# Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market



## Options Assessment Report - Second Draft

prepared for

**DG Enterprise and Industry**

August 2014

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| Quality Assurance | |
|---|---|
| **Project reference / title** | J835 / Nano Registry |
| **Report status** | Options Assessment Report - Second Draft |
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| **Approved for issue by** | Pete Floyd |
| **Date of issue** | 4 August 2014 |

| Document Change Record | | | |
|---|---|---|---|
| **Report** | **Version** | **Date** | **Change details** |
| Options Assessment | 1.0 | 11/06/2014 | |
| Options Assessment | 2.0 | 04/08/2014 | Refinement of Options |

## Disclaimer

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*Recommended citation: RPA et al (2014): Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market, Options Assessment Report – Second Draft, for DG Enterprise and Industry, August 2014, Loddon, Norfolk, UK*

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# List of Abbreviations

| | |
|---|---|
| **BNS** | Belgian Notification System |
| **CLP** | Regulation on Classification, Labelling and Packaging (of Chemicals) |
| **DNS** | Danish Notification System |
| **ECHA** | European Chemicals Agency |
| **EU** | European Union |
| **FNS** | French Notification System |
| **IA** | Impact assessment |
| **JRC** | European Commission's Joint Research Centre |
| **MNM** | Manufactured Nanomaterial |
| **REACH** | Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals |
| **SME** | Small or Medium Enterprise |

# 1 Introduction

## 1.1 Overview of Study

The overall aim of this study is to provide support to the European Commission in the preparation of an impact assessment to identify and develop the most adequate way to increase transparency and to ensure regulatory oversight for nanomaterials. The contractor is expected to:

- Gather relevant information on the experience from other nanomaterials register-like schemes;
- Provide information on health and safety, markets and research trends of nanomaterials for the better definition of the policy options to be assessed; and
- Support the impact assessment of the policy options.

The technical specifications set out a detailed framework for the study and identified five different tasks, namely:

- Task 1: Lessons learned from other schemes;
- Task 2: Background information for building blocks of policy options;
- Task 3: Organise and carry out public consultations;
- Task 4: Support for the option assessment; and
- Task 5: Validation workshop.

This Options Assessment Report documents the findings of Task 4, namely to identify the key issues which will need to be accounted for under each of the options being considered by the European Commission before a full impact assessment can be prepared. It is important to emphasise that this report is intended to inform future policy development and analysis by the European Commission and is not intended to represent a definitive position of the Commission.

## 1.2 Structure of Report

This report has been structured to reflect the approach recommended by the European Commission in its *Impact Assessment Guidelines*[1]. The Guidelines specify the following steps for an impact assessment:

- Step 1: Identification of existing problems and objectives of policy intervention;
- Step 2: Defining the policy options;
- Step 3: Identification of impacts that are relevant and key stakeholders that might be affected;
- Step 4: Initial assessment of the importance of these impacts based on their expected magnitude and on the likelihood of them occurring;
- Step 5: In-depth analysis of the most significant impacts;
- Step 6: Comparison of the policy options; and
- Step 7: Identification of the preferred policy option.

[1] European Commission (2009): **Impact Assessment Guidelines**, dated 15 January 2009 SEC(2009) 92

As such, Section 2 of this report covers the first two steps in the development of the options while Section 3 provides an introduction to the likely impacts of interest (Steps 3 and 4).

Section 4 provides more detail on the options taken forward for further analysis since the scale of certain impacts will depend on the exact nature of the options being considered. Section 5 provides a more detailed analysis of the possible impacts by option (Step 5). The final Steps 6 and 7 are beyond the scope of this study.

# 2 Development of Options

## 2.1 Step 1: Identification of existing problems and objectives of policy intervention

### 2.1.1 Issues at Stake

There appears to be a widespread (but not universal) view that available information on nanomaterials is insufficient for informed decision-making. This was reflected in the call by the European Parliament[2] in 2009 for the European Commission to compile:

> *"an inventory of the different types and uses of nanomaterials on the European market, while respecting justified commercial secrets such as recipes, and to make this inventory publicly available"*.

Since then, several Member States (most notably France) have launched initiatives for national registries for nanomaterials. Furthermore, Austria, Belgium, the Czech Republic, Denmark, France, Italy, Luxemburg, the Netherlands, Spain, Sweden and Croatia have asked the Commission[3] to *"propose legislation on registration or market surveillance of nanomaterials or products containing nanomaterials"*. Various stakeholders and non-governmental organisations have also called for a registry for nanomaterials.

### 2.1.2 Objectives

As set out in the Commission's Working Document, the objectives of the policy intervention may be defined from various perspectives as set out in Table 2-1.

**Table 2-1: Objectives of the Policy Intervention**

| General policy objectives | Specific policy objectives | Operational policy objectives |
|---|---|---|
| Ensure the protection of human health and the environment & ensure consumer protection related to nanomaterials on the market | Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials<br><br>Provide consumers with relevant information on products containing nanomaterials on the market | Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market |
| Ensure a proper functioning of the internal market and a level playing field for businesses marketing nanomaterials | Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs). | Ensure the proportionality of the information requirements and the associated costs and administrative burden.<br><br>Protect confidential business information |

[2] European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI))

[3] See the **Commission's Working Document**: *Draft of the First Chapters of the Impact Assessment* Report (as prepared for the Public Consultation and dated 7 May 2014) http://ec.europa.eu/DocsRoom/documents/5282/attachments/1/translations/en/renditions/native

## 2.2 Step 2: Defining the Policy Options

### 2.2.1 Summary

As set out in the Commission's Working Document and in the Public Consultation[4], the policy options to be considered are:

0. Baseline scenario
1. Recommendation on how to implement a "best practice model" for Member States wishing to establish a national system *(soft law approach)*
2. Structured approach to collect information *("Nanomaterials Observatory")*
3. Regulation creating an EU nanomaterial registry with one annual registration per substance for each manufacturer/importer/downstream user/distributor
4. Regulation creating an EU nanomaterial registry with one annual registration per use (including substances, mixtures and articles with intended release)

These are outlined in a little more detail below.

### 2.2.2 Baseline (Option 0)

The baseline scenario (Option 0) represents the 'status quo'. As such, this would include the current registration requirements for nanomaterials in cosmetics and in products on the French market. In the coming months, there could be further requirements for registering nanomaterials in Belgium and Denmark. The implications of this change in the baseline will need to be considered in the detailed analysis which follows.

### 2.2.3 Option 1: Best Practice Model

The Commission could identify[5] an existing or planned model, possibly with a number of modifications, as good practice model, and recommend it for implementation at national level. This option would promote the establishment of national notification systems with harmonised requirements across Member States. At the same time, it would leave Member States the leeway to opt out and/or take their own national approaches.

### 2.2.4 Option 2: Nanomaterials Observatory

This option would involve the establishment of a Nanomaterials Observatory[6] collecting relevant information on nanomaterials on the market and presenting it in a clear and user-friendly way to the public online. The existing JRC web platform[7] which provides general information on nanomaterials and useful links to other sources could be used as a basis for this initiative.

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[4] The Public Consultation on *transparency measures for nanomaterials on the market* was held from 13 May to 5 August 2014, via http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/public-consultation_en.htm

[5] At the time of writing (July 2014), the Commission has not identified such a model – since the evaluation work on existing/proposed schemes is ongoing.

[6] It is unfortunate that the findings from the earlier ObservatoryNANO FP7 project (2008-12) which was intended to establish a permanent European Observatory on Nanotechnologies are no longer readily accessible (see http://www.observatorynano.eu/)

[7] http://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials

It is worth noting that JRC is also involved with the major European NANoREG project[8] which is intended to provide regulators and legislators with additional scientifically based information to assist decision-makers.

### 2.2.5 Option 3: EU Nanomaterial Registry by Substance

Under this option, manufacturers and importers would be required to submit relevant substance identity information in line with REACH registration dossiers for any substance at nanoscale with an annual production volume of at least 100 grams (per manufacturer/importer). In addition, for each nanomaterial substance, an annual declaration of the total quantity of the substance per annum and the uses of the substance (including all professional users a substance was sold to) should be submitted by manufacturers and importers of such substance, producers and importers of mixtures containing such substance at nanoscale, producers and importers of articles with intended release of nanomaterials, as well as distributers selling such products to professional users.

Clearly, there is a wide range of possible sub-options depending on the nature of information requirements and on the potential range of derogations for particular types of substances and/or uses.

### 2.2.6 Option 4: EU Nanomaterial Registry by Application

This option is identical to Option 3, except that the annual registration is not made per manufacturer/importer/downstream user/distributor but per use of the substance (on its own, or in a mixture or article). This would require downstream users to submit a new declaration for each new nanomaterial-containing mixture or article that they put on the market. This would allow for full traceability of a nanomaterial across the supply chain. Of course, to be effective, this would require downstream users to be aware of the presence of nanomaterials in their products.

As for Option 3, there is a wide range of possible sub-options depending on the nature of information requirements and on the potential range of derogations for particular types of substances and/or uses.



[8] The NANoREG FP7 project has budget of nearly €50m and involves 59 partners (authorities, industry, and academia) in 15 European countries,

# 3 Screening of Impacts

## 3.1 Step 3: Identification of Impacts

The first stage of analysing the potential impacts of a policy intervention is to identify the types of impact (by inspection) which might be relevant within the broad areas of economic, social and environmental impacts using the categories set out in the Commission's *Impact Assessment Guidelines*. The results are shown in Table 3-1.

**Table 3-1: Initial screening of the relevance of impacts of some form of nanoregistry**

| Impact type | Relevant? |
|---|---|
| ***Economic Impacts*** | |
| **Functioning of the internal market and competition** | **Potentially relevant** |
| **Competitiveness, trade and investment flows** | **Potentially relevant** |
| **Operating costs and conduct of business/SMEs** | **Potentially relevant** |
| **Administrative burdens on businesses** | **Potentially relevant** |
| **Public authorities** | **Potentially relevant** |
| Property rights | Not relevant |
| **Innovation and research** | **Potentially relevant** |
| **Consumers and households** | **Potentially relevant** |
| **Specific regions and sectors** | **Potentially relevant** |
| **Third countries and international relations** | **Potentially relevant** |
| **Macroeconomic environment** | **Potentially relevant** |
| ***Social Impacts*** | |
| **Employment and labour markets** | **Potentially relevant** |
| Standards and rights related to job quality | Not relevant |
| Social inclusion and protection of particular groups | Not relevant |
| Gender equality, equality treatment and opportunities, non-discrimination | Not relevant |
| Individuals, private and family life, personal data | Not relevant |
| **Governance, participation, good administration, access to justice, media and ethics** | **Potentially relevant** |
| **Public health and safety** | **Potentially relevant** |
| Crime, terrorism and security | Not relevant |
| Access to and effects on social protection, health and educational systems | Not relevant |
| Culture | Not relevant |
| Social impacts in third countries | Not relevant |
| ***Environmental Impacts*** | |
| The climate | Not relevant |
| Transport and the use of energy | Not relevant |
| Air quality | Not relevant |
| Biodiversity, flora, fauna and landscapes | Not relevant |
| Water quality and resources | Not relevant |
| Soil quality or resources | Not relevant |
| Land use | Not relevant |
| Renewable or non-renewable resources | Not relevant |
| **The environmental consequences of firms and consumers** | **Potentially relevant** |
| Waste production/generation/recycling | Not relevant |
| **The likelihood or scale of environmental risks** | **Potentially relevant** |
| Animal welfare | Not relevant |
| International environmental impacts | Not relevant |

By inspection of Table 3-1, it can be seen that economic impacts are likely to be of most interest not only in terms of direct costs to industry but also in respect of the broader impacts on innovation and research and, potentially, international trade.

In relation to environmental impacts, it is important to stress that assigning 'not relevant' to, for example, 'water quality and resources' is not intended to suggest that the use of nanomaterials has no impact on this environmental compartment. Rather, it intended to reflect that it will be very difficult to differentiate levels of impact associated with moving from the current baseline to one of the policy options being proposed. With this in mind, the impacts to different compartments will be considered collectively within the 'environmental risks' category.

## 3.2 Step 4: Initial Assessment of Impacts

### 3.2.1 Introduction

Within the Commission's *Impact Assessment Guidelines*, there is a further set of questions to be considered for each of the categories listed in Table 3-1. These questions provide the framework to differentiate the scale of the impacts of each option with respect to the baseline. Of course, in some cases, not all questions are relevant for all options.

A preliminary review of a sample question from each of the areas of impact against each of the options is presented below.

### 3.2.2 Economic Impact - Example

Taking the category 'Operating costs and conduct of business/SMEs' as an example, Table 3-2 highlights the relevance/impact of each question for each option.

**Table 3-2: Further consideration of 'operating costs and conduct of business/SMEs'**

| Question | Option | | | |
|---|---|---|---|---|
| | 1 | 2 | 3 | 4 |
| Will it impose additional adjustment, compliance or transaction costs on businesses? | Yes | No | Yes | Yes |
| How does the option affect the cost or availability of essential inputs (raw materials, machinery, labour, energy, etc.)? | n/a | | | |
| Does it affect access to finance? | n/a | | | |
| Does it impact on the investment cycle? | Possibly | No | Possibly | Possibly |
| Will it entail the withdrawal of certain products from the market? Is the marketing of products limited or prohibited? | Possibly | No | Possibly | Possibly |
| Will it entail stricter regulation of the conduct of a particular business? | Yes | No | Yes | Yes |
| Will it lead to new or the closing down of businesses? | Possibly | No | Possibly | Possibly |
| Are some products or businesses treated differently from others in a comparable situation? | n/a | | | |

### 3.2.3 Social Impact - Example

Taking the category 'Governance, participation, good administration, access to justice, media and ethics' as an example, Table 3-3 highlights the relevance/impact of each question for each option.

| Table 3-3: Further consideration of 'governance, participation, good administration, access to justice, media and ethics' | | | | |
|---|---|---|---|---|
| | Option | | | |
| Question | 1 | 2 | 3 | 4 |
| Does the option affect the involvement of stakeholders in issues of governance as provided for in the Treaty and the new governance approach? | n/a | | | |
| Are all actors and stakeholders treated on an equal footing, with due respect for their diversity? Does the option impact on cultural and linguistic diversity? | n/a | | | |
| Does it affect the autonomy of the social partners in the areas for which they are competent? Does it, for example, affect the right of collective bargaining at any level or the right to take collective action? | n/a | | | |
| Does the implementation of the proposed measures affect public institutions and administrations, for example in regard to their responsibilities? | Possibly | No | Yes | Yes |
| Will the option affect the individual's rights and relations with the public administration? | Possibly | No | Possibly | Possibly |
| Does it affect the individual's access to justice? | n/a | | | |
| Does it foresee the right to an effective remedy before a tribunal? | n/a | | | |
| Does the option make the public better informed about a particular issue? Does it affect the public's access to information? | Yes | Yes | Yes | Yes |
| Does the option affect political parties or civic organisations? | n/a | | | |
| Does the option affect the media, media pluralism and freedom of expression? | n/a | | | |
| Does the option raise (bio) ethical issues (cloning, use of human body or its parts for financial gain, genetic research/testing, use of genetic information)? | Yes | Yes | Yes | Yes |
| | (*depending on perspective*) | | | |

### 3.2.4 Environmental Impact - Example

Taking the category 'The environmental consequences of firms and consumers' as an example, Table 3-4 highlights the relevance/impact of each question for each option.

| Table 3-4: Further consideration of 'the environmental consequences of firms and consumers' | | | | |
|---|---|---|---|---|
| | Option | | | |
| Question | 1 | 2 | 3 | 4 |
| Does the option lead to more sustainable production and consumption? | n/a | | | |
| Does the option change the relative prices of environmental friendly and unfriendly products? | Possibly | No | Possibly | Possibly |
| Does the option promote or restrict environmentally un/friendly goods and services through changes in the rules on capital investments, loans, insurance services etc? | n/a | | | |
| Will it lead to businesses becoming more or less polluting through changes in the way in which they operate? | Possibly | No | Possibly | Possibly |

### 3.2.5 Commentary

For the next draft of this report, similar consideration will be given to the detailed questions which are to be applied to the other impact categories identified in Table 3-1. However, even on the basis of the three examples presented above, it can be seen that the option with the lowest impact (in

terms of both costs and benefits) appears to be Option 2 – the creation of a Nanomaterials Observatory.

As might be expected, the impacts are likely to be most significant for the mandatory EU-wide nano-registry (as represented by Options 3 and 4). It is interesting to note that, at this qualitative stage of the analysis, it is not possible to differentiate between Options 3 and 4. In other words, the nature of the impacts will be similar but the scale may be different. The extent of such differences will only emerge after the more detailed analysis (see Section 5) but this, in turn, will depend on the precise nature of the options being considered as presented in Section 4.

# 4 Refinement of Options

## 4.1 Introduction

In order to undertake a more detailed analysis of the impacts of the options with respect to the baseline, it is necessary to have clarity over four key factors for each option:

- nanomaterials covered;
- products covered;
- organisations covered; and
- information requirements.

Of course, in relation to the nanomaterials being considered in this study, particular attention must be given to the recommended EC definition[9]:

> *'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.*

Further detail on these aspects is provided below.

## 4.2 Baseline (Option 0)

### 4.2.1 Overview

The baseline scenario (Option 0) represents the 'status quo'. As set out in the Commission's Working Document, "*most manufactured nanomaterials are substances in the sense of Regulations 1907/2006 ('REACH Regulation') and 1272/2008 ('CLP Regulation'). Therefore, the requirements of these Regulations apply to those nanomaterials.*"

Moreover, "*a revision of the Annexes to REACH is currently on-going to ensure clarity on the information requirements for registration dossiers covering nanomaterial forms of substances. The EU legislation on worker protection also applies to nanomaterials. This includes the Framework Directive 89/391/EEC, the Chemical Agent Directive 98/24/EC and the Carcinogen and Mutagen Directive 2004/37/EC, requiring employers to assess and manage the risks of nanomaterials at work. Furthermore, product-specific legislation applies to nanomaterials*" (e.g. Cosmetics Regulation, Biocidal Product Regulation, Food Additives Regulation).

"*Some Member States have established or proposed registries for nanomaterials and/or products containing nanomaterials on the market. France has introduced a notification system for substances in nano-form, including such substances in mixtures and in articles if intentionally released. Belgium and Denmark have notified the Commission regarding proposals for registries for nanomaterials, including mixtures and articles containing nano-substances.*"

For the purposes of the more detailed analysis and in order to highlight the positive and/or negative impacts of the transparency measures, consideration will be given to two sub-options:

[9] Commission Recommendation 2011/696/EU on the Definition of Nanomaterial

- Option 0A "No registries" – the chemicals legislative framework plus the product-specific legislation with specific provisions for nanomaterials;
- Option 0B "French, Belgian and Danish registries" – as above plus the French, Belgian and Danish transparency measures.

### 4.2.2 Nanomaterials Covered

***Option 0A "No registries"***

The REACH and the CLP Regulations apply to nanomaterials. Their requirements include:

- *"Registration of "a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year" by the manufacturer or importer (REACH Article 6).*
- *Registration and notification of substances in articles if "the substance is present in those articles in quantities totalling over one tonne per producer or importer per year" and either if "the substance is intended to be released under normal or reasonably foreseeable conditions of use" or if the substance is considered of very high concern (Annex XIV) and "present in the article above a concentration of 0.1% w/w" (REACH Article 7).*
- *These registration requirements do not apply to certain exempted product groups, such as medicinal products, food and feedstuff (REACH Article 1(5)), nor to substances included in REACH Annexes IV and V.*
- *Provision of safety data sheets for any substance considered hazardous or dangerous or meeting certain other criteria (REACH Article 31).*
- *Hazard classification of substances and mixtures, taking into account "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" (CLP Article 9), as well as appropriate labelling and packaging, ensuring the communication of these hazards to downstream users.*
- *Notification of hazardous substances (independently of tonnage) to the European Chemicals Agency."*[10]

Substances (and nanomaterials) which are imported or manufactured below the 1 tonne per year threshold are not subject to REACH registration (although their use would still be subject to the requirements of other regulations relating to worker protection and product safety). However if a substance is registered under the conventional form, it is subject to registration of the combined tonnage (conventional and nanoform), as well as to the deadlines applicable to the conventional substance.

A Commission study looking at the registration under REACH of MNMs up to 1 December 2012 found the identification of dossiers that included MNMs to be very challenging[11]. Since the publication of this document, limitations in the version of the REACH registration software available at the time of the initial registration phase have been addressed, and a definition of MNMs has been published. ECHA also updated its guidance on substance identification, information requirements and chemical safety assessment for REACH registration, in order for this guidance to adequately address substances in the nanoform. Moreover, the Commission is currently discussing potential amendments to the REACH Annexes in order to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers.

[10] See the **Commission's Working Document**: *Draft of the First Chapters of the Impact Assessment* Report (as prepared for the Public Consultation and dated 7 May 2014) http://ec.europa.eu/DocsRoom/documents/5282/attachments/1/translations/en/renditions/native

[11] JRC (2012): Scientific technical support on assessment of nanomaterials in REACH registration dossiers and adequacy of available information, NANO SUPPORT Project, European Commission Joint Research Centre Institute for Health and Consumer Protection, Final Report, March 2012.

For the purpose of this assessment, it is assumed that once the REACH Annexes have been amended, manufacturers and importers of nanomaterials will provide better and more comprehensive information on the nanoforms of the registered substances.

**It should be noted that if a substance is manufactured/imported in quantities of more than 1 tonne per year and a nanoform of that substance is manufactured/imported in quantities below 1 tonne per year, then the substance registration dossier will have to present information on the nanoform too. However, if a nanomaterial is manufactured/imported in quantities of less than 1 tonne per year and the nanoform is the only form of the substance that is put on the market[12], than manufacturers/importers do not have to register the substance. Nevertheless, a nanomaterial manufactured/imported in quantities less than 1 tonne per year that is put on the market and meets the criteria for classification as hazardous[13] needs to be notified to the Classification and Labelling Inventory.**

On the basis of the results of the assessment of the FNS,[14] around 250 different nanomaterials have been identified as manufactured/imported in the French market in 2012. Around 160 substances (60%) have already a REACH Registration dossier, with other 80 substances likely to be registered before the 2018 REACH deadline. This implies that between 60 to 90%[15] of the substances notified to the FNS would be covered by the REACH Regulation, with the high end being the most probable.

Ten to forty per cent of the substances notified to the FNS are thus outside the scope of REACH: when considering the low end, 10% of the substances notified to the FNS are polymers, naturally occurring substances, substances exclusively used in medicinal products for human or veterinary use and in food or feedingstuffs (Article 2(5)(a)(b)) or substances exclusively used for research and development purposes; when considering the high end, the additional 30% of the substances notified to the FNS and not found in the ECHA database might be manufactured/imported in quantities below 1 tonne per year and, thus, not subject to the registration requirement. However, as noted above, even if these low production volume substances are not covered by REACH, substances at the nanoscale that meets the criteria for classification as hazardous should anyway be notified to the Classification and Labelling Inventory.

When extrapolating the number of nanomaterials notified in France to the European level, it should be noted that during the first year of implementation, the French authorities received around 3,400 notifications. During the 2014 notification process, the French authorities received almost three times (over 10,000) the number of notifications received in 2013, many of which coming from the plant protection products and biocides sector. It is likely that most of these new notifications came from actors within the supply chains of the nanomaterials already notified that became aware of their notification duties, with just a small proportion referring to new nanomaterials.

With all this in mind, for the purpose of this study a range of 300 to 900 nanomaterials is considered on the European market. This range should ensure the coverage of any additional substance at the nanoscale notified to the FNS and of any other nanomaterial researched and/or put on the European market but not present on the French market.

[12] Or there are several nanoforms of the substance but the sum of their quantities does not reach the REACH threshold quantity of 1 tonne.

[13] It should be noted that any nanomaterial that is insoluble or poorly soluble should be regarded as hazardous, as it could be inhaled and induce irritation of the respiratory system.

[14] RPA et al (2014): Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market, Evaluation Report for DG Enterprise and Industry, August 2014, Loddon, Norfolk, UK

[15] 160 + 80 = 240 on 260 substances

Under Option 0A, the synergy between the REACH and the CLP Regulations would suggest **between 180 and 270 nanomaterials[16] if considering a total number of 300 nanomaterials on the EU market and between 540 and 810 nanomaterials**[17] when considering the upper estimate of a total of 900 nanomaterials on the European market.

***Option 0B "French, Belgian and Danish registries"***

Under the French, the Belgian and the Danish notification systems, a nanomaterial is defined in a similar way as the EC definition, but only manufactured NMs are covered.

Around 250 nanomaterials have been notified to the French authorities as on the French market in 2012. It is likely that some additional nanomaterial have been notified in the second year of the implementation of the system, taking the number of nanomaterials on the French market between 300 and 500. Due to the size of the Belgian and Danish markets and all the exemptions that apply to their schemes, it is unlikely that a significant number of nanomaterials is present in those countries and not on the French market.

As 180 substances of the 250 identified have already a registration dossier, the notification systems **identified/would identify an additional number of nanomaterials ranging from 80 to 320**. The high end (500) for the number of nanomaterials on the market is considered because of the high number of notifications received in 2013 (over 10,000): although it is likely the most of them came from actors within the supply chains of the nanomaterials already notified that became aware of their notification obligations only in 2013, it is possible that a significant number of notifications refers to newly identified nanomaterials, for example nanomaterials used exclusively in the biocides sector or newly identified nano-polymers or pigments and dyes for which companies have just carried out the relevant tests to verify their "nano" status.

### 4.2.3 Products covered

***Option 0A "No registries"***

As set out in the draft of the first chapters of the Commission's impact assessment report, "*product-specific legislation applies to nanomaterials. These are some of the most relevant requirements:*

- *The Cosmetics Regulation (No. 1223/2009) requires the notification of cosmetic products containing nanomaterials, including the submission of toxicological and safety data, six months prior to marketing (in addition to general notification for cosmetic products). Based on this information, a catalogue of all nanomaterials used in cosmetic products will be made available by the Commission by January 2014 (currently pending).*
- *The Biocidal Product Regulation (No. 528/2012) requires a dedicated risk assessment for the nanomaterial form of the substance and excludes biocidal products with nanomaterials from the simplified authorisation procedure.*
- *The Food Additives Regulation (No. 1333/2008) stipulates that a change in particle size of a substance requires a new entry in the list of authorised substances or a change in specifications.*
- *Without explicitly mentioning nanomaterials, a wide range of other product-specific legislation also applies to products containing nanomaterials. In addition, the General Product Safety Directive 2001/95/EC is intended to ensure a high level of product safety for consumer products that are not covered by specific sectorial legislation.*

[16] 300 x 60% = 180; 300 x 90% = 270

[17] 900 x 60% = 540; 900 x 90% = 810

- *Certain product-specific legislation requires the risk-independent labelling of ingredients with nanomaterials in consumer products with ingredient lists (e.g. cosmetic products, foodstuff and biocidal products).”*

***Option 0B “French, Belgian and Danish registries”***

The French notification system applies to nanomaterials (as such or as part of a mixture without being bound, or in articles intended to release such substances under normal or reasonably foreseeable conditions of use) being placed on the French market.

The Belgian notification system applies to nanomaterials (as such or as part of a mixture, or in articles and complex objects if the possibility of release cannot be excluded and if the release rate exceeds 0.1 percent of the initial mass contained in the article) being placed on the Belgian market. However, when the nanomaterials are contained in mixtures, articles or complex objects put on the market for professional users, are those mixtures, articles and complex objects to be the object of the notification (Article 4(2) and Article 11 of the Belgian Royal decree). The BNS exempts a variety of products from notification obligations, namely:

- Biocides and treated articles;
- Medicines for human use and veterinary medicines;
- The foodstuffs and materials and objects intended to come into contact with foodstuffs;
- Animal feed, medicines and medicated animal feed;
- Processing aids and other products which may be used in processing organically produced agricultural ingredients;
- Pigments, used for their optical properties in a mixture or article.

The Danish notification system applies to mixtures and articles that are intended for sale to the general public and which contain nanomaterials, where the nanomaterial itself is released under normal or reasonably foreseeable use of the mixture or article or where the nanomaterial itself is not released but substances in soluble form that are classified as CMRs or environmentally dangerous substances are released from the nanomaterial.

The mixtures and articles exempted with regard to the notification include:

a) Foodstuffs and food contact materials.
b) Feed.
c) Medicinal products.
d) Medical devices.
e) Cosmetic products.
f) Pesticides.
g) Waste.
h) Mixtures and articles in which the nanomaterial includes nanoscale substances listed in Annex IV or V to Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH).
i) Mixtures and articles for which the nanomaterial is not intentionally produced at the nanoscale.
j) Articles in which the nanomaterial is part of a fixed matrix, unless wear and tear, washing, breaking, and similar normal use of the article leads to the release of free nanomaterials.
k) Articles on which the nanomaterial is used as ink directly on the article or on the labels on the article, including newspapers, periodicals, magazines, packaging that is not coloured in the mass or dyed, etc.
l) Textiles with nanomaterial used as ink or for dyeing.
m) Paint, wood preservative, glue and filler that contains pigment on the nanoscale where the pigment is added solely for the purpose of colouring the mixture.

n) Articles of rubber, or rubber parts of articles that contain the nanomaterials carbon black (EINECS No 215-609-9) or silicon dioxide (EINECS numbers 231-545-4, 262-373-8, 238-455-4, 238-878-4 and 239-487-1 or CAS numbers 13778-37-5, 13778-38-6, and 17679-64-0).

In summary, only the Danish notification system targets consumer products containing nanomaterials. It is important to note that information on what mixtures and articles contain nanomaterials would not be disclosed to the public and would be kept confidential.

…

### 4.2.4 Organisations covered

***Option 0A "No registries"***

According to the REACH Regulation, the general obligation to register substances on their own or in one or more mixtures is on manufacturers and importers of those substances (Art. 6). Manufacturers and importers of articles containing substances that have not been registered by European chemical manufacturers/importers, have the obligation to register those substances if present in quantities totalling over one tonne per producer or importer per year and the substances are intended to be released under normal or reasonably foreseeable conditions of use.

For the Cosmetics Regulation, the duty is upon the **end-product producers** (typically cosmetic companies) to notify the presence of nanomaterials in their products.

***Option 0B "French, Belgian and Danish registries"***

Under the French system, the notification duty is on the manufacturers, importers and/or distributors to professional users of nanomaterials in quantities equal or in more than 100 grams per nanomaterial per annum. They have been defined as:

- "Manufacturer": any party, in the course of its professional activities in France, that manufactures a substance at nanoscale, on its own or contained in a mixture without being bound to it, or a material intended to release such a substance under normal or reasonably foreseeable conditions of use, for its own use or in view of their transfer free of charge or upon payment.
- "Importer": any party, in the course of its professional activities, introducing into France from another Member State of the European Union or from a non-EU State a substance at nanoscale, on its own or contained in a mixture without being bound to it, or a material intended to release such a substance under normal or reasonably foreseeable conditions of use.
- "Distributor": any party established in the territory, including retailers, providing storage and transfer services, free of charge or upon payment, intended for professional users, for a substance at nanoscale, on its own or contained in a mixture without being bound to it, or a material intended to release such a substance under normal or reasonably foreseeable conditions of use.

Figure 4-1 shows the distribution of the notifiers across the supply chain.

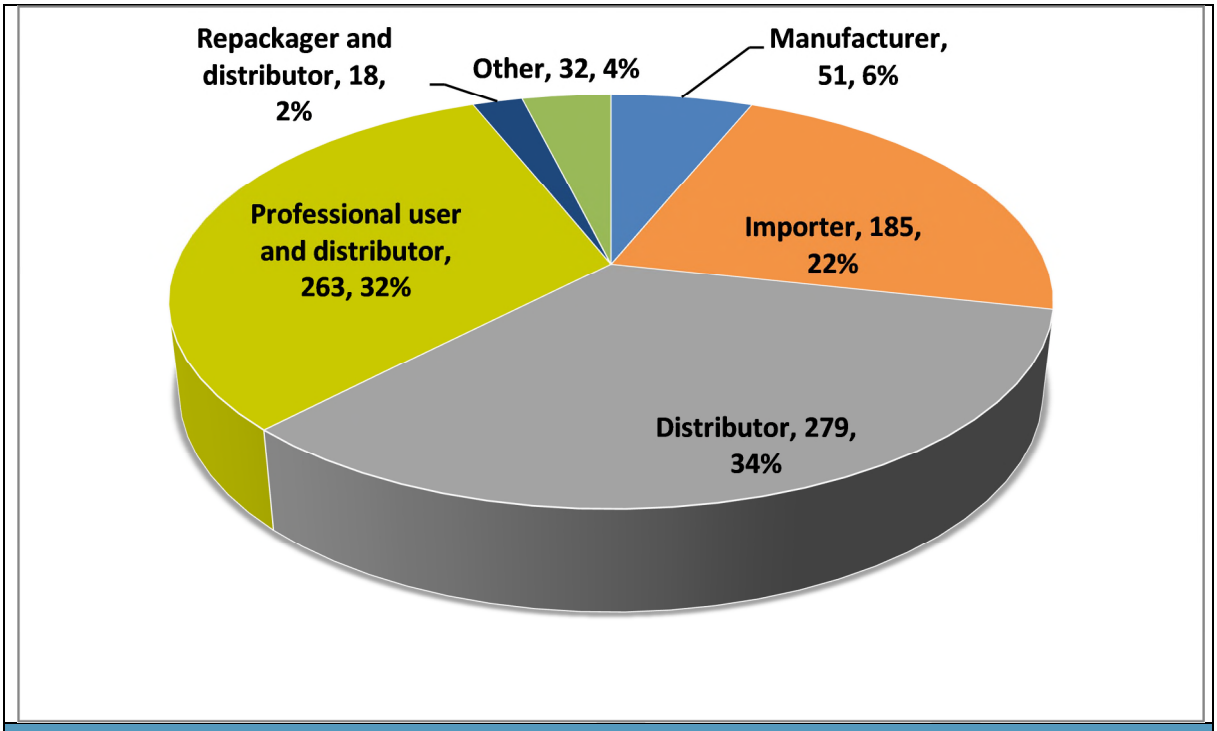


**Figure 4-1: Distribution of the notifiers across the supply chain. Source: French public report (2013)**

Table 4-1 presents the estimate of the number of notifiers in France following the steep increase in notifications registered in 2013.

**Table 4-1: Number of duty-holders under the FNS**

| | 2012 | 2013 |
|---|---|---|
| Total number of notifications | 3,400 | >10,000 |
| Manufacturer | 51 | 150 |
| Importer | 185 | 540 |
| Distributor | 279 | 820 |
| Professional user and distributor | 263 | 770 |
| Repackager and distributor | 18 | 50 |
| Other | 32 | 90 |
| Total of notifiers | 828* | 2,420** |

*Notes:*
** Source: French public report (2013)*
*** Own estimate (proportion on the total number of notifications)*

Under the Danish system, the duty is upon **end-product producers**. Of course, depending on the nature of the product, the end-product producer could also be a **nanomaterial manufacturer/importer** and/or **formulator**. Table 4-2 presents the estimates by the Danish Environment Agency[18] of the number of companies that would have a notification obligation by product category.

[18] Danish EPA (2013): Muligheder for reduktion af danske virksomheders administrative byrder ved indberetning til en nanoproduktdatabase (*Possibilities for reduction of Danish companies' administrative burden for reporting to a nano product database*), Miljøprojekt nr. 1462, 2013

| Table 4-2: Number of duty-holders by product category under the DNS | |
|---|---|
| **Product category** | **Number of companies** |
| Paint, varnish, coatings | 79 |
| Building materials | 18 - 36 |
| Sports | 16 - 21 |
| Cleaning | 9 - 13 |
| Textiles | 0 - 40 |
| Electric & electronic products | No data |
| Miscellaneous | No data |

For the Belgian system, the duty is on **manufacturers/importers/distributors of nanomaterials** and/or **formulators of mixtures** containing nanomaterials and/or **manufacturers/importers of articles and complex objects** containing nanomaterials.

| Table 4-3: Number of duty-holders under the BNS | |
|---|---|
| **Type of duty-holder** | **Number of companies** |
| Manufacturer | |
| Importer | |
| Distributor | |
| Professional user and distributor | |
| Repackager and distributor | |
| Other | |
| Manufacturer of articles and/or complex objects | |
| Importers of articles and/or complex objects | |
| | |

### 4.2.5 Information requirements

Tables 4-4, 4-5 and 4-6 presents the information requirements of the nanoregistries in France, Belgium and Denmark and highlights (in green) those information items expected to be contained in the REACH registration dossiers for the nanoforms of the substances manufactured/imported in quantities of more than 1 tonne per year. Information items that are not expected to be found within a REACH registration dossier are highlighted in red. The information items for which, at the time of writing, a clear decision has not been made, have been highlighted in yellow.

| Table 4-4: FNS information expected to be in a REACH registration dossier for substances manufactured/imported in quantities of more than 1 tonne per year | |
|---|---|
| **Information FNS** | **REACH** |
| **Identity of the notifier** | |
| **Company name*** | Yes (manufacturers and importers) |
| **Address* and Post Code*** | Yes |
| **Town/City*** | Yes |
| **EU VAT or National Directory of plants (RNE) number*** | Yes |
| **Country*** | Yes |
| **Role in the supply chain***<br>• Manufacturer;<br>• Distributor;<br>• Importer;<br>• Professional user and distributor; | No (manufacturer/importer/only representative) |

| Table 4-4: FNS information expected to be in a REACH registration dossier for substances manufactured/imported in quantities of more than 1 tonne per year | |
|---|---|
| **Information FNS** | **REACH** |
| • Repackager and distributor;<br>• European representative. | |
| **Public research organisation*** (Yes/No) | No |
| **Company registration certificate*** | Yes |
| **Business sector* (**NACE code list) | No |
| **Plants/sites interested*** (Name, address, post code, city and country) | Yes |
| **Identity of the Notification administrator*** (Name, surname, email) | Yes (contact person) |
| **Information on the notification** | |
| **Notification number** | Yes |
| **Year of the notification*** | - |
| **Role in the supply chain with regard to the notified NM*** <br>• Manufacturer;<br>• Distributor;<br>• Importer;<br>• Professional user and distributor;<br>• Repackager and distributor;<br>• Other. | No (Manufacturer/importer/only representative) |
| **NACE code (down to four digits) of the activities of interest** | No |
| **Plants/sites of interest*** | Yes |
| **Clients/Professional users identity per NACE code;<br>NACE code of the clients/professional users** | No |
| **Research and Development**<br>• Scientific research;<br>• R&D on products and processes;<br>• no R&D. | No |
| **R&D only?** (Yes/No) | No |
| **NACE code for the R&D activities** | No |
| **R&D NM put on the market?** (Yes/No) | No |
| **National Defence interest?** | No |
| **Substance identity** | |
| **State of the substance*** <br>• The substance is pure;<br>• The substance is contained in a mixture without being bound to it;<br>• The substance is contained in a material intended to release the substance under normal or reasonably foreseeable conditions of use | Yes |
| **Chemical name*** | Yes |
| **Chemical formula*** | Yes |
| **Is the NM contained in a mixture with a mass concentration equal to or higher than the applicable minimum threshold for the purposes of classification?** (Yes/No) | Yes |
| **N°CAS*** | Yes |
| **EC reference*** | Yes |
| **Commercial name*** | Yes |
| **IUPAC name** | Yes |
| **REACH registration number**[+] | - |
| **Impurities**[+] <br>Nature and quantity for each impurity with a mass concentration lower, equal to or higher than 0.1% | Yes |
| **Size of the particles*** <br>Mean particle size of the primary particles, associated with a standard delta | Yes |

| Table 4-4: FNS information expected to be in a REACH registration dossier for substances manufactured/imported in quantities of more than 1 tonne per year | | |
|---|---|---|
| **Information FNS** | | **REACH** |
| **Number size distribution for particles*** | | Yes |
| **Aggregation and agglomeration state*** | Mean size of aggregates with standard delta | ?? |
| | Aggregation state determination method used | ?? |
| | Is the substance sold in an agglomerated form? | ?? |
| | Mean agglomerate size, with standard delta | ?? |
| **Shape*** | Number of dimensions lower than 100 nm | Yes |
| | Qualitative description of the particle shape | Yes |
| **State of the mixture*** | | No |
| **Specific surface**[+] (Mean specific surface, associated with a standard delta) | | Yes |
| **Crystalline state**[+] | Common name, if exists. Otherwise indicate the Bravais lattice: Cubic primitive, Cubic body-centred, Cubic face-centred, Tetragonal primitive, Tetragonal body-centred, Orthorhombic primitive, Orthorhombic body-centred, Orthorhombic faced-centred, Orthorhombic base-centred, Monoclinic primitive, Monoclinic base-centred, Triclinic primitive, Rhombohedral primitive, Hexagonal primitive | No |
| | Is the substance contained in a mixture? | No |
| **Coating*** | Is there a coating? | Yes |
| | Nature of the coating: Organic, Inorganic, Other | yes |
| | Coating: Hydrophilic organic coating, Hydrophobic organic coating, Hydrophilic inorganic coating, Hydrophobic inorganic coating, Other | yes |
| **Surface charge**[+] | Zeta potential value | ?? |
| | Specify the pH conditions | ?? |
| | Specify the medium in which the value has been measured | ?? |
| **Quantities** | | |
| **Quantity*** | Quantity produced | Yes |
| | Quantity distributed | No |
| | Quantity imported | Yes |
| | Quantity distributed after use | No |
| | Quantity distributed after repackaging | No |

| Table 4-4: FNS information expected to be in a REACH registration dossier for substances manufactured/imported in quantities of more than 1 tonne per year | | |
|---|---|---|
| **Information FNS** | | **REACH** |
| | Other quantity | No |
| **Uses** | | |
| **Uses*** <br>Descriptor SU <br>Descriptor PC <br>Descriptor PROC <br>Descriptor AC | | Yes |
| **The properties claimed** | | Yes (technical function, but its optional) |
| **Commercial name of the mixture**[+] | | No |
| **Commercial name of the material**[+] | | No |
| **Users** | | |
| **Clients (professional users)*** <br>(Name, address, zip code, city, country, intercommunity VAT) | | No |

| Table 4-5: Information requirement of the Belgian Notification Register and REACH | | |
|---|---|---|
| **No.** | **Information requirements** | **REACH** |
| **Section 1: Identification of the notifier** | | |
| | Name of the person/company placing the substance on the market; *Banque Carrefour des Entreprises* (BCE) identification no.; Sector of activity; Address of their headquarters; In the case of companies headquartered outside the EEA: reference to the capacity of the extra-national legal body or authorised representative; Contact details of a natural person: surname, first name, address, telephone number, email address | Under REACH, companies need to provide identification details. However, companies do not have to specify sector of activity |
| **Section 2: Identification of the substance** | | |
| | Chemical identification of the substance(s), i.e. chemical name, chemical formula, CAS no., and, where applicable, the EC no (EINECS or ELINCS) | Yes |
| | Average and median particle size, relative to a standard deviation | Yes |
| | Particle size distribution curve (by number) | Yes |
| | Average aggregate size and, if the substance is sold in the form of agglomerates, the average agglomerate size, these sizes being given relative to a standard deviation when available | ?? |
| | Qualitative description of the particle shape | Yes |
| | Where appropriate, a qualitative description of particle coverings (coating) | Yes |
| **Information to be communicated if available at the time of notification** | | |
| | REACH registration number, if the substance has been registered under the REACH regulation (optional) | - |
| | Where appropriate, the nature and quantity of each impurity with a mass concentration exceeding 0.1% in the substance manufactured at the nanoscale and, where the transmission of this information is compulsory for other regulations, the nature and quantity of each impurity with a mass concentration lower than 0.1% in the substance manufactured at the nanoscale (optional) | Yes |
| | The nature of the crystallographic phases and, in the case of a mixture of phases, the proportion of each phase, including the amorphous phase if there is one (optional) | No |
| | The average specific surface area, associated with a standard deviation (optional) | Yes |
| | Zeta potential, indicating environmental, pH and ionic strength conditions | ?? |

| Table 4-5: Information requirement of the Belgian Notification Register and REACH | | |
|---|---|---|
| **No.** | **Information requirements** | **REACH** |
| (optional) | | |
| **Section 3: Quantity of the nanomaterial placed on the market during the reporting period** | | |
| Estimation of the total quantity of notified substance, which will be placed on the market by the notifier between the time of the notification and the end of the calendar year, as such or contained in mixtures (expressed in kg) | | Yes |
| If in a mixture, mass concentration of the nanomaterial(s) | | No |
| State in which the nanomaterial(s) is present in the notified mixture (Solid, liquid, gaseous, powder, mesophase or other) | | No |
| **Section 4: Uses of the nanomaterial (and, if applicable, of the mixture containing nanomaterial(s))** | | |
| All intended uses for the notified substance. If applicable, brief description of the use(s) of the nanomaterial(s) contained in the mixture and uses of the mixture | | Yes |
| Trade name or registered trademark of the substance as placed on the market | | Yes (not compulsory) |
| Claimed properties for which the notified substance is used (optional) | | Yes |
| **Section 5: Identity of the professional users to whom the notifier will be transferring the nanomaterial/ mixture containing nanomaterial(s) between the date of the notification and the end of the calendar year (if known at the moment of notification)** | | |
| Name of the party acquiring the notified substance (or mixture); *Banque Carrefour des Entreprises* (BCE) identification no.; Address of headquarters | | No |

| Table 4-6: Information requirements of the DNR and REACH | |
|---|---|
| **A. Identity of the company** | |
| Notifier's identity (CBR, entity name, address, contact name, type of entity, size of entity) | Yes |
| **B. Product Information** | |
| Product name | No |
| Production volume (number of products/volume/mass) during the reporting period | No |
| Professional application (yes/no) | No |
| Description of application (free text) | No |
| **C. Information on the nanomaterial** | |
| Name of nanomaterial | Yes |
| Is the nanomaterial, or substance with which the nanomaterial is made, registered in REACH? (Yes/no) | Yes |
| How the nanomaterial is included in the product | No |
| **D. Chemical information on the nanomaterial** | |
| Name of the chemical compound (IUPAC) | Yes |
| CAS No | Yes |
| EC number (EINECS/ELINCS/INCI) | Yes |
| Formula | Yes |
| **E. Category** | |
| Descriptors (PC, PROC, ERC, AC) (optional) | Yes |
| **F. Content of the nanomaterial in the article or mixture** | |
| Nano content/product (grams) (optional) | No |
| Nano content/product (%)(optional) | No |
| **G. Physical information on the nanomaterial** | |
| Particle size (optional) | Yes |
| Particle size distribution (by number) (optional) | Yes |
| Aggregation (optional) | ?? |
| Agglomeration (optional) | ?? |

| Table 4-6: Information requirements of the DNR and REACH | |
|---|---|
| Form (optional) | No |
| Specific Surface Area (optional) | Yes |
| Crystalline state (optional) | ?? |
| Surface chemistry (optional) | Yes |
| Surface charge (optional) | ?? |

In summary, once the REACH Annexes have been amended, ECHA will have access to information on:

- The identity of the manufacturers/importers of nanomaterials on the EU market;
- Identity of the substance at the nanoscale and relevant characterisation parameters by nanoform;
- Quantities manufactured/imported per year;
- Uses of the nanomaterials.

The French and the Belgian notification systems provide additional information with regard to the actors along the supply chain (identity and role on the supply chain per each nanomaterial). The REACH Regulation will provide (eco)toxicological information specific to the nanoforms of the substances registered. Moreover, it should be noted that the CLP Regulation requires the classification and labelling (C&L) of a substance to be composition/form specific. Currently, of the 258 substances at the nanoscale identified, only 23 have a notification to the Classification and Labelling Inventory[19] specific to the nanoform.[20] After the amendment of the REACH annexes, the number of C&L notifications specific to the nanoforms of the substances is expected to increase.

## 4.3 Option 1: Best Practice Model

### 4.3.1 Overview

The Commission would promote a pro-active desk-based research at national level aiming at identifying organisations manufacturing/importing and/or using nanomaterials on each national market. Following the identification of these organisations, the relevant national authorities would directly contact the organisations by telephone, in order to gather information on the activities and types of nanomaterials manufactured/imported and/or in use on the national markets.

The work could build on the information already available to the national competent authorities or on information passed by the Commission and available through the different European research channels (e.g. Framework Programme 7 projects).

The information gathering process should follow a harmonised format across the different Member States. This would allow the sharing of information and best practices.

This model would leave Member States the leeway to opt out and/or take their own national approaches.

[19] http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database

[20] RPA et al (2014): Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market, Building Blocks Report for DG Enterprise and Industry, August 2014, Loddon, Norfolk, UK

### 4.3.2 Nanomaterials Covered

Under this option, a nanomaterial is defined in terms of the EC definition, but only manufactured nanomaterials should be taken into consideration.

As indicated in the public consultation:

> *Natural and incidental (e.g. resulting from combustion processes) nanomaterials are not covered. Several legal instruments refer to "intentionally manufactured", or "engineered" nanomaterials. Due to the difficulty to clearly define intention, this consultation refers to manufactured nanomaterials in general (in a wide interpretation, probably most manufactured nanomaterials will be intentionally manufactured). It should also be noted that the definition of nanomaterials only covers solid nanoparticles and excludes liquid nanoparticles such as micelles (e.g. in milk, chocolate, mayonnaise etc.), unless otherwise stated.*

Participation in the surveys by the national authorities is voluntary. The amount of information that organisations are willing to provide will vary across the different Member States, across different sectors and depending on the types of nanomaterials involved. It is to be expected that nanomaterials object of research and development would not be disclosed.

### 4.3.3 Products covered

As for the coverage of nanomaterials, the effectiveness of the model in identifying products containing nanomaterials would vary across different sectors and Member States. The success of the national initiatives would also rely on the ability of the national authorities in identifying and approach the right contact persons within the organisations.

### 4.3.4 Organisations covered

As a minimum, manufacturers and importers of nanomaterials on the different national markets. Depending on the ambitiousness and capabilities of the different Member States, the model could also cover distributors, professional users and manufacturers/importers of articles and complex objects containing nanomaterials.

### 4.3.5 Information requirements

Table 4-7 presents the information that could/should be gathered through the telephone interviews.

| Table 4-7: Information to be gathered through the best practice model |
|---|
| **Identity of the notifier** |
| **Company name** |
| **Address and Post Code** |
| **Town/City** |
| **EU VAT or company registration certificate** |
| **Country** |
| **Role in the supply chain**<br>• Manufacturer;<br>• Distributor;<br>• Importer;<br>• Professional user and distributor;<br>• Repackager and distributor;<br>• European representative;<br>• Professional user;<br>• Manufacturer of mixtures containing nanomaterials; |

| Table 4-7: Information to be gathered through the best practice model |
|---|
| • Importer of mixtures containing nanomaterials;<br>• Manufacturer of articles and/or complex objects containing nanomaterials;<br>• Importer of articles and/or complex objects containing nanomaterials;<br>• Distributor of articles and/or complex objects containing nanomaterials |
| **Public research organisation** (Yes/No) |
| **Business sector (**NACE code list) |
| **Plants/sites interested** (Name, address, post code, city and country) |
| **Contact person** (Name, surname, role in the organisation, telephone number, email, location) |
| **Information on the nanomaterial** |
| **Identity of nanomaterial** (name of the nanomaterial, IUPAC name of the chemical compound, Chemical Formula, CAS number, EC number) |
| **Is the nanomaterial, or substance with which the nanomaterial is made, registered in REACH?** (Yes/no) |
| **How the nanomaterial is included in the product** |
| **R&D only?** (Yes/No)<br>**Research and Development**<br>• Scientific research;<br>• R&D on products and processes;<br>• no R&D. |
| **Quantities** |
| **Quantity produced** |
| **Quantity distributed** |
| **Quantity imported** |
| **Quantity distributed after use** |
| **Quantity distributed after repackaging** |
| **Other quantity** |
| **Uses** |
| **Uses***<br>Descriptor SU<br>Descriptor PC<br>Descriptor ERC<br>Descriptor PROC<br>Descriptor AC |
| **The properties claimed** |
| **Product Information** |
| **Product name** |
| **Production volume** (number of products/volume/mass) during the reporting period |
| **Professional application** (yes/no) |
| **Description of application** (free text) |
| **Content of the nanomaterial in the article/mixture** |
| **Nano content/product (grams)** |
| **Nano content/product (%)** |
| **Information on the supply chain** |
| **Identity of the suppliers (Name, address, zip code, city, country, VAT, role in the supply chain, NACE code)** |
| **Identity of the clients (Name, address, zip code, city, country, VAT, role in the supply chain, NACE code)** |

## 4.4 Option 2: Nanomaterials Observatory

### 4.4.1 Overview

This option would involve the establishment of a Nanomaterials Observatory collecting relevant information on nanomaterials on the market and presenting it in a clear and user-friendly way to the

public online. The existing JRC web platform[21] should form the basis on which to build and develop the observatory.

As described on its webpage, "*The web platform is a single-entry point to references (web links) to as much information sources as possible that are relevant to NMs.*

*This information is located at various levels: global, national, regional and single small entities. It can be found, via the Internet, in intergovernmental or international organisations, companies or NGOs, in the European Union Institutions, in national organisations, companies or interest groups, in SMEs, in regional governments, etc.*"

### 4.4.2 Nanomaterials Covered

Under this option, a nanomaterial is defined in terms of the EC definition, but the focus would be on manufactured nanomaterials – i.e. as for Option 1.

Of course, since the proposed Observatory would be a repository for a broad range of nanomaterial related information, it is likely that the Observatory would be a useful source of information on other forms of nanomaterials.

The JRC web platform presents links to resources providing information on existing or future nanomaterial types, their properties and available or produced quantities. Currently, it provides links to European and American portals, namely:

- DaNa: Knowledge database – funded by the German Federal Ministry of Education and Research, it presents the results of the "Data and knowledge on nanomaterials - processing of socially relevant scientific facts" project (2009-2013), aiming to provide "*non-biased, quality-approved and up-to-date knowledge base for more transparency*."[22]
- The Nanomaterial Registry - The Nanomaterial Registry, created and maintained by the research institute RTI International, is a data-driven tool aimed at enabling researchers to close the knowledge gaps in nanotechnology. Nanomaterials can be browse by material type, size, shape and surface area.[23]
- NIST Nanotechnology Portal – The U.S. National Institute of Standards and Technology (part of the U.S. Department of Commerce) developed a web portal providing links to different subject areas (e.g. Characterization, Nanometrology, and Nanoscale Measurements, Nanobiotechnology, Nanoelectronics and Nanoscale Electronics, Nanofabrication, Nanomanufacturing, and Nanoprocessing), programmes, projects, news and events and latest publications on nanomaterials and nanotechnology.[24]

### 4.4.3 Products covered

The JRC web portal provides links to sources of information on products containing nanomaterials by product type or by nanomaterial.

Currently, it lists:

- The NANO Supermarket – It is an initiative of the non-profit organisation Next Nature Network, aiming "*to visualize, research and understand the implications of this next nature on our everyday life*." It provides information on different product categories and

[21] http://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials

[22] http://nanopartikel.info/en/about-us

[23] https://www.nanomaterialregistry.org/

[24] http://www.nist.gov/nanotechnology-portal.cfm

technologies that might shape our next future, ranking them by their likelihood and feasibility.[25]

- Nanowerk Nanotechnology Products and Applications – It is a database aiming to give "*an idea of how and where in industry nanoscale materials, devices, structures and processes are being used.*"[26]

### 4.4.4 Organisations covered

Information can be provided by many different stakeholders including nanomaterial manufacturers/importers, formulators and end-product producers. Information could also be provided by national authorities and research institutions.

### 4.4.5 Information requirements

To be effective, it would be necessary to develop a structured approach to the type of information to be collected. This is likely to involve the development of a minimum cut set of information (for example, identify of the nanomaterial and area of application) and areas (e.g. health and safety, applications, tests and measurements).

Currently, the JRC web platform is organised by the following themes:

- Regulatory framework: it provides links to information sources on laws, regulations and standards on nanomaterials;
- General information: it provides links to information sources on nanoscience and nanotechnology and application areas and to the definition of nanomaterial;
- Nanomaterials, products and registries: it provides links to relevant information sources, as described in Sections 4.4.2 and 4.4.3;
- Research: it provides links to sources of information on research projects, programmes, companies or laboratories and scientific literature on nanomaterials;
- Ethics and society: it provides links to sources of information on ethical and societal issues linked to nanomaterials;
- Policy: it provides information sources on policies on nanomaterials pursued at global, European Union or national level and in other non-EU countries of the world.

## 4.5 Option 3: EU Nanomaterial Registry by Substance

### 4.5.1 Overview

The general aim of the establishment of an EU-wide nanomaterial registry by substance would be to improve the information available to the authorities. The specific objectives would be:

- To get a deeper knowledge on nanomaterials, their identities, the quantities handled and the different uses and applications;
- To obtain the traceability of the nanomaterials on the market: from the manufacturers or importers via the distributors to the final professional users.

The information to be gathered would be:

- The Notifier identity;
- The identity of the nanomaterial;
- The quantities manufactured, imported or distributed in the year preceding the notification;

[25] http://www.nanosupermarket.org/

[26] http://www.nanowerk.com/index.php

- The uses of the nanomaterial;
- The identities of the professional users to whom the notifier has provided the nanomaterial.

Manufacturers, importers and distributors to professional users of nanomaterials would be required to submit the relevant information for any substance at nanoscale with an annual production volume of at least 100 grams (per manufacturer/importer/distributor).

Duty-holders would receive a unique number for each notification, which would need to be passed on with all transfers of ownership to professional users and distributors so that they could make their notification referring to their suppliers' notification. All notifications would need to be updated annually and non-confidential information would be disclosed six months after the deadline for the notification.

With regard to the confidentiality of the information notified, the legislative framework would establish a partial disclosure to the public of the information about the identity and the uses of the nanomaterials. More precisely, however, the information about the identity of the nanomaterial, with the exception of the chemical name of the substance, would be considered confidential, as well as the information about the quantities, the commercial name of the nanomaterial or mixture and the identity of the professional users. Notifiers would have the possibility to claim confidentiality also for the identity and uses of the nanomaterials, providing a justification. In the justification form, notifiers would have to specify the interests that might be compromised by the disclosure of the information (if industrial or commercial secret or the intellectual property of research results), if the information is part of the general knowledge of the industry and if it is the object of an on-going patent application. Moreover, the notifier should be asked to provide more details on the reasons for the confidentiality claim, demonstrating that the disclosure of the information would cause damage and describing the measures adopted to ensure confidentiality.

Public research organisations would have the possibility to make a single submission for a given class of substances on behalf of all their research units. When the production, import or distribution is in the context of research and development, activities would be subject to notification with specific (simplified) provisions.

Non-compliance with the regulatory provisions would lead to a fine and daily penalties.

Distributors to the public would not be within the scope of the legislative framework and, thus, it would not be possible to identify precisely the final products on the market that might contain nanomaterials.

From an operational point of view, the annual notifications would have to be submitted electronically.

A web platform should be created, on the model of the French website www.r-nano.fr.

For the purpose of the assessment, two sub-options are defined:

- Option 3A "EU-wide nanomaterial notification system by substance with no exemptions";
- Option 3B "EU-wide nanomaterial notification system by substance with exemptions".

The differences between the two sub-options, in terms of nanomaterials covered, are described in the following sub-section.

### 4.5.2 Nanomaterials Covered

As for Option 1, a nanomaterial is defined in terms of the EC definition, but only manufactured nanomaterials should be taken into consideration. As before, it is intended to exclude "natural and incidental nanomaterials" and "liquid nanoparticles such as micelles."

***Option 3A "EU-wide nanomaterial notification system by substance with no exemptions"***

Under Option 3A, the system should exempt nanomaterials of national Defence interest only.

***Option 3B "EU-wide nanomaterial notification system by substance with exemptions"***

Under Option 3B, the system could exempt additionally:

- Nanomaterials object of research and development;
- Nanomaterials covered by other EU legislation. Namely:
  - Foodstuffs and food contact materials;
  - Feed;
  - Medicinal products;
  - Medical devices;
  - Cosmetic products;
  - Biocides;
  - Waste;
- Carbon black and silicon dioxide: these two nanomaterials constitute around 80-90% of the EU market. By exempting carbon black and/or silicon dioxide from the reporting obligation, the overall administrative burden would drastically decrease. If one or both of the NMs are exempted from the reporting obligation, the database will not give a satisfactory overview of the supply chains for these nanomaterials. On the other hand, it could be argued that the supply chains for carbon black and silicon dioxide are well-known and the database would focus more on NMs developed in recent years, and thus on NMs where the uncertainty regarding the health and environmental impacts is higher.

### 4.5.3 Products covered

Similar to the current French system, Option 3 would apply to nanomaterials (as such or as part of a mixture without being bound, or in articles intended to release such substances under normal or reasonably foreseeable conditions of use) being placed on the EU market.

### 4.5.4 Organisations covered

The notification duty would be on the manufacturers, importers and/or distributors to professional users of nanomaterials in quantities equal or in more than 100 grams per nanomaterial per annum. The definition of the different duty-holders would be:

- "Manufacturer": any party, in the course of its professional activities in the European Union, that manufactures a substance at nanoscale, on its own or contained in a mixture without being bound to it, or a material intended to release such a substance under normal or reasonably foreseeable conditions of use, for its own use or in view of their transfer free of charge or upon payment.
- "Importer": any party, in the course of its professional activities, introducing into the EU from a non-EU State a substance at nanoscale, on its own or contained in a mixture without being bound to it, or a material intended to release such a substance under normal or reasonably foreseeable conditions of use.
- "Distributor": any party established in the EU territory, including retailers, providing storage and transfer services, free of charge or upon payment, intended for professional users, for a substance at nanoscale, on its own or contained in a mixture without being bound to it, or a material intended to release such a substance under normal or reasonably foreseeable conditions of use.

### 4.5.5 Information requirements

Table 4-8 presents the information to be notified to the EU-wide nanomaterial registry by substance.

| Table 4-8: Information to be notified | | |
|---|---|---|
| **Information** | **Options** | **Examples/Notes** |
| **Identity of the notifier** | | |
| **Company name*** | | |
| **Address* and Post Code*** | | |
| **Town/City*** | | |
| **EU VAT*** | | |
| **Country*** | | |
| **Role in the supply chain*** | • Manufacturer;<br>• Distributor;<br>• Importer;<br>• Professional user and distributor;<br>• Repackager and distributor;<br>• European representative. | |
| **Public research organisation*** | Yes/No | Public research organisations can provide simplified notifications |
| **Company registration certificate*** | To be attached | |
| **Business sector*** | NACE code list | 10.41 Manufacture of oils and fats |
| **Plants/sites interested*** | Name, address, post code, city and country | |
| **Identity of the Notification administrator*** | Name, surname, email | |
| **Information on the notification** | | |
| **Notification number** | | Assigned automatically |
| **Year of the notification*** | | |
| **Role in the supply chain with regard to the notified NM*** | • Manufacturer;<br>• Distributor;<br>• Importer;<br>• Professional user and distributor;<br>• Repackager and distributor;<br>• Other. | Each company can submit as many notifications as nanomaterials of interest |
| **NACE code (down to four digits) of the activities of interest** | NACE code list | 10.41 Manufacture of oils and fats |
| **Plants/sites of interest*** | Name as previously specified | |
| **Clients/Professional users identity per NACE code** | For each NACE code activity, the notifiers have to enter manually or provide a list (in csv format) of the clients/professional users they provide the nanomaterial to, and their NACE code activities. If they have more than 30 clients for one NACE code activity, the notifiers can just indicate the number of clients/professional users with the provision to keep the list for possible inspections by the authorities. | |
| **NACE code of the clients/professional users** | | |
| **Research and Development** | • Scientific research;<br>• R&D on products and processes;<br>• no R&D. | Public research organisations can provide simplified notifications |
| **R&D only?** | Yes/No | |
| **NACE code for the R&D activities** | NACE code list | |
| **R&D NM put on the market?** | Yes/No | |
| **Substance identity** | | |
| The notifiers have the option to import this part of the notification by entering the notification number from which they wish to import the data. The notifier who imports the data can view just the chemical name of the substance and can then insert new information on this part (i.e. modification of the surface coating). | | |
| If any information about the substance identity is not available, the notifiers have the possibility to flag it and to select a reason between: | | |

| Table 4-8: Information to be notified | | |
|---|---|---|
| **Information** | **Options** | **Examples/Notes** |
| • Waiting for the results;<br>• Substance/mixture/article imported: information not available;<br>• The distributor did not pass the information. | | |
| **State of the substance*** | • The substance is pure;<br>• The substance is contained in a mixture without being bound to it;<br>• The substance is contained in a material intended to release the substance under normal or reasonably foreseeable conditions of use | Multiple choices are possible. |
| **Chemical name*** | | Titan dioxide |
| **Chemical formula*** | | $TiO_2$ |
| **Is the NM contained in a mixture with a mass concentration equal to or higher than the applicable minimum threshold for the purposes of classification?** | Yes/No | |
| **Types of substance concerned** *(This is only for public organisms that choose the simplified notification)* | Carbon (diamond, fullerene, graphene...), Noble metal (ex: Platinum for catalysts), Silica (silica colloidal , silicene...), Non-magnetic oxides (TiO2, ZnO, CeO2...), Carbides (SiC, BC...), Hydroxides and Silico-aluminate (boehmites, clay...), magnetic oxides (e.g. oxides of Fe, Cr...), Asbestos and amphibole, Diesel particles, Cd and alloys containing Cd, Transition metal and intermetallic alloys, Inorganic semiconductors (Quantum Dots) (without Cd, Be and non-nano scale toxic substances), Polymers, Lipids and liposomes, Fluorophores, describe if other category. | |
| **N°CAS*** | CAS number | 13463-67-7 |
| | CAS number not available | - |
| **EC reference*** | EC reference | 236-675-5 |
| | EC reference not available | - |
| **Commercial name*** | Commercial name if available | |
| | No commercial name | - |
| **IUPAC name** | | |
| **REACH registration number+** | REACH registration number | - |
| | No REACH registration number | - |
| **Impurities+** | Nature and quantity for each impurity with a mass concentration equal to or higher than 0.1% | |
| | Nature and quantity for each impurity with a mass concentration lower than 0,1% but mandatory according to other regulatory provisions | - |
| | Test guideline | |
| | Method used: X-Ray Fluorescence, ICP-OES, ICP-MS, Knowledge of the process, HPLC, GC, CE, NMR, FT-IR, other | Describe if other method and provide a justification if not available: pending results, method not available, other. |
| **Size of the particles*** | Mean particle size of the primary particles, associated with a standard delta | There might be one, two or three values, depending on the form.<br>Examples:<br>1 Average diameter: 10 nm<br>1 Standard deviation: ± 5 nm<br>2 Average diameter: 320 nm<br>2 Standard deviation: ± 12 nm |
| | Determination method used: TEM | Describe if other method. Attach |

| Table 4-8: Information to be notified | | |
|---|---|---|
| **Information** | **Options** | **Examples/Notes** |
| | (Transmission Electron Microscopy), MEB, AFM (Atomic Force Microscopy), other | file relative to the determination of the particle size. |
| | Test guideline | |
| **Number size distribution for particles*** | Determination method used: DLS, Laser diffraction, Gravitational sedimentation, Differential centrifugal sedimentation, Raman (NTC), other | Describe if other method. Attach the number size distribution graph. |
| | Test guideline | |
| **Aggregation and agglomeration state*** | Mean size of aggregates with standard delta | The unit is nm.<br>For example, for a monomodal distribution:<br>Average diameter of 1: 1200 nm<br>Standard deviation: ± 40 nm |
| | Aggregation state determination method used | - |
| | Is the substance sold in an agglomerated form? | Yes, No |
| | Mean agglomerate size, with standard delta | For example, for a bimodal distribution:<br>Mean diameter 1: 3 000 nm<br>Standard deviation 1: ± 500 nm<br>Mean diameter 2: 12 000 nm<br>Standard deviation 2: ± 1 000 nm |
| | Agglomeration state determination method used | - |
| | Test guideline | - |
| | Attach file relative to the determination of the aggregation and agglomeration state | |
| **Shape*** | Number of dimensions lower than 100 nm | 1, 2, 3 |
| | Qualitative description of the particle shape | Spherical, Pseudo spherical, Sticks, Star, Full fibre, Hollow fibre,<br>Film, Capsule, Specify if other shape |
| | Specify if other shape | |
| | Determination method used: MET, MEB, AFM, other | Describe if other method. Attach file relative to the determination of the shape |
| | Test guideline | |
| **State of the mixture*** | State of the mixture containing the substance | Solid, Liquid, Gas, Powder |
| **Specific surface**$^{+}$ | Mean specific surface, associated with a standard delta | Mean specific surface: 52 $m^2/g$<br>Standard deviation: : ± 10 $m^2/g$ |
| | Determination method used: BET using nitrogen, TEM/EM calculation, SAXS, other | Describe if other method and provide a justification if not available: pending results, method not available, other. |
| **Crystalline state**$^{+}$ | These information are available | Yes, No |
| | Is the substance contained in a mixture? | Yes, No |

| Table 4-8: Information to be notified | | |
|---|---|---|
| **Information** | **Options** | **Examples/Notes** |
| | Common name, if exists. Otherwise indicate the Bravais lattice: Cubic primitive, Cubic body-centred, Cubic face-centred, Tetragonal primitive, Tetragonal body-centred, Orthorhombic primitive, Orthorhombic body-centred, Orthorhombic faced-centred, Orthorhombic base-centred, Monoclinic primitive, Monoclinic base-centred, Triclinic primitive, Rhombohedral primitive, Hexagonal primitive | Justification for the non-availability: Pending results, Technic non available, Other specify justification. Attach the file relative to the crystalline state. |
| | Test guideline | |
| **Coating*** | Is there a coating? | Yes , No |
| | Nature of the coating: Organic, Inorganic, Other | Describe if other. |
| | Coating: Hydrophilic organic coating, Hydrophobic organic coating, Hydrophilic inorganic coating, Hydrophobic inorganic coating, Other | Provide a qualitative description if other. |
| **Surface charge**[+] | Zeta potential value | Attach file relative to the determination of the surface charge. Provide a justification for the non-availability: Pending results, Technic non available, Other specify justification. |
| | Specify the pH conditions | |
| | Specify the medium in which the value has been measured | |
| | test guideline | |
| **Quantities** | | |
| **Quantity*** | Quantity produced | The unit is kg. |
| | Quantity distributed | |
| | Quantity imported | |
| | Quantity distributed after use | |
| | Quantity distributed after repackaging | |
| | Other quantity | |
| **Uses** | | |
| **Uses*** | Descriptor SU<br>Descriptor PC<br>Descriptor PROC<br>Descriptor AC | |
| **The properties claimed** | | |
| **Commercial name of the mixture**[+] | | |
| **Commercial name of the material**[+] | | |
| **Users** | | |
| **Clients (professional users)*** | Name, address, zip code, city, country, intercommunity VAT | |

## 4.6 Option 4: EU Nanomaterial Registry by Application

### 4.6.1 Overview

The general aim of the establishment of an EU-wide nanomaterial registry by application would be to improve the information available to the authorities on the mixtures and articles containing nanomaterials which are intended for sale to the general public. The specific objective would be:

- To get a deeper knowledge on consumers products containing nanomaterials, the identities and quantities of nanomaterials in the products, the different uses and applications; and
- To obtain the traceability of the products containing nanomaterials on the market: from the manufacturers or importers via the distributors to the final professional users.

The reporting requirement to the EU-wide nano product register would include mixtures and articles intended for sale to the general public and which contain nanomaterials, where the nanomaterial itself is released under normal or reasonably foreseeable use of the mixture or article.

When reporting to the nano product register, the notifier would have the possibility to indicate that selected information should be regarded as a trade secret, including information on chemical information, substance identification, composition or purity. The reporting party would have to justify why the information has to be regarded as a trade secret.

The nano product register would not be publicly accessible. However, where urgent action would be essential to protect human health, safety or the environment, such as emergency situations, the information on the composition of the mixtures and on the precise use, function or application of a substance or mixture may be disclosed.

For the purpose of the assessment, two sub-options are defined:

- Option 4A "EU-wide nanomaterial notification system by application with no exemptions";
- Option 4B "EU-wide nanomaterial notification system by application with exemptions".

The differences between the two sub-options, in terms of nanomaterials covered, are described in sub-section 4.6.3.

### 4.6.2 Nanomaterials Covered

As for Option 1, a nanomaterial is defined in terms of the EC definition, but only manufactured nanomaterials should be taken into consideration. As before, it is intended to exclude 'natural and incidental nanomaterials' and 'liquid nanoparticles such as micelles'.

### 4.6.3 Products covered

***Option 4A "EU-wide nanomaterial notification system by application with no exemptions"***

Option 4A should exempt:

- Mixtures and articles produced or imported by individuals for their own, non-commercial use are not covered by this Order; and
- Articles in which the nanomaterial is part of a fixed matrix, unless wear and tear, washing, breaking, and similar normal use of the article leads to the release of free nanomaterials.

***Option 4B "EU-wide nanomaterial notification system by application with exemptions"***

Under Option 4B, the system could exempt additionally:

- Products containing nanomaterials object of research and development;
- Products containing nanomaterials covered by other EU legislation. Namely:
  - Foodstuffs and food contact materials;
  - Feed;
  - Medicinal products;
  - Medical devices;
  - Cosmetic products;
  - Biocides;
  - Waste;
- Articles of rubber, or rubber parts of articles that contain carbon black or silicon dioxide: these two nanomaterials constitute around 80-90% of the EU market. By exempting products containing carbon black and/or silicon dioxide from the reporting obligation, the overall administrative burden would drastically decrease. If one or both of the NMs are exempted from the reporting obligation, the database will not give a satisfactory overview of the application of these NMs in products. On the other hand, the database would focus more on NMs developed in recent years, and thus on NMs where the uncertainty regarding the health and environmental impacts is higher;
- Mixtures and articles in which the nanomaterial includes nanoscale substances listed in Annex IV or V to Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH).
- Mixtures and articles containing pigments where the pigments are added solely for the purpose of colouring the mixture(s)/article(s).

### 4.6.4 Organisations covered

Manufacturers and importers of mixtures and/or articles containing nanomaterials placed on the EU market and sold to the general public.

### 4.6.5 Information requirements

Table 4-9 presents the information requirements for an EU-wide notification system by application.

| Table 4-9: Information to be gathered through an EU-wide notification system by application |
|---|
| **Identity of the notifier** |
| **Company name** |
| **Address and Post Code** |
| **Town/City** |
| **EU VAT or company registration certificate** |
| **Country** |
| **Role in the supply chain**<br>• Manufacturer;<br>• Distributor;<br>• Importer;<br>• Professional user and distributor;<br>• Repackager and distributor;<br>• European representative;<br>• Professional user;<br>• Manufacturer of mixtures containing nanomaterials;<br>• Importer of mixtures containing nanomaterials;<br>• Manufacturer of articles and/or complex objects containing nanomaterials;<br>• Importer of articles and/or complex objects containing nanomaterials;<br>• Distributor of articles and/or complex objects containing nanomaterials |
| **Public research organisation** (Yes/No) |

| Table 4-9: Information to be gathered through an EU-wide notification system by application |
|---|
| **Business sector (**NACE code list) |
| **Plants/sites interested** (Name, address, post code, city and country) |
| **Contact person** (Name, surname, role in the organisation, telephone number, email, location) |
| **Information on the product** |
| **Product name** |
| **Production volume (number of products/volume/mass) during the reporting period** |
| **Professional application (yes/no)** |
| **Description of application (free text)** |
| **Information on the nanomaterial** |
| **Identity of nanomaterial** (name of the nanomaterial, IUPAC name of the chemical compound, Chemical Formula, CAS number, EC number) |
| **Is the nanomaterial, or substance with which the nanomaterial is made, registered in REACH?** (Yes/no) |
| **How the nanomaterial is included in the product** |
| **R&D only?** (Yes/No)<br>**Research and Development**<br>• Scientific research;<br>• R&D on products and processes;<br>• no R&D. |
| **Quantities** |
| **Quantity produced** |
| **Quantity distributed** |
| **Quantity imported** |
| **Quantity distributed after use** |
| **Quantity distributed after repackaging** |
| **Other quantity** |
| **Uses** |
| **Uses***<br>Descriptor SU<br>Descriptor PC<br>Descriptor ERC<br>Descriptor PROC<br>Descriptor AC |
| **The properties claimed** |
| **Content of the nanomaterial in the article/mixture** |
| **Nano content/product (grams)** |
| **Nano content/product (%)** |
| **Information on the supply chain** |
| **Identity of the suppliers (Name, address, zip code, city, country, VAT, role in the supply chain, NACE code)** |

# 5 In-depth Analysis of the Most Significant Impacts

## 5.1 Approach

The approach to the more detailed analysis (Step 5 of the Impact Assessment) will be to provide commentary on each of the relevant questions for each impact (as illustrated in Tables 3-2 to 3-4 above). This commentary will provide an overview of the relevant factors for each question followed by a more detailed analysis which will be quantitative where possible for each of the options in turn.

The more detailed analysis will draw upon the findings of the earlier study reports on Tasks 2[27] and 3[28] as well as upon further research and analysis (including any relevant information submitted as part of the Public Consultation).

In order to ensure a coherent and easy-to-read analysis, detailed and/or extensive calculations and discussions will be presented in a Technical Annex.

## 5.2 Economic Impacts

### 5.2.1 Functioning of the internal market and competition

*to be prepared but sections/sub-sections will be structured as shown below*

***Initial Assessment***

…..

***Commentary***

…..

***Analysis***

…..

***Summary***

….

### 5.2.2 Functioning of the internal market and competition

### 5.2.3 Competitiveness, trade and investment flows

[27] **Evaluation Report – Final**, prepared for DG Enterprise and Industry, June 2014

[28] **Building Blocks Report – 2nd Draft**, prepared for DG Enterprise and Industry, June 2014

### 5.2.4 Operating costs and conduct of business/SMEs

***Initial Assessment***

| Table 5-X: Further consideration of 'operating costs and conduct of business/SMEs' | | | | |
|---|---|---|---|---|
| Question | Option | | | |
| | 1 | 2 | 3 | 4 |
| Will it impose additional adjustment, compliance or transaction costs on businesses? | Yes | No | Yes | Yes |
| Does it impact on the investment cycle? | Possibly | No | Possibly | Possibly |
| Will it entail the withdrawal of certain products from the market? Is the marketing of products limited or prohibited? | Possibly | No | Possibly | Possibly |
| Will it entail stricter regulation of the conduct of a particular business? | Yes | No | Yes | Yes |
| Will it lead to new or the closing down of businesses? | Possibly | No | Possibly | Possibly |

***Commentary***

Clearly, the introduction of a mandatory EU-wide reporting scheme (Options 3 and 4) will entail costs upon businesses. There will also be costs associated with Option 1 (to follow 'best practice') at a national level. On the other hand, a voluntary Nano Observatory is unlikely to impose costs upon businesses.

Apart from the direct costs on businesses associated with meeting the information requirements for a nanoregistry, there is also the potential for additional consequential costs associated with adapting to the new legislative regime. It is possible, although at this stage very uncertain, that some businesses may need to change should further restrictions be placed upon placing certain nanomaterials on the market.

***Analysis***

The prime concern (at this stage) is the direct costs to businesses associated with moving from the current situation to one of the possible policy options.

In essence, the total costs will be a function of:

- the nature and extent of information required
- the cost of providing that information
- number of EU businesses affected

The detailed analysis of the costs for each policy option is presented in Annex …

***Summary***

….

### 5.2.5 Administrative burdens on businesses

### 5.2.6 Public authorities

### 5.2.7 Innovation and research

### 5.2.8 Consumers and households

### 5.2.9 Specific regions and sectors

### 5.2.10 Third countries and international relations

### 5.2.11 Macroeconomic environment

## 5.3 Social Impacts

### 5.3.1 Employment and labour markets

### 5.3.2 Governance, participation, good administration, access to justice, media and ethics

***Initial Assessment***

| Table 5-X: Further consideration of 'governance, participation, good administration, access to justice, media and ethics' | | | | |
|---|---|---|---|---|
| | Option | | | |
| Question | 1 | 2 | 3 | 4 |
| Does the implementation of the proposed measures affect public institutions and administrations, for example in regard to their responsibilities? | Possibly | No | Yes | Yes |
| Will the option affect the individual's rights and relations with the public administration? | Possibly | No | Possibly | Possibly |
| Does the option make the public better informed about a particular issue? Does it affect the public's access to information? | Yes | Yes | Yes | Yes |
| Does the option raise (bio) ethical issues (cloning, use of human body or its parts for financial gain, genetic research/testing, use of genetic information)? | Yes | Yes | Yes | Yes |
| | (*depending on perspective)* | | | |

***Commentary***

The introduction of further reporting schemes (through Options 1, 3 and 4) will place additional responsibilities upon public authorities. By way of example, it has been immediately apparent that the national authorities in France who have implemented the French reporting system for nanomaterials have been expected to provide information to the French public, to the Commission and to other stakeholders.

Of course, one of the key drivers for the establishment of some form of nanoregistry has been the perceived need to provide more information on the presence of nanomaterials in products to the public. To varying degrees, all the options will provide some additional information to the public.

One of the central arguments presented by industry is that most nanomaterials on the EU market are present in conventional products which have been marketed for decades. As such, it is argued that it is not necessary to consider that the use of nanomaterials raises ethical issues which are often associated with 'new' technologies. This view is not universally shared by those who are concerned about the expansion of nanotechnology when some of the associated hazards and risks appear uncertain.

***Analysis***

*[It is unlikely that much in the way of quantitative analysis can be added to provide more detailed analysis on this issue]*

***Summary***

….

### 5.3.3 Public health and safety

## 5.4 Environmental Impacts

### 5.4.1 The environmental consequences of firms and consumers

***Initial Assessment***

| Table 5-X: Further consideration of 'the environmental consequences of firms and consumers' | | | | |
|---|---|---|---|---|
| | Option | | | |
| Question | 1 | 2 | 3 | 4 |
| Does the option change the relative prices of environmental friendly and unfriendly products? | Possibly | No | Possibly | Possibly |
| Will it lead to businesses becoming more or less polluting through changes in the way in which they operate? | Possibly | No | Possibly | Possibly |

***Commentary***

Similar comments apply as for the social impacts considered above. Currently, the presence of nanomaterials does not automatically make a particular product environment friendly/unfriendly. (or more or less polluting). Rather, some stakeholders might argue that there is sufficient uncertainty about the environmental fate of nanomaterials that one should adopt a precautionary approach. On the other hand, some products containing nanomaterials are designed to enhance the environment.

***Analysis***

*[It is unlikely that much in the way of quantitative analysis can be added to provide more detailed analysis on this issue]*

***Summary***

….

### 5.4.2 The likelihood or scale of environmental risks

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