved at a detailed level in order to ensure traceability when necessary.

6.3.3 Increasing knowledge on exposure

Regardless of the chosen option for gathering the data, a clear overview of nanomaterials in products will result in an increase in information on (potential) exposure becoming available, in addition to the information required under other legislations, e.g. REACH. In addition, REACH may need adaptation to improve information availability. One of the options to adapt REACH could be to apply nano-specific information requirements to lower tonnage levels in the case of nanomaterials (see Chapter 4). This will generate more information on the exposure of nanomaterials, including potential risks and risk management measures at the level of product categories.

Summary of building block 5: A European register for products that contain nanomaterials

There is a need for information on nanomaterials in consumer products to increase transparency for stakeholders and traceability throughout the supply chain.

The details of what type of data are needed (e.g. do we need detailed information on each brand name, or is information on the product type sufficient?) is, however, not yet clear.

Apart from a separate register at EU level of products that contain nanomaterials, alternative options may be considered to obtain the necessary data.

An impact assessment on the different options to increase transparency for consumers and traceability throughout the supply chain appears therefore necessary before deciding on the best way forward. A call for tenders for such an impact assessment was issued on 23 June 2013.

7 Building block 6: Labelling of products that contain nanomaterials

7.1 State of play

There is an ongoing discussion about labelling of products containing nanomaterials. As with a register (see Chapter 6), labelling may very well be misinterpreted by the general public as an indication that all nanomaterials are hazardous substances. Indeed, this may be even more true of labelling, as people, particularly professionals, may associate labelling primarily with the CLP Regulation[45] (EU, 2008a) in which labelling is mandatory to indicate hazard classification.

On the other hand, several product legislations are already in place that require the indication of ingredients on packaging, including nanomaterials. The latest versions of the EU Cosmetics Regulation (EU, 2009) and the EU Food Improvement Agent Package (FIAP)[46] require labelling of products containing nanomaterials (name of the ingredient, followed by 'nano' in brackets) (EU, 2011e). In these legislations the labelling requirement is included to ensure that consumers can make an informed choice on the products they use.

7.2 Consumer products

For a proper informed choice, the requirements for identification and labelling of nanomaterials need to be straightforward. In cases of complicated regulation (e.g. differences between different regulatory frameworks), it is likely that the confidence of the consumers in the system (and authorities) will fail, potentially prohibiting an informed choice through conflicting information. Obviously, when a non-nanoform of a substance does not exist (i.e. the substance is always produced as a nanomaterial), adding a 'nano' label is of limited value.

7.3 Hazard classification and labelling

Currently, the CLP Regulation (EU, 2008a) requires labelling only of classified substances, i.e. those substances that are classified as hazardous. No specific requirements are indicated for nanomaterials, but the overall provisions taking account of the intrinsic properties of the substance obviously still apply.

In Article 9(5) the Regulation states that '*when evaluating the available information for the purposes of classification, the manufacturers, importers and downstream users shall consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used.*' The hazard classification should be based on available data on the intrinsic properties that relate to the forms or physical state in which the substance or mixture is placed on the market and in which it can reasonably

45 CLP: Classification, Labelling and Packaging.

46 The Food Improvement Agent Package (FIAP) is a set of four EU Regulations on the use of additives, enzymes and flavourings in food (EU, 2008b, c, d, e).

expected to be used (Article 5(1), 6(1) and 8(6)). Industry is expected to make use of relevant available information (e.g. under REACH) and conduct additional testing where required for physicochemical properties (Article 8(1–2)).

According to the guidance on classification[47], putative forms may comprise properties such as crystal structure, particle size, homogeneity (e.g. emulsion) and texture (e.g. viscosity, tablet form). Examples of physical state factors are agglomeration state, surface treatment, moisture content, residual solvent, activation, and stabilisation. Any tested substance should be representative of the substance or mixture as it is placed on the market. Therefore, if the form or physical state of a substance is changed during the manufacturing, it has to be evaluated whether that affects the classification. For nanomaterials an additional issue may be that nanomaterials may change in properties after they enter the market, raising questions on whether this happens under circumstances that can reasonably be expected during use and at what point in the life cycle it should be determined whether a nanomaterial is present in a product.

7.4 Products for professional use

Specific labelling of products containing nanomaterials is not required on the basis of the OHS Directive 92/58/EEC (EU, 1992), except when the nanomaterials involved pose a known risk that fulfils the criteria for classification as hazardous under Regulation 1272/2008 (see Section 7.3). In order to help the employer to fulfil his duty of care, adequate labelling, indicating that substances contain nanomaterials, would be advised (see Chapter 5).

In the United States such labelling is already in place. Employers are required to label all hazardous chemicals in the workplace (OSHA Hazard Communication Standard, 29 CFR 1910.1200[48]) as part of exposure control (NIOSH, 2012). Nanomaterials should be stored in labelled containers that indicate their chemical content and form. Liquids or dry particles should always be stored in unbreakable, tightly sealed containers. Secondary containment should be used when appropriate. Appropriate signage indicating the hazard, personal protection equipment requirements, and any other pertinent information should be posted at entry points to areas where hazardous compounds are handled or stored.

47 http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation.

48 http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10099.

Summary of building block 6: Labelling of products that contain nanomaterials

Because of the consumer's right to know, labelling should apply to all consumer products with nanomaterials that meet the EU definition of a nanomaterial. Such labels will inform consumers of the presence of nanomaterials.

Currently, legislation already exists (e.g. the Biocides Regulation) that includes a mandatory labelling of products that contain nanomaterials by indicating 'nano' in brackets after the name of the ingredient. As nanomaterials are not intrinsically hazardous, indicating nanomaterial ingredients as 'nano' on the label will provide no information on the risk of being exposed to them, and thus only focuses on the presence of the nanomaterial in the product.

The CLP regulation appears better suited to providing the hazard information, although for nanomaterials it may be necessary to decide on the moment in the life cycle that determines whether a nanomaterial is present in a product. In addition, hazard information on the nanomaterial should be available, as the CLP regulation does not demand information generation for hazard classification of any chemical substance.

In contrast, indicating nanomaterial ingredients as such on the label may very well be a suitable way to provide consumers with the necessary information to make an informed choice on the products they use. In addition, labelling may help in the traceability of nanomaterials in the supply chain. Nevertheless, it may still be seen by the general public as an indication that nanomaterials are hazardous and additional information may be necessary to avoid this.

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National Institute for Public Health and the Environment
P.O. Box 1 | 3720 BA Bilthoven
www.rivm.com