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

Options Assessment Report

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Executive Summary

This report is the final deliverable of the study on transparency measures on nanomaterials within the EU and draws upon the findings of the previous tasks. The report provides information supporting the assessment of the policy options defined by the Commission (e.g. number of nanomaterials on the EU market, costs for the characterisation of nanomaterials, etc.). The focus is on calculation of quantitative information where this is possible. In addition, the main qualitative conclusions on elements which cannot be quantified, and which result from the work on the previous reports, are recalled in this report. However, it is important to emphasise that this report does not give an overall assessment of the options nor does it recommend a 'preferred option'. These need to take into account further considerations, and will be done by as part of the impact assessment report, which will be prepared by the European Commission services.

As a working thesis, the main problem that this study aims to analyse is that

> *"The current level of available information on the presence of nanomaterials and products (i.e. mixtures or articles) containing nanomaterials on the market is insufficient for an adequate response to health and environmental risks and for informed consumer choice.*
>
> *In addition to the main problem described above, the establishment and proposals for national registration and notification systems for nanomaterials or products containing nanomaterials have caused concerns about internal market fragmentation and a divergence of requirements for the marketing of nanomaterials in different Member States. In particular, there are different obligations for downstream users and differences in exemptions for certain nanomaterials obligations between the established system in France and the proposed systems in Belgium and Denmark. This may hamper trade within the internal market" (European Commission's Working Document)*

The general objectives of the policy initiatives are to ensure the protection of human health and the environment and to ensure consumer protection related to nanomaterials on the market and to ensure a proper functioning of the internal market.

The following policy options have been defined:

1. *Recommendation on how to implement a "best practice model" for Member States wishing to establish national measures (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 where the nanomaterial itself is released under normal or reasonably foreseeable use of the mixture or article).*

For the calculation of quantitative elements of the baseline, the results of the second year of implementation of the French Notification System have been analysed, comparing the information provided with other information sources such as the ECHA registered substances database and the Classification and Labelling Inventory. This has allowed the determination of the percentage of substances with nanoforms notified to the FNS that are already registered or will be registered under the REACH Regulation. Moreover, the analysis permitted to determine the number of substances with nanoforms and the number of notifications per sector of use, product and article category. The results have been used to identify the number of substances with nanoforms, organisations and products covered by the different options. Ultimately, these data have been used as the basis for further assumptions for the estimate of the administrative burden of the options.

While Option 2, the Nanomaterials Observatory, would not entail any administrative burden on businesses, the burden posed by Option 3, the EU-wide nanomaterials registry per substance, has been estimated in ***€60 million - €145 million*** *the first year, with recurring costs of* ***€3.9 million****. These costs are significant, but, in general, they represent a small percentage of companies' value added although for some micro, small and medium enterprises in certain sectors this percentage could exceed 20% in the first year. Some exemptions (Option 3b) have been considered in order to avoid disproportionate costs on certain sectors of the economy. For example, given that over 50% of the nanomaterials notified have been identified as pigments and dyes, the most significant exemptions for the sector are the ones on nanomaterials used as pigments and dyes and on nanomaterial for which the parental substance has been / will be registered under the REACH Regulation. Option 4, the EU nanomaterials registry per application, stands as the most comprehensive scenario, where all nanomaterials, mixtures and articles containing nanomaterials, disregarding any consideration on the binding or intended release, would have to be notified by each actor along the supply chain down to the consumer retailers. This option would entail very high costs estimated in* ***€5,324 million*** *the first year with annual recurring costs of* ***€2,546 million****. Considering the exemption on nanomaterials bound to the mixtures and not intended to be release from the articles under reasonable or foreseeable conditions, the costs would be of around* ***€310 million*** *the first year with annual recurring costs of* ***€66 million****. It should be noted that these figures, given the extent of the assumptions needed for the calculation, should be regarded as indicating the order of magnitude of the costs: the accurate estimate of the administrative burden posed by the registries requires the perfect knowledge of all the supply chains and markets of each single nanomaterial per manufacturer or importer.*

With regard to the cost for public authorities, the costs for option 2a have been estimated ***between €560 thousand and €670 thousand*** *for the first year of implementation, with annual recurring costs of* ***€335 thousand****. With the active participation of Member States contributing national surveys to the Nanomaterials Observatory, the costs would be between* ***€860 thousand and €970 thousand*** *with annual recurring costs of* ***€435 thousand****. The costs for public authorities to implement Option 3 have been estimated in around* ***€700 thousand*** *the first year with annual recurring costs of €****3.8 million****, of which €3.4 million dedicated to enforcement. The costs for Option 4 may run up to* ***€1.1 million*** *with annual recurring costs of up to* ***€160 million****, assuming ambitious enforcement campaigns run by the Member States.*

Depending on the option chosen, more detailed information on nanomaterials on the market than currently available could be obtained. However, the degree of the value-added of this additional information for the various actors will also vary, depending on those options.

With regard to workers' safety, the evaluation of the FNS highlighted that, since companies have to keep track of the quantities of nanomaterials that they handle, a registry can increase the information on nanomaterials that are available to downstream companies, and if the information is passed on, to the workers in these companies. More downstream users may become aware of handling nanomaterials through the FNS. This might lead to some of them questioning the suitability of their risk management measures in dealing with nanomaterials.

With regard to consumers, option 4, the EU Nanomaterials Registry by application, which is intended to provide full traceability from manufacturers to consumers, could be, on paper, the option that delivers most information. However, the current systems do not make this information available to consumers: for example, the Danish Notification System is the only one, among the transparency measures currently implemented, to require information on consumers' products containing nanomaterials; the Danish authorities have clarified that this information will remain confidential and will be available to the authorities only. Option 3, as implemented in the FNS, gives only limited and aggregated information to the public, and therefore does not allow consumers to assess whether a particular product contains nanomaterials or not.

The EU Nanomaterials Registries by substance and by application would only require a partial physicochemical characterisation of the nanomaterials; no (eco)toxicological information is gathered through these options. Any potential benefits for human health and the environment are likely to stem from more focused action on long-term effects of nanomaterials (e.g. epidemiological studies), mostly by the public authorities, as other actors will have limited access to the information.

During the public consultation, consensus emerged on the fact that the provision of information concerning presence of nanomaterials in products would not lead to consumers being more inclined to purchase those products. Indeed, industry respondents noted that as a result of negative preconceptions and the current stigma associated with nanomaterials, providing information about the presence of nanomaterials in a product to consumers could result in them avoiding that product. However, in many instances the French notification scheme would appear to have had no impact on the purchasing decision and in some instances, companies will promote the presence of nanomaterials in their product (e.g. high-tech product).

Other industry respondents noted that the information indicating the presence of nanomaterials in products would result in customers, particularly business clients, requesting further information such as an explanation or assessment on the safety of the product.

With regard to the functioning of the internal market, the public consultation highlighted a strong concern from industry, a number of MS authorities and, to a lesser extent, from citizens and NGOs and other stakeholders that the establishment of multiple national registries and notification schemes causes additional administrative and bureaucratic burden, market fragmentation and hampers trade within the internal market. However, no concrete evidence could be found that the FNS significantly changed trade patterns between France and other Member States.

The public consultation also highlighted that many industry respondents were concerned that providing information about the presence of nanomaterials in a product could negatively impact nanotechnology innovation. A number of respondents claimed that the French national registry system undermined economic partners' trust in nanomaterials, which in turn negatively impacted competitiveness and innovation. It was also claimed to create uncertainties amongst economic actors towards the French market, raising question marks with regard to business developments and the location of research and development activities in France. However, as with the functioning of the internal market, no evidence could be found to substantiate these claims.

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List of Abbreviations

AC	Article Category
BNS	Belgian Notification System
CAD	Chemical Agents Directive
CCT	UK Environment Agency Chemical Compliance Team
C&L	Classification and Labelling
CLI	Classification and Labelling Inventory
CLP	Regulation on Classification, Labelling and Packaging (of Chemicals)
CMR	Carcinogens, mutagens and reprotoxic substances
Defra	UK Department for Environment, Food & Rural Affairs
DNS	Danish Notification System
DSD	Dangerous Substance Directive
DPD	Dangerous Preparation Directive
ECHA	European Chemicals Agency
EC	European Commission
ERC	Environmental Release Category
EU	European Union
FNS	French Notification System
IA	Impact Assessment
JRC	European Commission's Joint Research Centre
MEDDE	*Ministère de l'Écologie, du Développement durable et de l'Énergie*
MS	Member State (of the EU-28)
nm	Nanometre
NM	Manufactured nanomaterial, unless otherwise stated
OSH	Occuptional Health and Safety
PC	Product Category
PROC	Process Category
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.

The Options Assessment Report is the last of the several deliverables of this study (listed below):

- The Evaluation Report documents the findings of Task 1, describing the different European and national initiatives for the gathering of information on the nanomaterials and presenting the lessons that can be learned from the implementation of the French Notification System (FNS);
- The Building Blocks Report presents the findings of Task 2, providing information with regard to hazards and risks of nanomaterials, their value chains and the potential of growth and innovation associated with nanotechnology; and
- The Workshop Report documents the outcome of Task 5, presenting the views and discussions of the stakeholder representatives attending the Validation Workshop held in Brussels on 30 June 2014.

With regard to Task 3, the results of the first phase consultation focusing on the administrative burden of the FNS have been presented in the Evaluation Report, while the outcomes of the public consultation (launched on 13 May 2014 and closed on 5 August 2014) are presented in Annex I to this report.

The present document summarises the findings of the previous tasks, presenting the information necessary to enable the assessment of the policy options (e.g. number of nanomaterials on the EU market, costs for the characterisation of nanomaterials, etc.). Moreover, it provides a qualitative and, where possible, quantitative analysis of the possible impacts of the options.

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].

In parallel with this study, the European Commission has drafted the first chapters of the impact assessment. These cover the identification of the problem, the definition of the objectives and the development of the main policy options (presented in Section 2).

The impacts to be considered have been identified analysing the responses of the various stakeholders gathered during the public consultation (analysis presented in Annex I): as a result, nine criteria have been defined to be used in the analysis. These are:

- Criterion 1: costs on businesses
- Criterion 2: special sectors
- Criterion 3: costs authorities
- Criterion 4: health / environment
- Criterion 5: worker safety
- Criterion 6: consumer info & trust
- Criterion 7: internal market
- Criterion 8: research and innovation
- Criterion 9: confidential information

The description of the baseline is presented in Section 3. Option 1, "*Recommendation on how to implement a "best practice model" for Member States wishing to establish national measures*", will be assessed once specified by the Commission. Option 2, the "*Nanomaterials Observatory*", is presented in Section 5. Section 6 details Option 3, "*EU Nanomaterial Registry per substance*" and Section 7 presents Option 4, "*EU Nanomaterial Registry per application".* Each section describing the baseline and the options have been organised as follows:

- Overview
- Nanomaterials covered
- Products covered
- Organisations covered
- Information requirements and
- Administrative burden.

The latter has been included in each section for better clarifying sources of information, assumptions and calculations for each option.

Section 8 presents the comparison of the options and the broader assessment of the impacts.

Section 9 details the references.

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

2 Problem, Baseline and Objectives

2.1 The Problem

There appears to be a widespread (but not universal) view that available information on nanomaterials is insufficient for informed decision-making.[2] This was reflected in the call by the European Parliament[3] 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 Belgium, Denmark and France) have launched initiatives for national registries for nanomaterials. Furthermore, Austria, Belgium, Croatia, the Czech Republic, Denmark, France, Italy, Luxemburg, the Netherlands, Spain and Sweden have asked the Commission[4] to *"propose legislation on registration or market surveillance of nanomaterials or products containing nanomaterials"*. Stakeholders' opinions on transparency measures are diverse: non-governmental organisations have called for a "*publicly accessible inventory of registry for nanomaterials and consumer products containing nanomaterials […] at European level*"[5], the social partners of the European Chemical Industry favour "*expand[ing] the existing […] web platform on nanomaterials to include notifications of nanomaterials to all current regulatory schemes*"[6], while the chemicals industry states that "*additional reporting schemes, whether national or European, beyond existing data requirements, will not improve transparency*"[7].

There are two aspects of these concerns:

- The first aspect relates to the lack of sufficient and reliable information to perform a risk assessment and set up adequate risk management strategies; and
- The second aspect relates to the absence of sufficient information, in particular for consumers, concerning the presence of nanomaterials on the market and their uses.

Although the first aspect of the concerns is being addressed through a separate impact assessment on a revision of the Annexes to the REACH Regulation, for the purpose of the present analysis and for the definition of the baseline, both aspects need consideration. Nevertheless, the policy options have been defined with the aim to gather available information or to generate new information on the presence of nanomaterials and products containing nanomaterials on the market; the analysis of the potential impacts of the options will focus on how this information may be used to address health and environmental risks or inform consumers.

The information that may be collected could be used by various actors in different ways:

- Public authorities and policy makers (e.g. to prevent health and environmental damage);
- Downstream user industries and workers (e.g. to improve risk management measures);

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2 See the different views on the current level of available information on nanomaterials in Sections 3.2 and 3.3 of Annex I on the results of the public consultation.

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

4 EC (2014): Draft of the First Chapters of the Impact Assessment Report, European Commission's Working Document.

5 European NGOs (2014) European NGOs position paper on the Regulation of nanomaterials.

6 Sector Social Dialogue Committee of the European Chemical Industry (2014) Joint Declaration of the Social Partners of the European Chemical Industry on REACH and the inclusion of nanomaterials in its annexes, 9 September 2014.

7 Cefic (2014) Nanomaterials: No need for additional inventories, Cefic's reply to the Commission on additional measures to ensure transparency and adequate regulation, April 2014.

- Consumer and environmental associations (e.g. to identify particular nanomaterials with widespread use); and
- Consumers (e.g. to decide whether or not to buy products containing nanomaterials).

In summary:

> *As a working thesis, the main problem that this initiative aims to address is that the current level of available information on the presence of nanomaterials and products (i.e. mixtures or articles) containing nanomaterials on the market is insufficient for an adequate response to health and environmental risks and for informed consumer choice.*
>
> *In addition to the main problem described above, the establishment and proposals for national registration and notification systems for nanomaterials or products containing nanomaterials have caused concerns about internal market fragmentation and a divergence of requirements for the marketing of nanomaterials in different Member States. In particular, there are different obligations for downstream users and differences in exemptions for certain nanomaterials obligations between the established system in France and the proposed systems in Belgium and Denmark. This may hamper trade within the internal market* (EC, 2014).[8]

2.2 The Baseline

2.2.1 Introduction

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.*"

In order to ensure clarity on the information requirements for registration dossiers covering nanoforms of substances, "*a revision of the Annexes to REACH is currently on-going (…) 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).

Moreover, "*some Member States have established or proposed registries for nanomaterials and/or products containing nanomaterials on the market." (Ibid.)*

For the purposes of a more detailed analysis and in order to highlight the positive and/or negative impacts of the "transparency measures"[9], consideration will be given to two sub-options:

- Option 0A "No additional EU transparency measures" – the chemicals legislative framework (with the oncoming amendment of the REACH Annexes) plus the product-specific legislation with specific provisions for nanomaterials;
- Option 0B "Current national transparency measures" – as above plus the transparency measures implemented at national level.

[8] See also Section 3.3 of Annex I to this report on the views expressed during the public consultation about the fragmentation of the internal market.

[9] Policy initiatives to increase transparency and ensure regulatory oversight for nanomaterials.

2.2.2 Option 0A "No additional EU transparency measures"

Under the baseline, 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 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." (Ibid.)*

It should be noted that if a substance is manufactured/imported in quantities of more than 1 tonne per year per manufacturer/imported 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 substance (with or without nanoforms) is manufactured/imported in quantities of less than 1 tonne per year per manufacturer/importer and is put on the market, the manufacturers/importers do not have to register the substance.

Nevertheless, a substance (with or without nanoforms) manufactured/imported in quantities less than 1 tonne per year per manufacturer/importer that is put on the market and meets the criteria for classification as hazardous[10] needs to be notified to the Classification and Labelling Inventory and is subject to the occupational health and safety (OSH) legislation.

Other legislation that currently applies to nanomaterials is the OSH legislation (namely 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) and the product-specific legislation.

OSH legislation makes extensive use of the CLP Regulation and the REACH Regulation. More precisely, the Chemical Agents Directive (CAD, Art. 4) requires employers to carry out a risk assessment and to take all necessary preventive measures whenever "*hazardous chemical agents are present or may be present at the workplace*" (Art. 1(2)). Article 2(b) defines a "hazardous chemical agent" as:

i) A chemical agent which meets the criteria for classification as a dangerous substance according to Annex VI to the Dangerous Substance Directive (DSD); or
ii) A dangerous preparation according to the Dangerous Preparation Directive (DPD)[11] or

[10] It should be noted that, under CLP, many nanomaterials that are insoluble or poorly soluble may carry the hazard statement *H335: May cause respiratory irritation*

[11] The DSD and the DPD were replaced by Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (known as CLP).

iii) Any chemical agent that may present a risk to the safety and health of workers because of its physicochemical, chemical or toxicological properties and the way it is used or is present in the workplace.

Although nanomaterials are not explicitly included within the scope of the Directive, the Art. 2(b)(iii) ensures that they are covered in principle. The CAD applies provided the hazard is known, where "hazard" means "*the intrinsic property of a chemical agent with the potential to cause harm*" (Art. 2(g)) and "risk" means "*the likelihood that the potential for harm will be attained under the condition of use and/or exposure*". The identification of a "chemical hazard" therefore relies on information passed by the supplier of the substances or mixtures through the safety data sheets accompanying them.

With regard to the product-specific legislation applying to nanomaterials, EC (2014) lists 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 of the nanomaterial, 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.*
- *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). However, as described above in section 1.2, the labelling of nanomaterials is outside the scope of this impact assessment."*

2.2.3 Option 0B "Current national transparency measures"

Belgium, Denmark and France have introduced notification systems:

- In Belgium, the notification obligation is for substances manufactured at the nanoscale, as such or in a mixture, must be notified if more than 100 grams are placed on the market for professional users per year. The notification obligation is also for articles and complex objects containing nanomaterials, 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[12];
- In Denmark, the reporting requirement of the register includes 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 (category 1A or 1B) or environmentally dangerous substances (acute category 1 or chronic category 1-4) under Regulation (EC) No 1272/2008 (CLP) are released from it;
- In France, the notification obligation is for manufactured nanomaterials produced, imported or distributed in quantities above 100 grams per year (as such or as part of a mixture without

[12] However, the application of the notification obligations for articles and complex objects has been postponed and the date will be decided after an evaluation of the articles.

being bound, or in articles intended to release such substances under normal or reasonably foreseeable conditions of use).

The notification systems in Belgium and Denmark provide some exemptions:

- In Belgium, the following products (subject to other regulatory provisions) are exempted from the notification duties:
  - Biocides and treated articles falling within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocides and biocides which have been registered or authorised in accordance with the Royal Decree of 22 May 2003 concerning the placing on the market and use of biocides;
  - Medicines falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;
  - Medicines for human use and veterinary medicines falling within the scope of the Royal Decree of 14 December 2006 on medicinal products for human and veterinary use;
  - The foodstuffs and materials and objects intended to come into contact with foodstuffs referred to in Article 1(1) and 1(2)(b) of the Law of 24 January 1977 on the protection of consumer health in regard to foodstuffs and other products;
  - Animal feed, as defined in Article 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
  - Medicines and medicated animal feed falling within the scope of the Law of 21 June 1983 on medicated animal feed;
  - Processing aids and other products which may be used in processing organically produced agricultural ingredients, mentioned in Part B of Annex VIII to Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for implementing Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and inspections;
  - Pigments, defined as substances which are insoluble in typical suspension media, used for their optical properties in a mixture or article.
- In Denmark, the following mixtures and articles are exempted from the notification duties:
  - Foodstuffs and food contact materials.
  - Feed.
  - Medicinal products.
  - Medical devices.
  - Cosmetic products.
  - Pesticides.
  - Waste.
  - 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 for which the nanomaterial is not intentionally produced at the nanoscale.
  - 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.
  - 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.

- Textiles with nanomaterial used as ink or for dyeing.
- 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.
- 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).
- Furthermore, mixtures and articles produced or imported by individuals for their own, non-commercial use are not covered by the Order.

Part of the baseline are also the other "transparency measures" implemented in other Member States:

- Austria is carrying out a nanomaterial inspection project as part of the Austrian Nanotechnology Action Plan adopted by the Federal Government in March 2010, with the objective to identify the nanomaterials on the Austrian market and whether the REACH requirements are being fulfilled[13];
- Norway requires that all the notifications of the chemical products (substances and mixtures) submitted to the Norwegian Product Register clarify whether the substances have nanoforms or the mixtures contain nanomaterials; and
- The United Kingdom updates annually the lists of producers and users of nanomaterials in the UK and of the types of nanomaterials in use and on the UK market. The update is carried out through a desk-based research followed up by surveying the companies via direct telephone contact.[14]

2.3 The Objectives

During the public consultation, respondents were asked to rate the importance of the possible objectives (see Table 2-1) on a scale between 1 and 5 (1-not important at all / 5-very important).

Table 2-1: Objectives of Possible Intervention	
A	Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials
B	Provide consumers with relevant information on products containing nanomaterials on the market
C	Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)
D	Ensure consumer trust in products containing nanomaterials
E	Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market
F	Ensure the proportionality of the information requirements and the associated costs and administrative burden
G	Protect confidential business information

There was a consensus amongst all stakeholders that *Objective A - Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials* was very important.

[13] http://newsletter.echa.europa.eu/home/-/newsletter/entry/5_14_guest-column-nanomaterials

[14] For an extensive description of the transparency measures implemented so far in these Member States, please consult RPA *et al* (2014b): Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market, **Evaluation Report** for DG Enterprise and Industry, November 2014, Loddon, Norfolk, UK.

There was also general consensus that *Objective D - Ensure consumer trust in products containing nanomaterials* was either very important (rating of 5) or of considerable importance (rating of 4).

Industry stakeholders considered three further objectives to be very important while most MS Authorities considered that these were either very important (rating of 5) or of considerable importance (rating of 4):

- *Objective C - Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)*
- *Objective F - Ensure the proportionality of the information requirements and the associated costs and administrative burden*
- *Objective G - Protect confidential business information*

Citizens and NGOs and other stakeholders indicated that the remaining two objective were very important (with significant support also from MS Authorities):

- *Objective B - Provide consumers with relevant information on products containing nanomaterials on the market*
- *Objective C - Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market*

Moreover, trade unions highlighted the importance of providing information on hazards and exposure of nanomaterials to workers.

For more information on the public consultation, see Annex I to this report. For a more detailed analysis of the results of the public consultation on the problem definition and the objectives of the possible policy intervention, see Section 3 of Annex I.

The Commission has taken into account the various perspectives and has subsequently defined the objective of the possible policy intervention. Table 2-2 presents the objectives as set out in the Commission's Working Document.

Table 2-2: Objectives of the Policy Intervention

General policy objectives	Specific policy objectives
Ensure the protection of human health and the environment & ensure consumer protection related to nanomaterials on the market	Provide decision makers, regulatory/risk assessment authorities, professional users and workers with information that allows for an appropriate response to possible health or environmental risks of nanomaterials Provide consumers with relevant information on products containing nanomaterials on the market and hence contribute to consumer trust
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, associated costs and administrative burden Protect confidential business information

Figure 2-1 reproduces the problem tree as shown in the Commission's Working Document.

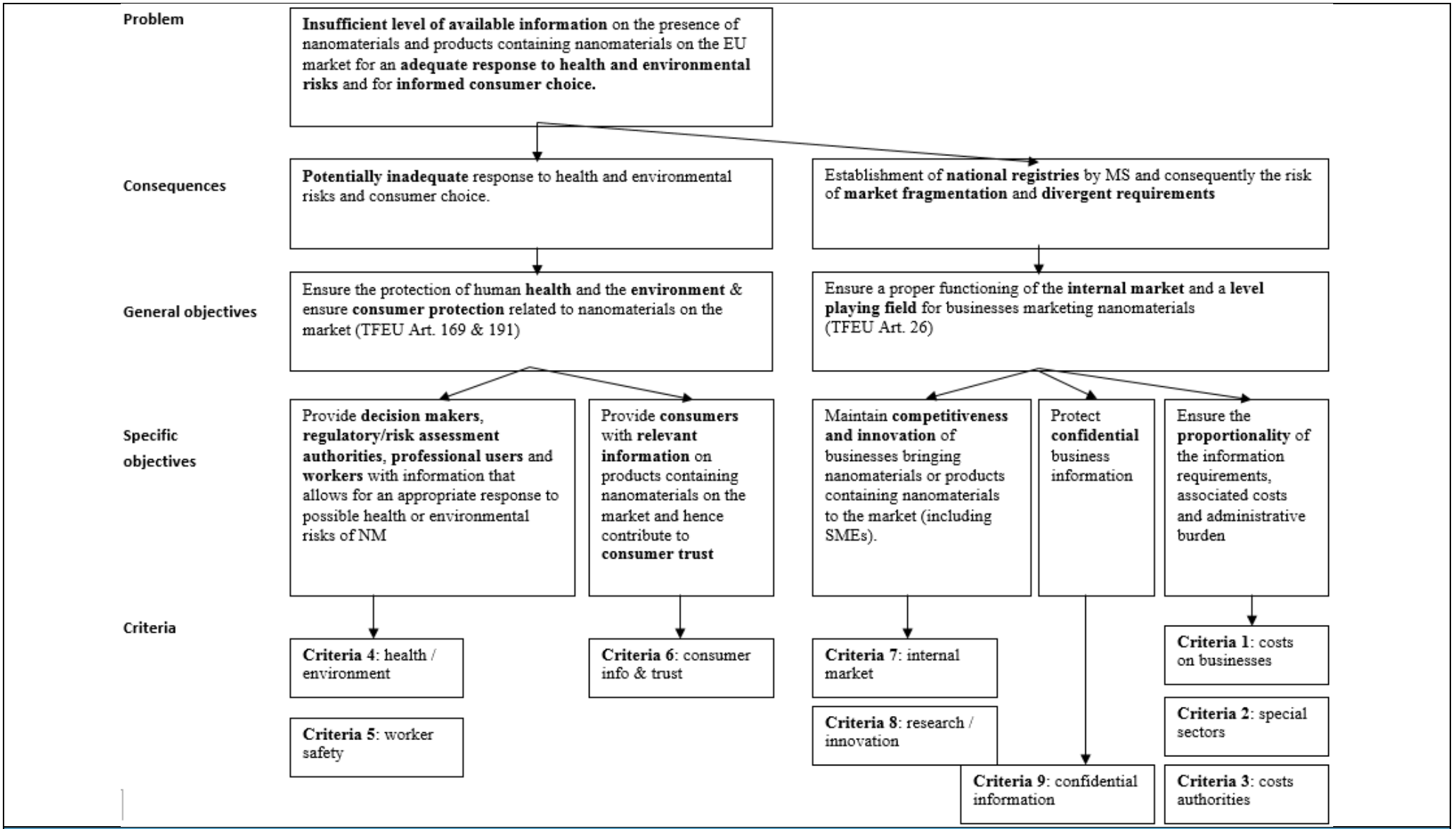

Figure 2-1: Transparency measures for nanomaterials on the market: problem tree (*Source: CWD, 2014*)

2.4 The Policy Options

2.4.1 Summary

As set out in the Commission's Working Document, the policy options considered for the assessment are:

1. *Recommendation on how to implement a "best practice model" for Member States wishing to establish national measures (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 where the nanomaterial itself is released under normal or reasonably foreseeable use of the mixture or article)*

For options 3 and 4, a number of variants, taking into account specific substances, mixtures or articles, shall be considered.

These are outlined in a little more detail below.

2.4.2 Option 1: Recommendation for National Measures

According to the Commission's Working Document:

"This option would involve recommendations on how to implement a particular registry model at national level. Following analysis and discussion on the various models below, the Commission could identify an existing or planned model, possibly with a number of modifications, as best practice model, and recommend it for implementation at national level. The identification of this best practice model would be supported by the outcomes of the impact assessment of the different registry models (and their building blocks) described below. In addition to a best practice model, the recommendation could also include other aspects, such as the alignment of IT systems and the interoperability of databases in order to avoid multiple registrations in different Member States.

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."

2.4.3 Option 2: Nanomaterials Observatory

Option 2A "No national surveys"

According to the Commission's Working Document:

"*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*[15] *which provides general information on nanomaterials and useful links to other sources could be used as a basis for this initiative.*

The Observatory could contain both existing data, collected from existing databases and registries, and new information gathered in further studies and surveys. Data is already gathered through various systems: REACH registration dossiers (for nanomaterials that are subject to the registration duties of the REACH Regulation), notifications of nanomaterials in cosmetic products (through the Cosmetics

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

Regulation), authorisations of biocides containing nanomaterials (under the Biocidal Product Regulation) and national registration or notification systems.

With regard to the existing data, the Nanomaterials Observatory should systematically extract information on nanomaterials, their markets and available safety information in a structured and consistent manner, in particular by linking releasable data from the systems mentioned earlier (…)

With regard to new data, available information could be complemented by relevant market studies and by systematically gathering and analysing scientific information (curating data) on nanomaterials. While it may not be possible to guarantee the completeness and exhaustiveness of the collected data, this would involve no further requirements for manufacturers, importers or downstream users. Based on public funding, it would require the continuous collection and analysis of available data by the Commission, as well as the establishment of a format to make the results of these aggregated data and meta-analyses available to decision-makers, authorities and the general public in a user-friendly way.

Option 2B "With national surveys"

In addition to new data collected on an EU level, a recommendation to Member States to conduct data similarly to the voluntary industry surveys conducted by the United Kingdom authorities (DEFRA) can complement the existing information by ensuring regular contact with nanomaterial manufacturers and taking stock of the nanomaterials that are being manufactured and used. This will be considered as ***sub-option 2b****."*

2.4.4 Option 3: EU Nanomaterial Registry by Substance

Option 3A "No exemptions"

According to the Commission's Working Document:

"*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 above a certain threshold, i.e. in principle at least 100 grams based on the requirements of the French registry. 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 nanomaterials likely to be extracted or released under normal or reasonably foreseeable conditions of use, as well as distributers selling such products to professional users.*

A notification dossier contains 49 entries, divided in 6 categories: identity of the notifier, information on the notification, substance identity, quantities, uses and users. It is important to distinguish the requirements for each of the duty holders. Manufacturers and importers would be responsible for submitting a dossier with substance identity information (including particle size, number size distribution, aggregation and agglomeration state, shape, surface and coating), as well as the quantity and use of the nanomaterial substance and the identification of the clients (professional users). Downstream users, including re-formulators or article manufacturers, and distributers of the substance would not be required to submit substance identity information (unless they modify the substance identity) and, instead, may refer to a registration number they receive from their supplier. Information requirements would reflect the current requirements of the French notification system.

The information requirements would apply in addition to existing requirements (option 0: baseline). Compared to existing requirements, this option would expand obligations in three dimensions: firstly, it would generate additional information requirements for any duty holder; secondly, it would apply to

substances that are not yet covered by existing requirements; and thirdly, it would apply to additional duty holders."

Option 3B "With exemptions"

"Different variants for this option shall be assessed. A minimum model will be considered, in which only substances need to be registered that do not fall in one of the following categories:

- *Nanomaterials only used in scientific research and development*
- *Nanomaterials only used in product and process oriented research and development*
- *Nanomaterials only used in as pigments*
- *Nanomaterials only used in as fillers*
- *Substances registered in REACH*
- *Substances in articles covered by existing registration requirements for nanomaterials*

In a building block approach, the categories listed above will be assessed individually. A combination of all these building blocks represents the maximum model."

2.4.5 Option 4: EU Nanomaterial Registry by Application

Option 4A "No exemptions"

According to the Commission's Working Document:

"[Under Option 4] 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.

The reporting requirement to the EU-wide nanomaterials register by application would include substances in nanoform, as well as mixtures and articles intended for sale to the general public and which contain nanomaterials (with and without intended release) with an annual volume of at least 100 grams (per manufacturer/importer/distributor).

Option 4B "With exemptions"

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.

3 Description of the Baseline

3.1 Baseline 0A "No Additional EU Transparency Measures"

Despite the publication of the Commission Recommendation on the definition of nanomaterial[16], the improvements to the REACH registration software and the update by ECHA of the guidance on substance identification, information requirements and chemical safety assessment for REACH registration (in order for this guidance to adequately address substances in the nano-form), ECHA has received so far around six joint submissions and two individual submissions of dossiers for which registrants had ticked the "nano" box in the IUCLID dossier (section 2.1 & 4.1) referring to 13 substances only[17]. Table 3-1 provides more details on the extent to which nanomaterials are identified in REACH registrations.

Table 3-1: Nanomaterials in REACH registrations*

	2010	2013	Non-phase-in
No. of substances	5	4	4
No. of dossiers in the joint submissions	10, 100, 134, 1 individual submission, 54	1, 3, 81, 1 individual submission	NA

Notes:
**indicated by ticking "nano" box by the registrants in the IUCLID dossier (section 2.1 & 4.1)*
Source: http://echa.europa.eu/documents/10162/5399565/1_holmqvist_ws_nanomaterials_en.pdf

As mentioned, in order to ensure clarity on the information requirements for registration dossiers covering nanoforms of substances, the Commission, in collaboration with the Member States Competent Authorities, is revising the REACH Annexes. Nevertheless, at this stage is not possible to estimate the quality and quantity of the information that will be reached by the initiative. ECHA, having recognised that companies are facing challenges in relation to the provision of information on nanomaterials and is trying to enhance this aspect following two different approaches:

- Supportive initiatives:
  - Organising generic activities aimed at the wider audience of registrants and industrial sectors (webinars, workshops, bilateral discussions);
  - Inviting individual registrants to contact ECHA to seek help and advice;
- Formal initiatives (using legal instruments):
  - Article 36 decisions; and
  - Dossier evaluation.

As of March 2013, ECHA had already sent around 170 "Article 36" letters urging companies to submit as much information on nanomaterials as possible in order to demonstrate safe use[18]. The dossier evaluations carried out in 2013 resulted in the general recommendation to registrants of clearly identifying the substances, of demonstrating the relevance of the testing undertaken, of providing clear information on use and exposure and of making good use of available information and alternative approaches. These initiatives, however, seem to have increased neither the quantity nor the quality of the dossiers with information specific to nanomaterials; moreover, industry is

[16] Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU). Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF

[17] Presentation by Jenny Holmqvist at the ECHA Topical Scientific Workshop on Regulatory Challenges in Risk Assessment of Nanomaterials, 22-23 October 2014. Available at: http://echa.europa.eu/documents/10162/5399565/1_holmqvist_ws_nanomaterials_en.pdf

[18] CW (2013): "ECHA wants industry to clarify nanomaterial safety", news of 26 March 2013, http://chemicalwatch.com/index.cfm?go=14265

challenging the legitimacy and proportionality of requiring more information on the nanoforms of the substances: on 16 September 2014, ECHA's Board of Appeal received an appeal regarding ECHA decision, following the evaluation of the registration dossier of titanium dioxide, asking the registrants to submit more information on phases of the substance, the nanoforms and the surface treatment of the nanoforms[19]. The registrants claim that the Agency breached the principle of proportionality requesting additional information that is not required by legislation (referring to Section 2 of Annex VI of the REACH Regulation) and is not necessary.

Table 3-2 provides some arguments about the potential obstacles and incentives to compliance even after the implementation of the amendment to the REACH Annexes.

Table 3-2: Potential obstacles and incentives to compliance[20]
Would the target group be able and willing to comply? This may depend on the following: • **Compliance costs**, including administrative burdens, may affect overall compliance rates, in particular for SMEs.
Administrative burdens have to be compared to the value added per company by company size. Where their incidence is high, companies, especially SMEs, might face difficulties in absorbing these costs.
• **Overly complicated and technical regulation may not be properly understood**. Inaccessible and incomprehensible rules will reduce compliance, particularly for SMEs, which may lack time and resources to deal with large volumes of complex rules. Moreover, it may appear not to have any clear purpose, leading to a loss of confidence in the regulators and a tendency to evasive behaviour.
The revision of the REACH Annexes and all the other initiatives by ECHA (e.g. update of IUCLID, update of the guidance documents) aim to clarify the rules applying to nanomaterials. Nevertheless, the REACH Regulation remains a burdensome piece of legislation, especially for SMEs[21]. In addition, regulatory challenges remain in the risk assessment of nanomaterials[22].
• **Coherence** with existing market practices or cultural norms may help raise compliance rates.
With regard to coherence, the revision of the REACH Annexes should ensure that the principle "no data, no market" is applied to nanomaterials too.
• **Prior consultation** builds in a sense of 'ownership', or at least understanding, of the rule and can ease compliance concerns.
Within the study to support the impact assessment of the revision of the REACH Annexes, a public consultation was launched in order to gather the views of the stakeholders over the problem and the potential impacts of the policy options under consideration.
• **Networking and co-ordination between Member State authorities** can be required for the effective application of the law.
There is an ongoing discussion among the Commission and the Member States Competent Authorities. The REACH Regulation established a Forum formed by representatives of each Member States which is in charge, among other tasks, of proposing, coordinating and evaluating harmonised enforcement projects and joint inspections and identifying enforcement strategies, as well as best practice in enforcement.
• **Rigorous monitoring arrangements, appeal mechanisms and sanctions for non-compliance** can be expected to increase compliance rates and be more effective than the Commission being called on to intervene.
The monitoring arrangements, appeal mechanisms and sanctions for non-compliance are the ones already set up by the Regulation and are not expected to change.
• **Providing information and other support measures** can affect the ability of the target group to comply with the rule.
ECHA has launched supportive initiatives as illustrated above.

[19] http://echa.europa.eu/documents/10162/13574/a_011_2014_announcement_en.pdf

[20] The aspects to be considered when dealing with compliance are suggested by the Commission's Impact Assessment Guidelines.

[21] Results of the public consultation on the TOP10 most burdensome legislative acts for SMEs. Available at: http://ec.europa.eu/enterprise/policies/sme/files/smes/top10report-final_en.pdf

[22] See proceedings of the Topical Scientific Workshop on the Regulatory Challenges in Risk Assessment of Nanomaterials held in Helsinki on 24 October 2014.

However, for the purpose of this assessment, it is assumed that once the REACH Annexes have been revised and amended, there will be full compliance[23], meaning that manufacturers and importers of nanomaterials for which the substances have registration dossiers or need to be registered by 2018 will provide the information requested by the Regulation.

In order to proceed with the comparison between the baseline and the policy options, some assumptions need to be done with regard to the expected amendments to the REACH Annexes; therefore, it is assumed that the Annexes will require the inclusion of relevant information on the nanoforms of substances in the chemical safety reports. When nanoforms are covered by a registration dossier, the chemical safety assessment will include scientific justifications and conclusions specific to the nanoforms, also with regard to exposure scenarios and risk management measures. When information relevant to a different (nano)form of the substance is used for one or more nanoforms of the substance (grouping and read-across), scientific justifications will need to be provided. When a registration dossier of a substance covers one or more nanoforms, registrants will have to provide some additional parameters for the characterisation of those nanoforms:

- Any other identifiers of the nanoforms of the substances;
- Particle number size distribution (there will be the opportunity for grouping different nanoforms of the same substance deemed to have the same toxicological or ecotoxicological information);
- Description of surface functionalization or treatment (opportunity for grouping);
- Shape, aspect ratio and other morphological characterisation (opportunity for grouping);
- Surface area (opportunity for grouping);
- Description of the analytical methods.

The information on manufacture and uses will have to be specific to the nanoforms of the substance, as well as the information on exposure. Moreover, any relevant physicochemical, toxicological and ecotoxicological information on the nanoforms should include the characterisation of the nanoforms and the test conditions.

As previously mentioned, a substance (with or without nanoforms) manufactured/imported in quantities less than 1 tonne per year per manufacturer/importer that is put on the market and meet the criteria for classification as hazardous need to be notified to the Classification and Labelling Inventory.

EC (2012) identified 14 substances where information on nanomaterials was included in C&L notifications (received by the end of June 2011)[24]. RPA *et al* (2014a) cross-analysed the FNS with the CLI and identified 23 substances that have been notified to the FNS with at least one notification referring to the nanoform(s) of the substances in the CLI[25].

During the CASG Nano meeting held in Brussels on 4 December 2014, ECHA announced that both the database on the registered substances and the classification and labelling inventory will be made searchable for nanomaterials. Although this initiative might not foster compliance directly, it will make the available information on nanomaterials more accessible to the public.

[23] For the comparison between baseline and policy options, full compliance need to be assumed in both cases. The likelihood of compliance with the policy options will be discussed in the relevant Sections.

[24] EC (2012), page 74.

[25] RPA *et al* (2014a), page 20.

3.2 Baseline 0B "Current National Transparency Measures"

The results of the first year of implementation of the FNS have been described and analysed in RPA *et al* (2014b). In summary, the authors found that around 260 different substances[26] at the nanoscale were notified to the FNS. They noted however that this number referred to the first year of implementation of the system and that in the second year the French authorities received three times (over 10,000) the number of notifications received in 2013. The authors ascribed this sharp increase in the number of notification, mostly, to the increased awareness of duty-holders (especially distributors) about their notifications duties and, only partially, to new substances at the nanoscale being notified, as then confirmed in the report on the second year of implementation of the FNS published in November 2014[27]. Figure 3-1 shows the increase in the number of notifications and the relative increase of the number of substances at the nanoscale notified in 2013 and 2014.

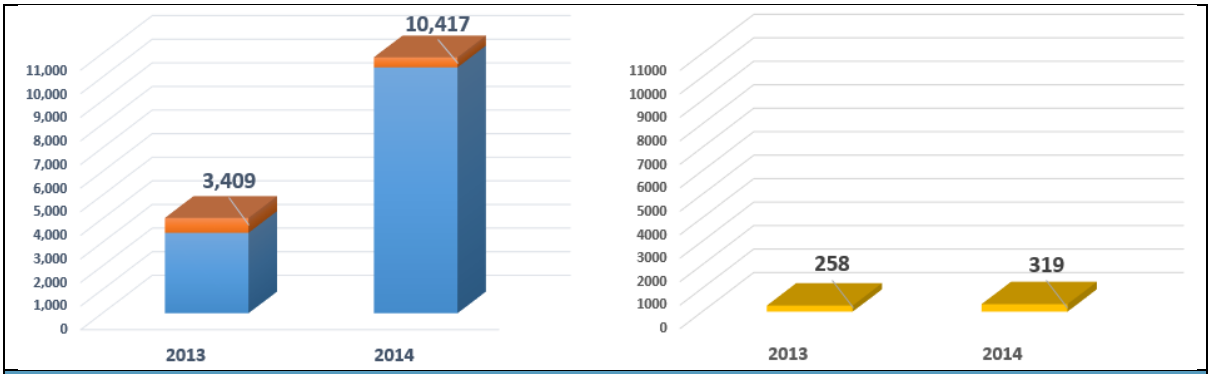

Figure 3-1: Number of notifications received and number of substances at the nanoscale notified in 2013 and 2014. In orange, the number of notifications that have not been analysed.
Source: RPA et al (2014b) and MEDDE (2014)

The French authorities identified 319 different substances at the nanoscale[28] notified in 2014 by French notifiers (the analysis does not cover the notifications received from countries other than France; however, only 0.5% of the notifications have been received from non-French entities). The number and percentage of substances at the nanoscale notified by tonnage bands declared in 2013 and 2014 are presented in Table 3-3.

In 2013, 42.8% of the substances at the nanoscale notified to the FNS reported quantities below 1 tonne per year per manufacturer/importer. In 2014, this percentage increased to 50.4%. This information is important as one tonne per year per manufacturer/importer is the minimum quantity triggering the REACH registration. Figure 3-2 presents the nanomaterial tonnage band distribution in 2013 and 2014.

[26] The number has been rounded: although 258 different substances have been identified in the list published in MEDDE (2013), due to the fact that the CAS numbers were not published, a rounded number is deemed more appropriate.

[27] MEDDE (2014): Éléments issus des déclarations des substances à l'état nanoparticulaire – exercice 2014, Ministère de l'Écologie, du Développement durable et de l'Énergie, page 16. Available at: http://www.developpement-durable.gouv.fr/IMG/pdf/rapport-nano-2014.pdf

[28] MEDDE (2014), page 23.

Table 3-3: Number and percentage of substances in nanoforms per notified quantities to the FNS in 2013 and 2014						
Notified quantities	**Number of substances 2013**	**% on the total number of substances 2013**	**% over the 206 substances with reported quantities 2013**	**Number of substances 2014**	**% on the total number of substances 2014**	**% over the 246 substances with reported quantities 2014**
Not reported	52	20.2%	-	73*	22.9%	-
0.1 - 1 kg	8	3.1%	3.9%	16	5.0%	6.5%
1-10 kg	9	3.5%	4.4%	7	2.2%	2.8%
10-100 kg	20	7.8%	9.7%	31	9.7%	12.6%
100 kg-1 t	51	19.8%	24.8%	70	21.9%	28.5%
1-10 t	47	18.2%	22.8%	58	18.2%	23.6%
10-100 t	45	17.4%	21.8%	43	13.5%	17.5%
100-1000 t	15	5.8%	7.3%	12	3.8%	4.9%
>1000 t	11	4.3%	5.3%	9**	2.8%	3.7%
Total	**258**	**100%**	**-**	**319**	**100%**	**-**

Notes:
** 46 substances at nanoscale with "N.D.", not declared, in the tonnage band field plus 27 substances at the nanoscale that could not be analysed/found in Annex 1 of MEDDE (2014)*
*** 9 substances at the nanoscale manufactured/imported in quantities over 1,000 tonnes per year, with:*
5 substances at the nanoscale manufactured/imported in quantities between 1,000 t and 10,000 t
2 substances at the nanoscale manufactured/imported in quantities between 10,000 t and 100,000 t
2 substances at the nanoscale manufactured/imported in quantities over 100,000 t

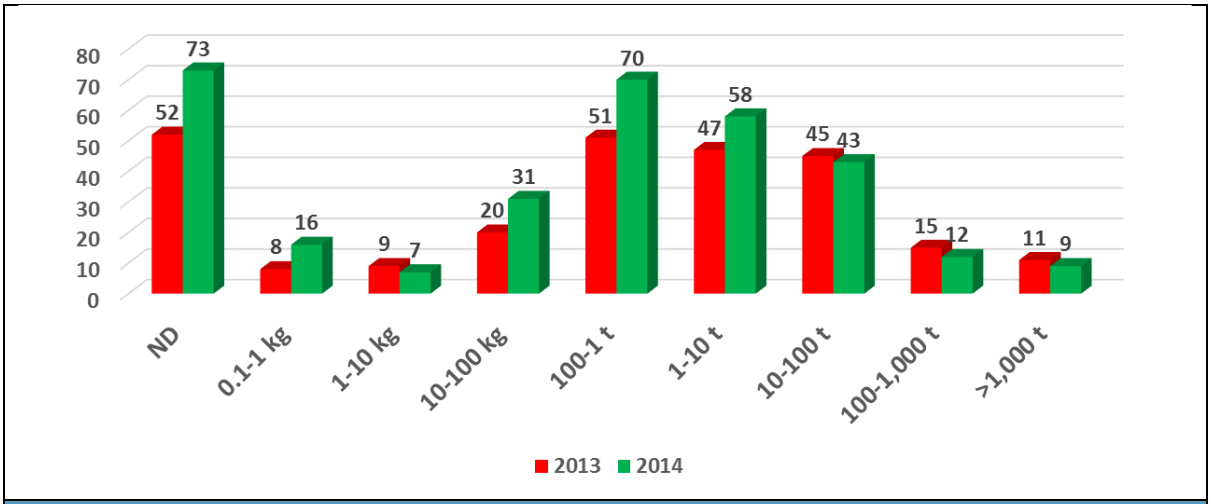

Figure 3-2: Nanomaterial tonnage band distribution in 2013 and 2014

The list of substances notified to the FNS in 2014 (Annex I of MEDDE, 2014) has been analysed in order to compare it with the ECHA registered substances database. The annex contains 301 entries[29]; 14 entries could not be further considered for the comparison[30]. The remaining 287 entries refer to 287 different substances, of which 211 were already reported in 2013 and 76 are substances newly notified

[29] It should be noted that the report quotes 319 different substances (or "categories of substances"): it is assumed that the difference is made of substances that has been kept confidential.

[30] Entry "CALIBRA-CALLISTO" (p. 22 of Annex I) has not be considered because the active substance of this pesticide is reported at page 32 of the Annex (entry "mesotrione"); entry "Eolys dpx42" (page 26) has not be considered because it is reported in the annex as "isostearate d'oxyde de cerium" at page 29; other 12 entries could not be considered because the name was not reported ("vide" page 46) or is too generic ("exxon" at page 27, "feruwax" at page 27, "microwax" at page 32, "munzing" at page 32, "paraffine" at page 36, five different entries reporting "vernis sol-gel" at page 45 and "waradur" (a type of montan wax) at page 45.

in 2014. One hundred and seventy-one substances (60%) have been found in the ECHA registered substances database[31]. Of the 116 substances that have not been found in the ECHA registered database:

- 24 substances are outside the scope of the REACH Regulation because used in medicinal products for human or veterinary use (Art. 2(5)(a));
- 13 substances are polymers and thus outside the scope of the Regulation (Art. 2(9)); and
- 11 substances occur in nature and are covered by the exemptions listed in Annex V according to Article 2(7)(b).

Of the 68 remaining substances, 58 have been identified as pigments and dyes; 16 substances will certainly have to be registered by 2018 since the quantities notified to the FNS exceed the threshold of one tonne per year[32]. Table 4-4 and Figure 4-3 summarise these statistics.

Table 3-4: Analysis of Annex I of MEDDE (2014) and comparison with the ECHA registered substances	
Entries in Annex I of MEDDE (2014)	301
Entries (substances) further considered for the comparison	287
Substances found in the ECHA registered substances database	171 (60%)
Substances to be registered with certainty by 2018	16 (5%)
Substances outside the scope of REACH	48 (17%)
Substances not found in the ECHA registered substances database and notified in quantities below one tonne per year	52 (18%)

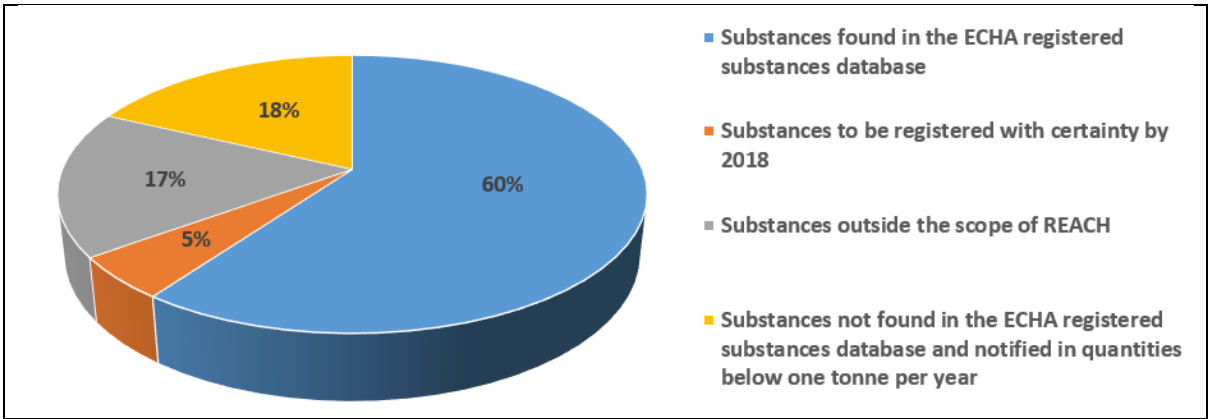

Figure 3-3: Results of the comparison between the list of substances notified to the FNS in 2014 and the ECHA registered substances database

It is important to note that the analysis refers to the chemical substances as defined by the REACH Regulation and that the information in the REACH registration dossiers of the substances that were found in the ECHA database is unspecific and does not refer to the nanoforms.

Moreover, MEDDE (2014) refers to "categories of substances", meaning that each entry represents a substance that might cover several nanoforms. At the date[33], it is not clear how the amendment of the REACH Annexes will deal with quantities below one tonne per year per manufacturer/importer of different nanoforms of the same substance manufactured/imported above 1 tonne per year per manufacturer.

[31] Ten substances are used in plant protection and biocidal products and, although not listed in the ECHA registered substances database, are regarded as being registered according to Article 15 of the REACH Regulation.

[32] It should be noted that the tonnages reported in MEDDE (2014) are aggregated; however, it is reasonable to assume that, especially for the lower quantities, tonnages refer to one single manufacturer/importer.

[33] February 2015.

In order to take into account this uncertainty, for the purpose of the assessment a range of 35% to 65% of nanomaterials that will be covered by the REACH Regulation has been considered, where 35% is the percentage of notifications referring to quantities above one tonne per year received by the French authorities in 2014, and 65% is the percentage of substances registered or expected to be registered by 2018[34].

It is important to remind that the FNS is a very recent system and the results between the first year of implementation and the second year have considerably evolved and certainly do not reflect yet the real image of the market. Thus, results of the analysis and extrapolation from the French scale to the European scale should be considered with great caution.

The Belgian Notification System will enter into force on 1 January 2016, while the first reporting period of the Danish Notification System is currently undergoing.

[34] It has to be noted that the list of substances notified to the FNS and presented in MEDDE (2014) refers to aggregate tonnages. Sixty-five percent is therefore the maximum percentage of nanomaterials that would be covered by the REACH Regulation after the possible amendments of the REACH Annexes. This estimate is based on the analysis of the 2014 FNS data and, consequently, it is subject to revision.

4 Option 1: Recommendation for National Measures

4.1 Overview

The nature of Option 1 has yet to be specified by the Commission. As such, no further detail can be provided.

5 Option 2: Nanomaterials Observatory

5.1 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 on Nanomaterials[35] can 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*.

The opportunity for Member States to carry out surveys on their markets, the results of which could feed into a Nanomaterials Observatory at EU level, is considered as sub-option (Option 2b).

5.2 Nanomaterials Covered

Under this option, a nanomaterial is defined in terms of the EC definition, but the focus would be on manufactured nanomaterials. 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.*

Of course, since the proposed Observatory would be a repository for a broad range of manufactured nanomaterial related information, it is likely that the Observatory would also be a useful source of information on other nanomaterials - such as natural and incidental nanomaterials and liquid nanoparticles mentioned above.

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*."[36]
  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

[35] http://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials
[36] http://nanopartikel.info/en/about-us

close the knowledge gaps in nanotechnology. Nanomaterials can be browse by material type, size, shape and surface area.[37]

- 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.[38]

5.3 Products Covered

As already indicated, the Nanomaterials Observatory could contain both existing data, collected from existing databases and registries, and new information gathered in further studies and surveys. As such the products covered could include a wide range of substances, mixtures and articles.

In relation to existing requirements, data gathered on a range of products could be entered on to the Nanomaterials Observatory. Such data could be drawn from REACH registration dossiers (for nanomaterials that are subject to the registration duties of the REACH Regulation), notifications of nanomaterials in cosmetic products (through the Cosmetics Regulation), authorisations of biocides containing nanomaterials (under the Biocidal Product Regulation) and national registration or notification systems.

With regard to new data on (new) products, available information could be complemented by relevant market studies and by systematically gathering and analysing scientific information on nanomaterials.

The JRC Web Platform provides an example of how this might work in practice as it 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 technologies that might shape our next future, ranking them by their likelihood and feasibility.[39]

- 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.*"[40]

5.4 Organisations Covered

A Nanomaterials Observatory would provide a platform for the organisation of the information available through the Internet: this information may be made available by many different stakeholders, including nanomaterial manufacturers/importers, downstream users, NGOs and academia. Important sources of information are also articles and papers published by research institutes.

[37] https://www.nanomaterialregistry.org/
[38] http://www.nist.gov/nanotechnology-portal.cfm
[39] http://www.nanosupermarket.org/
[40] http://www.nanowerk.com/index.php

Under Option 2b, some of the information would also be provided by national authorities choosing the observatory as the means for the dissemination of the results. In some cases, such information would be captured also under Option 2a, where national information was made publicly available on the Internet (e.g. on the websites of Competent Authorities) by the Member States.

5.5 Information Requirements

5.5.1 Base information (Option 2a)

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, identity 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 5.2 and 5.3;
- 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.

It should be noted that the JRC is working on a substantial upgrade of the current web platform on nanomaterials. In particular, the upgrade will improve the search functionalities, allowing users to open an account and to create a profile: this will enable the targeting and collection of those information of most interest for the user and to organise it in “mini-reports” structured by areas (e.g. policy, research, applications). The system could also geo-localise the source of information.

It is worth noting that the JRC Web Platform could assist with the dissemination of the results of EU-funded FP7 or Horizon 2020 projects in nanomaterial-related research or of European Commission own-initiatives in the field of nanomaterials.

5.5.2 Additional information from Member States (Option 2b)

The UK provides a useful illustrative example of how a national authority might contribute (on a voluntary basis) to an EU-based Nanomaterials Observatory. The UK has effectively established a company register, albeit a voluntary one that places the burden of contact between regulatory agency and company on the former. That is to say, the regulatory agency seeks out companies operating in the NM sector and reaches out to them by phone – there is no obligation on the company to take part. Nevertheless, this scheme provides some useful information (see Table 5-1) on the nature and extent of the nanomaterial markets in the UK by surveying manufacturers, importers and professional users of nanomaterials. It is envisaged that under Option 2b, Member State authorities would collect and collate similar information and pass it to the Nanomaterials Observatory, taking account of any confidentiality concerns where appropriate.

It is important to note that voluntary schemes in the past have not been successful, obtaining very low rate of participation. The latter UK initiative had a participation rate of around 25%[41].

Table 5-1: Type of information gathered though the UK scheme
Identity of the notifier
Company name
Address and Post Code
Town/City
EU VAT or company registration certificate
Country
Role in the supply chain • Manufacturer; • Distributor; • Importer; • Professional user and distributor; • Repackager and distributor; • European representative; • Professional user; • Manufacturer of mixtures containing nanomaterials; • Importer of mixtures containing nanomaterials; • Manufacturer of articles and/or complex objects containing nanomaterials; • Importer of articles and/or complex objects containing nanomaterials; • 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) **Research and Development** • Scientific research; • R&D on products and processes; • no R&D.
Quantities
Quantity produced
Quantity distributed
Quantity imported
Quantity distributed after use
Quantity distributed after repackaging
Other quantity
Uses
Uses *(based on ECHA Guidance)* Descriptor SU Descriptor PC Descriptor ERC Descriptor PROC Descriptor AC
The properties claimed
Product Information
Product name

[41] Chemical Compliance Team Annual Report 2012 to 2013: Main report. Available at: https://www.gov.uk/government/publications/environment-agencys-chemical-compliance-team-annual-report-2012-to-2013

Table 5-1: Type of information gathered though the UK scheme
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)

5.6 Cost for Public Authorities

5.6.1 Overview

The costs of a Nanomaterials Observatory would largely be borne by public authorities with particular regard to:

a) Centralised costs for collating data and operating an on-line platform;
b) (Optional) costs by national authorities to provide national data on companies, legislation, policies, etc.

These are considered further below as two sub-options.

5.6.2 Operational Costs (Option 2a)

The costs of a running an observatory will depend on the nature and scale of its operation as well as the type of organisation hosting it. By way of example, it would be possible for the observatory to be a simple repository of publicly available information with minimal costs. On the other hand, the operation of the observatory could involve the structured collection, collation and analysis of information in order to disseminate, for example, regular country reports on the latest nanomaterial market trends. This, in turn, would require greater resources.

There are various existing observatories funded (in part at least) by the European Commission and some information on the associated costs is available as illustrated in the examples below.

The European Risk Observatory (ERO) in Bilbao is run by the European Agency for Safety and Health at Work (EU-OSHA). Its work may be summarised[42] as follows:

> *The ERO adds value by gathering and analysing information, putting it in context (in particular in relation to the European social agenda and the Community Strategy), looking for trends in order to 'anticipate change', and communicating the key issues effectively to our target audience: policy-makers and researchers. We also aim to stimulate debate and reflection among EU-OSHA's stakeholders and to provide a platform for debate between experts and policy-makers at various levels.*

The work of the ERO was undertaken by the Pollution & Research Unit of EU-OSHA which had a staff of 20 and budget approaching €3m per annum[43]. This unit was also responsible for another major

[42] https://osha.europa.eu/en/riskobservatory/index_html

[43] EU-OSHA 2013 Annual Management Plan & Work Programme. *Note that under the current EU-OSHA's Multiannual Strategic Programme 2014-2020, the priorities have changed so that the ERO is no longer explicitly mentioned in the Annual Management Plans for 2014 and 2015.*

area of OSHA's work – to provide information to improve the working environment. As an indication, it is likely that the ERO accounted for, perhaps, a third of this budget – i.e. around €1m per annum.

The European Observatory of Working Life (EurWORK) in Dublin is run by the European Foundation for the Improvement of Living and Working Conditions (Eurofound), a European Union Agency and its activities may be summarised[44] as follows:

> *EurWORK gathers all Eurofound's resources on working conditions and industrial relations, and is supported by a network of European correspondents across all EU Member States and Norway.*
>
> *EurWORK aims to serve the main Eurofound stakeholders, i.e. European social partners, EU institutions and member state governments, as well as policy-makers and practitioners in the employment and restructuring fields.*

EurWORK provides a range of regular outputs including quarterly updates, topical reports and annual reports. Eurofound has around 100 staff and a budget of €20m per annum – of which €1.4m is for allocated for running EurWORK[45].

The European Observatory on Infringements of Intellectual Property Rights is managed by the Office for Harmonization in the Internal Market (OHIM) based in Alicante with the following objectives[46]:

- *Provide evidence-based contributions and data to enable EU policymakers to shape effective IP enforcement policies and to support innovation and creativity*
- *Provide data, tools and databases to support the fight against IP infringement*
- *Provide knowledge and learning programmes for IP and enforcement authorities as well as for businesses and IP practitioners*
- *Develop initiatives to help innovators, creators and businesses (especially SMEs) protect their IP rights*
- *Design campaigns to raise awareness of the value of IP and the negative consequences of IP infringement*

A key element of this observatory is that it involves a 'high level' network of representatives from Parliament, Member States, business associations as well those from the Commission and other international organisations (such as Interpol). The associated budget for this observatory is €3.5m per annum[47] – although it is worth noting that about €2m of this is allocated to proactive 'limited consultations, studies and surveys'.

Finally, in a recent tender to establish an **Observatory for the Construction Sector**[48], the contractor was expected to provide:

- National profiles (for the EU-28 countries) with annual updates including details on major markets, companies, legislation, policies, etc.;
- Fact sheets covering specific topics of interest (around 25 per annum);
- Analytical reports to inform on key issues and to suggest possible policy recommendations (around six per annum); and
- To regularly update dedicated web-pages to inform all interested parties (from policy makers to the general public).

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44 http://eurofound.europa.eu/observatories/european-observatory-of-working-life-eurwork/about-eurwork
45 Eurofound Annual Work Programme 2015
46 https://oami.europa.eu/ohimportal/en/web/observatory/about-us
47 European Observatory on Infringements of Intellectual Property Rights Work Programme 2013
48 Invitation to Tender No. EASME/COSME/2014/001 (closing date: 30 September 2014)

The associated budget was of the order of €400k per annum.

For the purpose of this assessment, cost estimates have been provided by the Joint Research Centre with regard to the development, operation and maintenance of the **updated JRC Web Platform** (expected to be online by the end of 2015 and to become a 'European Commission web platform on nanomaterials') and for the case of a complete re-development due to changes in scope and objectives. The operating costs are strongly dependent on the actual scope that would be assigned to the Nanomaterials Observatory and could be substantially higher than €250k per annum. Table 5-2 presents the cost estimates.

Table 5-2: Cost Estimates for the JRC Web Platform		
Cost estimates for Upgrading the JRC Web Platform		
	One-off costs, first year	**Recurring annual costs**
Maintenance (software, hardware/consumables, energy, bandwidth, security)		≈€23,000
Maintenance (IT staff – external)		≈€90,000
Operating Commission staff, including overheads		≈€157,000
Total recurring costs		**≈€270,000**
Development hardware and software	≈€3,000	
Development (IT staff – external)	≈€110,000	
Total one-off costs	**≈€113,000**	
Total	**≈€383,000 for the first year ≈€270,000 per annum thereafter**	
Cost estimates for a re-development of the JRC Web Platform due to change in scope and objectives		
	One-off costs, first year	**Recurring annual costs**
Development hardware and software	≈€15,000	
Development IT staff	≈€320,000	
Total one-off costs	**≈€335,000**	
Total recurring costs – same as above		**≈€270,000**
Total	**≈€605,000 for the first year ≈€270,000 per annum thereafter**	

Against this background, it would be expected that the costs of running a **Nanomaterials Observatory** would be more comparable to those for the Construction Sector, for the European Risk Observatory and for the JRC Web Platform. The costs for the OHIM Observatory would probably be significantly higher due to the greater emphasis on additional studies associated with the need to collate information to combat counterfeiting of goods and other IP infringements. Similarly, the operation of EurWORK involves the collection and processing of much larger volumes of data than would be expected to be associated with the Nanomaterials Observatory.

With these points in mind, the base costs for the collection, collation and analysis of the data plus the maintenance of the hardware and the regular update of the software have been taken as €270k per annum (as for the JRC Web Platform detailed above).

A further potential cost is the possible need for the translation of web-pages, fact sheets and (short) topical/country reports. Given the diversity of EU languages, the translation costs could be significant. It is of note that 10% of the OHIM Observatory's budget is allocated to translation.

The resultant costs for Option 2a are then estimated as: €270k (data + operations) + €65k (translations) = **€335k per annum**. For the first year, the costs could be between €225k and €335k higher depending on the complexity of the development of the web platform (based on the information for the development of the JRC Web Platform).

5.6.3 Operational Costs (Option 2b)

The costs for the operation of the Nanomaterials Observatory under Option 2a would be incurred by the Commission and similar bodies. As such, these costs do not constitute any 'administrative burden' upon public authorities at national level. However, should national authorities assist with data collection and other aspects of the Observatory on a voluntary basis, then there would be additional costs. The UK provides a useful illustrative example as to the costs associated with the operation of system to collect data on the nature and extent of the nanomaterial markets in the UK by surveying manufacturers, importers and professional users of nanomaterials.

Based on information provided by the UK authorities, the associated resource costs (based on a €45 hourly rate[49]) are modest and have been estimated at about €20,000 for the first year, with recurring annual costs of around €7,000 thereafter per participating MS[50].

The degree of participation by national authorities is difficult to determine but an initial estimate of 50% of the EU-28 has been assumed. This is based, to some extent, on the degree of active participation in product safety registers. Although, the Rapid Alert System for non-food dangerous products ("rapid exchange" also known as RAPEX) has 31 participating countries (EU-28 plus Norway, Iceland and Liechtenstein), inspection of the associated annual reports[51] show that most of the 2,000 notifications are done by just a few countries. The situation appears more marked in the EU's Information and Communication System on Market Surveillance (ICSMS). The ICSMS seeks to create a network that provides current information on the actions undertaken by market surveillance bodies across Europe. Of note is that it consists of both 'closed' and 'public' areas which are accessible in the full range of EU languages. However, inspection of the 'public area' suggests that nearly all recent notifications are from Germany[52]. The closed area enables communications amongst market surveillance authorities, customs authorities and the European Commission and contains confidential product information, test results, etc.[53].

Although there would be variations in resources committed by Member State authorities to assist with providing information to the Observatory, it has been assumed that half of the EU-28 countries would actively participate. Furthermore, it has been assumed that, on average, the resources provided would be similar to that associated with the UK scheme.

With these points in mind, the additional cost to Member States would be **€280k for the first year** (based on 14 x €20k), with **recurring annual costs of around €100k** thereafter.

It is important to note that businesses voluntarily participating in the national surveys would entail a certain administrative burden: assuming half a day per company and a participation of 20% of the businesses in the nanomaterials field[54] in 50% of the Member States of the EU28, the costs would be of around **€30k per annum**.

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[49] This €45 hourly rate for labour (wage) cost has been agreed with the Commission and has been derived as follows: Typical profession salary €60k + 25% overheads = €75k for 220 days each of 7.5 hours = €45 per hour.

[50] Based on an initial 12 work weeks x 37.5 hours x €45 = €20,250 and recurring costs of (4 work weeks/per year x 37.5 x €45) = €6,750

[51] http://ec.europa.eu/consumers/consumers_safety/safety_products/rapex/reports/index_en.htm

[52] https://webgate.ec.europa.eu/icsms/public/productSearch.jsp?locale=en

[53] For further information on ICSMS, see: http://ec.europa.eu/growth/single-market/goods/building-blocks/icsms/index_en.htm

[54] The latest UK initiative has had so far a participation rate of around 25% (of the 268 organisations which were identified as potentially producing and/or using nanomaterials, 66 provided information relating to the production, use and/or distribution of nanomaterials in the UK).

5.6.4 Summary

Summating the figures presented above suggests that, **in the first year, the overall cost for Option 2a (no national surveys) could be €560k to around €670k depending on the complexity of the web platform and with the active participation of 14 MS (Option 2b), the costs could be nearly €300k higher, ranging from €860k to €970k in total.**

Thereafter, the recurring costs for Option 2a would be around **€335k per annum** and, with the active participation of 14 MS (Option 2b) with additional costs of €7,000 per MS, around **€435k per annum** in total.

6 Option 3: EU Nanomaterial Registry by Substance

6.1 Overview

Option 3 foresees the establishment of a nanomaterial registry modelled upon the French system but on an EU-wide level.

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 have been 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.

6.2 Nanomaterials Covered

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

6.2.1 Option 3a "EU-wide nanomaterial notification system by substance with no exemptions"

Under Option 3a, the system would exempt nanomaterials of national Defence interest only. The French authorities have identified 319 different categories of substances[55] at the nanoscale notified in 2014, rising from 258 that were instead identified (RPA *et al*, 2014b) from the notifications in 2013.

This number is likely to increase in the coming years, as new companies become aware of their notification duties, information on the status of their substances (whether they are within the parameters of the EU recommended definition of nanomaterial) become available and more nanomaterials are notified for certain chemical product categories (e.g. plant protection products, pharmaceuticals).

6.2.2 Option 3b "EU-wide nanomaterial notification system by substance with exemptions"

Under Option 3b, the system would exempt additionally:

- Nanomaterials only used in scientific research and development;
- Nanomaterials only used in product and process oriented research and development;
- Nanomaterials only used in as pigments;
- Nanomaterials only used in as fillers;
- Nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation; and
- Nanomaterials in articles covered by existing registration requirements. These are:
  - Nanomaterials within the scope of the Cosmetics Regulation (No. 1223/2009). This Regulation 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).
  - Nanomaterials within the scope of the Biocidal Product Regulation (No. 528/2012). This Regulation requires a dedicated risk assessment for the nanomaterial form of the substance and excludes biocidal products with nanomaterials from the simplified authorisation procedure.
  - Nanomaterials within the scope of the Food Additives Regulation (No. 1333/2008). This Regulation 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.
  - Nanomaterials within the scope of Regulation (EC) No 726/2004 on medicinal products for human or veterinary use.

Table 6-1 presents the share and numbers of nanomaterials on the EU market covered by the exemptions above. In the table it is assumed that the current number of nanomaterials on the EU

[55] MEDDE (2014) refers to "*catégories de substances à l'état nanoparticulaire*". A definition is not provided, but it is explained (MEDDE, 2014, p. 32) that in the list of substances presented, some CAS numbers have been grouped in broad families of substances, such as silicon dioxide and titanium dioxide. The same approach has been followed in RPA *et al* (2014b).

market is between 500 and 2,000 (where 500 is the number of different substances with nanoforms and 2,000 is 4 times 500, with 4 being the estimated average number of nanoforms per substance). This range has been consistently used in the previous assessments over the last few years (Matrix, 2014; BiPRO *et al*, 2013; RPA, 2012). This estimate is based on a preliminary survey conducted by VCI in 2012 amongst German companies and further discussions with relevant industry associations (RPA, 2012). The wide range is due to the level of uncertainty and ambiguity surrounding existing measurement techniques to determine whether or not a material will fall within a nanomaterial definition based on the metrics of percentage of the particle number distribution for some of the most common classes of materials, e.g. pigments.[56]

Table 6-1: Number of nanomaterials covered by the exemptions on the EU market			
Exemptions	**No. in the FNS**	**Share**	**No. in the EU**
Total number of nanomaterials	287[57]		500
Nanomaterials only used in scientific research and development or in product and process oriented research and development	12[58]	4%	21
Nanomaterials only used as pigments	150	52%	261
Nanomaterials only used as fillers	8	3%	14
Nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation	187	65%[59]	326
Nanomaterials in articles covered by existing registration requirements (cosmetic products)	1[60]	0.3%	2
Nanomaterials in articles covered by existing registration requirements (biocidal and plant protection products)	10	3%	17
Nanomaterials in articles covered by existing registration requirements (medicinal products)	24	8%	42

The steering group and key consultees for RPA (2012) also suggested that around 50% of nanomaterials currently placed on the market are pigments, with a further 10% of the materials being fillers, catalysts and other high volume substances. These assumptions have been confirmed by the findings of the analysis carried out by RPA on the substances at the nanoscale notified to the FNS (RPA *et al*, 2014b). As validation for this assumption, the Austrian initiative compiled a list containing 432 substances with nanoforms on the Austrian market[61].

It should be noted however that the assumption on the current number of nanomaterials on the EU market has been used neither for the calculation of the administrative burden for businesses nor for the assessment of the costs for the public authorities. This is because the costs depend on the numbers of notifications rather than on the numbers of nanomaterials.

[56] For the problems in the characterisation of nanomaterials and the range of different results depending on metrics and methods used, see the presentation of Dr Wendel Wohlleben given during the Scientific Topical Workshop on regulatory challenges in risk assessment of nanomaterials held in Helsinki on 23-24 October 2014. Available at: http://echa.europa.eu/documents/10162/5399565/4_wohllebenws_nanomaterials_en.pdf

[57] Although 319 different substances have been identified by the French authorities, 287 is the number of substances on which it was possible to carry out the analysis. Thus, the percentages to be applied on the EU level have been calculated on this number.

[58] 43 substances have been notified for SU24 "Scientific research and development", just 12 substances have been notified as used solely in R&D.

[59] With regard to the nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation, the range 35% to 65% has been considered in the analysis, as explained in Section 3.2.

[60] Although 17 substances have been notified with PC39 "Cosmetics, personal care products" (MEDDE, 2014, Annex I, page 9), only one (2,2'-methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)) is solely used in cosmetic products, while the other substances have also been notified with other product categories.

[61] http://newsletter.echa.europa.eu/home/-/newsletter/entry/5_14_guest-column-nanomaterials

6.3 Products Covered

It is important to note that the system does not cover consumer products: distributors to consumers do not have any notification duties. Nevertheless, the notification of the descriptors (and in particular chemical product categories and article categories) provides information on the market sectors at the supply level and on the types of articles containing nanomaterials.

6.3.1 Option 3a "No exemptions"

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.

In 2014, the 9,990 notifications that have been analysed by the French authorities reported 11,009 Sector of Use (SU) descriptors, 2,631 Chemical Product Categories (PC) and 414 Article Categories (AC).

Tables 6-2 to 6-5 present:

- Number of substances with nanoforms per descriptor;
- Number of notifications per descriptor; and
- Shares on the total number of each type of descriptors notified (SU, PC and AC).

Table 6-2: Sectors of Use (FNS 2014 data)

Code	Supplementary descriptor: Sectors of end-use	NACE codes[62]	No. of NMs	No.	%
SU1	**Agriculture, forestry, fishery**	**A**	**37**	**6,417**	**58.28**
SU2a	Mining, (without offshore industries)	B	3	4	0.04
SU2b	Offshore industries	B 6	0	0	0
SU4	Manufacture of food products	C 10,11	8	233	2.12
SU5	Manufacture of textiles, leather, fur	C 13-15	7	13	0.12
SU6a	Manufacture of wood and wood products	C 16	4	6	0.05
SU6b	Manufacture of pulp, paper and paper products	C 17	18	44	0.40
SU7	Printing and reproduction of recorded media	C 18	4	14	0.13
SU8	Manufacture of bulk, large scale chemicals (including petroleum products)	C 19.2+20.1	10	36	0.3
SU9	Manufacture of fine chemicals	C 20.2-20.6	26	119	1.1
SU10	**Formulation [mixing] of preparations and/or re-packaging (excluding alloys)**	**C 20.3-20.5**	**158**	**2,131**	**19.4**
SU11	Manufacture of rubber products	C 22.1	26	161	1.5
SU12	Manufacture of plastics products, including compounding and conversion	C 22.2	71	161	1.5
SU13	Manufacture of other non-metallic mineral products, e.g. plasters, cement	C 23	12	31	0.3
SU14	Manufacture of basic metals, including alloys	C 24	2	10	0.1
SU15	Manufacture of fabricated metal products, except machinery and equipment	C 25	14	33	0.3
SU16	Manufacture of computer, electronic and optical products, electrical equipment	C 26-27	7	49	0.4
SU17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	C 28-30,33	22	330	3.0
SU18	Manufacture of furniture	C 31	3	5	0.0
SU19	Building and construction work	F	29	84	0.8
SU20	Health services	Q 86	11	20	0.2

[62] Notifiers have to submit information on the Sectors of Use. Corresponding NACE codes have been assigned to Sectors of Use by ECHA.

Table 6-2: Sectors of Use (FNS 2014 data)					
Code	**Supplementary descriptor: Sectors of end-use**	**NACE codes[62]**	**No. of NMs**	**No.**	**%**
SU23	Electricity, steam, gas water supply and sewage treatment	C 35-37	2	5	0.0
SU24	Scientific research and development	C72	43	227	2.1
SU0	Other		182	877	8.0

Table 6-3: Chemical Product categories (FNS 2014 data)				
Code	**Category for describing market sectors (at supply level) regarding all uses (workers and consumers)**	**No. of NMs**	**No.**	**%**
PC1	Adhesives, sealants	10	52	2.0
PC2	Adsorbents	3	7	0.3
PC3	Air care products	3	3	0.1
PC4	Anti-Freeze and de-icing products	0	0	0
PC7	Base metals and alloys	2	2	0.1
PC8	Biocidal products (e.g. Disinfectants, pest control)	3	15	0.6
PC9a	**Coatings and paints, thinners, paint removers**	**89**	**631**	**24.0**
PC9b	Fillers, putties, plasters, modelling clay	8	47	1.8
PC9c	Finger paints	0	0	0
PC11	Explosives	0	0	0
PC12	Fertilizers	1	1	0
PC13	**Fuels**	**5**	**216**	**8.2**
PC14	Metal surface treatment products, including galvanic and electroplating products	9	24	0.9
PC15	Non-metal-surface treatment products	9	18	0.7
PC16	Heat transfer fluids	0	0	0
PC17	Hydraulic fluids	1	1	0.0
PC18	Ink and toners	22	44	1.7
PC19	Intermediate	6	16	0.6
PC20	Products such as ph-regulators, flocculants, precipitants, neutralization agents	2	12	0.5
PC21	Laboratory chemicals	3	15	0.6
PC23	Leather tanning, dye, finishing, impregnation and care products	1	4	0.2
PC24	Lubricants, greases, release products	3	5	0.2
PC25	Metal working fluids	0	0	0
PC26	Paper and board dye, finishing and impregnation products: including bleaches and other processing aids	2	5	0.2
PC27	**Plant protection products**	**13**	**575**	**21.9**
PC28	Perfumes, fragrances	4	12	0.5
PC29	Pharmaceuticals	13	57	2.2
PC30	Photo-chemicals	3	4	0.2
PC31	Polishes and wax blends	1	2	0.1
PC32	**Polymer preparations and compounds**	**27**	**160**	**6.1**
PC33	Semiconductors	2	24	0.9
PC34	Textile dyes, finishing and impregnating products; including bleaches and other processing aids	1	1	0.0
PC35	Washing and cleaning products (including solvent based products)	3	11	0.4
PC36	Water softeners	0	0	0
PC37	Water treatment chemicals	1	1	0.0
PC38	Welding and soldering products (with flux coatings or flux cores.), flux products	0	0	0.0
PC39	**Cosmetics, personal care products**	**17**	**605**	**23.0**
PC40	Extraction agents	0	0	0
PC0	Other (use UCN codes: see last row)	13	61	2.3

Table 6-4: Article categories, no release intended (AC) (FNS 2014 data)				
Code	**Categories of complex articles**	**No. of NMs**	**No.**	**%**
AC1	**Vehicles**	**10**	**49**	**11.8**
AC2	**Machinery, mechanical appliances, electrical/electronic articles**	**36**	**82**	**19.8**
AC3	Electrical batteries and accumulators	1	3	0.7
Code	**Categories of material based articles**			
AC4	Stone, plaster, cement, glass and ceramic articles	10	29	7.0
AC5	Fabrics, textiles and apparel	0	0	0
AC6	Leather articles	1	1	0.2
AC7	**Metal articles**	**13**	**39**	**9.4**
AC8	Paper articles	4	11	2.7
AC10	**Rubber articles**	**5**	**99**	**23.9**
AC11	Wood articles	0	0	0
AC13	**Plastic articles**	**22**	**56**	**13.5**

Table 6-5: Use descriptor for articles with intended release of substances (FNS 2014 data)				
Code	**Descriptor based on an indicative list of examples**	**No. of NMs**	**No.**	**%**
AC30	**Other articles with intended release of substances, please specify**	**12**	**45**	**10.9**
AC31	Scented clothes	0	0	0
AC32	Scented eraser	0	0	0
AC34	Scented Toys	0	0	0
AC35	Scented paper articles	0	0	0
AC36	Scented CD	0	0	0
AC38	Packaging material for metal parts, releasing grease/corrosion inhibitors	0	0	0

On the basis of these results, it is still too soon to draw any conclusion on which sectors of the economy will be the most affected in terms of notification requirements to a centralised system. The sharp rise in the notifications reporting SU1 "Agriculture, forestry, fishery" does not automatically mean that this is the sector where most of the nanomaterials are used but could just reflect an increased awareness of the notification duties within the sector's actors in association with long supply chains of the nanomaterials used (from the manufacturers and importers of the nanomaterials to formulators of mixtures to repackagers to distributors…)[63]. Indeed, MEDDE (2014) concludes that it is possible that the length of the supply chains are still underestimated[64]. However, it can be concluded that nanomaterials are present in every sector of the economy[65] and in a wide range of product categories.

6.3.2 Option 3b "With exemptions"

The exemptions would have the following effects on the products within the scope of the system:

- With regard to nanomaterials only used in scientific research and development or in product and process oriented research and development, the exemption would not have, by definition, any effect on the products within the scope of the register;
- With regard to nanomaterials only used as pigments, the following chemical product categories would be outside the scope of the register (or would result in a drastic reduction of the number of notifications for these categories):

[63] See also MEDDE (2014), p.16.
[64] MEDDE (2014), p.21.
[65] The only sector with no notification (so far) is SU2b "Offshore industries".

- Coatings and paints, thinners, paint removers (PC9a);
- Ink and toners (PC18);
- Polymer preparations and compounds (PC32);
- Cosmetic products (PC39).

Moreover, it has to be noted that this exemption would cover carbon black and titanium dioxide (respectively, the first and the fourth nanomaterial in terms of tonnage on the market) where they are used as pigments;

- With regard to nanomaterials only used as fillers, although only 8 nanomaterials have been notified in this category (PC9b), six of them are produced in high volumes, making well over 95% of the nanomaterials market in terms of tonnage;
- The exemption on nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation would result in many of the chemical product categories being outside the scope of the register; the categories within the scope would be the one covered by other regulations (e.g. biocidal products, plant protection products, cosmetic products, pharmaceuticals);
- On the opposite, the exemption on nanomaterials in articles covered by existing registration requirements would leave outside the scope of the register categories such as biocidal products, plant protection products, cosmetic products, pharmaceuticals and food additives.

6.4 Organisations Covered

6.4.1 Introduction

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 (as for the FNS) is:

- "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.

Table 6-5 presents number of notifiers per role, number of notifications per role and average number of notifications per role in the supply chain in France in 2013 and 2014.

From Table 6-5, it can be concluded that there has been a sharp increase in the number of distributors submitting notifications to the FNS. In terms of the average number of notifications submitted per role, this has remained constant across the different actors with the exception of the distributors, for which it has doubled (due to an increased awareness of their notification duties).

Table 6-5: Average number of notification per role in the supply chain						
Role	2013			2014		
	No.	No. of notifications	Notifications per notifier	No.	No. of notifications	Notifications per notifier
Manufacturer	51	149	3	54	171	3
Importer	185	923	5	209	1,025	5
Distributor	279	1,121	4	962	7,460	8
Professional user and distributor	263	982	4	410	1,781	4
Repackager and distributor	18	35	2	31	52	2
Other	32	n/a	n/a	34	n/a	n/a
Notes: *No information has been reported on the entities that indicated "other" as role in the supply chain. It must be noted that the notifiers could indicate multiple roles for each notification.*						

Figure 6-1 presents numbers and percentages of notifiers per role within the supply chain.

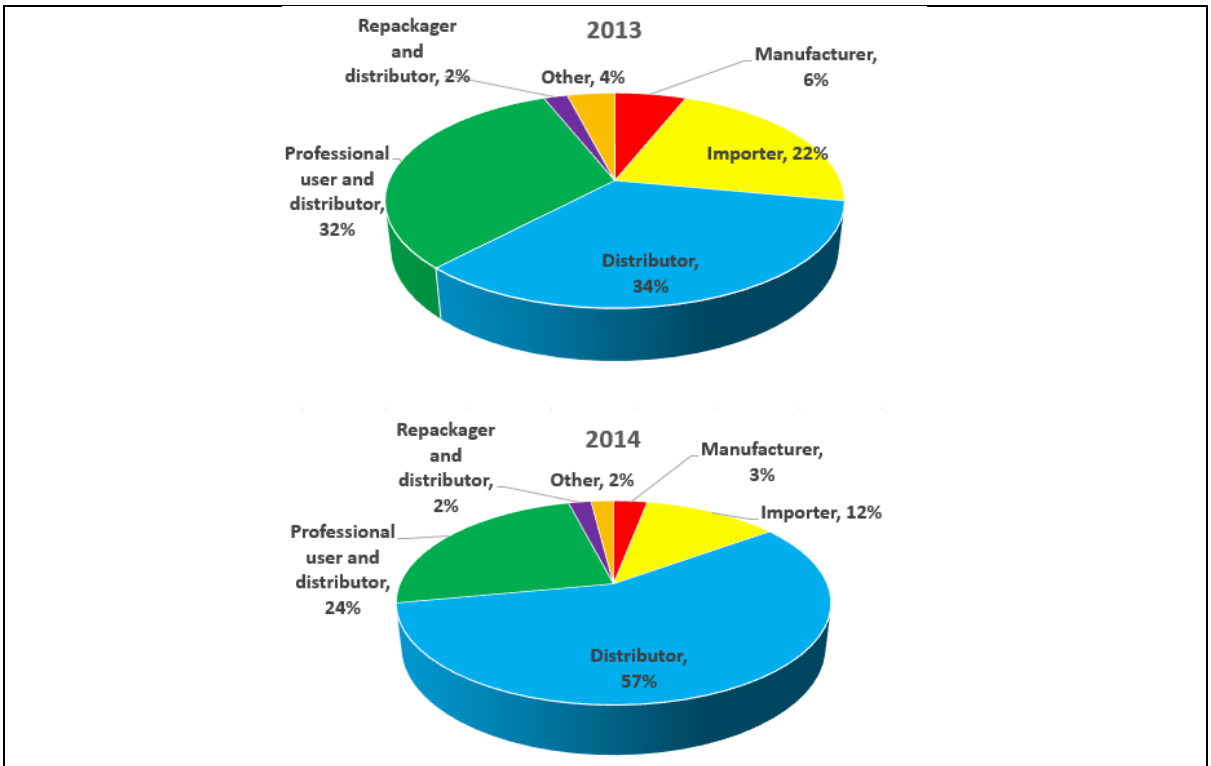

Figure 6-1: Distribution of the notifiers across the supply chain in 2013 and 2014

6.4.2 Option 3a "No exemptions"

In order to extrapolate the results of the analysis of the FNS to the EU level, it is essential to know the classification of the economic activities (NACE codes) of the companies that had to notify to the FNS. This information has been obtained through the survey on the administrative burden that was carried out in March 2014 and was presented in Table 5-5 of the Evaluation report[66]. In light of the latest statistics published in MEDDE (2014), two other NACE codes have been added (referring to pharmaceuticals and plastics in primary forms). Table 6-6 presents NACE codes and descriptions of the sectors considered.

[66] RPA *et al* (2014), p. 61.

Table 6-6: NACE codes considered	
NACE	**Description**
C20.12	Manufacture of dyes and pigments
C20.13	Manufacture of other inorganic basic chemicals
C20.14	Manufacture of other organic basic chemicals
C20.16	Manufacture of plastics in primary forms
C20.20	Manufacture of pesticides and other agrochemical products
C20.30	Manufacture of paints, varnishes and similar coatings, printing ink and mastics
C20.41	Manufacture of soap and detergents, cleaning and polishing preparations
C20.42	Manufacture of perfumes and toilet preparations
C20.59	Manufacture of other chemical products
C21.10	Manufacture of basic pharmaceutical products
C21.20	Manufacture of pharmaceutical preparations
G46.45	Wholesale of perfume and cosmetics
G46.46	Wholesale of pharmaceutical goods
G46.75	Wholesale of chemical products
M72.1	Research and experimental development on natural sciences and engineering

Table 6-7 presents the number of companies in the Belgium, Denmark, France and the EU28 per NACE code identified[67]. The data from Belgium, Denmark and France have been considered in order to determine the marginal impact (to Baseline 0b) of Option 3 on the number of notifications for which notifiers will have to characterise the nanomaterial.

Not all the companies accounted within the business sectors deal with nanomaterials, therefore some educated guesses had to be made on the share of companies with notification duties within those sectors. These are presented in the table and justified below.

It is assumed that the following percentages of companies in the different business sectors have notification duties:

- All the manufacturers of pigments and dyes (C20.12): given that over 50% of the nanomaterials identified are pigments and dyes, it is likely that all the manufacturers of pigments and dyes have in their product portfolio at least one substance at the nanoscale;
- 25% of the manufacturers of other inorganic basic chemicals (C20.13): among these companies there are the manufacturers of very common nanomaterials produced in high volumes, such as carbon black, silicon dioxide, calcium carbonate and silicic acid salts;
- 10% of the manufacturers of other organic basic chemicals (C20.14): among these companies there are manufacturers specialised in e.g. fullerenes, carbon nanotubes and grapheme;
- 10% of the manufacturers of plastics in primary forms (C20.16): among these companies there are manufacturers of plastic films such as PVC film (PVC at the nanoscale is among the top ten nanomaterials in terms of tonnage in France);
- 10% of the manufacturers of pesticides and other agrochemical products (C20.20): so far, around 13 pesticides at the nanoscale have been notified in France; currently there are around 500 approved active substances in the EU Pesticide Database[68];
- 90% of the manufacturers of paints, varnishes and similar coatings, printing ink and mastics (C20.30): this percentage should cover those manufacturers of paints that act as importers of pigments and dyes from outside France or that manufacture their own pigments and dyes;
- 10% of the manufacturers of soap and detergents, cleaning and polishing preparations (C20.41);
- 10% of the manufacturers of perfumes and toilet preparations (C20.42): this percentage should cover those manufacturers of cosmetic products that act as importers of nanomaterials from outside France or that manufacture their own substances at the nanoscale;

[67] Eurostat Structural Business Statistics.

[68] http://ec.europa.eu/sanco_pesticides/public/?event=activesubstance.selection&language=EN

- 10% of the manufacturers of other chemical products (C20.5): manufacturers of nanomaterials used as e.g. absorbents, lubricants, greases, release products;
- 10% of the manufacturers of basic pharmaceutical products (C21.10): 24 nanomaterials have been notified so far in France as used in pharmaceutical products, but this number is likely to increase in the oncoming years;
- 10% of the manufacturers of pharmaceutical preparations (C21.20): this percentage should cover those manufacturers of pharmaceutical preparations that act as importers of nanomaterials from outside France or that manufacture their own substances at the nanoscale;
- With regard to the wholesale of nanomaterials or products containing nanomaterials, the determinant factor is whether the nanomaterials are bound to the mixtures that are distributed[69]; for example, silicon dioxide is virtually present in all categories of food and beverages[70] as anti-caking and anti-foaming agent (under the name E551). In case this would be considered not bound, the number of companies with notification duties would increase substantially (there are around 19,000 wholesalers of food and beverages in France; assuming that 30% deal with processed food, around 6,000 companies in France would have notification duties, around 105,000 in Europe). With regard to wholesalers of perfume and cosmetics, of pharmaceutical products and of chemicals, 5% of the companies have been assumed to have notification duties; and
- 10% of the entities in research and experimental development on natural sciences and engineering has been assumed to have ongoing research on nanotechnology and therefore, with notification duties.

It should be noted that some NACE codes in which, potentially, there are companies manufacturing, importing or distributing some nanomaterials on their own or in mixtures without being bound to them or in articles with intended release have not been considered[71]. These are:

- Manufacture of glues (C20.52);
- Manufacture of essential oils (C20.53);
- Wholesale of wood, construction materials and sanitary equipment (including wholesale of paint and varnish) (G46.73);
- Wholesale of solid, liquid and gaseous fuels and related products (G 46.71).

[69] Nanomaterials in articles intended to release such substances under normal or reasonably foreseeable conditions of use have not been considered. So far, around 12 nanomaterials have been notified as used in articles with intended release.

[70] http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=284

[71] In order to be conservative with the estimates, only the NACE codes reported by the companies during the survey on the administrative burden of the FNS and the two NACE codes (referring to pharmaceuticals and plastics in primary forms) added in light of the last data provided by MEDDE (2014) have been considered.

Table 6-7: Number of companies per NACE code and number of companies with notification duties									
	Number of companies				Share of companies with notification duties	Number of companies with notification duties			
NACE	EU 28	Belgium	Denmark	France		EU28[+]	Belgium[+]	Denmark[+]	France[+]
C20.12	592	13	5	61	1	590	10	10	60
C20.13	1,086	28	4	87	0.25	270	10	-	20
C20.14	1,980	102	11	220	0.1	200	10	-	20
C20.16	2,546	77	14	165	0.1	250	10	-	20
C20.20	623	11	6	80	0.1	60	-	-	10
C20.30	4,000	118	42	266	0.9	3,600	110	40	240
C20.41	3,725	86	41	354	0.1	370	10	-	40
C20.42	4,557	77	44	861	0.1	460	10	-	90
C20.59	4,335	57	38	285	0.1	430	10	-	30
C21.10	900	36	24	57	0.1	90	-	-	10
C21.20	3,172	89	68	347	0.1	320	10	10	30
G46.45	19,837	489	180	2,261	0.05	990	20	10	110
G46.46	38,496	1,376	611	3,149	0.05	1,920	70	30	160
G46.75	27,877	884	181	2,033	0.05	1,390	40	10	100
M72.1	37,800	502	495	3,600	0.1	3,780	50	50	360
Total	151,526	3,945	1,764	13,826		14,720	370	160	1,300
Source: Eurostat Structural Business Statistics 2012. *Notes:[+]Rounded to the nearest ten*									

6.4.3 Option 3b "With exemptions"

The exemptions would have the following effects on the number of organisations with notification duties in the EU:

- With regard to the exemption on nanomaterials used in R&D, it has been estimated that around 3,800 European research institutes/universities would not have to comply with the register;
- The exemption on nanomaterials only used as pigments could result in up to 4,000 organisations not having to notify to an EU register (companies in the manufacture of dyes and pigments and in the manufacture of paints, varnishes and similar coatings, printing ink and mastics);
- The exemption on nanomaterials only used as fillers would decrease (of 25%) the number of manufacturers of other inorganic basic chemicals having to notify to an EU register;
- The exemption on nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation would have the effect of decreasing the number of duty-holders across all the business sectors apart from those that are explicitly left outside the scope of REACH (manufacturers of pesticides and other agrochemical products, manufacturers of plastics in primary forms, manufacturers and wholesalers of basic pharmaceutical products or pharmaceutical preparations and the wholesalers of chemical products). It should be noted that plant protection and biocidal products are considered as already registered under the REACH Regulation (Article 15): depending on the interpretation of the scope of the exemption, companies in the manufacture of pesticides and agrochemical products would be exempted too;
- The exemption on nanomaterials in articles covered by existing registration requirements would decrease the number of duty-holders across the manufacturers of basic pharmaceutical products and preparations, the manufacturers and wholesalers of perfumes and toilet preparations, the manufacturers of pesticides and other agrochemical products, the wholesalers of chemical products and, importantly, the wholesalers of food and beverages.

6.5 Information Requirements

The information to be collected by the registry can be divided ***into five main areas:***

- The Notifier identity;
- The identity of the nanomaterial;
- The quantities manufactured, imported or distributed in the year preceding the notification;
- The uses of the nanomaterial;
- The identities of the professional users to whom the notifier has provided the nanomaterial.

Table 6-8 presents the detailed description of the information to be notified to the EU-wide nanomaterial registry by substance.

Table 6-8: 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; • Distributor;	

Table 6-8: Information to be notified		
Information	**Options**	**Examples/Notes**
	• Importer; • Professional user and distributor; • Repackager and distributor; • 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; • Distributor; • Importer; • Professional user and distributor; • Repackager and distributor; • 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; • R&D on products and processes; • 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: • Waiting for the results; • Substance/mixture/article imported: information not available; • The distributor did not pass the information.		
State of the substance*	• The substance is pure; • The substance is contained in a mixture without being bound to it; • 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*		Titanium dioxide
Chemical formula*		TiO_2

Table 6-8: Information to be notified		
Information	**Options**	**Examples/Notes**
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 (TiO_2, 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. Examples: 1 Average diameter: 10 nm 1 Standard deviation: ± 5 nm 2 Average diameter: 320 nm 2 Standard deviation: ± 12 nm
	Determination method used: TEM (Transmission Electron Microscopy), SEM (Scanning Electron Microscopy), AFM (Atomic Force Microscopy), other	Describe if other method. Attach 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	

Table 6-8: Information to be notified		
Information	**Options**	**Examples/Notes**
Aggregation and agglomeration state*	Mean size of aggregates with standard delta	The unit is nm. For example, for a monomodal distribution: Average diameter of 1: 1200 nm 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: Mean diameter 1: 3 000 nm Standard deviation 1: ± 500 nm Mean diameter 2: 12 000 nm 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, 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 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
	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.

Table 6-8: Information to be notified		
Information	**Options**	**Examples/Notes**
	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 Descriptor PC Descriptor PROC 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	

6.6 Administrative Burden on Businesses

6.6.1 Option 3a "No exemptions"

In essence, the total cost is a function of:

- The nature and extent of information required;
- The cost of providing that information;
- Number of EU businesses affected.

More precisely, the following cost categories have been considered, differentiating between one-off costs and recurring costs:

1. Administrative costs:
   - Understanding of the legal requirements (Total hours); **(one-off cost)**
   - Gathering of information to be submitted (Total hours); **(recurring cost)**[72]
   - Submission of the information (Total hours); **(recurring cost)**
   - Responding to clients' enquiries (Total hours); **(recurring cost)**

2. Substance analysis characterisation costs (only the part of information generated for the purpose of the notification) (Euros (€) and/or total hours); **(one-off cost)**
3. IT alignment and/or adapting product/account databases (Euros (€) and/or total hours). **(one-off cost)**

It should be noted that even for the recurring costs, a certain learning curve (and thus a decrease in the costs) is expected: the information submission exercise should take less time once the responsible person has familiarised with the online system (www.r-nano.fr) and enquiries from the clients are expected to decrease in the long run. For a detailed discussion on these cost categories, please consult Section 5.3.6 of the Evaluation report[73].

Option 3, as the French Notification Scheme, would require the mandatory submission of information only on a limited number of parameters, namely:

- Size of the particles;
- Particle number size distribution;
- Aggregation/agglomeration state;
- Shape;
- Coating.

Information on any impurities, the crystalline state and the surface charge should be submitted if available at the time of notification.

With regard to the estimate of the costs associated with the characterisation of nanomaterials, the following cost figures and assumptions have been used for the assessment:

- The cost for generating all the information for the purposes of notification range between €3,000 to €10,000;
- The cost for generating only part of the information range between €3,000 to €5,000;
- For 70% of the notifications completed by manufacturers and importers, the information had to be generated completely for the purposes of the notification; for 20% only part of the information had to be generated, for the remaining 10% of the notifications completed by manufacturers and importers, the information was already available for product development purposes.

The cost figures and assumptions are based on the results of the survey on the administrative burden posed by the FNS carried out during March 2014 for the purpose of this study. In particular, the costs to characterise the nanomaterials have been reported by nine companies, two of which ranking among the companies that notified the highest number of nanomaterials to the FNS. Costs vary depending on the type of nanomaterial tested and on the characterisation method used per parameter: different measurement techniques are needed for different nanomaterials[74].

[72] Each year, companies will have to verify whether the information submitted in the previous year is still valid or new/updated information needs to be submitted.

[73] RPA *et al* (2014b), page 63.

[74] Presentation on "Implementation of the risk-neutral, wide scope EC nano-definition: Practical concepts and test cases" given by Dr Wohllenben during the Topical Scientific Workshop on regulatory challenges in risk assessment of nanomaterials on 23-24 October 2014 in Helsinki (Finland). Available at: http://echa.europa.eu/documents/10162/5399565/4_wohllebenws_nanomaterials_en.pdf

During the first year of implementation, companies would also face costs in terms of resources and time dedicated to deal with the registry. Table 6-9 presents the associated costs figures.[75]

Table 6-9: Estimate of the total cost for the notifiers to gather and submit the information, to respond to clients' enquiries and to adapt their product/account databases		
Parameter	**Hours (median)**	**Unit Cost***
Understanding of the legal requirements (per notifier) • Manufacturers and importers • Distributors	 30 25	 €1,050 €875
Gathering of the information (per notification)	10	€350
Submission of the information (per notification)	1	€35
Responding to enquiries (per notification)	2	€70
Adapting product/account databases (per notification)	10	€350
*Notes: * Assuming an average hourly gross wage of €35*		

The cost for the characterisation of nanomaterials used in the manufacturing of biocides, pesticides, cosmetic products and pharmaceutical products has not been accounted, as this cost should be apportioned to the respective legislation requiring the characterisation of the nanomaterials.

It is also important to note that during the Validation Workshop and the public consultation, non-governmental organisations and trade unions expressed the opinion that the costs for the characterisation of the nanomaterials should not be considered as administrative burden of the FNS since companies should characterise the nanomaterials to comply with the CLP Regulation and the Health and Safety legislation. Moreover, they argued that most of the companies will have characterised their nanomaterials for product development purposes[76].

In order to take into account these considerations, the costs for the characterisation of the nanomaterials have been singled out in the analysis.

The number of notifications have been estimated multiplying the average numbers of notifications per role in the supply chain for the number of duty-holders. The average number of notifications by research institutes could not be estimated from the results of the FNS. Therefore, it has been assumed that research institutes submit an average of 10 notifications. As research institutes can submit simplified notifications, reduced resources have been assumed for the different cost categories: three hours for the understanding of the legal requirements, one hour for the submission of the information, two hours for the gathering of the information.

The average numbers of notifications per role in the supply chain have been assumed to follow the same pattern as in the second year of the FNS (presented in Table 6-5). **When calculating the number of notifications for which the characterisation of the nanomaterials will have to be carried out, the notifications referring to substances expected to be covered by the REACH Regulation have been**

[75] All cost figures and assumptions are based on the results of the survey on the administrative burden of the FNS (RPA *et al*, 2014b).

[76] With regard to the latter, further clarifications were requested to an industry representative of the pigments and dyes sector; these are presented below:

- Particle size: for the application properties, in most cases the relevant metric is volume or mass based and existing particle size measurements will presumably be performed in the application medium or in the actual state of the product;
- Number size distribution: it is not relevant for the application properties, therefore is measured only in exceptional cases;
- Aggregation and agglomeration state: the state of agglomeration/aggregation (in the application medium) is the most important factor determining the application behaviour of a given material. It is based on the dispersion status in a given medium; the dispersion state is often measured indirectly though;
- Shape: it is often known.

subtracted, as the notifications that should come from Belgium, Denmark and France (considering the respective exemptions under the national schemes), since the notifiers will have already the required information. Moreover, it has been assumed that 50% of the notifications that should come from Belgium, Denmark and France will be submitted by large companies with multiple plants in different Member States that will be able to use the characterisation data generated to comply with the national schemes.

Furthermore, it has been assumed that, during the first year of implementation of an EU registry of nanomaterials, a certain number of companies (in particular, those companies manufacturing substances in powder form) would have to check whether the substances they manufacture are at the nanoscale. In order to take into account the additional testing costs, it has been assumed that for every ten substances resulting at the nanoscale, there would be an additional substance that, once tested, would result to have particle size above the 100 nm threshold. This assumption has been considered for the following sectors:

- C20.12 - Manufacture of dyes and pigments;
- C20.13 - Manufacture of other inorganic basic chemicals;
- C20.14 - Manufacture of other organic basic chemicals;
- C20.16 - Manufacture of plastics in primary forms;
- C20.30 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics;
- C20.41 - Manufacture of soap and detergents, cleaning and polishing preparations;
- C20.59 – Manufacture of other chemical products.

Table 6-10 presents the estimates of the cost in the first year and of the annual recurring cost, marginal to baseline 0b, incurred by the companies following the implementation of an EU wide nanomaterials registry.

In its first year of implementation, the total costs for the businesses of an EU registry of nanomaterials per substance have been estimated between **€60 million and €145 million**. Annual recurring costs have been estimated in around **€3.9 million**.

Annex 2 presents the calculation steps followed for the assessment of the total and recurring costs of Option 3 (with and without exemptions).

Table 6-10: Total cost for businesses of an EU registry – First year of implementation and annual cost							
NACE codes	No. of companies with notifications duties in the EU28	No. of notifications in the EU28	Nanomaterial characterisation costs	Costs for understanding legal requirements and adapting product databases	Cost for the gathering of the information, submission of the information and for responding to enquiries	Total cost – first year	Annual cost
C20.12 - Manufacture of dyes and pigments	590	2,360	€1,410,000 - €9,950,000	€826,000	€1,073,800	€3,310,000 - €11,850,000	€124,000
C20.13 - Manufacture of other inorganic basic chemicals	270	1,080	€600,000 - €4,400,000	€378,000	€491,400	€1,469,000 - €5,269,000	€57,000
C20.14 - Manufacture of other organic basic chemicals	200	800	€300,000 - €2,900,000	€280,000	€364,000	€944,000 - €3,544,000	€42,000
C20.16 - Manufacture of plastics in primary forms	250	1,000	€510,000 - €4,000,000	€350,000	€455,000	€1,315,000 - €4,805,000	€53,000
C20.20 - Manufacture of pesticides and other agrochemical products	60	240	-	€84,000	€109,200	€193,000 - €193,000	€13,000
C20.30 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics	3,600	14,400	€10,080,000 - €65,300,000	€5,040,000	€6,552,000	€21,672,000 - €76,892,000	€756,000
C20.41 - Manufacture of soap and detergents, cleaning and polishing preparations	370	1,480	€660,000 - €5,600,000	€518,000	€673,400	€1,851,000 - €6,791,000	€78,000
C20.42 - Manufacture of perfumes and toilet preparations	460	1,840	-	€644,000	€837,200	€1,481,000 - €1,481,000	€97,000
C20.59 – Manufacture of other chemical products	430	1,720	€1,080,000 - €7,500,000	€602,000	€782,600	€2,465,000 - €8,885,000	€90,000
C21.10 – Manufacture of basic pharmaceutical products	90	360	-	€126,000	€163,800	€290,000 - €290,000	€19,000
C21.20 – Manufacture of pharmaceutical preparations	320	1,280	-	€448,000	€582,400	€1,030,000 - €1,030,000	€67,000
G46.45 – Wholesale of perfume and cosmetics	990	7,920	-	€1,212,750	€3,603,600	€4,816,000 - €4,816,000	€416,000
G46.46 – Wholesale of pharmaceutical goods	1,920	15,360	-	€2,352,000	€6,988,800	€9,341,000 - €9,341,000	€806,000
G46.75 – Wholesale of chemical products	1,390	11,120	-	€1,702,750	€5,059,600	€6,762,000 - €6,762,000	€584,000
M72.1 – Research and experimental development on natural sciences and engineering	3,780	37,800*	-	€661,500	€2,646,000	€3,308,000 - €3,308,000	€662,000
Total	**14,720**	**98,760***	**€14,640,000 - €99,650,000**	**€15,225,000**	**€30,382,800**	**€60,247,000 - €145,257,000**	**€3,864,000**

Notes:

* The average number of notifications by research institutes could not be estimated from the results of the FNS. Therefore, it has been assumed that research institutes submit an average of 10 notifications. As research institutes can submit simplified notifications, reduced resources have been assumed for the different cost categories: 3 hours for the understanding of the legal requirements, one hour for the submission of the information, two hours for the gathering of the information.

Given the wide range of assumptions, these figures should be interpreted as illustrative of the order of magnitude of the costs associated with an EU registry. In particular, the accurate estimate of the percentage of companies with notification duties would require an in-depth knowledge of the supply chains and markets of all the nanomaterials manufactured by each company. It should be noted that the estimated costs refer to a full compliance scenario, where all the companies with notification duties notify their nanomaterials in the first year. Applying the same assumptions on number of French companies with notification duties and number of notifications per sector, it has been estimated that in 2014, the compliance rate with the FNS was around 66%.

In order to estimate any potential impact on the European businesses, the administrative burden has been compared with the value added at factor cost[77], taking into consideration the size of the companies. Table 6-11 presents the value added per company by company size[78].

Table 6-11: Value added per company by company size

	Total	0 - 9 employees	10 - 19 employees	20 - 49 employees	50 - 249 employees	≥250 employees
C20.12	€4,916,000	€149,000	€486,000	€1,950,000	€7,858,000	€85,317,000
C20.13	€6,582,000	€199,000	€651,000	€2,611,000	€10,522,000	€114,241,000
C20.14	€13,613,000	€411,000	€1,347,000	€5,400,000	€21,760,000	€236,263,000
C20.16	€5,082,000	€154,000	€503,000	€2,016,000	€8,124,000	€88,207,000
C20.30	€2,609,000	€143,000	€664,000	€1,899,000	€8,089,000	€42,580,000
C20.41	€1,545,000	€90,000	€579,000	€1,460,000	€5,838,000	€43,217,000
C20.42	€1,818,000	€106,000	€681,000	€1,717,000	€6,868,000	€50,837,000

With regard to the administrative burden per company size, the following illustrative examples have been considered:

- A micro-enterprise (0-9 employees) submitting 5 notifications;
- A small company (10-19 employees) submitting 10 notifications;
- A small-medium company (20-49 employees) submitting 25 notifications;
- A medium company (50-249 employees) submitting 50 notifications;
- A large company (over 250 employees) submitting 100 notifications.

Table 6-12 presents the cost estimates for the cases listed above.

Table 6-12: Administrative burden for five illustrative examples based on company size and number of notifications

Company size	No. of notifications	Total costs first year (low end)	Total costs first year (high end)	Recurring costs
Micro-enterprise (0-9 employees)	5	€19,000	€73,000	€300
Small company (10-19 employees)	10	€36,000	€142,000	€500
Small-medium company (20-49 employees)	25	€88,000	€351,000	€1,300
Medium company (50-249 employees)	50	€174,000	€698,000	€2,600
Large company (over 250 employees)	100	€347,000	€1,394,000	€5,300

[77] *The value added at factor cost is the gross income from operating activities after adjusting for operating subsidies and indirect taxes."* Source: http://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:Value_added_at_factor_cost

[78] Although the European Commission definition of small-medium enterprise refers to number of employees, turnover and annual balance sheet total, Eurostat statistics are available per company size defined by the number of employees only. The value added at factor cost per company size is available per NACE codes three digits; percentages per company size have been calculated and applied to the value added per NACE codes four digits and then divided per number of companies per company size.

Table 6-13 presents the incidence of the total cost (in the first year) and of the recurring annual costs on the value added per company by company size in the manufacturing sectors considered.

Table 6-13: Total costs (first year) and recurring costs on value added per company by company size					
	0 - 9 employees	10 - 19 employees	20 - 49 employees	50 - 249 employees	≥250 employees
Total costs first year on value added					
C20.12	12.75% - 48.99%	7.41% - 29.22%	4.51% - 18.00%	2.21% - 8.88%	0.41% - 1.63%
C20.13	9.55% - 36.68%	5.53% - 21.81%	3.37% - 13.44%	1.65% - 6.63%	0.30% - 1.22%
C20.14	4.62% - 17.76%	2.67% - 10.54%	1.63% - 6.50%	0.80% - 3.21%	0.15% - 0.59%
C20.16	12.34% - 47.40%	7.16% - 28.23%	4.37% - 17.41%	2.14% - 8.59%	0.39% - 1.58%
C20.30	13.29% - 51.05%	5.42% - 21.39%	4.63% - 18.48%	2.15% - 8.63%	0.81% - 3.27%
C20.41	21.11% - 81.11%	6.22% - 24.53%	6.03% - 24.04%	2.98% - 11.96%	0.80% - 3.23%
C20.42	17.92% - 68.87%	5.29% - 20.85%	5.13% - 20.44%	2.53% - 10.16%	0.68% - 2.74%
Recurring costs on value added					
C20.12	0.201%	0.103%	0.067%	0.033%	0.006%
C20.13	0.151%	0.077%	0.050%	0.025%	0.005%
C20.14	0.073%	0.037%	0.024%	0.012%	0.002%
C20.16	0.195%	0.099%	0.064%	0.032%	0.006%
C20.30	0.210%	0.075%	0.068%	0.032%	0.012%
C20.41	0.333%	0.086%	0.089%	0.045%	0.012%
C20.42	0.283%	0.073%	0.076%	0.038%	0.010%

The incidence of the total costs on the value added during the first year, especially in the case of micro, small and small-medium enterprises, is high, suggesting that a phased notification system for smaller companies would be advisable. The recurring costs of an EU nanomaterials registry are unlikely to have a significant impact on the margins of the EU companies.

6.6.2 Option 3b "With exemptions"

Exemption on nanomaterials only used in scientific research and development or in product and process oriented research and development

In 2014, 43 nanomaterials (15% of the nanomaterials analysed) have been notified as being "used" in SU24 "Scientific research and development". However, only 227 notifications (2% of the total number of notifications analysed by the French authorities) reported descriptor SU24.

Nanomaterials only used in scientific research and development or in product and process oriented research and development are likely to be characterised for R&D purposes, therefore an exemption would not generate any cost savings on the nanomaterials characterisation side.

Assuming that the same proportion of nanomaterials on the EU market are object of research and development and that these nanomaterials would generate the same proportion of notifications across the different sectors considered (as for the FNS, 2%), the exemption on nanomaterials only used in scientific research and development or in product and process oriented research and development **would save around €3.2 million the first year and around €730 thousand in annual recurring costs**.

Exemption on nanomaterials only used as pigments

Around 150 nanomaterials notified to the FNS in 2014 have been identified as pigments and dyes (52% of the nanomaterials analysed). It is assumed that the same proportion of nanomaterials on the EU market are pigments and dyes, and that these nanomaterials would generate the same proportion of notifications across the different sectors considered.

Moreover, it is assumed that the following percentages of notifications per sector would be avoided:

- 100% of the notifications from C20.12 - Manufacture of dyes and pigments;
- 10% of the notifications from C20.13 and C20.14 - Manufacture of other inorganic and organic basic chemicals, C20.59 – Manufacture of other chemical products (this percentage should cover those manufacturers that produce some pigments and dyes as secondary activity);
- 75% of the notifications from C20.30 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics (notifications submitted by companies with main activity in the manufacture of paints but that manufacture pigments and dyes too);
- 50% of the notifications from G46.45 – Wholesale of perfume and cosmetics and G46.75 – Wholesale of chemical products.

Table 6-14 presents the total cost in the first year (**€35 million to €68 million**) and the annual cost (**€2.6 million**) of an EU wide registry of nanomaterials with the exemption of pigments and dyes.

Exemption on nanomaterials only used as fillers

Only 8 nanomaterials notified to the FNS in 2014 have been identified as pigments and dyes (3% of the nanomaterials analysed). It is assumed that the same proportion of nanomaterials on the EU market are fillers. However, as previously noted, these nanomaterials are the most common and make well over 95% of the market in terms of tonnage. It is assumed that the exemption on nanomaterials only used as fillers would have the following effects:

- 25% of the companies (and of their notifications) in C20.13 - Manufacture of other inorganic basic chemicals would be exempted;
- 25% of the notifications from companies in C20.30 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics would be avoided;
- 10% of the notifications from C20.59 – Manufacture of other chemical products would be avoided;
- There would be a decrease of 25% in the notifications from G46.75 – Wholesale of chemical products.

Table 6-15 presents the total cost in the first year (**€52 million to €122 million**) and the annual cost (**€3.5 million**) of an EU wide registry of nanomaterials with the exemption of fillers.

Exemption on nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation

For around 187 nanomaterials notified to the FNS in 2014 the parental substance has been registered/will be registered under the REACH Regulation (65% of the nanomaterials analysed). It is assumed that the same proportion of nanomaterials on the EU market have/will have the parental substance registered, and that these nanomaterials would generate the same proportion of notifications across the different sectors considered.

As noted in Section 3.2, MEDDE (2014) refers to "categories of substances", meaning that each entry represents a substance that might cover several nanoforms. As it is not clear how the amendment of the REACH Annexes will deal with quantities below one tonne per year per manufacturer/importer of different nanoforms of the same substance, for the purpose of the assessment a range of 35% to 65% of nanomaterials that will be covered by the REACH Regulation has been considered, where 35% is the percentage of notifications referring to quantities above one tonne per year received by the

French authorities in 2014, while 65% is the percentage of substances registered or expected to be registered by 2018.

Table 6-16 presents the total cost in the first year (**€42 million to €127 million**) and the annual cost (**€2.3 million**) of an EU wide registry of nanomaterials with the exemption of nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation.

Nanomaterials in articles covered by existing registration requirements

Around 35 nanomaterials notified to the FNS in 2014 have been notified as used in articles covered by existing registration requirements (12% of the nanomaterials analysed). It is assumed the same proportion for the EU market, and the same proportion of notifications across the different sectors considered.

It is also assumed that:

- 100% of the companies in C20.20 - Manufacture of pesticides and other agrochemical products, C21.10 – Manufacture of basic pharmaceutical products, C21.20 – Manufacture of pharmaceutical preparations, G46.45 – Wholesale of perfume and cosmetics and in G46.46 – Wholesale of pharmaceutical goods would not have to notify;
- 25% of the companies in C20.41 - Manufacture of soap and detergents, cleaning and polishing preparations would not have to notify (those companies that only manufacture soap and detergents, cleaning and polishing preparations for the cosmetic products industry).

Moreover, it is assumed that the following percentages of notifications per sector would be avoided:

- 5% from C20.12 - Manufacture of dyes and pigments, C20.13 and C20.14 - Manufacture of other inorganic and organic basic chemicals, C20.59 – Manufacture of other chemical products and G46.75 – Wholesale of chemical products;
- 100% from C20.20 - Manufacture of pesticides and other agrochemical products, C20.42 - Manufacture of perfumes and toilet preparations, C21.10 – Manufacture of basic pharmaceutical products, C21.20 – Manufacture of pharmaceutical preparations, G46.45 – Wholesale of perfume and cosmetics and G46.46 – Wholesale of pharmaceutical goods;
- 50% from C20.41 - Manufacture of soap and detergents, cleaning and polishing preparations.

Table 6-17 presents the total cost in the first year (**€42 million to €124 million**) and the annual cost (**€2.4 million**) of an EU wide registry of nanomaterials with the exemption of nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation.

Summary

Table 6-18 and figures 6-2 and 6-3 summarise the effects of the exemptions on the administrative burden.

Table 6-14: Total cost for businesses – Exemption on pigments and dyes							
NACE codes	No. of companies with notifications duties in the EU28	No. of notifications in the EU28	Nanomaterial characterisation costs	Costs for understanding legal requirements and adapting product databases	Cost for the gathering of the information, submission of the information and for responding to enquiries	Total cost – first year	Annual cost
C20.12 - Manufacture of dyes and pigments	-	-	-	€-	€-	-	€-
C20.13 - Manufacture of other inorganic basic chemicals	270	972	€540,000-€4,000,000	€378,000	€442,260	€1,360,000-€4,820,000	€51,000
C20.14 - Manufacture of other organic basic chemicals	200	720	€270,000-€2,550,000	€280,000	€327,600	€878,000-€3,158,000	€38,000
C20.16 - Manufacture of plastics in primary forms	250	1,000	€510,000-€4,000,000	€350,000	€455,000	€1,315,000-€4,805,000	€53,000
C20.20 - Manufacture of pesticides and other agrochemical products	60	240	-	€84,000	€109,200	€193,000-€193,000	€13,000
C20.30 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics	-	3,600	€2,520,000-€16,300,000	€-	€1,638,000	€4,158,000-€17,938,000	€189,000
C20.41 - Manufacture of soap and detergents, cleaning and polishing preparations	370	1,480	€660,000-€5,600,000	€518,000	€673,400	€1,851,000-€6,791,000	€78,000
C20.42 - Manufacture of perfumes and toilet preparations	460	1,840	-	€644,000	€837,200	€1,481,000-€1,481,000	€97,000
C20.59 – Manufacture of other chemical products	430	1,548	€990,000-€6,700,000	€602,000	€704,340	€2,296,000-€8,006,000	€81,000
C21.10 – Manufacture of basic pharmaceutical products	90	360	-	€126,000	€163,800	€290,000-€290,000	€19,000
C21.20 – Manufacture of pharmaceutical preparations	320	1,280	-	€448,000	€582,400	€1,030,000-€1,030,000	€67,000
G46.45 – Wholesale of perfume and cosmetics	990	3,960	-	€1,212,750	€1,801,800	€3,015,000-€3,015,000	€208,000
G46.46 – Wholesale of pharmaceutical goods	1,920	15,360	-	€2,352,000	€6,988,800	€9,341,000-€9,341,000	€806,000
G46.75 – Wholesale of chemical products	1,390	5,560	-	€1,702,750	€2,529,800	€4,233,000-€4,233,000	€292,000
M72.1 – Research and experimental development on natural sciences and engineering	3,780	37,800	-	€661,500	€2,646,000	€3,308,000-€3,308,000	€662,000
Total	**10,530**	**75,720**	**€5,490,000-€39,150,000**	**€9,359,000**	**€19,899,600**	**€34,749,000-€68,409,000**	**€2,654,000**

Table 6-15: Total cost for businesses – Exemption on fillers							
NACE codes	No. of companies with notifications duties in the EU28	No. of notifications in the EU28	Nanomaterial characterisation costs	Costs for understanding legal requirements and adapting product databases	Cost for the gathering of the information, submission of the information and for responding to enquiries	Total cost – first year	Annual cost
C20.12 - Manufacture of dyes and pigments	590	2,360	€1,410,000 - €9,950,000	€826,000	€1,073,800	€3,310,000 - €11,850,000	€124,000
C20.13 - Manufacture of other inorganic basic chemicals	203	810	€480,000-€3,300,000	€283,500	€368,550	€1,132,000-€3,952,000	€43,000
C20.14 - Manufacture of other organic basic chemicals	200	800	€300,000-€2,900,000	€280,000	€364,000	€944,000-€3,544,000	€42,000
C20.16 - Manufacture of plastics in primary forms	250	1,000	€510,000-€4,000,000	€350,000	€455,000	€1,315,000-€4,805,000	€53,000
C20.20 - Manufacture of pesticides and other agrochemical products	60	240	-	€84,000	€109,200	€193,000-€193,000	€13,000
C20.30 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics	2,700	10,800	€7,560,000-€48,950,000	€3,780,000	€4,914,000	€16,254,000-€57,644,000	€567,000
C20.41 - Manufacture of soap and detergents, cleaning and polishing preparations	370	1,480	€660,000-€5,600,000	€518,000	€673,400	€1,851,000-€6,791,000	€78,000
C20.42 - Manufacture of perfumes and toilet preparations	460	1,840	-	€644,000	€837,200	€1,481,000-€1,481,000	€97,000
C20.59 – Manufacture of other chemical products	387	1,548	€990,000-€6,700,000	€541,800	€704,340	€2,236,000-€7,946,000	€81,000
C21.10 – Manufacture of basic pharmaceutical products	90	360	-	€126,000	€163,800	€290,000-€290,000	€19,000
C21.20 – Manufacture of pharmaceutical preparations	320	1,280	-	€448,000	€582,400	€1,030,000-€1,030,000	€67,000
G46.45 – Wholesale of perfume and cosmetics	990	7,920	-	€1,212,750	€3,603,600	€4,816,000-€4,816,000	€416,000
G46.46 – Wholesale of pharmaceutical goods	1,920	15,360	-	€2,352,000	€6,988,800	€9,341,000-€9,341,000	€806,000
G46.75 – Wholesale of chemical products	1,043	8,340	-	€1,277,063	€3,794,700	€5,072,000-€5,072,000	€438,000
M72.1 – Research and experimental development on natural sciences and engineering	3,780	37,800	-	€661,500	€2,646,000	€3,308,000-€3,308,000	€662,000
Total	**13,362**	**91,938**	**€11,910,000-€81,400,000**	**€13,384,613**	**€27,278,790**	**€52,573,000-€122,063,000**	**€3,506,000**

Table 6-16: Total cost for businesses – Exemption on nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation							
NACE codes	No. of companies with notifications duties in the EU28	No. of notifications in the EU28	Nanomaterial characterisation costs	Costs for understanding legal requirements and adapting product databases	Cost for the gathering of the information, submission of the information and for responding to enquiries	Total cost – first year	Annual cost
C20.12 - Manufacture of dyes and pigments	207 - 384	826 - 1,534	€1,410,000 - €9,950,000	€289,000	€376,000	€2,075,000 - €10,615,000	€43,000
C20.13 - Manufacture of other inorganic basic chemicals	095 - 176	378 - 702	€600,000 - €4,400,000	€132,000	€172,000	€904,000-€4,704,000	€20,000
C20.14 - Manufacture of other organic basic chemicals	070 - 130	280 - 520	€300,000 - €2,900,000	€98,000	€127,000	€525,000-€3,125,000	€15,000
C20.16 - Manufacture of plastics in primary forms	088 - 163	350 - 650	€510,000 - €4,000,000	€123,000	€160,000	€793,000-€4,283,000	€18,000
C20.20 - Manufacture of pesticides and other agrochemical products	060 - 060	240 - 240	-	€84,000	€109,000	€193,000-€193,000	€13,000
C20.30 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics	1,260 - 2,340	5,040 - 9,360	€10,080,000 - €65,300,000	€1,764,000	€2,293,000	€14,137,000-€69,357,000	€265,000
C20.41 - Manufacture of soap and detergents, cleaning and polishing preparations	130 - 241	518 - 962	€660,000 - €5,600,000	€181,000	€235,000	€1,076,000-€6,016,000	€27,000
C20.42 - Manufacture of perfumes and toilet preparations	460 - 460	1,840 - 1,840	-	€644,000	€837,000	€1,481,000-€1,481,000	€97,000
C20.59 – Manufacture of other chemical products	151 - 280	0,602 - 1,118	€1,080,000 - €7,500,000	€211,000	€274,000	€1,565,000-€7,985,000	€32,000
C21.10 – Manufacture of basic pharmaceutical products	090 - 090	360 - 360	-	€126,000	€164,000	€290,000-€290,000	€19,000
C21.20 – Manufacture of pharmaceutical preparations	320 - 320	1,280 - 1,280	-	€448,000	€582,000	€1,030,000-€1,030,000	€67,000
G46.45 – Wholesale of perfume and cosmetics	990 - 990	7920 - 7920	-	€1,213,000	€3,604,000	€4,817,000-€4,817,000	€416,000
G46.46 – Wholesale of pharmaceutical goods	1,920 - 1,920	15,360 - 15,360	-	€2,352,000	€6,989,000	€9,341,000-€9,341,000	€806,000
G46.75 – Wholesale of chemical products	487 - 904	3,892 - 7,228	-	€596,000	€1,771,000	€2,367,000-€2,367,000	€204,000
M72.1 – Research and experimental development on natural sciences and engineering	1,323 - 2,457	13,230 - 24,570	-	€232,000	€926,000	€1,158,000-€1,158,000	€232,000
Total	**7,648 - 10,912**	**52,116 - 73,644**	**€14,640,000 - €99,650,000**	**€8,493,000**	**€18,619,080**	**€41,752,000-€126,762,000**	**€2,274,000**

Table 6-17: Total cost for businesses – Exemption on nanomaterials in articles covered by existing registration requirements							
NACE codes	No. of companies with notifications duties in the EU28	No. of notifications in the EU28	Nanomaterial characterisation costs	Costs for understanding legal requirements and adapting product databases	Cost for the gathering of the information, submission of the information and for responding to enquiries	Total cost – first year	Annual cost
C20.12 - Manufacture of dyes and pigments	590	2,242	-	€826,000	€1,020,110	€3,166,000-€11,296,000	€118,000
C20.13 - Manufacture of other inorganic basic chemicals	270	1,026	€570,000-€4,250,000	€378,000	€466,830	€1,415,000-€5,095,000	€54,000
C20.14 - Manufacture of other organic basic chemicals	200	760	€300,000-€2,800,000	€280,000	€345,800	€926,000-€3,426,000	€40,000
C20.16 - Manufacture of plastics in primary forms	250	1,000	€510,000-€4,000,000	€350,000	€455,000	€1,315,000-€4,805,000	€53,000
C20.20 - Manufacture of pesticides and other agrochemical products	-	-	-	€-	€-	-	€-
C20.30 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics	3,600	14,400	€10,080,000-€65,300,000	€5,040,000	€6,552,000	€21,672,000-€76,892,000	€756,000
C20.41 - Manufacture of soap and detergents, cleaning and polishing preparations	278	740	€330,000-€2,800,000	€388,500	€336,700	€1,055,000-€3,525,000	€39,000
C20.42 - Manufacture of perfumes and toilet preparations	-	-	-	€-	€-	-	€-
C20.59 – Manufacture of other chemical products	430	1,634	€1,020,000-€7,150,000	€602,000	€743,470	€2,365,000-€8,495,000	€86,000
C21.10 – Manufacture of basic pharmaceutical products	-	-	-	€-	€-	-	€-
C21.20 – Manufacture of pharmaceutical preparations	-	-	-	€-	€-	-	€-
G46.45 – Wholesale of perfume and cosmetics	-	-	-	€-	€-	-	€-
G46.46 – Wholesale of pharmaceutical goods	-	-	-	€-	€-	-	€-
G46.75 – Wholesale of chemical products	1,390	11,120	-	€1,702,750	€5,059,600	€6,762,000-€6,762,000	€584,000
M72.1 – Research and experimental development on natural sciences and engineering	3,780	37,800	-	€661,500	€2,646,000	€3,308,000-€3,308,000	€662,000
Total	**10,788**	**70,722**	**€14,130,000-€95,750,000**	**€10,228,750**	**€17,625,510**	**€41,984,000-€123,604,000**	**€2,392,000**

Table 6-18: Cost savings ensured by the exemptions				
Exemptions	**Cost savings first year**	**Annual cost savings**	**Total cost – first year**	**Annual recurring cost**
EU nanomaterials registry with no exemptions	-	-	**€60M - €145M**	**€3.9M**
Nanomaterials only used in scientific research and development or in product and process oriented research and development	**€3M**	**€0.7M**	**€57M - €142M**	**€3.2M**
Nanomaterials only used as pigments	**€25M - €77M**	**€1.3M**	**€35M - €68M**	**€2.6M**
Nanomaterials only used as fillers	**€8M - €23M**	**€0.4M**	**€52M - €122M**	**€3.5M**
Nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation	**€18M**	**€1.6M**	**€42M - €127M**	**€2.3M**
Nanomaterials in articles covered by existing registration requirements	**€18M - €21M**	**€1.5M**	**€42M - €124M**	**€2.4M**

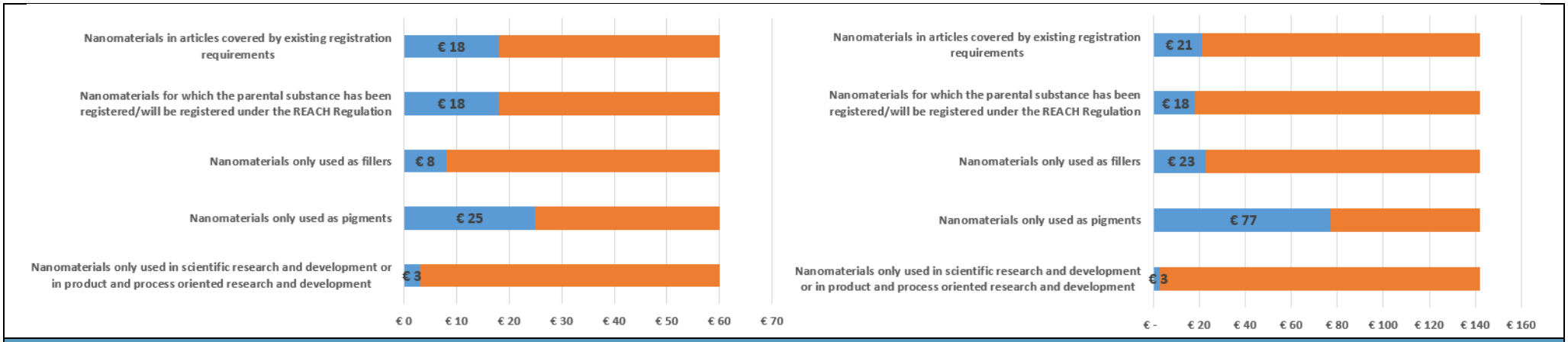

Figure 6-2: First year cost savings (€m) by exemption – low and high end

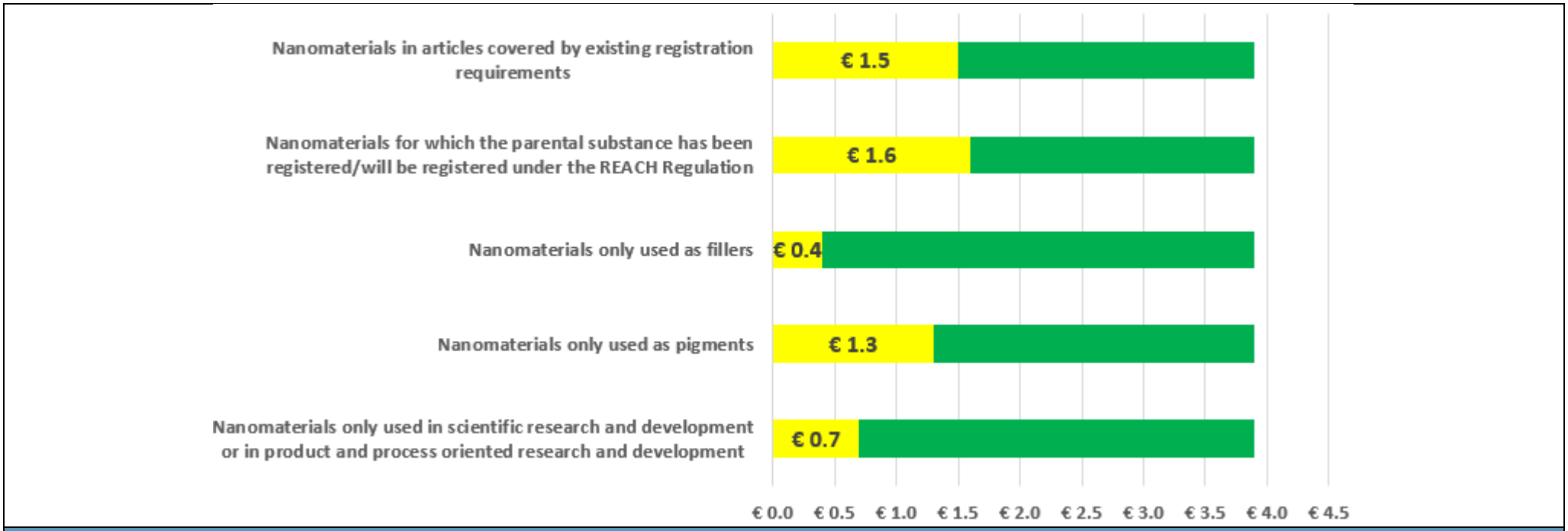

Figure 6-3: Annual cost savings (€m) by exemption

6.7 Costs for Public Authorities

The introduction of a mandatory EU Nanomaterial Registry by Substance will entail costs upon public authorities – namely those responsible for the establishment and operation of the registry. The main cost drivers for the setting up and operation of the registry would be:

- Acquisition of hardware/software; and
- Administrative aspects.

On the basis of the analysis of the public costs for the setting up and maintenance of the French Notification System and the Cosmetic Products Notification Portal, it is expected that the development of a registry would result in one-off costs of €250k (hardware and software) plus around €450k of annual recurring costs (operating staff).[79] The recurring costs, similar to the annual costs reported by DG SANCO for the operation of the CPNP, are based on the assumption of having six officers working full time in tasks such as organising stakeholder meetings, drafting FAQs, answering inquiries, communicating on the registry, liaising with relevant DGs within the Commission, assisting in answering enquiries, managing the IT tool development and maintenance, preparing the annual report, ensuring confidentiality and extracting the data for authorised organisations.

The need for the translation of the web-page, guidance on the notification process, FAQs and reports of the results, given the diversity of EU languages, would result in significant additional costs. Assuming translation costs of 10% of the annual budget, this would result in additional €45k.

In summary, a nanomaterials registry per substance would cost in the first year around €750 thousand, with annual recurring costs of €500 thousand.

To the latter should be added the costs for the enforcement of the measure: unfortunately, no information has been found or obtained with regard to costs of actual enforcement in the countries implementing nanomaterials registries (i.e. Belgium, Denmark and France). However, for the purposes of this assessment some estimates have been generated on the basis of the following assumptions:

- The target is to verify 5% of the notifications submitted;
- A desk-based inspection would require two days of work for an officer in full time equivalent (going through the product portfolio of a company and checking the notifications submitted) for a cost of €525 (15 hours);
- Every year in 5% of the companies the inspectors would test whether a product is in the nanoform (it is assumed that the test would cost around €10,000).

Around 100,000 notifications are expected to be submitted every year in the EU28: the inspection (desk-based) of 5% of these notifications would cost around **€2.6 million**. The testing of one product in 5% of the companies every year would cost around **€750k**[80].

[79] Based on RPA *et al* (2014b), Section 4, page 50.

[80] 5% of 15,000 companies x €10,000.

7 Option 4: EU Nanomaterial Registry by Application

7.1 Overview

The reporting requirement to the EU wide nanomaterials registry by application would include substances in nanoform, as well as mixtures and articles intended for sale to the general public and which contain nanomaterials (with and without intended release) with an annual volume of at least 100 grams (per manufacturer/importer/distributor).

When reporting to the EU wide nanomaterials registry by application, 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 EU wide nanomaterials registry by application 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".

7.2 Nanomaterials and Products Covered

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

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'.

In terms of products, Option 4A only exempt:

- Nanomaterials and mixtures and articles containing nanomaterials produced or imported by individuals for their own, non-commercial use; and
- Nanomaterials and mixtures and articles containing nanomaterials produced, imported or used for national Defence interest.

BiPRO *et al* (2013), analysing the potential impact of the Belgian Notification system, estimated around 2,000-5,000 unique substances, 80,000-160,000 unique preparations, and 800,000-1,300,000 unique articles containing NMs[81].

[81] It must be noted that a single substance at the nanoscale may be sold as several different unique products according to their physicochemical characteristics and grade of purity. For example, carbon black is used in over 40 grades by the rubber industry alone. Many additional grades are marketed for non-rubber applications (source: http://monographs.iarc.fr/ENG/Monographs/vol93/mono93-6.pdf). This has been reflected in the estimates. In addition, preparations and articles with an identical chemical composition, being sold under different brand names are considered "unique products".

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

Under Option 4B, the following exemptions have been considered:

- Nanomaterials only used in scientific research and development or in product and process oriented research and development;
- Nanomaterials only used as pigments;
- Nanomaterials only used as fillers;
- Nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation;
- Nanomaterials in articles covered by existing registration requirements:
  - Nanomaterials within the scope of the Cosmetics Regulation (No. 1223/2009). This Regulation 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);
  - Nanomaterials within the scope of the Biocidal Product Regulation (No. 528/2012). This Regulation requires a dedicated risk assessment for the nanomaterial form of the substance and excludes biocidal products with nanomaterials from the simplified authorisation procedure;
  - Nanomaterials within the scope of the Food Additives Regulation (No. 1333/2008). This Regulation establishes that a change in particle size of a substance requires a new entry in the list of authorised substances or a change in specifications;
  - Nanomaterials within the scope of Regulation (EC) No 726/2004 on medicinal products for human or veterinary use.

In terms of mixtures and articles, Option 4B considers additionally the following exemptions:

- Mixtures and articles containing nanomaterials object of research and development;
- Mixtures and articles containing pigments in nanoform. Virtually all the mixtures and articles, for both professional users and consumers, contain pigments. A very high percentage of these are known to be at the nanoscale. For example, many mixtures (inks and paints) and articles (of rubber, paper and plastics) of black colour contain carbon black: it should be noted that the main purpose might not be the black pigmentation but to give different properties (as a filler) such as desired level of reinforcement and tear strength;
- Mixtures and articles containing fillers in nanoform. The eight nanomaterials notified to the FNS as used as fillers are all among the most widely diffuse nanomaterials, making over 99% of the French market in terms of tonnage. It is likely that the same share applies to the EU market. Carbon black is for example used as reinforcing filler in tyres and other rubber products, as it is amorphous silica; calcium carbonate in plastics and paper products;
- Mixtures and articles containing pigments and fillers in nanoform. Many mixtures and articles contain both pigments and fillers in nanoform and excluding these mixtures and articles will significantly reduce the number of items to be notified.
- Mixtures and articles containing nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation;
- Mixtures and articles covered by existing registration requirements such as cosmetics, biocidal and plant protection products;
- Mixtures where the nanomaterials is bound and articles without intended release.

7.3 Organisations Covered

7.3.1 Option 4a "No exemptions"

Under Option 4, notification duties would be on manufacturers, importers and distributors (wholesalers and retailers) of nanomaterials and mixtures and articles containing nanomaterials.

BiPRO *et al* (2013) provides an overview on the sectors of the Belgian economy that are very likely to have products containing nanomaterials[82]. These are allocated to the following product groups:

- Substance Manufacturers;
- Cosmetics;
- Health Care;
- Food & Feed;
- Coatings & Inks;
- Cleaning & Disinfection;
- Tyres & other Rubber Products;
- Plastic Products;
- Building & Construction;
- Textiles;
- Paper Products;
- Wood Products;
- Sporting Goods;
- Electronics;
- Complex Objects;
- Miscellaneous.

For all sectors evaluated, the number of companies placing a NM-containing product on the market was estimated to be between 35,000-45,000 enterprises. This represents approximately 15-20% of all the enterprises in Belgium.

The categories stated above are used as the basis for quantifying the administrative burden on industry. The impact assessment from the Danish Environmental Protection Agency also used the following categories: "paint, varnish and coatings", "other building materials" (e.g. bricks, cement/concrete), "sports", "cleaning", "textiles" as well as "electric and electronic products", and "miscellaneous"[83] thereby forming the basis for the analysis.

The total number of companies in each sector, the share and number of companies required to notify a nanomaterial or product containing a nanomaterial is provided in Table 7-1. The very high numbers of companies in some categories are due to the consideration of the wholesalers (that are part of the supply chain).

Table 7-1: Estimate of the number of companies with notification duties in France and in the EU

Product Group[1]	No. of companies in the EU28	Share of companies with notification duties	No. of companies with notifications duties in the EU28
1. Substances	5,200	23%[a]	1,210
2. Cosmetics[2]	24,400	6%[a]	1,450
3. Health Care[2]	41,700	5%[a]	2,250
4. Food & Feed[2]	359,200	5%	17,960
5. Coatings & Inks[2,3]	29,700	90%[a,b]	26,700

[82] BiPRO *et al* (2013), page 10.

[83] Included in the category "miscellaneous": catalysts, lubricants, fuel additives, polymer nano-composites such as thermoplastic products, tires and other rubber products.

Table 7-1: Estimate of the number of companies with notification duties in France and in the EU			
Product Group[1]	**No. of companies in the EU28**	**Share of companies with notification duties**	**No. of companies with notifications duties in the EU28**
6. Cleaning & Disinfection[2]	22,000	10% [a]	2,200
7. Tyres & Other Rubber Products[2]	16,600	100% [c]	16,600
8. Plastic Products	60,550	87% [a,c]	52,500
9. Building & Construction	6,100	10% [b]	610
10. Textiles[2]	213,700	10% [b]	21,400
11. Paper Products	18,500	50% [c]	9,300
12. Wood Products	142,695	25% [c]	35,700
13. Sporting Goods	4,300	35% [c]	1,505
14. Electronics[2,3]	247,300	60% [c]	148,400
15. Complex Objects[2,3]	2,123,500	60% [c]	1,274,100
16. Miscellaneous	96,000	5% [a,c]	5,100
Total[4]	**3,411,500**	**47%**	**1,617,000**
Notes: *[1] Refer to BiPRO et al (2013) for a breakdown of all NACE codes found in each category.* *[2] Groups containing wholesale as an economic activity generally resulting in high numbers in comparison to groups consisting of primarily manufacturing* *[3] Groups containing retail as an economic activity* *[4] Company totals are rounded to the nearest hundred* *The share of companies with notification duties is based on:* *[a] The FNS results for corresponding NACE Codes;* *[b] The impact assessment from the Danish EPA (where a range was provided, the average value was selected);* *[c] Own estimate based on expert interviews.*			

7.3.2 Option 4b "With exemptions"

The exemptions for nanomaterials have the same influence on the number of companies obliged to notify nanomaterials as in Option 3. The product groups covered by the exemptions listed in 7.2.2 are summarised in Table 7-2. The reduction in share of companies with notification duties is based on the results of the second impact assessment[84] from the Danish EPA combined with educated guesses based on expert consultation for the work performed in BiPRO *et al* (2013). The impact of the exemptions on the companies with notification duties are listed as follows:

1. *Products (mixtures and articles) containing nanomaterials object of research and development*. In 2014, 43 nanomaterials (around 13% of the total) have been notified as object of research and development (SU24)[85]: however, it is not possible to identify for what type of products and processes and for what sector these nanomaterials are being experimented. It is assumed that around 2% of the companies carry out R&D on products containing nanomaterials and would be therefore exempted;

2. *Products containing pigments in nanoform*. Many mixtures containing pigments would be exempted. It is assumed that the number of companies in coatings & paints would be reduced by 60% (DEPA, 2013), and all other companies putting mixtures on the market by 25%. However, most products that contain pigments also contain fillers and therefore will not be exempted. Moreover, for companies manufacturing mixtures and/or articles containing e.g.

[84] Danish Environmental Protection Agency, *Muligheder for reduktion af danske virksomheders administrative byrder ved indberetning til en nanoproduktdatabase*, Miljøprojekt no. 1462, 2013.

[85] Table 7-2.

carbon black, there would be the problem to establish the purpose of the nanomaterial, where this can be used as a filler and pigment;

3. *Products containing fillers in nanoform*. The eight nanomaterials notified to the FNS as used as fillers are all among the most widely diffuse nanomaterials, making over 99% of the French market in terms of tonnage. It is likely that this is the share in the EU market too. For example, carbon black is used as reinforcing filler in tyres and other rubber products, as it is amorphous silica; calcium carbonate is used in plastics, health care products and paper products. However, fillers are unlikely to be the sole nanomaterials in many mixtures and products and therefore only a few sectors are expected to be affected: companies with notification duties in the Cosmetics, Health Care, Food & Feed, Cleaning & Disinfection and Paper Products sectors are assumed to be reduced by 35%, while the other sectors remain unchanged;
4. *Products containing pigments and fillers in nanoform*. Many products contain both pigments and fillers in nanoform and excluding products that contain both pigments and fillers in nanoform will significantly reduce the number of products to be notified. Therefore, the reduction in companies with notification duties are estimated to be 85%[86] for mixtures and articles with complex articles being estimated at 75% since it is likely that an article with so many components will have at least one other nanomaterial.
5. *Products containing nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation*. As stated in Option 3, this accounts for approximately 65% of all nanomaterials on the EU market. It is assumed the same percentage of all companies would be exempted from notification;
6. *Products covered by existing registration requirements such as cosmetics, biocidal and plant protection products*. Therefore, the number of companies in the sectors "Cosmetics, Cleaning & Disinfection" and "Food & Feed" will be reduced by 100%;
7. *Articles without intended release and substances bound in a mixture*. According to the UK REACH Competent Authority[87], there are very few examples of intended release of a substance from an article (e.g. release of lotion from pants or fragrance from a scented bin liner). Many of such examples contain mixtures and are released via a controlled mechanism (e.g. pen ink, aerosol can, etc.). Therefore, it is assumed that 99% of companies putting articles on the market will be exempted, where the categories "wood products", "electronics", and "complex articles", are assumed to have 100% of companies exempted since these products do not have components with intended release of substances. For the purpose of these calculations, it is assumed that nanomaterials in liquid and powder mixtures[88] are considered bound;

Table 7-2 presents a summary of the effects of the exemptions on the number of companies with notification duties by product group. These figures have been used to estimate the costs for Option 4 and its various exemptions.

[86] This estimate is based on value provided for the paints & coatings sector in the Danish Impact Assessment for that case that products with fillers (Carbon Black) and TiO2 are exempted.

[87] UK REACH Competent Authority Information Leaflet Number 9 – Articles – April 2014.

[88] The decreasing size of powder particles increases the likelihood of cohesion in a mixtures (Bridgewater, 1976, Fundamental powder mixing mechanisms, Powder Technology 15 (2): 215:236.

Table 7-2: Number of companies covered by the exemptions on the EU market										
Product Group	No. of companies in the EU28	Share of companies with notification duties	No. of companies with notification duties in the EU28 (after exemptions)							
			No exemptions	R&D	Products containing pigments	Products containing fillers	Products with pigments & fillers	Products containing NM registered under REACH	Products covered by other regulations	Products without intended release
1. Substances	5,200	23%	1,210	1,170	590	1,180	550	430	1,080	1,210
2. Cosmetics	24,400	6%	1,450	1,430	1,090	950	220	510	0	1,450
3. Health Care	41,700	5%	2,250	2,210	1,690	1,470	340	790	1,470	1,690
4. Food & Feed	359,200	5%	17,960	17,610	13,470	11,680	2,700	6,290	0	17,960
5. Coatings & Inks	29,700	90%	26,700	26,170	10,680	26,700	4,010	9,350	26,700	26,700
6. Cleaning & Disinfection	22,000	10%	2,200	2,160	1,650	1,430	330	770	0	2,200
7. Rubber Products	16,600	100%	16,600	16,270	16,600	16,600	2,490	5,810	16,600	170
8. Plastic Products	60,550	87%	52,500	51,450	52,500	52,500	7,880	18,380	52,500	530
9. Building & Construction	6,100	10%	610	600	460	610	100	220	610	310
10. Textiles	213,700	10%	21,400	20,980	21,400	21,400	3,210	7,490	21,400	220
11. Paper Products	18,500	50%	9,300	9,120	9,300	9,300	1,400	3,260	9,300	100
12. Wood Products	142,695	25%	35,700	34,990	35,700	35,700	5,360	12,500	35,700	360
13. Sporting Goods	4,300	35%	1,505	1,480	1,510	1,510	230	530	1,510	20
14. Electronics	247,300	60%	148,400	145,440	148,400	148,400	22,260	51,940	148,400	0
15. Complex Objects	2,123,500	60%	1,274,100	1,248,620	1,274,100	1,274,100	318,530	445,940	1,274,100	0
16. Miscellaneous	96,000	5%	5,100	5,000	5,100	5,100	770	1,790	5,100	60
Total	**3,411,500**		**1,617,000**	**1,584,700**	**1,594,300**	**1,608,700**	**370,400**	**566,000**	**1,594,500**	**53,000**

7.4 Information Requirements

Table 7-3 presents the information requirements for an EU-wide notification system by application.

Table 7-3: 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 • Manufacturer; • Distributor; • Importer; • Professional user and distributor; • Repackager and distributor; • European representative; • Professional user; • Manufacturer of mixtures containing nanomaterials; • Importer of mixtures containing nanomaterials; • Manufacturer of articles and/or complex objects containing nanomaterials; • Importer of articles and/or complex objects containing nanomaterials; • 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 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)
Physicochemical characteristics: Particle size, Number size distribution, Aggregation and agglomeration state, shape, specific surface area, description of the coating, surface charge
How the nanomaterial is included in the product
R&D only? (Yes/No) **Research and Development** • Scientific research; • R&D on products and processes; • no R&D.
Quantities
Quantity produced
Quantity distributed
Quantity imported
Quantity distributed after use
Quantity distributed after repackaging
Other quantity
Uses
Uses* Descriptor SU Descriptor PC

Table 7-3: Information to be gathered through an EU-wide notification system by application
Descriptor ERC Descriptor PROC 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)

7.5 Administrative Burden on Businesses

7.5.1 Option 4a "No exemptions"

The administrative burden for businesses has been estimated on the basis of the number of companies in different economic sectors[89] with notification duties since this was considered the most reliable calculation method. The percentages of companies with notification duties for each sector is based on the figures used in two impact assessments[90] carried out by the Danish Environmental Protection Agency and on the study of the proposed Belgium registry (BiPRO *et al*, 2013). Since the notification costs from the Danish impact assessment are available on a company basis (e.g. 150h/company) and not a notification basis, it was not necessary to estimate the number of products to be notified[91] in order to estimate the administrative burden. Therefore, the emphasis on quantifying the impacts of Option 4 is placed on estimating the effects of different building blocks on the number of companies with notification duties.

The total costs to businesses resulting from the introduction of a mandatory EU Nanomaterial Registry by Application is calculated on a per company basis.

The costs for the notifications of the manufactured substances (product group in table 7-1) in are based on the calculations according Option 3.

The costs for the articles and mixtures are calculated on a company basis according to the formulas used in the impact assessment by the Danish EPA.

$$\text{Cost} = \text{No. of companies notifying} * \text{Cost}_{\text{Notification Duties}} + \text{No. of companies not notifying} * \text{Cost}_{\text{No Notification Duties}}$$

As for Option 3, the basis for converting from hours to Euro is 35€/h.

The above formula reflects that companies will have to check their products and enquire up the supply chain (and respond to enquiries down the supply chain) to determine if they have notification duties, thus incurring costs. The implementation and annual costs per company are summarised according to product group in Table 7-4.

[89] Eurostat Structural Business Statistics.

[90] Danish Environmental Protection Agency, *Anvendelse af nanoprodukter på det danske marked - Vurdering af de administrative konsekvenser for virksomheder ved indberetning til en nanoproduktdatabase*, Miljøprojekt no. 1451, 2012 and Danish Environmental Protection Agency, *Muligheder for reduktion af danske virksomheders administrative byrder ved indberetning til en nanoproduktdatabase*, Miljøprojekt no. 1462, 2013.

[91] It should be noted that basing the cost analysis on the number of notifications would introduce a much higher source of uncertainty into the calculations, since there are no reliable data on the number of different products on the market in the various sectors.

As reported by DEPA (2012) "*the administrative burdens connected to reporting to the database will vary from each sector of trade to each sector of trade especially due to substantial differences in what the companies know about the contents of nanomaterials in the products and the possibility of obtaining such information. A limited knowledge related to obtaining information especially applies to importers. The administrative burdens of the subsequent annual reporting also varies, depending on a company's number of products containing nanomaterials and the frequency of which new products are introduced.*

Especially in connection with companies dealing with paint and coating as well as plastics the administrative burdens will be very heavy as almost all products in these categories are nano products that have to be reported to the nanomaterials registry by application. The estimates of the administrative burdens are stated in the table below."

Section A2.4 in Annex 2 presents the calculation steps followed for the assessment of the total and recurring costs for Option 4 (with and without exemptions).

Table 7-4: Estimate of the administrative burden (first year and annual recurring cost) per company

Product Group	Implementation Administrative Burden (hours) [€/company/year]		Recurring Administrative Burden [€/company/year]	
	Company with notification duties	Company without notification duties	Company with notification duties	Company without notification duties
1. Substances	†	0	†	0
2. Cosmetics[b]	(110 h) €3,850	(15 h) €525	(25 h) €875	(5 h) €175
3. Health Care[b]	(110 h) €3,850	(15 h) €525	(25 h) €875	(5 h) €175
4. Food & Feed[b]	(110 h) €3,850	(15 h) €525	(25 h) €875	(5 h) €175
5. Coatings & Inks[a]	(150 h) €5,250	(20 h) €700	(30 h) €1,050	(5 h) €175
6. Cleaning & Disinfection[a]	(65 h) €2,925	(10 h) €350	(15 h) €525	(5 h) €175
7. Tyres & Other Rubber Products[c]	(75 h) €2,275	(15 h) €525	(40 h) €1,400	(5 h) €175
8. Plastic Products[c]	(75 h) €2,275	(15 h) €525	(40 h) €1,400	(5 h) €175
9. Building & Construction[a]	(100 h) €3,500	(10 h) €350	(20 h) €700	(5 h) €175
10. Textiles[a]	(50 h) €1,750	(20 h) €700	(30 h) €1,050	(5 h) €175
11. Paper Products[c]	(75 h) €2,625	(15 h) €525	(40 h) €1,400	(5 h) €175
12. Wood Products[c]	(75 h) €2,625	(15 h) €525	(40 h) €1,400	(5 h) €175
13. Sporting Goods[a]	(100 h) €3,500	(10 h) €350	(50 h) €1,750	(5 h) €175
14. Electronics[c]	(75 h) €2,625	(15 h) €525	(40 h) €1,400	(5 h) €175
15. Complex Objects[c]	(75 h) €2,625	(15 h) €525	(40 h) €1,400	(5 h) €175
16. Miscellaneous[c]	(75 h) €2,625	(15 h) €525	(40 h) €1,400	(5 h) €175

Notes:
† The total cost for the notification of substances are presented in Table 8-5 and follows the methodology used for Option 3.
The costs according to product group have been estimated as follows:
[a] Estimated hours from DEPA (2012); the recurring costs have been adjusted to reflect feedback from FNS industry surveys;
[b] Average number of hours for the notification of mixtures (DEPA, 2012);
[c] Average number of hours for the notification of articles (DEPA, 2012).

Furthermore, the phase-in of the legislation will affect the cost burden for industry. In this regard, it is assumed that the phase-in period will consist of the following notification rounds in order to facilitate an orderly implementation of the legislation for the different actors in the supply chain:

- Notification Round 1: Only manufactured and imported nanomaterials are to be notified;

- Notification Round 2: All manufactured and imported mixtures containing nanomaterials and all nanomaterials put on the market are to be notified;
- Notification Round 3: All nanomaterials and mixtures and articles containing nanomaterials put on the market are to be notified.

Each notification round will allow a certain period (e.g. 1 year) for the communication of the notification ID and associated information along the supply chain.

The implementation and annuals costs for Option 4 without exemptions is summarised according to product group in Table 7-5. Including all products containing nanomaterials along the supply chain in an EU-wide registry per application results in a high number of companies having to notify, leading to extremely high costs for industry across several sectors. These costs are over **37 times higher than Option 3 in the first year and over 650 times higher in terms of annual recurring costs**. This is due to the notification of mixtures and articles containing nanomaterials, disregarding whether the nanomaterials are bound to the matrix or are intended to be released from the articles under reasonable or foreseeable conditions.

Table 7-5: Total administrative burden of an EU-wide registry per application – first year of implementation and annual cost

Product Groups	No. of companies in the EU28	Share of companies with notification duties	No. of companies with notifications duties in the EU28	Implementation costs	Annual costs
1. Substances	5,200	23%	1,210	34,835,900 €	435,600 €
2. Cosmetics	24,400	6%	1,450	17,631,250 €	5,285,000 €
3. Health Care	41,700	5%	2,250	29,373,750 €	8,872,500 €
4. Food & Feed	359,200	5%	17,960	248,297,000 €	75,432,000 €
5. Coatings & Inks	29,700	90%	26,700	142,275,000 €	28,560,000 €
6. Cleaning & Disinfection	22,000	10%	2,200	11,935,000 €	4,620,000 €
7. Tires & Other Rubber Products	16,600	100%	16,600	43,575,000 €	23,240,000 €
8. Plastic Products	60,550	87%	52,500	142,038,750 €	74,908,750 €
9. Building & Construction	6,100	10%	610	4,056,500 €	1,387,750 €
10. Textiles	213,700	10%	21,400	172,060,000 €	56,122,500 €
11. Paper Products	18,500	50%	9,300	29,242,500 €	14,630,000 €
12. Wood Products	142,695	25%	35,700	149,884,875 €	68,704,125 €
13. Sporting Goods	4,300	35%	1,505	6,245,750 €	3,122,875 €
14. Electronics	247,300	60%	148,400	441,472,500 €	225,067,500 €
15. Complex Objects	2,123,500	60%	1,274,100	3,790,447,500 €	1,932,385,000 €
16. Miscellaneous	96,000	5%	5,100	61,110,000 €	23,047,500 €
Total	**3,411,500**		**1,617,000**	**5,324,500,000 €**	**2,545,900,000 €**

When compared to a registry by substance, Option 4 would entail a much higher administrative burden on the EU businesses: even without considering the costs for the characterisation of the nanomaterials used, manufacturers and importers of mixtures and articles would have to screen through their product portfolio (containing from tens to thousands different product types) to identify those products containing nanomaterials in order to comply with the notification duties. **The Category "Complex Objects", that include manufacturers, wholesalers and retailers of e.g. cars, refrigerators, furniture, etc. would sustain over 70% of the total administrative burden**.

It can be concluded that:

- The administrative burden would vary between the different economic sectors due to substantial differences in companies' knowledge of the content of nanomaterials in their products and the possibility of obtaining such information;
- Limited knowledge and issues associated with obtaining information would apply especially to importers;
- The administrative burden with regard to subsequent annual reporting would vary between the different economic sectors depending on the number of products containing nanomaterials and the frequency of introduction of new products.

7.5.2 Option 4b - With exemptions

The exemptions considered, in particular on mixtures and articles containing nanomaterials used as pigments and/or fillers only, on mixtures and articles containing nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation and on mixtures and articles covered by existing registration requirements would result in substantial cost savings as summarised in Table 8-6.

Table 8-6: Cost savings by exemption – first year of implementation and annual cost

Exemption	EU companies with notifications duties	Savings on implementation costs	Savings on annual costs	Implementation costs	Annual costs
No exemptions	1,617,000	-	-	€ 5,324,500,000	€ 2,545,900,000
R&D	1,584,700	€ 70,200,000	€ 39,000,000	€ 5,254,300,000	€ 2,506,900,000
Mixtures and articles containing pigments	1,594,300	€ 110,200,000	€ 18,300,000	€ 5,214,300,000	€ 2,527,600,000
Mixtures and articles containing fillers	1,608,700	€ 27,400,000	€ 5,600,000	€ 5,297,100,000	€ 2,540,300,000
Mixtures and articles with pigments & fillers	370,400	€ 2,696,000,000	€ 1,501,000,000	€ 2,628,500,000	€ 1,044,900,000
Mixtures and articles containing NMs registered under REACH	566,000	€ 2,274,200,000	€ 1,267,300,000	€ 3,050,300,000	€ 1,278,600,000
Mixtures and articles covered by other regulations[1]	1,594,500	€ 284,200,000	€ 86,000,000	€ 5,040,300,000	€ 2,459,900,000
Mixtures and articles without intended release[2]	53,000	€ 5,014,300,000	€ 2,479,500,000	€ 310,200,000	€ 66,400,000

Notes:

[1] For product groups covered by other legislation, companies have neither implementation nor annual costs. The affected product groups are 2, 4, and 6.

2 The formula for calculating the costs for this exemption is different for product groups containing articles (product groups 7, 8, 10, 11, 12, 13, 14, 15, 16). Only companies putting articles on the market with notification duties (i.e. intended release) will incur costs. All other companies in exempted product groups will not incur costs since it will be clear that they are unaffected by the new legislation.

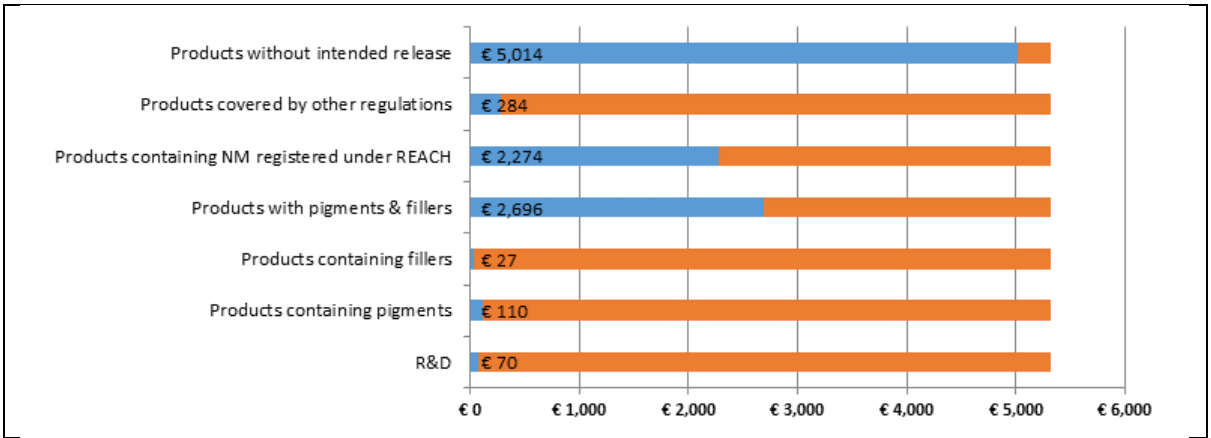

Figure 7-1: Cost savings (€m) by exemption – first year

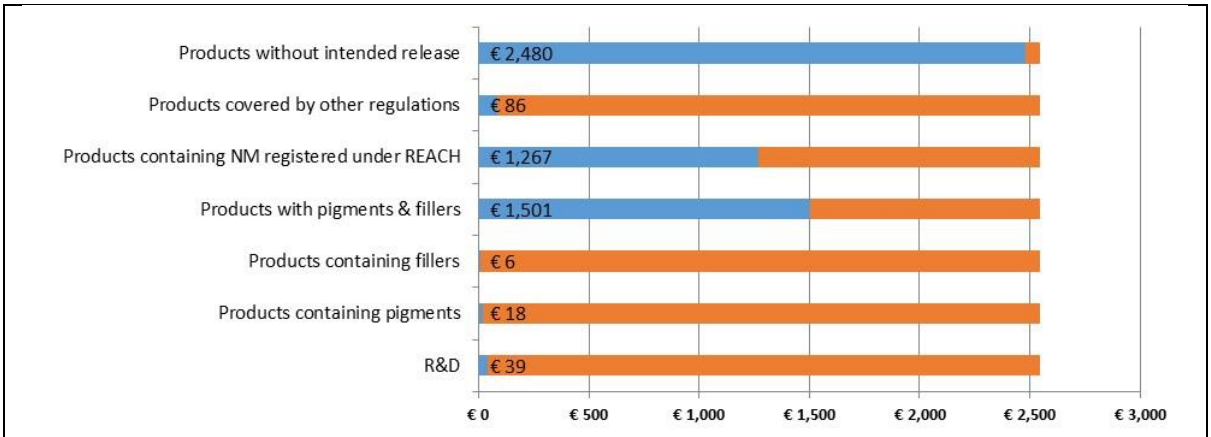

Figure 7-2: Annual cost savings (€m) by exemption

7.6 Public Authorities

The introduction of a mandatory EU Nanomaterial Registry by application will entail costs upon public authorities – namely those responsible for the establishment and operation of the registry. The main cost drivers for the setting up and operation of the registry would be:

- Acquisition of hardware/software; and
- Administrative aspects.

As for option 3, it is expected that the development of a registry would result in one-off costs of €250,000 (hardware and software). With regard to the annual recurring costs, the following has been considered: the number of notifications that would be received under Option 4 would drive up also the administrative costs of the registry, in particular in terms of dedicated staff to tasks such as organising stakeholder meetings, drafting FAQs, answering inquiries, communicating on the registry, liaising with relevant DGs within the Commission, assisting in answering enquiries, managing the IT tool development and maintenance, preparing the annual report and extracting the data for authorised organisations. As illustrative example, assuming that 10 officers would work full time in managing the registry, the additional costs would be of €750k.

The need for the translation of the web-page, guidance on the notification process, FAQs and reports of the results, given the diversity of EU languages, would result in significant additional costs. Assuming translation costs of 10% of the annual budget, this would result in additional €75k.

In summary, a nanomaterials registry per application might cost the first year over €1.1 million, with annual recurring costs of €825 thousand.

To the latter should be added the costs for the enforcement of the measure: unfortunately, no information has been found or obtained with regard to costs of actual enforcement in the countries implementing nanomaterials registries (i.e. Belgium, Denmark and France). However, for the purposes of this assessment some estimates have been generated on the basis of the following assumptions:

- The target is to inspect every year 2% of the companies that might manufacture, import or commercialise nanomaterials or mixtures and articles containing nanomaterials;
- A desk-based inspection would require five days of work for an officer in full time equivalent (going through the product portfolio of a company and checking the notifications submitted) for a cost of €1,310 (37.5 hours);
- In each inspection, the inspectors would test whether a product is in the nanoform (it is assumed that the test would cost around €10,000).

70,000 companies would be inspected for a cost of around **€91.7 million**. The testing of one product in each company inspected would cost around **€70 million** every year.

8 Options Comparison

8.1 Introduction

This section presents the comparison of the baseline and the defined options against the nine criteria defined by the Commission, namely:

- Criterion 1: costs on businesses;
- Criterion 2: special sectors;
- Criterion 3: costs authorities;
- Criterion 4: health / environment;
- Criterion 5: worker safety;
- Criterion 6: consumer information & trust;
- Criterion 7: internal market;
- Criterion 8: research and innovation;
- Criterion 9: confidential information.

It should be noted that, while for Option 3 it has been possible to use the preliminary findings of the evaluation of the French Notification System[92], the assessment of Option 4 is mainly based on the assumptions used in the studies commissioned by the Belgian and Danish authorities for the scoping of their own national schemes and before the final texts of the legislative acts were drafted. Moreover, Option 4 does not perfectly reflect either the Belgian or the Danish system and these two national schemes differ between themselves (the Belgian system, as the French one, focuses on professional users, while the Danish system covers mixtures and articles that are intended for sale to the general public).

8.2 Criterion 1: Costs on Businesses

Table 8-1 summarises the administrative burden on businesses of the policy options defined, including the exemptions considered.

Table 8-1: Administrative burden on businesses

Option	Implementation costs (first year)	Annual recurring costs
Option 1 - Recommendation for National Measures	-	-
Option 2a - Nanomaterials Observatory	-	-
Option 2b - Nanomaterials Observatory with national surveys	-	€30k
Option 3a - EU Nanomaterial Registry by Substance	€60M – €145M	€3.9M
Option 3b – R&D exemption	€57M – €142M	€3.2M
Option 3b – Pigments and dyes exemption	€35M - €68M	€2.6M
Option 3b – Fillers exemption	€52M - €122M	€3.5M
Option 3b - REACH Regulation exemption	€42M - €127M	€2.3M
Option 3b – Product Specific Legislation exemption	€42M - €124M	€2.4M
Option 4a - EU Nanomaterial Registry by Application	€5,324M	€2,546M
Option 4b - R&D exemption	€5,254M	€2,507M
Option 4b - Pigments and dyes exemption	€5,214M	€2,528M
Option 4b - Fillers exemption	€5,297M	€2,540M
Option 4b – Pigments and filler exemption	€2,628M	€1,045M

[92] It is important to remind that the evaluation of the FNS has been carried out on the information available for the first two years of implementation (2013 and 2014); the French authorities noted that this information is likely to change and might not give a trustful picture of the actual situation on the market.

Table 8-1: Administrative burden on businesses		
Option	**Implementation costs (first year)**	**Annual recurring costs**
Option 4b - REACH Regulation exemption	€3,050M	€1,279M
Option 4b - Product Specific Legislation exemption	€5,040M	€2,460M
Option 4b – Without intended release exemption	€310M	€66M

8.3 Criterion 2: Special Sectors

Criterion 2 is aimed to avoid the situation where particular industrial sectors incur in significantly high costs due to the options.

Since the beginning of the study, it has been apparent that the pigments and dyes sector[93] would be particularly affected by the setting up of a registry: over 50% of the nanomaterials notified to the FNS in 2014 have been identified as either pigments or dyes.

Through the comparison of the administrative burden with the added value per company, it has been highlighted that the incidence of the total costs on the value added during the first year, especially in the case of micro, small and small-medium enterprises, is high, suggesting that a phased notification system for SMEs would be advisable. This suggestion might be particularly important for the pigments and dyes sector, as the administrative burden during the first year is directly proportional to the number of notifications to be submitted.

The recurring costs of an EU nanomaterials registry are unlikely to have a significant impact on the margins of the EU companies.

8.4 Criterion 3: Costs Authorities

With regard to the costs for authorities, none of the options entail prohibitive costs. Table 8-2 summarises the results.

Table 8-2: Costs for the public authorities		
Option	**Implementation costs (first year)**	**Annual recurring costs**
Option 1 - Recommendation for National Measures	-	-
Option 2a - Nanomaterials Observatory	€560k - €670k	€335k
Option 2b - Nanomaterials Observatory with national surveys	€860k - €970k	€435k
Option 3 - EU Nanomaterial Registry by Substance	€700k	€450k + €3.3M (enforcement)
Option 4 - EU Nanomaterial Registry by Application	€1.1M	€825k + €160M (enforcement)

8.5 Criterion 4: Health / Environment

For Criterion 4, it is important to establish how the options perform in terms of:

[93] Classified by Eurostat as NACE C20.12 “Manufacture of pigments and dyes” and C20.30 “Manufacture of paints, varnishes and similar coatings, printing ink and mastics”.

- The level of information achieved and made available to the authorities on nanomaterials, their identities, the quantities handled and the different uses and applications;
- The traceability of the nanomaterials on the market: from the manufacturers or importers via the distributors to the final professional users;
- The level of information on hazard and exposure of nanomaterials.

The level of information made available to the workers is analysed in Section 8.6 (criterion 5); the level of information made available to the consumers is analysed in Section 8.7 (criterion 6).

Without any doubt, if the Commission would have to implement a registry, either by substance or by application, would get all the information regarding the identities of the nanomaterials on the EU market, their quantities, the different uses and applications. The Nanomaterials registry by application, being more ambitious, would provide a very detailed picture of the situation on the market. However, it is opinion of the study team that Option 4, without considering the exemption on mixtures and articles where the nanomaterial is not released under normal or reasonably foreseeable conditions, suffers from its own ambition: it would be very difficult for companies to comply with and for the Member States to enforce it. As noted in the two impact assessments commissioned by the Danish Environment Protection Agency, the administrative burden would vary between the different economic sectors due to substantial differences in companies' knowledge of the content of nanomaterials in their products and the possibility of obtaining such information. It is important to note that both the Belgian and the Danish schemes exempted mixtures and articles where the nanomaterial is not released under normal or reasonably foreseeable conditions.

In order to assess whether a Nanomaterials registry would provide a deeper knowledge on nanomaterials, their identities, the quantities handled and the different uses and applications, the comparison between the information requirements of the REACH Regulation (and of the amended Annexes) with the information requirements of the nano registries implemented in Belgium, Denmark and France is presented (Tables 8-4, 8-5 and 8-6).

The tables present the information requirements of the nano registries 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 that should be covered by the amendments of the REACH Annexes have been highlighted in yellow.

Table 8-4: 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* • Manufacturer; • Distributor; • Importer; • Professional user and distributor; • Repackager and distributor; • European representative.	No (manufacturer/importer/only representative)
Public research organisation* (Yes/No)	No
Company registration certificate*	Yes
Business sector* (NACE code list)	No

Table 8-4: 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**
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* • Manufacturer; • Distributor; • Importer; • Professional user and distributor; • Repackager and distributor; • 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; NACE code of the clients/professional users		No
Research and Development • Scientific research; • R&D on products and processes; • 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* • The substance is pure; • The substance is contained in a mixture without being bound to it; • 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+ Nature and quantity for each impurity with a mass concentration lower, equal to or higher than 0.1%		Yes
Size of the particles* Mean particle size of the primary particles, associated with a standard delta		Yes
Number size distribution for particles*		Yes
Aggregation and agglomeration state*	Mean size of aggregates with standard delta	??
	Aggregation state determination method used	??

Table 8-4: 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**
	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
	Other quantity	No
Uses		
Uses* Descriptor SU Descriptor PC		Yes

Table 8-4: 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**
Descriptor PROC Descriptor AC	
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)* (Name, address, zip code, city, country, intercommunity VAT)	No

Table 8-5: 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 (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

Table 8-5: Information requirement of the Belgian Notification Register and REACH		
No.	**Information requirements**	**REACH**
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 8-6: 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)	??
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 and registrants have updated their dossiers accordingly, 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 REACH Regulation will provide (eco)toxicological information specific to the nanoforms of the substances registered. It should also be noted that the CLP Regulation requires the classification and labelling (C&L) of a substance to be composition/form specific. Currently, of the 287 substances at the nanoscale analysed, only 23 have a notification to the Classification and Labelling Inventory[94] specific to the nanoform. After the amendment of the REACH Annexes, the number of C&L notifications specific to the nanoforms of the substances is expected to increase.

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 EU wide nanomaterials registries by Substance and by Application would therefore provide additional information with regard to the actors along the supply chain, achieving the traceability of the nanomaterials from the manufacturers down to the professional end users (in the case of Option 4, down to the retailers).

The data collected (including the confidential data), could be passed on to designated public agencies and institutes for risk assessment. These data might allow a better prioritisation strategy for the risk assessment of nanomaterials. Although the options do not collect (eco)toxicological information, they might foresee the possibility for the authorities to ask for that kind of information when available.

However, it is opinion of the study team that the traceability does not have any particular added value in terms of "fast action" on public health and the environment: for generic products, RAPEX (Rapid Alert System for Non-Food Dangerous Products) is the EU system which allows the rapid exchange of information between Member States and the European Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers; for particular products of interest (e.g. cosmetic products), the Commission already requires the notification of the nanomaterials and the labelling of the substances as "nano" in the ingredient list displayed on the product label. Moreover, as presented in the Building Blocks report (RPA *et al*, 2014), most of the concerns over nanomaterials are on their potential chronic effects: therefore the ability to act in a fast way given by the traceability is of limited value.

The French authorities have acknowledged that there are already several studies that have been launched making use of the data collected. For example, the INVS has renewed for the second year its request for an access to specific data in the setting up of an epidemiological study. The INERIS is also making use of some data to assess the accidental risk of powders (flammability, explosivity, reactivity) and to predict consequences of accidents involving nanomaterials.

Importantly, since January 2015 the Anses has appointed an experts working group that will analyse the gathered data in order to prioritise substances that should be submitted to a health risk assessment, to improve knowledge on exposure and to identify improvement areas of the scheme. The French authorities argue that, in the future, the public and the workers could directly benefits from the findings of the studies carried out by the national agencies using the information collected by the scheme.

It should be noted that, from the results of the public consultation, citizens and NGOs are of the opinion that there is currently no legislation or database which provides adequate or standardised information concerning products which contain nanomaterials on the European market. Moreover,

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

this is predominantly limited to food, cosmetics and biocides. In their responses, stakeholders frequently referred to REACH but were generally of the opinion that the information on nanomaterials recorded under this legislation is extremely limited and inadequate – a view shared by several MS authorities. It was felt that REACH is not sufficiently adapted for nanomaterials given the absence of a definition, a tonnage band restriction of 1 tonne per annum and the fact that it considers nanomaterials to be identical to the bulk material.

With regard to the environment and the quantification of any impact on the environmental media, Option 3 might provide some new information in the case the Environmental Release Categories (ERC) descriptor is required. ERC are used for describing the broad conditions of use of the substances from the environmental perspective and relevant for their subsequent service life in articles.

Any exemption considered to the implementation of an EU wide nanomaterials registry by substance or by application would result in fewer information collected by either schemes.

With regard to the Nanomaterials Observatory, the option does not require the generation of any new information; however, the Observatory might help in organising the information in suitable manners on both health and environmental aspects of nanomaterials according to the profiles of the observatory users.

Given that any benefit on the human health and the environment would stem from the subsequent use by the public authorities of the information gathered through the options and by the results of the risk assessments carried out by the national agencies, it has not been possible to quantify these benefits.

8.6 Criterion 5: Worker Safety

For the assessment of the options in terms of their ability to increase worker safety, it is important to determine whether the options increase the level of information available to the workers.

During the evaluation of the FNS, it has been noted that a registry increases awareness of downstream users in being handling nanomaterials. The information might be passed to workers and this might led to some of them questioning the suitability of their risk management measures in dealing with nanomaterials.

In terms of the information required for the risk assessment that each employer should carry out in order to comply with the occupational health and safety legislation[95], it should be noted that each company have to provide information on the quantities (necessary for the estimate of the exposure) but only some manufacturers and importers characterise the physicochemical parameters of the nanomaterials, with downstream actors able only to refer to the notification numbers of their suppliers without having access to that information. However, some downstream users might ask their suppliers for the information on the characterisation of the nanomaterials in order to carry out the required risk assessment.

It should be noted that the options (3 and 4) require only a basic characterisation of the nanomaterials: for some nanomaterials, further characterisation is required in order to investigate any toxicological and ecotoxicological effects.

Nevertheless, the increased awareness of employers and workers in dealing with nanomaterials might result in new investment in OSH measures. Various study have concluded that expenditure on occupational safety and health is an investment that "pays off" and calculated the Return on

[95] See for example, the Chemical Agents Directive 98/24/EC.

Prevention (ROP) to be 2.2[96] or the Benefit-Cost Ratio to be between 1.04 and 2.70[97]. Although the increased awareness of the actors within the supply chains of being handling nanomaterials has been identified as the main benefit of a registry, the quantification of the benefits in terms of workers' health and safety is not possible, as it would require the knowledge of:

- The number of companies that, becoming aware of handling nanomaterials, would reassess their risk management measures (RMMs);
- The number of cases where this reassessment would lead to new RMMs;
- The nature and cost of the RMMs implemented;
- The hazard profile of the nanomaterials handled and whether companies has access to the partial characterization of the nanomaterials and how this had contribute to the reassessment of the RMMs.

In terms of the utility of the nanomaterials registries for launching and focusing the epidemiological study on some nanomaterials instead of others, registries can indeed provide easy accessible tools to identify manufacturers/importers of determined nanomaterials and their downstream users: this enable a precise estimate of the workers population exposed to the nanomaterials to be investigated. It should be noted however that for the assessment of the exposure, *in situ* investigations are necessary. Moreover, the workers potentially exposed should be contacted to propose them a long term medical monitoring, updated on a regular basis. Given these last two steps, the need for a registry in order to carry out epidemiological studies has to be reappraised. The setting up of a mandatory notification system does not seem fully justified, in the opinion of the study team, by the planning of epidemiological studies, as these need anyway the collaboration of the companies involved. Registries will indeed provide some data time series (with regard to workers' population exposure) that might be of value in the coming years for the study of any chronic effect of the nanomaterials. This value resides on the ability to enable a better monitoring of exposure pattern changes and to identify any potential disease directly related to the nanoform(s) of the substances or to focus on the potency of the nanoform(s) fraction of the substances to which the cohorts are exposed.

As for the health and environment criterion, any exemption considered to the implementation of an EU wide nanomaterials registry by substance or by application would result in fewer information collected by either schemes.

With regard to Option 2, a Nanomaterials Observatory can provide valid basic information (e.g. known hazards, uses) for workers that are interested/concerned about nanomaterials. However, this option does not increase the awareness of employers and workers with regard to the presence of nanomaterials in their activities, increased awareness that is instead triggered by the registries.

8.7 Criterion 6: Consumer Information & Trust

To determine whether the options increase the level of information available to consumer and whether they enhance the consumers' trust on nanomaterials, it is important to determine what information might be accessible by consumers.

Option 4, the EU Nanomaterials registry by Application, aiming to get full traceability from manufacturers to consumers, could be, on paper, the option that most information deliver to all stakeholders, including consumers. It is opinion of the study team however that, due to its too wide scope, Option 4 would be very difficult to comply with and to enforce, failing to achieve its objectives.

[96] Kohstall *et al* (2013): Calculating the international return on prevention for companies. Costs and benefits of investments on occupational safety and health. DGUV.

[97] EC (2011): Socio-economic costs of accidents at work and work-related ill health, DG for Employment, Social Affairs and Inclusion.

Moreover, it is not clear whether the information would be provided to consumers: for example, the Danish Notification System is the only one among the transparency measures currently implemented, to require information on consumers' products containing nanomaterials; however, the Danish authorities have clarified that this information will remain confidential and will be available to the authorities only.

During the public consultation, consensus emerged on the fact that the provision of information concerning presence of nanomaterials in products would not lead to consumers being more inclined to purchase those products. Indeed, industry respondents noted that as a result of negative preconceptions and the current stigma associated with nanomaterials, providing information about the presence of nanomaterials in a product to consumers could result in them avoiding that product. However, in many instances the French notification scheme would appear to have had no impact on the purchasing decision and in some instances, companies will promote the presence of nanomaterials in their product (e.g. high-tech product).

Other industry respondents noted that the information indicating the presence of nanomaterials in products would result in customers, particularly business clients, requesting further information such as an explanation or assessment on the safety of the product. It is opinion of the study team that this is the main driver of any potential benefits on the human health and the environment stemming from the nanomaterials registries.

Of note is that the responses from citizens and NGOs suggested that consumers were more likely to search for more information rather than to simply avoid the products and this view was shared by MS authorities and other respondents.

Further comments from citizens and NGOs, MS authorities and other respondents suggest that there are many factors to consider with regard to the impacts of labelling products with nanomaterials (e.g. type of product, type of nanomaterial, utility, etc.). However, providing information concerning the presence of nanomaterials will stimulate interest in some consumers, who will then be likely to search for further information so that they can make an informed and conscious choice. Other respondents noted that the purchasing decision of some consumers would be unaffected because of a lack of knowledge of nanomaterials and their potential health impacts. Finally, some consumers would perceive 'nano' as a selling point, while there would be those consumers concerned about the health impacts of certain nanomaterials that would avoid such products.

As for the health and environment and the workers' safety criteria, any exemption considered to the implementation of an EU wide nanomaterials registry by substance or by application would result in fewer information collected by either schemes.

With regard to the role that a Nanomaterials Observatory might play on enhancing consumers' trust, this is directly related to the quality and reliability of the information reported.

In order to show the challenges in:

- Identifying products on the consumer markets;
- Verifying and validating the information; and
- Keeping the information updated;

The Consumer Products Inventory (CPI) of the Project on Emerging Nanotechnologies (http://www.nanotechproject.org/cpi/) is described in more detail below and some shortcomings are highlighted. The CPI aims to provide information to the public on how nanotechnology is entering the market; currently, the inventory provides information on over 1,600 consumer products based on nanotechnology. Registered users are encouraged to submit evidence-based data. The managers of the inventory decide on what to include following three criteria: the product can be readily purchased by the consumers; the product is identified as nano-based by the manufacturer or another source; the claim that the product is nano-based seems reasonable.

Professor Maynard, one of the CPI co-founders has recently discussed[98] the risks linked with the misuse of the information provided through the inventory with particular reference to the presence of titanium dioxide in foods (in the European Union, E171) which is not normally a nanomaterial (the majority of the particles has particle size of hundreds nanometres).

Although the CPI has a ranking system in order to give less or more 'trustworthiness' to the information presented, its reliability is open to debate. By way of example, the study team searched the CPI with the key word 'lead' which identified one product as containing lead nanoparticles, with a confidence level category 2 (Verified claim). However, further inspection suggested that the word 'lead' was in fact associated with the phrase a 'lead' (as in leading) product in the sector.

8.8 Criterion 7: Internal Market

From the results of the public consultation it can be seen that there was strong agreement from industry with considerable agreement from MS authorities and, to a lesser extent, from citizens and NGOs and other stakeholders that the establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market. Industry respondents reported that multiple national schemes would increase the administrative and bureaucratic burden as a result of each database having its own scope, requirements and definitions, which means time must be spent gathering and inputting relevant information. There may also be linguistic barriers.

On this regard, the setting up of an EU-wide Nanomaterials Registry might avoid the implementation of diverging national schemes. However, it is not clear what would happen with those systems already implemented and different in scopes (e.g. the Danish System vs the French Notification System).

Industry respondents commented that a nanomaterial registry would severely disadvantage EU companies: EU companies would be required to register their nanomaterials at all stages of development and processing whereas those companies outside of the EU would only have to register products once they enter the EU market. The additional burden placed upon intra-EU companies would thus give companies outside of the EU a competitive advantage. It was also suggested that the costs of complying with the additional requirements would be borne by consumers, which would result in increased prices for value chains in EU vs non-EU markets. The comparison of the administrative burden with the value added per company does not substantiate these arguments.

MS authorities questioned whether there would be any intra-EU impacts on competitiveness as the same requirements would be imposed on all companies within the EU. In fact, it may stimulate innovation as the registry may encourage government support for nanotechnologies in the form of funding, levies and tax breaks to encourage development of the right products. The view that intra-EU competitiveness would be stimulated was supported by most citizen and NGO and other respondents. However, it was noted that the French registry hampered competition immediately following its introduction, but this was only temporary and receded following the correct control on importation and dialogue. In any event, providing adequate information to consumers should far outweigh the consideration of market impacts, as a health crisis may be detrimental for the EU industry in the long term.

Although most citizen and NGO indicated that extra-EU competitiveness would also be enhanced, MS authorities and other respondents were more cautious in their responses.

The vast majority of industry respondents indicated that they experience or expect significant barriers to their company/members of their association from diverging notification obligations in the schemes in France/Belgium/ Denmark.

[98] https://theconversation.com/no-metal-oxide-nanoparticles-in-your-food-wont-kill-you-27545

With regard to Option 2, although the Nanomaterials Observatory is not expected to have any impact on the internal market, its implementation would not result in a harmonisation at the European level, as it is likely that the national transparency measures would be left in place.

8.9 Criterion 8: Research and Innovation

From the results of the public consultation, many industry respondents were concerned that providing information about the presence of nanomaterials in a product would negatively impact nanotechnology innovation. A number of respondents noted that the French national registry system undermined economic partners' trust in nanomaterials, which in turn negatively impacted competitiveness and innovation. It also brought uncertainties amongst economic actors towards the French market, raising question marks with regard to business developments and the location of research and development activities in France. It should be noted that the evaluation of the FNS did not substantiated these claims.

More generally, it was noted that imposing requirements to provide further information would increase administrative burden across the whole supply chain, resulting in additional costs that would otherwise be spent on research and development. This could deter the emergence of further nanomaterial producers or alternatively, they may choose to locate themselves outside of the EU.

A recent paper by the OECD[99], however, provide evidence that more stringent environmental policies of recent years have had no negative effect on overall productivity growth.

From the results of the public consultation, numerous industry respondents also stressed that any requirement to provide information must be carefully balanced against the need for confidentiality. A failure to strike the right balance could negatively impair innovation. On the other hand, it was also noted that dissemination of information on nanomaterials could result in better knowledge of their properties, particularly around hazard and handling guidelines, which could stimulate innovation.

Citizens and NGOs and, to a lesser extent, MS authorities and other respondents, believe that information provision would stimulate innovation. Many respondents stated that, by labelling products that contain nanomaterials, greater legal certainty would be created in the market. This is important because legal uncertainty has been highlighted by nano producing/distributing companies as one of the main factors stifling the innovation of nanotechnologies.

8.10 Criterion 9: Confidential Information

During the public consultation, industry stakeholders and Member States authorities considered that the protection of confidential business information was a very important objective. Numerous industry respondents also stressed that any requirement to provide information must be carefully balanced against the need for confidentiality. A failure to strike the right balance could negatively impair innovation. There was a certain consensus that the current legislation does meet the objective of preserving the confidentiality of the information.

Almost the entirety of industry respondents indicated that a disclosure of the information to be notified to a nanomaterials registry would conflict with the confidentiality of business information.

[99] Albrizio *et al* (2014): Do Environmental Policies Matter for Productivity Growth? Insights from New Cross-Country Measures of Environmental Policies, OECD Economics Department Working Papers. Available at: http://www.oecdobserver.org/news/fullstory.php/aid/4647/Environmental_policies_don_92t_have_to_hurt_productivity.html#sthash.m3t2zLtt.dpuf

Most concern was the possibility of revealing the name or description of the substance, as competitors may not be aware that a substance can exist at nanoscale. Other comments related to:

- Information linked to substance identify (characterisation of the nanomaterial);
- The uses;
- The quantities put on the market; and
- Name of the customers.

On the other hand, it was noted that dissemination of information on nanomaterials could result in better knowledge of their properties, particularly around hazard and handling guidelines, which could stimulate innovation.

When analysing the different options defined in terms of the management of confidential information, it should be noted that a Nanomaterials Observatory (Option 2a), since it gathers and present information already publicly available, would not collect any confidential information. With regard to the national surveys that might feed the observatory (Option 2b), these have a voluntary nature, therefore companies are unlikely to pass any business sensitive information unless reinsured about the confidentiality treatment.

An EU wide nanomaterials registry by substance (Option 3), as described in Section 6.1, would establish a partial disclosure to the public of the information about the identity and the uses of the nanomaterials. 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.

With regard to an EU wide nanomaterials registry by application (Option 4), the notifier would have the possibility to indicate that certain information should be regarded as confidential, including the chemical information, the substance identification, the composition and the purity of the substances, mixtures and articles, as well as the information about the quantities, the commercial name of the nanomaterial or mixture and the identity of the downstream users. As for Option 3, the notifiers would have to justify the reasons for the confidentiality treatment of the information.

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Annex I – Public Consultation

A1.1 Respondents

A1.1.1 Industry respondents

There were 98 completed questionnaires from industry respondents across Europe and further afield. There was a 50:50 split between individual companies and industry associations.

93 industry respondents provided details of their organisation including a country location (see Table A1-1).

Table A1-1: Location of Industry Respondents	
Responses	**Countries**
31	Germany
29	Brussels
9	France
6	United Kingdom
2	Finland, Netherlands, Spain, Switzerland
1	Czech Republic, Denmark, Italy, Japan, Lithuania, Nigeria, Norway, Portugal, Sweden, United States of America

Of these 93 respondents, 50 indicated that they were listed on the EU's Transparency Register[100] and provided their ID number. Of those that were on the Transparency Register, most were industry associations, often based in Brussels.

A1.1.2 Responses from Member State authorities

There were 12 completed questionnaires from Member State authorities across Europe. These comprised five responses from federal and regional authorities in Germany and one from each of France, Denmark, UK, Italy, Belgium, Estonia and Sweden.

A1.1.3 Responses from citizens

There were 74 completed questionnaires from citizens and citizen groups from across Europe and some responses from further afield. The make up of the 74 respondents is shown in (see Table A1-2).

Table A1-2: Nature of Citizen Respondents	
Responses	**Nature of Respondent**
39	A consumer organisation/trade union/environmental organisation/non-governmental organisation
35	An individual

Of these 74 respondents, 17 indicated that they were listed on the EU's Transparency Register and provided their ID number. Of those that were on the Transparency Register, most were in the first category of Table A1-2 ('consumer organisation/trade union/environmental organisation/non-governmental organisation') often based in Brussels. Table A1-3 (next page) indicates the location of the respondents.

[100] http://ec.europa.eu/transparencyregister/info

Table A1-3: Location of Citizen Respondents	
Responses per Country	**Countries**
25	France
13	Belgium
5	Denmark, Sweden
4	Germany
3	UK
2	Australia, Netherlands, Norway. Switzerland, USA
1	Brazil, Bulgaria, Finland, Ghana, Hungary, Japan, Mexico, Poland
Note: One respondent did not provide a specific country	

A1.1.3 Other respondents

There were 15 completed questionnaires from other respondents from across Europe. The make up of these 15 respondents is shown in Table A1-4.

Table A1-4: Nature of Other Respondents	
Responses	**Nature of Respondent**
5	A health and safety institute/academic organisation/research organisation
10	Others

Of these 15 respondents, one indicated that they were listed on the EU's Transparency Register and provided their ID number. Table A1-5 indicates the location of the respondents.

Table A1-5: Location of Other Respondents	
Responses per Country	**Countries**
6	France
2	Germany, Netherlands
1	Belgium, Bulgaria, Ireland, Spain, Switzerland

A1.1.4 Notes on responses

At the outset of this analysis, it is important to stress that most respondents not only provided the minimum answers required but also many additional comments. Indeed, for most questions, over 60% of respondents provided such comments.

All of the comments have been read and considered. In the report that follows, efforts have been to summarise the key points highlighted by respondents in relation to each of the issues being addressed. For those wishing to examine these comments in depth, the Commission has published all responses to the public consultation[101] (where the respondent was content for their contribution to be published).

[101] http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/public-consultation_en.htm

A1.2 Supply Chain Characterisation (Industry Respondents)

A1.2.1 Overview

16 (16%) industry respondents indicated that they had participated in the online survey (undertaken by RPA/BiPRO for the European Commission in early 2014) on the administrative burden of existing notification schemes. These respondents were therefore not asked for detailed information on their operations and proceeded to questions on 'problem definition and objectives' (see Section A-3).

The remaining 82 industry respondents were asked for further information on their activities. As already noted there was an approximate 50:50 split between companies and associations.

A profile of the industry respondents is presented in Table A1-6.

Table A1-6: Profile of Industry Respondents	
Our company or member company	**% Industry Respondents (n=79)**
has to notify to the French Notification System	61%
has to notify to the Cosmetic Products Notification Portal	28%
is a manufacturer of nanomaterials	58%
is an importer of nanomaterials	54%
is a formulator of mixtures containing nanomaterials	66%
is a manufacturer of articles containing nanomaterials without intended release	51%
is a manufacturer of articles containing nanomaterials with intended release	11%
is a distributor of nanomaterials and/or mixtures containing nanomaterials	41%
is a distributor of articles containing nanomaterials	23%
None of the above	9%
Not sure whether we deal with nanomaterials	9%

A1.2.2 NACE codes

59 respondents provided some information on the four-digit NACE code of their primary business sector and 27 provided some information on the four-digit NACE code of their secondary business sector. Because some of the respondents (both companies and associations) had a range of interests, it was difficult for them to provide one (or two) specific codes.

Overall, it appeared that the primary activity of about half of the respondents could be classified as 20xy (Manufacture of chemicals and chemicals products).

A1.2.3 Company size

Although many of the industry respondents were (or represented) large companies with more than 250 employees, a significant portion were (or represented) small and medium enterprises (SMEs) as summarised in Table A1-7.

TableA1-7: Company Size by Employees	
Number of Employees	**% Industry Respondents (n=63)**
1-9 employees (micro enterprise in terms of employees)	6%
10-49 employees (small enterprise in terms of employees)	16%
50-249 employees (medium enterprise in terms of employees)	8%
≥ 250 employees (large enterprise in terms of employees)	70%

A similar picture emerged when considering total turnover and turnover associated with nanomaterials as summarised in Table A1-8.

Table A1-8: Company Size by Turnover		
Turnover Value	**Annual**	**Nano-related**
	% Respondents (n=53)	**%Respondents (n=40)**
<€250k (micro enterprise in terms of turnover)	9%	15%
<€2m (micro enterprise in terms of turnover)	2%	3%
€2m to €10m (small enterprise in terms of turnover)	8%	10%
€10m to €50m (medium enterprise in terms of turnover)	9%	13%
≥ €50m (large enterprise in terms of turnover)	72%	60%

A1.2.4 Markets for nanomaterials

Respondents were asked to indicate the number of nano-related products (where these include nanomaterials (NMs) as well as mixtures (Mixt) and articles containing nanomaterials (Art)) which they (or the companies they represent) place on the national, EU and global markets. The results are summarised in Table A1-9.

Table A1-9: Markets for Nanomaterials									
Number of Products	**National market**			**EU market**			**Global market**		
	NMs	**Mixt**	**Art**	**NMs**	**Mixt**	**Art**	**NMs**	**Mixt**	**Art**
Less than 6	63%	29%	35%	66%	21%	33%	58%	18%	28%
Between 6 and 10	15%	0%	0%	10%	6%	0%	15%	9%	6%
Between 11 and 50	4%	6%	0%	3%	6%	0%	4%	6%	0%
Between 51 and 100	0%	12%	0%	3%	12%	6%	4%	12%	6%
Between 101 and 250	0%	3%	0%	0%	6%	0%	0%	6%	0%
Between 251 and 500	4%	3%	6%	3%	3%	6%	4%	3%	6%
Between 501 and 1,000	0%	3%	6%	0%	6%	6%	0%	6%	6%
Over 1,000	15%	44%	53%	14%	41%	50%	15%	41%	50%
Number of Respondents	**27**	**34**	**17**	**29**	**34**	**18**	**26**	**34**	**18**
Note that products are identified as nanomaterials (NMs); mixtures (Mixt); and articles containing nanomaterials (Art)									

It is apparent from Table A1-9 that most respondents were either specialising in a few products or were involved with a very wide of range of products. It is also worth noting that there appear to be few significant differences between the geographical types of market.

A similar picture emerged when considering numbers of suppliers and customers[102]. In other words, most respondents had either few suppliers/customers or had a large number of suppliers/ customers as shown in Table A1-10.

Table A1-10: Numbers of Customers/Suppliers		
Number	**% Respondents Customers**	**% Respondents Suppliers**
Less than 6	10%	27%
Between 6 and 15	2%	27%
Between 16 and 30	5%	10%
Between 31 and 50	0%	3%
Between 51 and 100	5%	17%
Over 100	78%	17%
Number of Respondents	**41**	**30**

A1.3 Problem Definition and Objectives

A1.3.1 Objectives of possible intervention

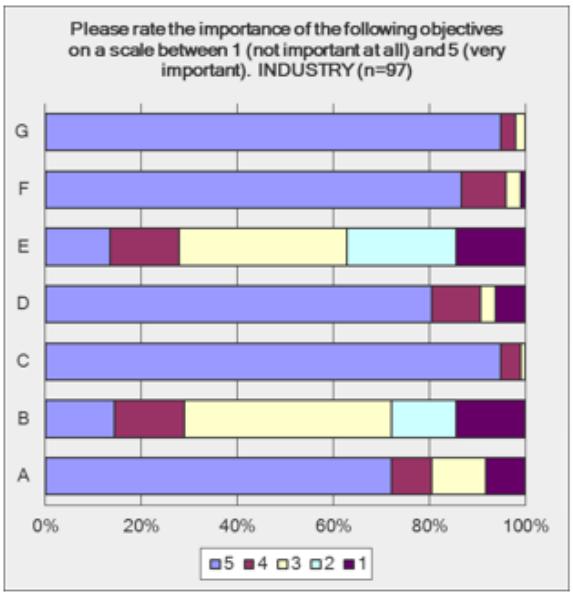
Respondents were asked to rate the importance of the possible objectives (see Table A1-11) on a scale between 1 and 5 (1-not important at all / 5-very important).

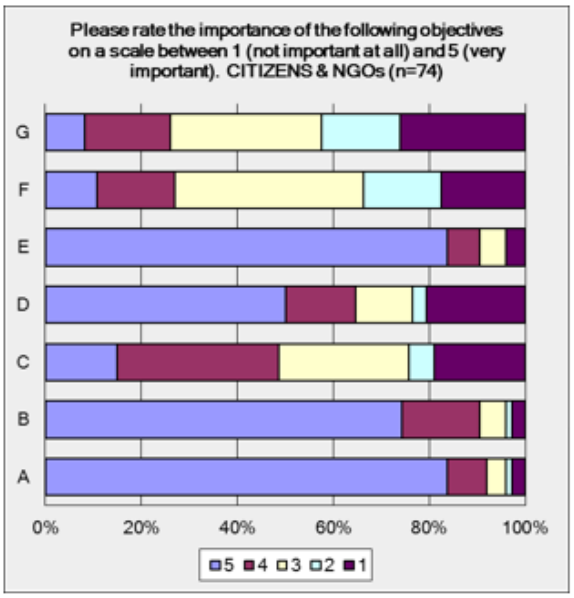
Table A1-11: Objectives of Possible Intervention	
A	Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials
B	Provide consumers with relevant information on products containing nanomaterials on the market
C	Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)
D	Ensure consumer trust in products containing nanomaterials
E	Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market
F	Ensure the proportionality of the information requirements and the associated costs and administrative burden
G	Protect confidential business information

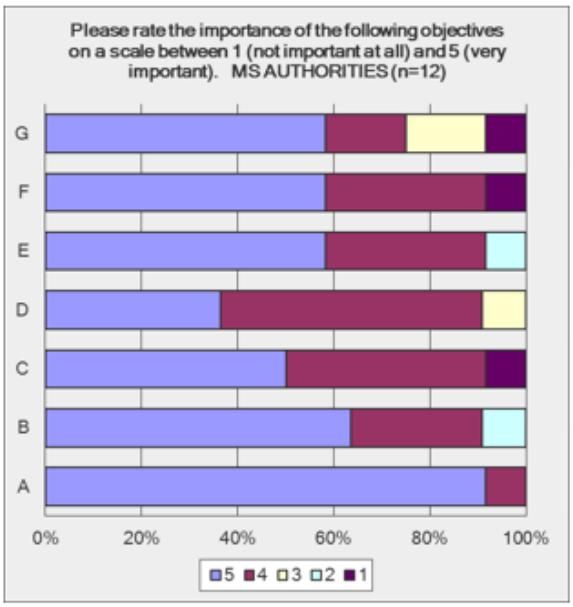
The responses are illustrated overleaf (Figure A1-1). By inspection, it can be seen that there was a consensus amongst all stakeholders that *Objective A - Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials* was very important.

There was also general consensus that *Objective D - Ensure consumer trust in products containing nanomaterials* was either very important (rating of 5) or of considerable importance (rating of 4).

[102] The extent to which these results are influenced by responses from associations rather than individual companies is being investigated.







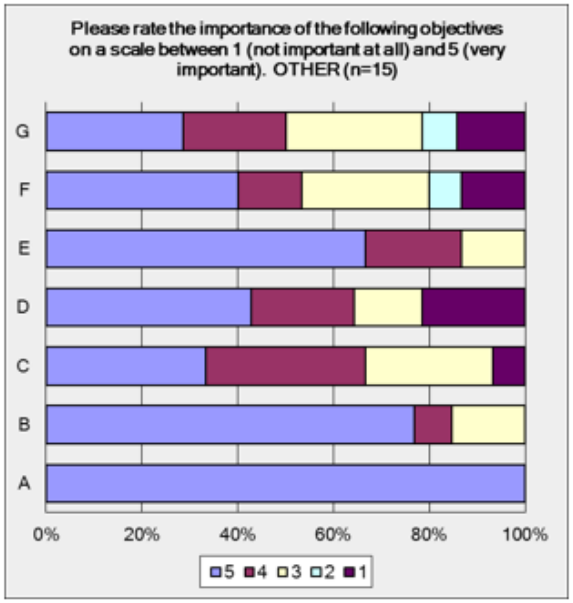


Figure A1-1: Importance of Objectives

Key:

G - Protect confidential business information
F - Ensure the proportionality of the information requirements and the associated costs and administrative burden
E - Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market
D - Ensure consumer trust in products containing nanomaterials
C - Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)
B - Provide consumers with relevant information on products containing nanomaterials on the market
A - Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials

Industry stakeholders considered three further objectives to be very important while most MS Authorities considered that these were either very important (rating of 5) or of considerable importance (rating of 4):

- *Objective C - Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)*
- *Objective F - Ensure the proportionality of the information requirements and the associated costs and administrative burden*
- *Objective G - Protect confidential business information*

Citizens and NGOs and other stakeholders indicated that the remaining two objective were very important (with significant support also from MS Authorities):

- *Objective B - Provide consumers with relevant information on products containing nanomaterials on the market*
- *Objective C - Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market*

In the additional comments provided, the predominant message from industry was that nanomaterials should be regarded in the same way as other substances, with REACH and other legislation applying only when appropriate. According nanomaterials different treatment (e.g. providing consumers with information on products containing nanomaterials even if safe has used has been demonstrated) will result in a stigmatisation of nanomaterials, with a negative effect on consumer trust. There was also concern that informing consumers about the presence of nanomaterials in a product offers little benefit if the specific impact of that material in a product is not known. Finally, there was underlying concern that the measures should not create a heavy administrative burden with duplication of work and that they should not reveal confidential information.

There was a widespread view amongst responses from citizens and NGOs that, in the interest of the health of consumers and workers, and to a lesser extent the environment, the precautionary principle should be borne in mind concerning the unknown implications of exposure to nanomaterials. Stakeholders made the link between building consumers' trust and providing relevant information on products containing nanomaterials, whether through labelling of products or a dedicated registry. Such transparency was highlighted as essential for building consumer trust and facilitates informed decision making. Further comments from some of the MS Authorities stressed that while there remained some uncertainties, it was important to retain the principle of proportionality.

A1.3.2 Do existing legislation/databases meet objectives

Respondents were asked to rate the degree (from 1 - not at all to 5 - fully) to which the current legislative framework (including the REACH and CLP Regulations and product-specific legislation) and the currently available databases (including the JRC Web Platform) meet particular objectives (as listed in Table A1-12.

Table A1-12: Do Existing Legislation/Databases meet Objectives	
A	Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials
B	Provide consumers with relevant information on products containing nanomaterials on the market
C	Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)
D	Ensure consumer trust in products containing nanomaterials
E	Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market
F	Ensure the proportionality of the information requirements and the associated costs and administrative burden.
G	Protect confidential business information

The responses are illustrated overleaf (Figure A1-2). By inspection, it can be seen that there was a consensus amongst all stakeholders that *Objective G - Protect confidential business information* was being met (predominance of ratings 4 and 5).

Thereafter, there was a divergence of views with industry respondents being more favourable towards the existing framework. Industry respondents considered that (in addition to Objective G), a further two objectives were being met:

- *Objective A - Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials*
- *Objective E - Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market*

On the other hand, other stakeholders (MS authorities, citizens and NGOs, and others) were of the view that these two objectives were not being met (predominance of ratings 1 and 2). These stakeholders also considered that a further two objectives were not being met:

- *Objective B - Provide consumers with relevant information on products containing nanomaterials on the market*
- *Objective D - Ensure consumer trust in products containing nanomaterials*

There appeared to be a diverse a range of opinions (both within and amongst different stakeholder groups) with respect to the remaining two objectives:

- *Objective C - Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)*
- *Objective F - Ensure the proportionality of the information requirements and the associated costs and administrative burden*

Industry respondents were keen to stress in their additional comments that the current legal regime is appropriate, noting that this is the most comprehensive framework applicable to nanomaterials in the world. With this in mind, consumer trust could be improved through better implementation of these measures alongside explanatory dialogue with consumers. To introduce additional requirements would constitute an administrative burden for companies, with no guarantee of a potential positive impact on the supply chain or consumer trust. Moreover, further requirements may negatively impact the competitiveness and innovative capacity of the chemical industry.

Industry respondents also noted that the objectives in question may be better met if the definition of nanomaterials, implementation registers and measuring methods were more closely defined and clarified.

In general, comments from citizens and NGOs noted that that there is currently no legislation or database which provides adequate or standardised information concerning products which contain nanomaterials on the European market. Moreover, this is predominantly limited to food, cosmetics and biocides. In their responses, stakeholders frequently referred to REACH but were generally of the opinion that the information on nanomaterials recorded under this legislation is extremely limited and inadequate – a view shared by several MS authorities. It was felt that REACH is not sufficiently adapted for nanomaterials given the absence of a definition, a tonnage band restriction of 1 tonne per annum and the fact that it considers nanomaterials to be identical to the bulk material.

The JRC Web Platform was referenced by several stakeholders and is generally seen as being complicated, incomplete and not user friendly for consumers.

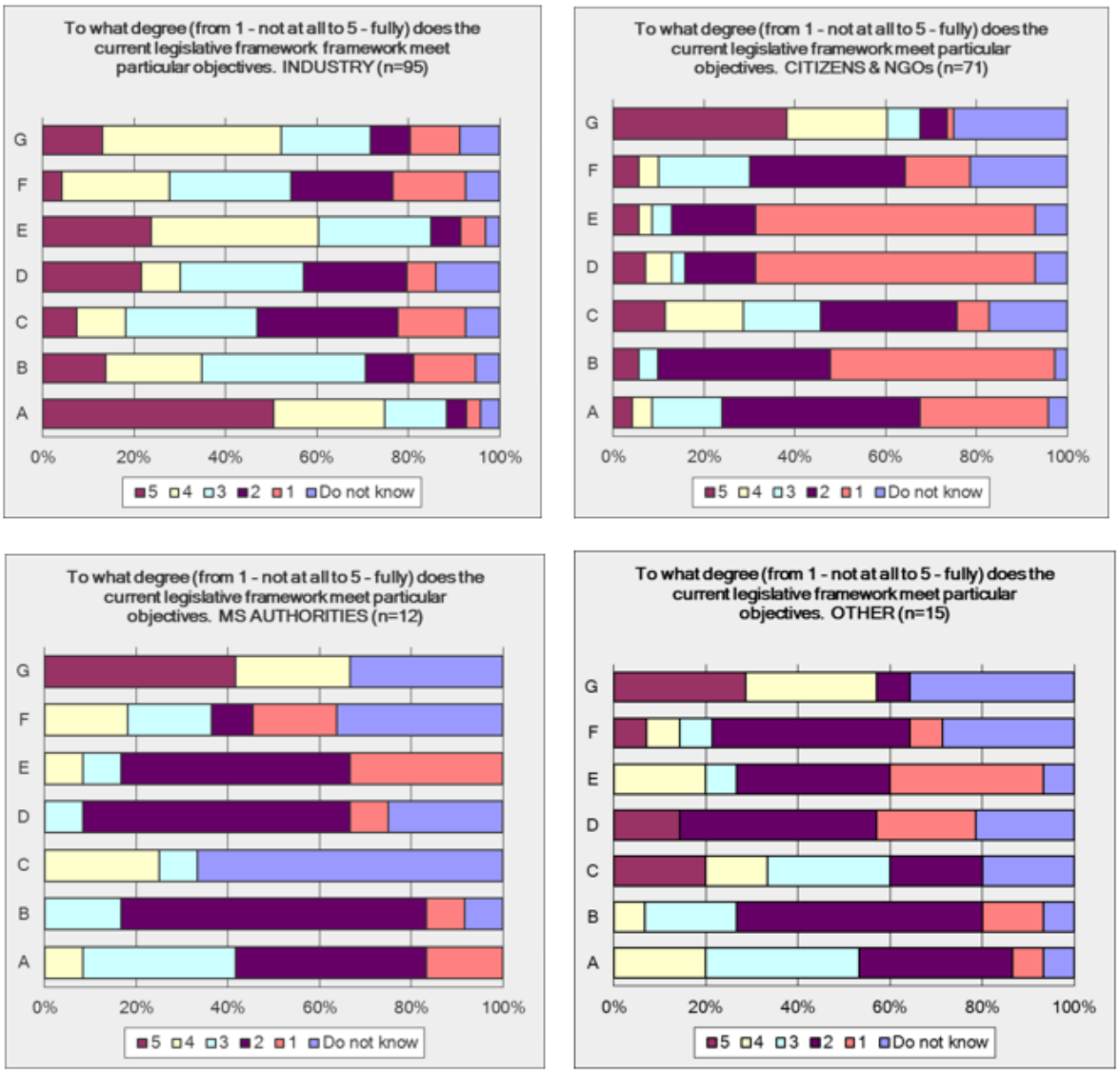


Figure A1-2: Do Existing Legislation/Databases meet Objectives?

Key:

G - Protect confidential business information

F - Ensure the proportionality of the information requirements and the associated costs and administrative burden.

E - Ensure the availability of relevant information on the presence of nanomaterials or products containing nanomaterials on the market

D - Ensure consumer trust in products containing nanomaterials

C - Maintain competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs)

B - Provide consumers with relevant information on products containing nanomaterials on the market

A - Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to health or environmental risks of nanomaterials

A1.3.3 Views on information on nanomaterials

Respondents were asked to rate their agreement with various statements (see Table A1-13) from 1 (strongly disagree) to 5 (strongly agree).

Table A1-13: Views on Information on Nanomaterials	
A	The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient for an adequate response to health and environmental risks
B	The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient for informed consumer choice
C	The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust
D	The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way
E	The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market

The responses are illustrated overleaf (**Figure A1-3**). By inspection, it can be seen that there was strong agreement from industry with considerable agreement (mostly ratings 4 and 5) from MS authorities and, to a lesser extent, from citizens and NGOs and other stakeholders for:

- *Statement E - The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market*

There was strong agreement from citizens and NGOs with strong/considerable agreement from MS authorities and other stakeholders (but not industry) for two statements:

- *Statement A - The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient for an adequate response to health and environmental risks*
- *Statement B - The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient for informed consumer choice*

There was also considerable agreement (mostly ratings 4 and 5) from MS authorities, citizens and NGOs and other stakeholders (but not industry) for the remaining two statements:

- *Statement C - The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust*
- *Statement D - The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way*

Further comments provided by industry reflected the responses presented above, with respondents noting that national schemes create obstacles to trade within the internal market. Indeed, many cited the French notification system, which it is claimed has imposed a high burden (effort and cost) on industry, particularly SMEs. Industry respondents also claim that the presence of other national schemes in Belgium and Denmark has only made matters worse. However, several MS authority respondents noted that there was a lack of evidence to provide robust opinions on such issues.

Industry also noted that an adequate response to health and environment risks is not achieved by providing information on the presence of nanomaterials in a product, but by an effective and reliable risk assessment of the nanomaterial (as foreseen by REACH and product-specific regulations).

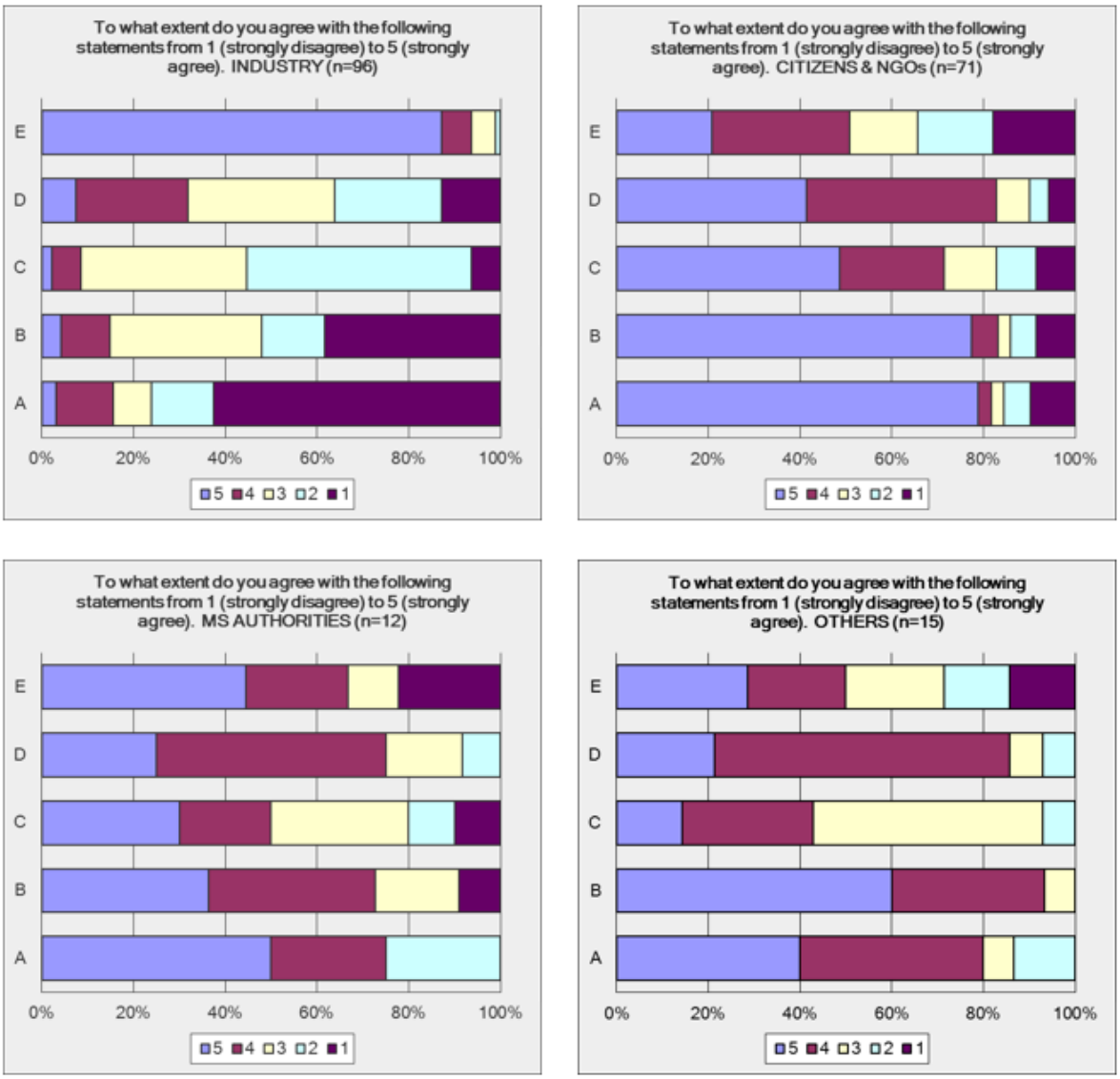


Figure A1-3: Views on information on nanomaterials

Key:

E - The establishment of national registries and notification schemes causes market fragmentation and hampers trade within the internal market

D - The available information on the presence of nanomaterials and products containing nanomaterials on the market is presented in an incoherent or ineffective way

C - The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is detrimental to consumer trust

B - The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient for informed consumer choice

A - The current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient for an adequate response to health and environmental risks

Finally, with respect to industry respondents, regulatory provisions for nanomaterials (substances) used as cosmetic ingredients and for cosmetic products that contain these nanomaterials, cover all of the objectives of a potential EU nanomaterial observatory/registry.

Conversely, additional comments provided by citizens and NGOs again highlighted that the current legislative framework is not particularly suited for nanomaterials, leading to insufficient information regarding the risk to the health of consumers and workers. Many of the stakeholders highlighted the need for an EU wide registry of products containing nanomaterials, rather than the disjointed national

registries, which have further compounded the issue of inconsistent and incomparable data collection across the EU. It was commented that the establishment of an EU wide register would not only build consumer trust but would also ensure that authorities can conduct their roles effectively.

A1.4 Health and Environmental Aspects

A1.4.1 Awareness of issues

With regard to health and environmental hazards and risks of specific nanomaterials/types of nanomaterials, respondents were asked whether or not they were aware of particular issues associated with nanomaterials as shown in Table A1-14.

Table A1-14: Awareness of issues

I am aware of….	% respondents			
	Industry (n=92)	MS Authorities (n=12)	Citizens & NGOs (n=67)	Other (n=15)
health and/or environmental hazards of specific nanomaterials/types of nanomaterials	**89%**	**92%**	**93%**	**87%**
specific nanomaterials that are classified as hazardous under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures	54%	50%	21%	20%
DNELs/PNECs/OELs set for specific nanomaterials/types of nanomaterials	60%	58%	15%	20%
significant exposure of workers/users/ consumers to specific nanomaterials/types of nanomaterials	37%	50%	85%	60%

There was a high level of awareness of health and/or environmental hazards across all stakeholders. There was a reasonable level of awareness of specific classifications and limit values amongst both industry and MS authority respondents – but this level of awareness was not shared by citizens and NGOs and other stakeholders.

There was a high level of awareness of significant exposures amongst citizens and NGOs and, to a lesser extent, amongst MS authorities and other stakeholders.

Supplementary comments provided by industry acknowledged that hazards may be associated with some nanomaterials, but that nanomaterials are no more hazardous than other chemicals. Here it was asserted that the hypothesis that smaller means more reactive and thus more toxic is unsubstantiated by the published data. Over 60% of citizen and NGO respondents provided further comments related to the health and environmental effects of nanomaterials. The health effects frequently mentioned were carcinogenicity, pulmonary effects, endocrine disruption, reproductive toxicity, anti-microbial resistance and environmental toxicity. Several MS authorities cited examples of hazards and limit values associated with specific nanomaterials.

Industry respondents noted that although consumers may be exposed to nanomaterials in products (e.g. cosmetics), such products are subject to an official risk assessment and authorisation. Similarly, workers may also be exposed to nanomaterials, but safety is ensured through the application of personal protection measures (e.g. personal protective equipment) safety protection measurements and exposure limit values.

Many industry respondents also cited examples of nanomaterials for which DNELS and reference values have been set, the most frequent being titanium dioxide (TiO_2), carbon nanotubes and nanowires. Specific nanomaterials identified by non-industry stakeholders where concerns exist include zinc oxide (in sun screens), titanium dioxide, nanosilver and carbon nanotubes. More

specifically, the risk to workers through occupational exposure was highlighted. Several stakeholders provided particular examples of DNELs, PNECs and OELs in Member States.

A1.4.2 Awareness of incidents

With regard to the use of nanomaterials, respondents were asked whether or not they were aware of particular health and/or environmental incidents which have occurred as shown in Table A1-15.

Table A1-15: Awareness of Incidents				
Response	% respondents			
	Industry (n=95)	MS Authorities (n=11)	Citizens & NGOs (n=65)	Other (n=12)
I am aware of health and/or environmental incidents which have occurred	14%	45%	61%	42%

Reflecting the results in Table A1-15, the majority of industry respondents were unaware of health or/and environmental incidents associated with nanomaterials. Where incidents involving nanomaterials have been reported, industry respondents advocated that the hazard itself was not attributable to the nanoscale dimension of the substance and that the exposure was caused by failure to comply with appropriate safety precautions.

It would appear from comments by citizens and NGOs that the main means of raising the awareness of the health and environmental effects of nanomaterials are laboratory research involving animal studies, *in vitro* and *in vivo* toxicological experiments and human case studies of occupational or accidental exposure. Stakeholders reported on a number of chronic and acute illnesses which have been linked to short-term and prolonged exposure to nanomaterials. These ranged from allergies, burns, cancer, pulmonary effects, endocrine effects and reproductive toxicity.

Two specific reported cases of exposure to nanomaterials were highlighted by a number of respondents. The first was that of several workers in China who were exposed to nanomaterials for 5-13 months and experienced shortness of breath and pleural effusions. The other reported case was that of a 26 year old chemist working with nickel nanoparticle powder and subsequently developed a nickel allergy and was unable to return to work due to recurrent symptoms. From stakeholder responses, it appears that most cases relating to the health effects of nanomaterials results from occupational exposure. However, it was pointed out by some that, due to the lack of information available, employers may be unaware that their staff are handling nanomaterials and consequently the necessary precautions are not taken. The environmental effects were mentioned less frequently.

A1.4.3 Impact of nanomaterials registry

With regard to establishment of an EU nanomaterials registry, respondents were asked whether or not it would contribute to reducing the risks. The responses are summarised in Table A1-16.

Table A1-16: Impact of nanomaterials registry				
Response	% respondents			
	Industry (n=94)	MS Authorities (n=12)	Citizens & NGOs (n=70)	Other (n=14)
[A nanomaterials registry] would significantly contribute to reducing the health and/or environmental risks related to the use of NMs	2%	75%	74%	36%

Industry respondents were of the view that risks posed by nanomaterials can be controlled by implementing the current European framework (REACH, CLP and sectoral legislation). The added value of an EU registry as regards controlling the potential risks posed by nanomaterials is considered to be negligible, since it would not contribute to the identification of risks and is therefore unlikely to

improve safety. Rather, a registry is likely to create additional burdens, particularly for SMEs, and will create a negative public perception of nanotechnologies.

Nevertheless, several industry respondents acknowledged that an EU-wide registry would be preferable to 28 national registries.

In contrast, MS authorities, citizens and NGOs considered that a registry would make a significant difference. Further comments from MS authority (and some 'other') respondents suggested that an EU-wide registry would provide useful information on the use of nanomaterials through their lifecycle. This, in turn, would assist with assessments of exposure and risk as well as identifying appropriate risk management measures.

Such views were reiterated by citizens and NGOs with an emphasis on the need for a registry to provide for vigilance across the production chain and enhance the availability of information to all users.

A1.5 Consumer Trust

A1.5.1 Impacts on consumer behaviour

With regard to the provision of information concerning presence of nanomaterials in products, respondents were asked as to the potential reactions (as listed in Table A1-16) of customers with the results shown in Figure A1-4.

Table A1-16: Impacts on Consumer Behaviour	
A	They would be more inclined to purchase those products
B	They would try to avoid those products
C	Their purchasing decisions would not be affected
D	They would search for more information

There was a consensus that the provision of information concerning presence of nanomaterials in products would not lead to consumers being more inclined to purchase those products (Statement A).

Indeed, industry respondents noted that as a result of negative preconceptions and the current stigma associated with nanomaterials, providing information about the presence of nanomaterials in a product to consumers could result in them avoiding that product. On the other hand, in many instances the French notification scheme would appear to have had no impact on the purchasing decision (Statement C) and in some instances, companies will promote the presence of nanomaterials in their product (e.g. high-tech product).

Other industry respondents noted that the information indicating the presence of nanomaterials in products would result in customers, particularly business clients, requesting further information such as an explanation or assessment on the safety of the product.

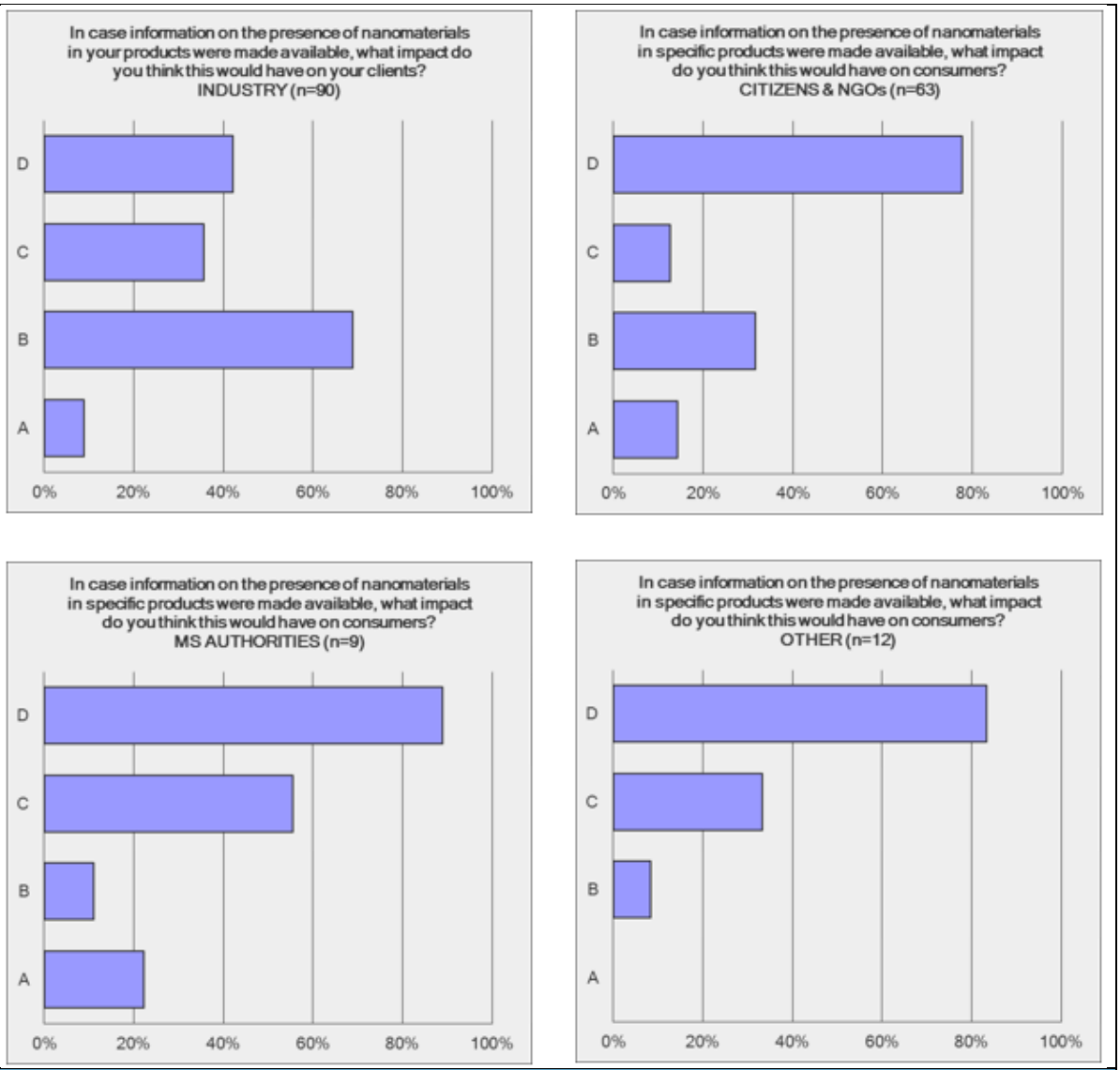


Figure A1-4: Impacts on consumer behaviour

Of note is that the responses from citizens and NGOs suggested that consumers were more likely to search for more information (Statement D) rather than to simply avoid the products (Statement B) and this view was shared by MS authorities and other respondents.

Further comments from citizens and NGOs, MS authorities and other respondents suggest that there are many factors to consider with regard to the impacts of labelling products with nanomaterials (e.g. type of product, type of nanomaterial, utility, etc.). However, providing information concerning the presence of nanomaterials will stimulate interest in some consumers, who will then be likely to search for further information so that they can make an informed and conscious choice. Other respondents noted that the purchasing decision of some consumers would be unaffected because of a lack of knowledge of nanomaterials and their potential health impacts. Finally, some consumers would perceive 'nano' as a selling point, while there would be those consumers concerned about the health impacts of certain nanomaterials that would avoid such products.

A1.5.2 Impacts on consumer attitudes

Respondents were asked to consider the likely impacts of information on the presence of nanomaterials in products. The responses are summarised in Table A1-17.

Table A1-17: Impacts on Consumer Attitudes				
Information on the presence of nanomaterials in products would….	% Respondents			
	Industry (n=90)	MS Authorities (n=9)	Citizens & NGOs (n=57)	Other (n=10)
generate trust among consumers and the broad public, and thus have a positive effect on the market for the concerned products	0%	**55%**	39%	**40%**
have no significant impact	16%	33%	**40%**	30%
generate insecurity or stigmatise such products, and thus have a negative effect on the market for the concerned products	**84%**	11%	21%	30%

As is evident from Table A1-17, the majority of industry respondents believe that providing information on the presence of nanomaterials will result in adverse feeling towards the product. This is because there is a lack of consumer knowledge coupled with predefined negative views of nanomaterials. Consequently, such a label may confuse consumers, with there being the possibility for them to interpret the information as a warning label.

However, it was also noted by some industry respondents that cosmetics products are already labelled with a full list of ingredients, including nanomaterials, and there has, to date, been no significant impact on consumer behaviour.

A number of MS authorities and citizens and NGOs stated that information on the presence of nanomaterials will improve transparency, which is one of the first steps to establishing consumer trust. Other citizens and NGOs noted that openly disclosing the presence of nanomaterials carries the risk of stigmatising products, with companies and consumers choosing to boycott them.

A1.6 Innovation and Competitiveness

A1.6.1 Impacts on innovation

With regard to innovation, respondents were asked as to the likely impacts of information on nanomaterials and products containing nanomaterials that could be gathered in a nanomaterial registry. From Table A1-18, it is apparent that there are very divergent views amongst stakeholders.

Table A1-18: Impacts on Innovation				
Information on the presence of nanomaterials in products would….	% Respondents			
	Industry (n=93)	MS Authorities (n=10)	Citizens & NGOs (n=62)	Other (n=12)
stimulate innovation (e.g. through increased consumer trust, increased awareness on nanomaterials)	2%	**60%**	**71%**	**50%**
have no significant impact on innovation	13%	10%	26%	25%
hamper innovation in the EU (e.g. through concerns about confidential business information or through additional costs related to providing information)	**85%**	30%	3%	25%

Many industry respondents were concerned that providing information about the presence of nanomaterials in a product would negatively impact nanotechnology innovation. A number of

respondents noted that the French national registry system undermined economic partners' trust in nanomaterials, which in turn negatively impacted competitiveness and innovation. It also brought uncertainties amongst economic actors towards the French market, raising question marks with regard to business developments and the location of research and development activities in France.

More generally, it was noted that imposing requirements to provide further information would increase administrative burden across the whole supply chain, resulting in additional costs that would otherwise be spent on research and development. This could deter the emergence of further nanomaterial producers or alternatively, they may choose to locate themselves outside of the EU.

Numerous industry respondents also stressed that any requirement to provide information must be carefully balanced against the need for confidentiality. A failure to strike the right balance could negatively impair innovation. On the other hand, it was also noted that dissemination of information on nanomaterials could result in better knowledge of their properties, particularly around hazard and handling guidelines, which could stimulate innovation.

Citizens and NGOs and, to a lesser extent, MS authorities and other respondents, believe that information provision would stimulate innovation. Many respondents stated that, by labelling products that contain nanomaterials, greater legal certainty would be created in the market. This is important because legal uncertainty has been highlighted by nano producing/distributing companies as one of the main factors stifling the innovation of nanotechnologies. Indeed, a registry would encourage the commercialisation of products that are both safer and meet the needs of consumers. This alongside additional transparency has the potential to secure a market for the long term, and it is this that will prove to be the source of innovation.

A1.6.2 Impacts on competitiveness

With regard to competitiveness of EU companies manufacturing nanomaterials or products containing nanomaterials, respondents were asked as to the likely impacts of information on nanomaterials and products containing nanomaterials that could be gathered in a nanomaterial registry. From Table A1-19, it is apparent that there are very divergent views amongst stakeholders.

Industry respondents commented that a nanomaterial registry would severely disadvantage EU companies. EU companies would be required to register their nanomaterials at all stages of development and processing whereas those companies outside of the EU would only have to register products once they enter the EU market. The additional burden placed upon intra-EU companies would thus give companies outside of the EU a competitive advantage. It was also suggested that the costs of complying with the additional requirements would be borne by consumers, which would result in increased prices for value chains in EU vs non-EU markets.

MS authorities questioned whether there would be any intra-EU impacts on competitiveness as the same requirements would be imposed on all companies within the EU. In fact, it may stimulate innovation as the registry may encourage government support for nanotechnologies in the form of funding, levies and tax breaks to encourage development of the right products. The view that intra-EU competitiveness would be stimulated was supported by most citizen and NGO and other respondents. However, it was noted that the French registry hampered competition immediately following its introduction, but this was only temporary and receded following the correct control on importation and dialogue. In any event, providing adequate information to consumers should far outweigh the consideration of market impacts, as a health crisis may be detrimental for the EU industry in the long term.

Although most citizen and NGO indicated that extra-EU competitiveness would also be enhanced, MS authorities and other respondents were more cautious in their responses.

Table A1-19: Impacts on EU Competitiveness				
Impacts on Intra-EU Competitiveness				
Information on the presence of nanomaterials in products would….	**% Respondents**			
	Industry (n=90)	**MS Authorities (n=10)**	**Citizens & NGOs (n=63)**	**Other (n=11)**
stimulate intra-EU competitiveness	1%	30%	**57%**	**55%**
have no significant impact on intra-EU competitiveness	19%	**70%**	19%	18%
hamper intra-EU competitiveness	**44%**	10%	5%	18%
Impacts on Extra-EU Competitiveness				
Information on the presence of nanomaterials in products would….	**% Respondents**			
	Industry (n=90)	**MS Authorities (n=10)**	**Citizens & NGOs (n=63)**	**Other (n=11)**
enhance the competitiveness of European companies against extra-EU companies	3%	**40%**	**57%**	27%
have no significant impact on the competitiveness of European companies against extra-EU companies	3%	30%	19%	9%
hamper the competitiveness of European companies against extra-EU companies	**92%**	20%	6%	27%

A1.7 Possible Impact of a Registry on Companies (Industry Respondents)

A1.7.1 Perceived impacts

Industry respondents were asked as the likely effects of a possible obligation to notify nanomaterials at the EU level assuming that no exemptions were to be made from 1 (no impact) to 5 (significant impact). These ratings were used to derive an overall weighted score[103] for each impact which were then ranked as shown in Table A1-20.

Table A1-20: Perceived Impacts (by Industry Respondents)		
Significance of impacts resulting from an obligation to notify nanomaterials at the EU level	**Rank**	**% "Significant impact"**
with respect to nanomaterials in mixtures	1	77%
with respect to articles containing nanomaterials in general (i.e. in case also articles without an intended release of nanomaterials were to be covered)	2	60%
with respect to nanomaterials on their own	3	45%
with respect to articles with intended release of the nanomaterials	4	28%

With regard to engineered nanomaterials in Europe, the market is currently nascent with one of the major producers of nanotubes selling less than 200 tonnes of nanotubes in Europe. Conversely, the volume of conventionally used materials that may fall under the definition of a nanomaterial is potentially much bigger (e.g. there is around 47 million tonnes of plastics produced within the EU).

Considering articles that contain nanomaterials in general and the matter of intended release, industry respondents noted that nanomaterials may be 'fixated' in the product via binding materials. However,

[103] Weighted scores are derived by summing N(i) x i where N(i) is the number of respondents scoring i. By way of example, suppose 3 people rated the first objective as a 1 (no impact), 2 people rated it as a 3 and 4 rated it as a 5 (significant impact), then the weighted score would be: (3 x 1) + (2 x 3) + (4 x 5) = 29.

it may be the case that the product would peel or flake, perhaps as a result of abrasion, but the size of any peelings or flakes are unlikely to fall within the definition of a nanomaterial. Nevertheless, one respondent claimed that research and development in one sector was stopped because of uncertainty as to whether the product would fall within the definition of a nanomaterial. Although it was acknowledged that it is difficult to define what constitutes an article containing nanomaterials without intended release, to prevent significant impacts (e.g. deterring research and development), it was suggested that such products should be beyond the scope of notification. Another respondent was primarily concerned that confidential business information could be compromised by not excluding such suppliers.

If the significance of any impacts is measured in terms of the breadth, then consideration should be given to those who commented that pigments and fillers are present in nearly every product and article of our daily life. Consequently, nearly every product and article would need to be registered if there was no exemption. Specific responses from different sectors included:

- Within the paint and printing ink more than 500,000 mixtures would be affected annually in Germany alone;
- For dental manufacturers of mixtures and articles, the obligation of notification would impact an estimate 90% of all dental materials (e.g. materials usually contain nano-scale fillers (aerosol) to tune the viscosity of any paste like material);
- the automotive industry uses nanomaterials in substances and mixtures and the notification requirement would add an additional burden with questionable effect;
- Within the chemical industry, EU notification would mainly impact substances and mixtures, although nanomaterials are sometimes already embedded in a matrix at production level, which could be considered part of articles. This information would need to be provided to article producers, with the burden also placed upon suppliers; and

Any additional notification within the cosmetics industry would create an additional burden without added benefits.

A1.7.2 Business confidentiality

Ninety-eight percent of the 87 industry respondents to this question indicated that a disclosure of the notified information would conflict with the confidentiality of business information.

Industry respondents commented that much would depend on the extent of disclosure and specific information that would need to be submitted. Of most concern for industry was the possibility of revealing the name or description of the substance, as competitors may not be aware that a substance can exist at nanoscale. Other comments related to:

- Information linked to substance identify (characterisation of the nanomaterial);
- The uses;
- The quantities put on the market; and
- Name of the customers.

A1.7.3 Expected difficulties with national schemes

91% of the 87 industry respondents to this question indicated that they experience or expect significant barriers to their company/members of their association from diverging notification obligations in the schemes in France/Belgium/ Denmark.

Industry respondents reported that multiple national schemes would increase the administrative and bureaucratic burden as a result of each database having its own scope, requirements and definitions, which means time must be spent gathering and inputting relevant information. There may also be linguistic barriers.

A1.7.4 National markets

Eighty-six percent of the 77 industry respondents to this question indicated that there is not any significant difference amongst EU national markets for their nanomaterials and/or products containing nanomaterials.

Industry respondents commented that there may be differences in the respective administrative burden associated with marketing a particular product in a Member State as a result of national specific registers. The extent of industrial development within a Member State may also result in differences between EU markets. Finally, the market for plastics with nanomaterials has declined due to the cost of materials and fears that the regulatory burden will increase.

A1.7.5 Elements of best practice

Industry respondents were asked: In case the European Commission were to recommend a best practice model for national notification schemes based on the experiences in France, Belgium and Denmark, which elements of these systems can be considered as "best practice"?

The vast majority of the 75 industry respondents were not positive in their responses stating that there was no national 'best practice'. However, some respondents commended the Danish system because it only required essential information, concerns only consumer products and exempts cosmetic ingredients and products. The way in which the French system is linked to substances according to REACH was also praised, specifically its use of the REACH number instead of the creation of a new (national) notification number. This aspect of the notification scheme helped downstream users, particularly SMEs, to reduce the administrative burden if the same substance is bought from different suppliers.

A1.8 Possible Options and Exemptions

A1.8.1 Type of notification

Respondents were asked about the added value of a notification per use (i.e. for each mixture/article) compared to a notification per substance?

Views from 90 industry respondents were largely negative. The majority of respondents stated that there would be no added value of notification per use when compared with existing regulations (e.g. cosmetic regulation, food information/regulation, biocides) as the information for downstream user companies and workers is already covered by safety data sheets. For this reason, many industry respondents did not provide responses to the next two questions (see Sections A1.8.2 and A1.8.3 below) which concerned the scope of potential notifications.

Where comments were positive, it was noted that this approach could be a good start for the nanomaterials observatory. Notification per use may also be more appropriate for mixtures as the conditions of use may impact the health and environmental risks. Notification per use may also allow for better estimation of potential exposure routes (oral, inhalation, dermal).

10 MS authority, 57 citizen and NGO and 12 other respondents provided additional comments, with many commenting that notification per use would enable full traceability and the tracking of nanomaterials along the supply chain, as well as the monitoring of new nanoproducts that enter the market. A further added value of notification per use is the availability of information on both uses of, and exposure to, nanomaterials in different situations.

However, several MS authorities noted that such a requirement could lead to a significant administrative burden. Indeed some suggested that an annual notification scheme would lead to an

unmanageable stream of information, with it suggested that this was one of the main reasons for the failure of the former EU existing chemicals regulation (793/93/EEC).

A1.8.2 Notification along the supply chain

Respondents were asked about which actors along the supply chain should be subject to notification requirements as summarised in Table A1-21.

Table A1-21: Notification along the Supply Chain				
Notification should apply to	% Respondents			
	Industry* (n=52)	MS Authorities (n=11)	Citizens & NGOs (n=65)	Other (n=14)
Manufacturers of nanomaterials	**96%**	**100%**	95%	**100%**
Importers of nanomaterials	**96%**	**100%**	**97%**	93%
Downstream users (e.g. re-formulators, manufacturers of products containing nanomaterials)	40%	82%	92%	86%
Distributors to professional users (e.g. wholesalers)	10%	36%	86%	65%
Distributors to consumers (e.g. retailers)	10%	9%	89%	50%
**Note that many industry respondents did not consider that such notifications are merited and did not respond to this question*				

Industry respondents were of the view that manufacturers (and importers) were the only actors likely to know the exact content of product, and therefore only they were capable of providing the relevant information. Furthermore, the burden should be on them as they bring the materials to market within the EU. It was also noted that with regard to these issues, downstream users were covered by sectoral legislation (e.g. cosmetic regulation contains nano-notification scheme).

MS authorities and other respondents were of the view that the notification requirements should extend beyond manufacturers and importers to include downstream users (e.g. re-formulators, manufacturers of products containing nanomaterials). Several MS authorities noted that such requirements would correlate with the requirements of the REACH Regulation.

For their part, citizens and NGOs indicated that all actors within the supply chain should be subjected to notification requirements to ensure information is effectively conveyed to consumers. A full understanding of the production chain would allow for a life cycle assessment of products containing nanomaterials. This would ensure that all possible impacts are systematically discovered (e.g. workers can take appropriate preventative measures to protect themselves).

A1.8.3 Subject of notification

Respondents were asked about which nanomaterials and associated products should be subject to notification requirements as summarised in Table A1-22.

Table A1-22: Subject of notification				
Notification should apply to	% Respondents			
	Industry* (n=40)	MS Authorities (n=11)	Citizens & NGOs (n=66)	Other (n=14)
Substances	**88%**	91%	93%	**93%**
Mixtures containing nanomaterials	40%	**100%**	**97%**	**93%**
Articles with intended release of nanomaterials	43%	91%	**97%**	**93%**
Articles containing nanomaterials without intended release	10%	36%	86%	57%
**Note that many industry respondents did not consider that such notifications are merited and did not respond to this question*				

Industry respondents commented that the currently regime is sufficient, with several regulatory frameworks (e.g. REACH, Cosmetics Regulation) already requiring notifications. Reflecting the responses in Table A1-22, it was also noted that to ask for information on all articles (even those with no intended release) may lead to overarching vague notifications that would detract from the value of a notification system.

The majority of non-industry respondents believe that notification for nanomaterials should apply to all substances, mixtures or articles that may contain nanomaterials – although most MS authority respondents were not persuaded to extend the scope to include articles containing nanomaterials without intended release. It was noted that experience from the French registry, which excludes nanomaterials whose release is not intentional, has resulted in some nanomaterials that may pose a risk to health or the environment being excluded (e.g. nanosilver). With this in mind, respondents stated that to exclude these nanomaterials would create legal uncertainty in the interpretation of what is intended release and unintended release. Moreover, information on articles where release is not intended would still be relevant to workers in order to implement workplace risk management measures.

A1.8.4 Exemptions

Respondents were asked whether there should be exemptions for certain types and/or for certain uses of nanomaterials. The responses are summarised in Table A1-23.

Table A1-23: Exemptions				
Response	% Respondents			
	Industry	MS Authorities	Citizens & NGOs	Other (n=14)
Yes, certain types of nanomaterials should be exempted from a notification system	89% (n=74)	50% (n=10)	11% (n=65)	21%
Yes, certain uses of nanomaterials should be exempted from a notification system	92% (n=71)	78% (n=9)	7% (n=62)	29%

Greatest support for exemptions was provided by industry, followed by MS authorities and other respondents. Responses from citizens and NGOs were strongly against granting exemptions.

A number of industry respondents again reiterated that a notification was unnecessary and all nanomaterials should be exempted. Specific examples of types and/or certain uses of nanomaterials to be exempted included:

- Nanomaterials that are integrated into the matrix and will not be released during use (e.g. pigments, fillers and plastic);
- Naturally existing nanomaterials (e.g. iron oxides) or those with a long history of use (e.g. inorganic fillers, pigments);
- Nanomaterials not intentionally manufactured to the nano-scale.

Several MS authorities commented that exemptions (for materials and uses) could be considered provided a full assessment of the associated risks demonstrated safe use. Several citizen and NGO respondents noted that such assessments would need to cover the whole life cycle, especially in the manufacturing and disposal phase.

Examples of specific types of nanomaterials to be exempted that were cited by non-industry respondents included:

- Dental materials, as no evidence exists for a risk to patients and users; and
- Liquid nanoparticles such as micelles in mayonnaise.

Examples of nanomaterials to be exempted that were cited by both industry and non-industry respondents included:

- Nanomaterials subject to other legislation (e.g. e.g. REACH, CLP, Cosmetic Regulation, Biocides Directive) on the basis that information on the nanomaterial is already available; and
- Uses of nanomaterials associated with (scientific) research and development as they are often used in low quantities and compliance would burden research laboratories.

As is clear from Table A1-23, most citizen and NGO respondents thought it was better not to exclude any types or uses of nanomaterials, as it would undermine the purpose of the registry, which is to provide an accurate and transparent picture of the market situation to the regulator and to improve the knowledge for risk assessment (hazard assessment and characterization of exposure). Moreover, the national schemes in Belgium and Denmark have demonstrated that legal uncertainty can arise if certain uses of nanomaterials are excluded from the notification requirements. More generally, responses from citizens and NGOs commented that a notification scheme based on the use of substances would be more useful in the context of risk assessment scenario.

A1.9 Structured Approach to Collect Information ("Nanomaterials Observatory")

A1.9.1 Information to be collected

Respondents were asked what type of information (as listed Table A1-24) should be collected for a Nanomaterials Observatory should this be established instead of an EU-wide registry.

Table A1-24: Information to be Collected	
A	Information from existing notification systems
B	Information from market studies on nanomaterials and products containing nanomaterials
C	Information on the use of nanomaterials across Europe
D	information concerning products containing nanomaterials
E	Information on the hazards and risks of nanomaterials
F	Other

As can be seen from **Figure A1-5** (next page), there was a much greater degree of coherence amongst respondents. In particular, there was general agreement that the following items should be collected:

- *A - Information from existing notification systems*

- *E - Information on the hazards and risks of nanomaterials*

There was also general agreement amongst MS authorities, citizens and NGOs and other respondents, with a slightly lower level of support from industry respondents, for a further two items to be collected:

- *B - Information from market studies on nanomaterials and products containing nanomaterials*
- *C - Information on the use of nanomaterials across Europe*

Although there was also general agreement amongst MS authorities, citizens and NGOs and other respondents for *information concerning products containing nanomaterials* to be provided, this was not supported by industry respondents.

Industry respondents commented that information established in an observatory should be taken from existing sources (e.g. current regulatory schemes and voluntary submissions) rather than from new and/or additional legislation. Comments from several MS authorities noted that an observatory could be a useful information resource (for example by incorporating FP7 research project findings).

Citizen and NGO respondents commented that the type of information to be collected would be linked to the purpose of the observatory. If the primary objective of the observatory is transparency and traceability, risk information may be less important. Of course, if the aim of the observatory is to ensure the safe use of nanomaterials throughout the supply chain, risk information is essential. To provide added value, an observatory should collect information on the:

- Application of the nanomaterial;
- Functionality of the nanomaterial(s) employed;
- Characterisation of nanomaterial;
- Nanomaterial concentration in the respective product; and
- Manufactured or imported tonnage bands of nanomaterial.

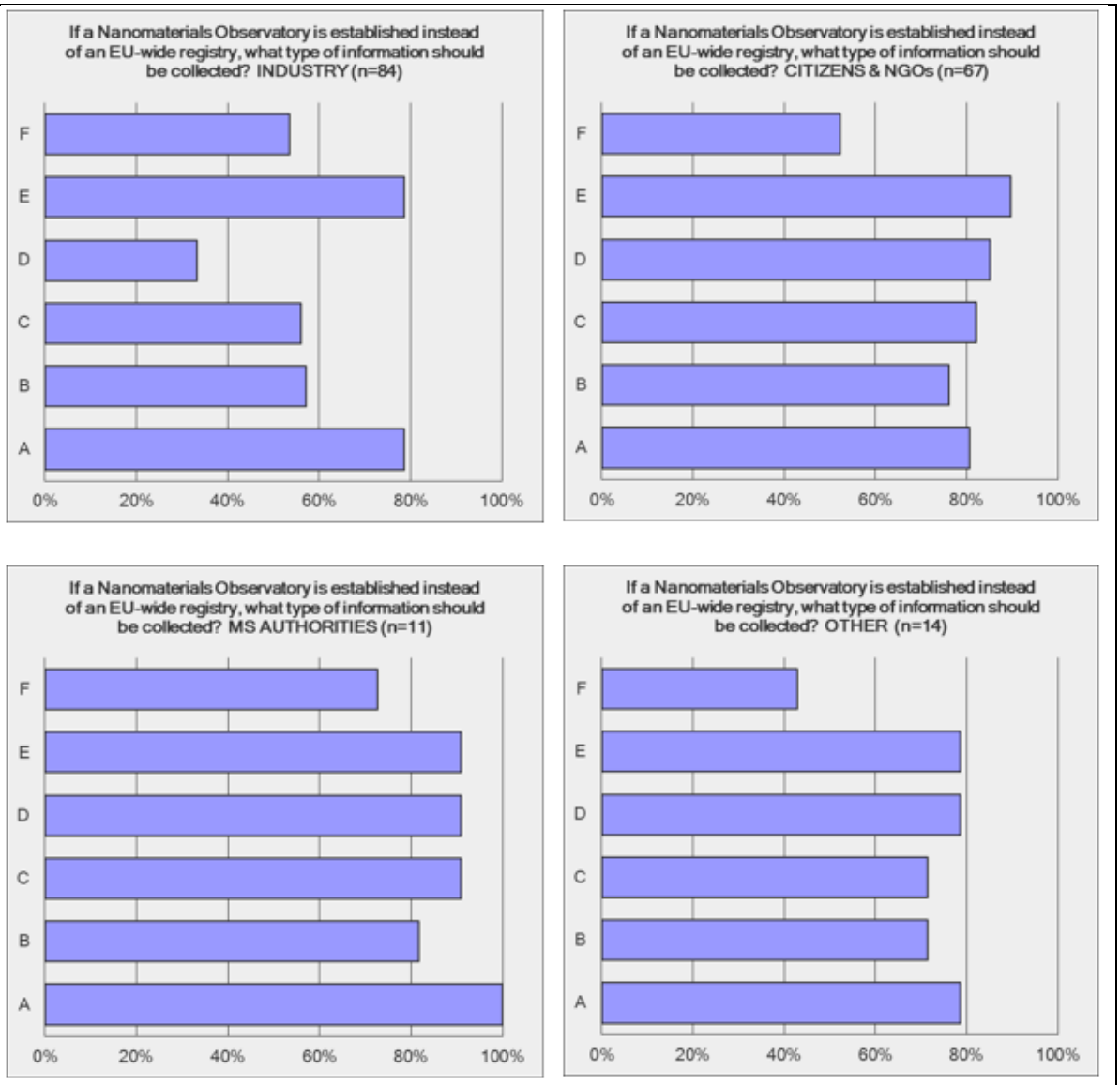


Figure A1-5: Information for a Nanomaterials Observatory

A1.9.2 Information presented

82 industry, 11 MS authority, 53 citizen and NGO, and 13 other respondents provided views on how the information in a Nanomaterials Observatory should be presented in order to reach the consumers, workers and authorities.

Industry respondents commented that information collated from all current regulatory schemes could be brought together and made available to consumers in a format that can be easily accessed, such as the German DaNa[104]. Alternatively, this information could be presented to consumers in the form of market studies. For workers and authorities, more detailed safety information would be useful.

There was a general consensus amongst MS authorities, citizens and NGOs and other respondents that information presented should be suitable for the user and tailored for targeted groups.

Specific examples suggested included:

- Booklets produced by independent and objective experts;

[104] http://www.nanopartikel.info/en

- A comprehensive online database that is searchable, can be easily navigated by consumers and is available in all EU languages;
- Product labels; and
- An interactive map (similar to, for example, the European Pollutant Release and Transfer Register (E-PRTR)) that would, by region, indicate the quantities of nanomaterials:

  - Imported;
  - Manufactured;
  - Handled in businesses;
  - Distributed;
  - Marketed and used by workers and consumers;
  - Destroyed/recycled.

A1.10 Potential Use and Benefits of a Nanomaterial Registry

A1.10.1 Information uses

Respondents were asked in what ways the information on nanomaterials from registries would be potentially useful (as listed in Table A1-25) and the results are shown in Figure A1-6 (overleaf).

Table A1-25: Potential Information Uses	
A	Risk assessment and/or risk management
B	Enforcement of worker protection
C	Promotion of safe use of nanomaterials in products
D	Development of strategies to ensure the safe use of nanomaterials
E	Informed purchasing decisions by consumers
F	General education of the public
G	Other purposes (please specify)

The majority of responses from industry reiterated the view that a registry for nanomaterials is not necessary as the current EU regulatory regime is sufficient. However, it was noted that it may be a means to educate the general public and raise the awareness of nanomaterials and their safe use in products.

Over 80% of citizen and NGO respondents considered that all the uses specified in **Table A1-25** would be potentially useful.

MS authority other respondents were slightly more cautious with over 75% of respondents identifying four items as being potentially useful:

- *A - Risk assessment and/or risk management*
- *B - Enforcement of worker protection*
- *C - Promotion of safe use of nanomaterials in products*
- *D - Development of strategies to ensure the safe use of nanomaterials*

Further comments from MS authority respondents suggested a range of further potential uses, including:

- Prioritising policy actions regarding nanomaterials
- Assisting with assessing insurance requirements/responsibilities

- Raising awareness of risk and risk management amongst employers
- Improved traceability of nanomaterials

Several citizens and NGOs repeated the same suggestion that a nanomaterials registry would:

- Assist with the safe disposal, reuse and recycling of products containing nanomaterials.

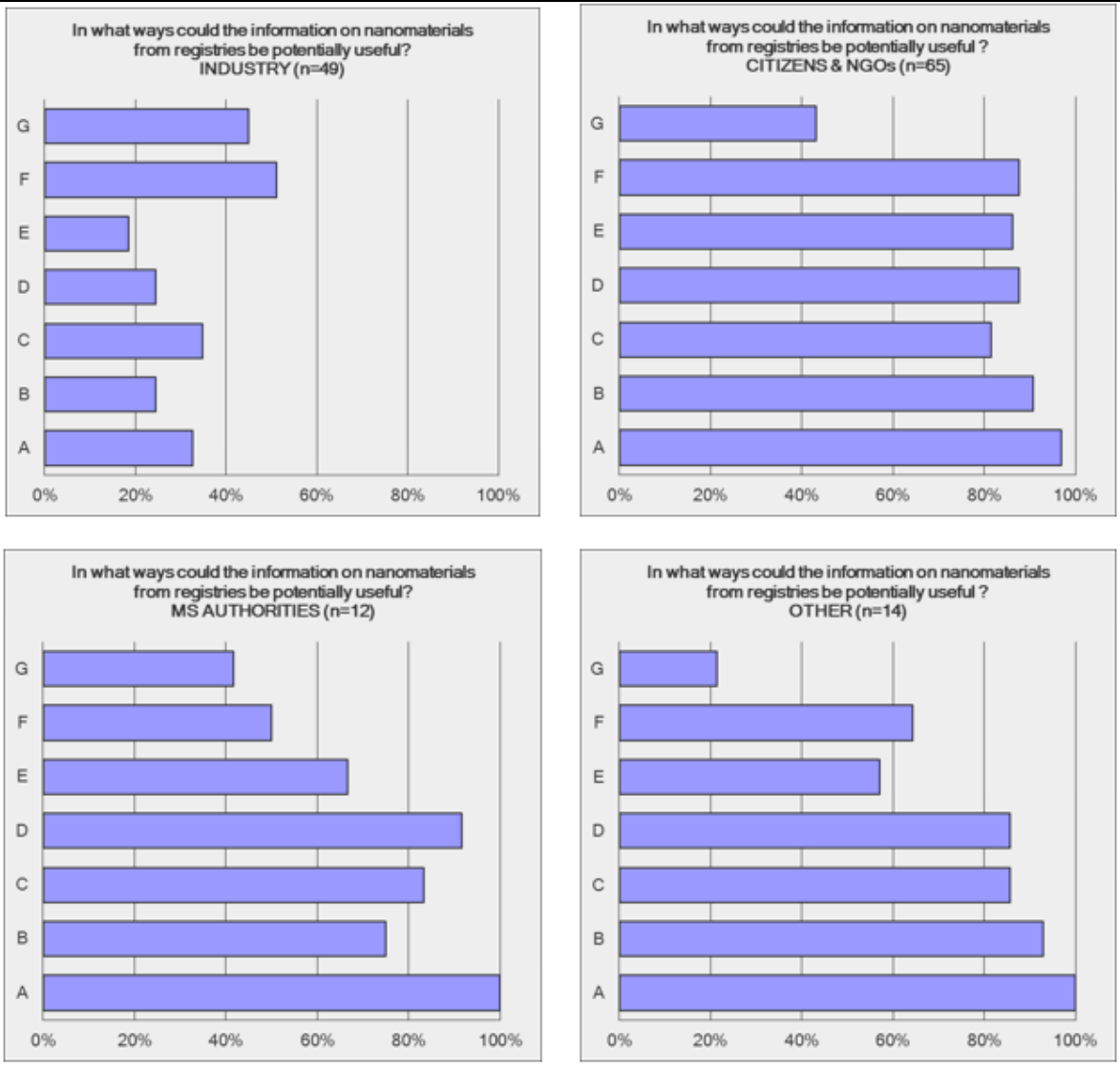


Figure A1-6: Information uses

A1.10.2 Added value

Respondents were asked in to indicate the added value of a European nanomaterial registry beyond the current framework of chemicals legislation, including REACH registration.

Comments were provided by 89 industry respondents, who were predominantly sceptical as to the added value of a European nanomaterial registry, although it was noted that an EU registry is more beneficial than multiple national registers.

Comments were provided by 11 MS authority and 14 other respondents, who were mainly of the view that the prime added value of a European nanomaterial registry would be to extend the information already collected under REACH in two main areas. Firstly, there would be an explicit reference to the

presence of nanomaterials and, secondly, a registry would not need to be restricted by the current one tonne per annum threshold which applies to chemicals under REACH.

Comments were provided by 57 citizen and NGO respondents, who were largely positive about the potential added value that a European nanomaterial registry may bring. Many stakeholders noted that a registry may redress the gaps and loopholes that exist with REACH with regard to nanomaterials. Here it was suggested that REACH has failed to deliver significant information on nanomaterials, in part because of the threshold of 1 tonne which is not relevant for nanomaterials. An EU registry would also harmonise the information about formulations or products that contain nanomaterials.

More generally, citizen and NGO respondents noted that transparency is essential to build public trust and ensure that nanomaterials are properly regulated. Transparency will also assist with product recalls, should this measure ever need to be undertaken. Of course an EU registry is not the sole option, with product labelling an alternative or perhaps complimentary means of achieving this goal.

Annex 2 Calculations

A2.1 Number of Companies with Notifications Duties

In order to extrapolate the results of the analysis of the FNS to the EU level, it is essential to know the classification of the economic activities (NACE codes) of the companies that had to notify to the FNS. This information has been obtained through the survey on the administrative burden that was carried out in March 2014 and was presented in Table 5-5 of the Evaluation report[105]. In light of the latest statistics published in MEDDE (2014), two other NACE codes have been added (referring to pharmaceuticals and plastics in primary forms). Table A2-1 presents NACE codes and descriptions of the sectors considered.

Table A2-1: NACE codes considered	
NACE	**Description**
C20.12	Manufacture of dyes and pigments
C20.13	Manufacture of other inorganic basic chemicals
C20.14	Manufacture of other organic basic chemicals
C20.16	Manufacture of plastics in primary forms
C20.20	Manufacture of pesticides and other agrochemical products
C20.30	Manufacture of paints, varnishes and similar coatings, printing ink and mastics
C20.41	Manufacture of soap and detergents, cleaning and polishing preparations
C20.42	Manufacture of perfumes and toilet preparations
C20.59	Manufacture of other chemical products
C21.10	Manufacture of basic pharmaceutical products
C21.20	Manufacture of pharmaceutical preparations
G46.45	Wholesale of perfume and cosmetics
G46.46	Wholesale of pharmaceutical goods
G46.75	Wholesale of chemical products
M72.1	Research and experimental development on natural sciences and engineering

Table A2-2 presents the number of companies in the Belgium, Denmark, France and the EU28 per NACE code identified[106]. The data from Belgium, Denmark and France have been considered in order to determine the marginal impact of Option 3 on the number of notifications for which notifiers will have to characterise the nanomaterial.

Not all the companies accounted within the business sectors deal with nanomaterials, therefore some educated guesses had to be made on the share of companies with notification duties within those sectors. These are presented in the table and justified at pages 39-40.

[105] RPA *et al* (2014), p. 61.

[106] Eurostat Structural Business Statistics.

Table A2-2: Number of companies per NACE code and number of companies with notification duties									
	Number of companies				Share of companies with notification duties	Number of companies with notification duties			
NACE	EU 28	Belgium	Denmark	France		EU28[+]	Belgium[+]	Denmark[+]	France[+]
C20.12	592	13	5	61	1	590	10	10	60
C20.13	1,086	28	4	87	0.25	270	10	-	20
C20.14	1,980	102	11	220	0.1	200	10	-	20
C20.16	2,546	77	14	165	0.1	250	10	-	20
C20.20	623	11	6	80	0.1	60	-	-	10
C20.30	4,000	118	42	266	0.9	3,600	110	40	240
C20.41	3,725	86	41	354	0.1	370	10	-	40
C20.42	4,557	77	44	861	0.1	460	10	-	90
C20.59	4,335	57	38	285	0.1	430	10	-	30
C21.10	900	36	24	57	0.1	90	-	-	10
C21.20	3,172	89	68	347	0.1	320	10	10	30
G46.45	19,837	489	180	2,261	0.05	990	20	10	110
G46.46	38,496	1,376	611	3,149	0.05	1,920	70	30	160
G46.75	27,877	884	181	2,033	0.05	1,390	40	10	100
M72.1	37,800	502	495	3,600	0.1	3,780	50	50	360
Total	151,526	3,945	1,764	13,826		14,720	370	160	1,300
Notes: [+]Rounded to the nearest ten									

A2.2 Option 3a

This Section (Tables A2-4 to A2-9) presents the calculation steps for the assessment of the costs of the implementation of the EU wide nanomaterials registry by substance in the situation where no information has been generated to comply with REACH or with the national registries.

In essence, the total cost is a function of:

- The nature and extent of information required;
- The cost of providing that information;
- The number of EU businesses affected; and
- The number of notifications submitted.

Table A2-3 summarises the assumptions and values used for the calculations.[107]

The cost for the characterisation of nanomaterials used in the manufacturing of biocides, pesticides, cosmetic products and pharmaceutical products has not been accounted, as this cost should be apportioned to the respective legislation requiring the characterisation of the nanomaterials.

The average numbers of notifications per role in the supply chain have been assumed to follow the same pattern as in the second year of the FNS (presented in Table 6-5 and Table A2-3).

Furthermore, it has been assumed that, during the first year of implementation of an EU registry of nanomaterials, a certain number of companies (in particular, those companies manufacturing substances in powder form) would have to check whether the substances they manufacture are at the nanoscale. In order to take into account the additional testing costs, it has been assumed that for every ten substances resulting at the nanoscale, there would be an additional substance that, once tested, would result to have particle size above the 100 nm threshold. This assumption has been considered for the following sectors:

- C20.12 - Manufacture of dyes and pigments;
- C20.13 - Manufacture of other inorganic basic chemicals;
- C20.14 - Manufacture of other organic basic chemicals;
- C20.16 - Manufacture of plastics in primary forms;
- C20.30 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics;
- C20.41 - Manufacture of soap and detergents, cleaning and polishing preparations;
- C20.59 – Manufacture of other chemical products.

[107] All cost figures and assumptions are based on the results of the survey on the administrative burden of the FNS (RPA *et al*, 2014b).

Table A2-3: Assumptions			
Number of notifications per actor in the supply chain			
No. of notifications per manufacturer/importer	4		
No. of notifications per distributor	8		
No. of notifications per research institute	10		
Cost items	**Hours**	**€/h**	
Understanding of the legal requirements (per notifier) - M/I	30	€ 35	€ 1,050
Understanding of the legal requirements (per notifier) - Distributors	25	€ 35	€ 875
Understanding of the legal requirements (per notifier) - Research institutes	5	€ 35	€ 175
Gathering of the information (per notification)	10	€ 35	€ 350
Gathering of the information (per notification) - Research institutes	1	€ 35	€ 35
Submission of the information (per notification)	1	€ 35	€ 35
Responding to enquiries (per notification)	2	€ 35	€ 70
Adapting product/account databases (per notifier)	10	€ 35	€ 350
Recurring costs - M/I	1.5	€ 52.5	
Recurring costs - Research Institutes	0.5	€ 17.5	
Characterisation costs and assumptions			
Characterisation of the information requirements - low end	€ 3,000		
Characterisation of the information requirements - high end	€ 10,000		
Characterisation of the information requirements - low end - part of the information	€ 3,000		
Characterisation of the information requirements - high end - part of the information	€ 5,000		
No. of the notifications for which the information had to be generated completely for the purposes of the notification – M/I	70%		
No. of notifications for which only part of the information had to be generated - M/I	20%		
Notes: All cost figures and assumptions are based on the results of the survey on the administrative burden of the FNS (RPA et al, 2014b), with the exception of the assumptions for research institutes, that are our own (no information has been provided by the French public reports).			

Table A2-4: Characterisation costs of the notifications for which the information will have to be generated completely for the purposes of the notification									
NACE	**No. of companies with notification duties**	**Average number of notifications per notifier**	**No. of notifications in the EU28**	**% of notifications for which the information will have to be generated completely for the purposes of the notification**	**No. of notifications for which the information will have to be generated completely for the purposes of the notification**	**Low end**	**High end**	**Costs – low end**	**Costs –high end**
C20.12	590	4	2,360	70%	1,650	€3,000	€10,000	€4,950,000	€16,500,000
C20.13	270	4	1,080	70%	760	€3,000	€10,000	€2,280,000	€7,600,000
C20.14	200	4	800	70%	560	€3,000	€10,000	€1,680,000	€5,600,000
C20.16	250	4	1,000	70%	700	€3,000	€10,000	€2,100,000	€7,000,000
C20.20	60	4	240	0%	-	€3,000	€10,000	€-	€-
C20.30	3,600	4	14,400	70%	10,080	€3,000	€10,000	€30,240,000	€100,800,000
C20.41	370	4	1,480	70%	1,040	€3,000	€10,000	€3,120,000	€10,400,000
C20.42	460	4	1,840	0%	-	€3,000	€10,000	€-	€-
C20.59	430	4	1,720	70%	1,200	€3,000	€10,000	€3,600,000	€12,000,000
C21.10	90	4	360	0%	-	€3,000	€10,000	€-	€-
C21.20	320	4	1,280	0%	-	€3,000	€10,000	€-	€-
G46.45	990	8	7,920	0%	-	€3,000	€10,000	€-	€-
G46.46	1,920	8	15,360	0%	-	€3,000	€10,000	€-	€-
G46.75	1,390	8	11,120	0%	-	€3,000	€10,000	€-	€-
M72.1	3,780	10	37,800	0%	-	€3,000	€10,000	€-	€-
Total	**14,720**		**98,760**		**15,990**			**€47,970,000**	**€159,900,000**
Notes: The number of notifications is calculated multiplying the number of companies with notification duties for the average number of notifications per notifier.									

Table A2-5: Characterisation costs of the notifications for which the information will have to be generated partially for the purposes of the notification									
NACE codes	No. of notifications in the EU28	% of notifications for which only part of the information had to be generated	Additional testing (negative results)		No. of notifications for which only part of the information had to be generated	Low end	High end	Costs – low end	Costs –high end
C20.12	2,360	20%	10%	30%	710	€3,000	€5,000	€2,130,000	€3,550,000
C20.13	1,080	20%	10%	30%	320	€3,000	€5,000	€960,000	€1,600,000
C20.14	800	20%	10%	30%	240	€3,000	€5,000	€720,000	€1,200,000
C20.16	1,000	20%	10%	30%	300	€3,000	€5,000	€900,000	€1,500,000
C20.20	240	0%	-	0%	-	€3,000	€5,000	€-	€-
C20.30	14,400	20%	10%	30%	4,320	€3,000	€5,000	€12,960,000	€21,600,000
C20.41	1,480	20%	10%	30%	440	€3,000	€5,000	€1,320,000	€2,200,000
C20.42	1,840	0%	-	0%	-	€3,000	€5,000	€-	€-
C20.59	1,720	20%	10%	30%	520	€3,000	€5,000	€1,560,000	€2,600,000
C21.10	360	0%	-	0%	-	€3,000	€5,000	€-	€-
C21.20	1,280	0%	-	0%	-	€3,000	€5,000	€-	€-
G46.45	7,920	0%	-	0%	-	€3,000	€5,000	€-	€-
G46.46	15,360	0%	-	0%	-	€3,000	€5,000	€-	€-
G46.75	11,120	0%	-	0%	-	€3,000	€5,000	€-	€-
M72.1	37,800	0%	-	0%	-	€3,000	€5,000	€-	€-
Total	**98,760**				**6,850**			**€20,550,000**	**€34,250,000**

Table A2-6: Characterisation costs					
	Characterisation costs of the notifications for which the information will have to be generated completely for the purposes of the notification		Characterisation costs of the notifications for which the information will have to be generated partially for the purposes of the notification		Total Characterisation costs - low and high end
NACE codes	Costs – low end	Costs –high end	Costs – low end	Costs –high end	
C20.12	€4,950,000	€16,500,000	€2,130,000	€3,550,000	€7,080,000 - €20,050,000
C20.13	€2,280,000	€7,600,000	€960,000	€1,600,000	€3,240,000 - €9,200,000
C20.14	€1,680,000	€5,600,000	€720,000	€1,200,000	€2,400,000 - €6,800,000
C20.16	€2,100,000	€7,000,000	€900,000	€1,500,000	€3,000,000 - €8,500,000
C20.20	€-	€-	€-	€-	-
C20.30	€30,240,000	€100,800,000	€12,960,000	€21,600,000	€43,200,000 - €122,400,000
C20.41	€3,120,000	€10,400,000	€1,320,000	€2,200,000	€4,440,000 - €12,600,000
C20.42	€-	€-	€-	€-	-
C20.59	€3,600,000	€12,000,000	€1,560,000	€2,600,000	€5,160,000 - €14,600,000
C21.10	€-	€-	€-	€-	-
C21.20	€-	€-	€-	€-	-
G46.45	€-	€-	€-	€-	-
G46.46	€-	€-	€-	€-	-
G46.75	€-	€-	€-	€-	-
M72.1	€-	€-	€-	€-	-
Total	**€47,970,000**	**€159,900,000**	**€20,550,000**	**€34,250,000**	**€68,520,000 - €194,150,000**

Table A2-7: Costs for understanding legal requirements and adapting product/account databases						
NACE codes	EU companies with notification duties	Understanding of the legal requirements (per notifier)	Understanding legal requirements	Adapting product/account databases (per notifier)	Adapting product/ account databases	Understanding legal requirements + Adapting product/account databases
C20.12	590	€1,050	€619,500	€350	€206,500	€826,000
C20.13	270	€1,050	€283,500	€350	€94,500	€378,000
C20.14	200	€1,050	€210,000	€350	€70,000	€280,000
C20.16	250	€1,050	€262,500	€350	€87,500	€350,000
C20.20	60	€1,050	€63,000	€350	€21,000	€84,000
C20.30	3,600	€1,050	€3,780,000	€350	€1,260,000	€5,040,000
C20.41	370	€1,050	€388,500	€350	€129,500	€518,000
C20.42	460	€1,050	€483,000	€350	€161,000	€644,000
C20.59	430	€1,050	€451,500	€350	€150,500	€602,000
C21.10	90	€1,050	€94,500	€350	€31,500	€126,000
C21.20	320	€1,050	€336,000	€350	€112,000	€448,000
G46.45	990	€875	€866,250	€350	€346,500	€1,212,750
G46.46	1,920	€875	€1,680,000	€350	€672,000	€2,352,000
G46.75	1,390	€875	€1,216,250	€350	€486,500	€1,702,750
M72.1	3,780	€175	€661,500	0	€-	€661,500
Total	**14,720**		**€11,396,000**		**€3,829,000**	**€15,225,000**

Table A2-8: Costs for the gathering of the information, submission of the information, responding to enquiries						
NACE codes	No. of notifications in the EU	Per notification	Gathering of the information	Per notification	Submission of the information, Responding to enquiries	Gathering of the information, Submission of the information, Responding to enquiries
C20.12	2,360	€350	€826,000	€105	€247,800	€1,073,800
C20.13	1,080	€350	€378,000	€105	€113,400	€491,400
C20.14	800	€350	€280,000	€105	€84,000	€364,000
C20.16	1,000	€350	€350,000	€105	€105,000	€455,000
C20.20	240	€350	€84,000	€105	€25,200	€109,200
C20.30	14,400	€350	€5,040,000	€105	€1,512,000	€6,552,000
C20.41	1,480	€350	€518,000	€105	€155,400	€673,400
C20.42	1,840	€350	€644,000	€105	€193,200	€837,200
C20.59	1,720	€350	€602,000	€105	€180,600	€782,600
C21.10	360	€350	€126,000	€105	€37,800	€163,800
C21.20	1,280	€350	€448,000	€105	€134,400	€582,400
G46.45	7,920	€350	€2,772,000	€105	€831,600	€3,603,600
G46.46	15,360	€350	€5,376,000	€105	€1,612,800	€6,988,800
G46.75	11,120	€350	€3,892,000	€105	€1,167,600	€5,059,600
M72.1	37,800	€35	€1,323,000	€35	€1,323,000	€2,646,000
Total	**98,720**		**€22,659,000**		**€7,723,800**	**€30,382,800**

Table A2-9: Total cost for businesses of an EU registry – First year of implementation and annual cost						
NACE codes	Total Characterisation costs - low and high end	Understanding legal requirements + Adapting product/account databases	Gathering of the information, Submission of the information, Responding to enquiries	Total cost – first year		Recurring costs
C20.12	€7,080,000 - €20,050,000	€826,000	€1,073,800	€8,980,000 - €21,950,000	€52.5	€124,000
C20.13	€3,240,000 - €9,200,000	€378,000	€491,400	€4,109,000 - €10,069,000	€52.5	€57,000
C20.14	€2,400,000 - €6,800,000	€280,000	€364,000	€3,044,000 - €7,444,000	€52.5	€42,000
C20.16	€3,000,000 - €8,500,000	€350,000	€455,000	€3,805,000 - €9,305,000	€52.5	€53,000
C20.20	-	€84,000	€109,200	€193,000	€52.5	€13,000
C20.30	€43,200,000 - €122,400,000	€5,040,000	€6,552,000	€54,792,000 - €133,992,000	€52.5	€756,000
C20.41	€4,440,000 - €12,600,000	€518,000	€673,400	€5,631,000 - €13,791,000	€52.5	€78,000
C20.42	-	€644,000	€837,200	€1,481,000	€52.5	€97,000
C20.59	€5,160,000 - €14,600,000	€602,000	€782,600	€6,545,000 - €15,985,000	€52.5	€90,000
C21.10	-	€126,000	€163,800	€290,000	€52.5	€19,000
C21.20	-	€448,000	€582,400	€1,030,000	€52.5	€67,000
G46.45	-	€1,212,750	€3,603,600	€4,816,000	€52.5	€416,000
G46.46	-	€2,352,000	€6,988,800	€9,341,000	€52.5	€806,000
G46.75	-	€1,702,750	€5,059,600	€6,762,000	€52.5	€584,000
M72.1	-	€661,500	€2,646,000	€3,308,000	€17.5	€662,000
Total	**€68,520,000 - €194,150,000**	**€15,225,000**	**€30,382,800**	**€114,128,000 - €239,758,000**		**€3,864,000**

A2.3 Option 3a compared with Baseline 0a

This Section (Tables A2-10 to A2-16) presents the calculation steps for the assessment of the marginal costs of the implementation of the EU wide nanomaterials registry by substance to baseline 0a, that is where for 35% to 65% of the notifications, no characterisation of the nanomaterials needs to be carried out as the information would be already available from the REACH Registration dossiers of the substances in the bulk form.

It should be noted that the number of companies having to notify might be lower too. This would decrease the total marginal costs for understanding the legal requirements, adapting product/account databases, gathering and submitting the information, responding to enquiries and, ultimately, the recurring annual costs too.

The range 35% to 65% in the number of notifications that would not need the characterisation of the nanomaterials has been considered in order to take into account of the following:

- The analysis presented in Section 3.2 refers to the chemical substances as defined by the REACH Regulation while MEDDE (2014) refers to "categories of substances", meaning that each entry represents a substance that might cover several nanoforms;
- The information in the REACH registration dossiers of the substances that were found in the ECHA database is unspecific and does not refer to the nanoforms;
- At the date (April 2015), it is not clear how the amendment of the REACH Annexes will deal with quantities below one tonne per year per manufacturer/importer of different nanoforms of the same substance manufactured/imported above 1 tonne per year per manufacturer.

Thirty-five percent is the percentage of notifications referring to quantities above one tonne per year received by the French authorities in 2014; sixty-five percent is the percentage of substances registered or expected to be registered by 2018.

Table A2-10: Number of notifications not covered by REACH					
NACE	**No. of notifications in the EU28**	**% covered by REACH**		**Notifications not covered by REACH**	
C20.12	2,360	35%	65%	1,530	830
C20.13	1,080	35%	65%	700	380
C20.14	800	35%	65%	520	280
C20.16	1,000	35%	65%	650	350
C20.20	240	0%	0%	-	-
C20.30	14,400	35%	65%	9,360	5,040
C20.41	1,480	35%	65%	960	520
C20.42	1,840	0%	0%	-	-
C20.59	1,720	35%	65%	1,120	600
C21.10	360	0%	0%	-	-
C21.20	1,280	0%	0%	-	-
G46.45	7,920	0%	0%	-	-
G46.46	15,360	0%	0%	-	-
G46.75	11,120	0%	0%	-	-
M72.1	37,800	0%	0%	-	-
Total	**98,760**			14,840	8,000

Table A2-11: Characterisation costs of the notifications for which the information will have to be generated completely for the purposes of the notification								
NACE	Notifications not covered by REACH		% of notifications for which the information will have to be generated completely for the purposes of the notification	No. of notifications for which the information will have to be generated completely for the purposes of the notification	Low end	High end	Costs – low end	Costs –high end
C20.12	1,530	830	70%	580 - 1,070	€3,000	€10,000	€1,740,000	€10,700,000
C20.13	700	380	70%	270 - 490	€3,000	€10,000	€810,000	€4,900,000
C20.14	520	280	70%	200 - 360	€3,000	€10,000	€600,000	€3,600,000
C20.16	650	350	70%	250 - 460	€3,000	€10,000	€750,000	€4,600,000
C20.20	-	-	0%	-	€3,000	€10,000	€-	€-
C20.30	9,360	5,040	70%	3,530 - 6,550	€3,000	€10,000	€10,590,000	€65,500,000
C20.41	960	520	70%	360 - 670	€3,000	€10,000	€1,080,000	€6,700,000
C20.42	-	-	0%	-	€3,000	€10,000	€-	€-
C20.59	1,120	600	70%	420 - 780	€3,000	€10,000	€1,260,000	€7,800,000
C21.10	-	-	0%	-	€3,000	€10,000	€-	€-
C21.20	-	-	0%	-	€3,000	€10,000	€-	€-
G46.45	-	-	0%	-	€3,000	€10,000	€-	€-
G46.46	-	-	0%	-	€3,000	€10,000	€-	€-
G46.75	-	-	0%	-	€3,000	€10,000	€-	€-
M72.1	-	-	0%	-	€3,000	€10,000	€-	€-
Total	**14,840**	**8,000**		**5,610 - 10,380**			**€16,830,000**	**€103,800,000**

Table A2-12: Characterisation costs of the notifications for which the information will have to be generated partially for the purposes of the notification										
NACE codes	Notifications not covered by REACH		% of notifications for which only part of the information had to be generated	Additional testing (negative results)		No. of notifications for which only part of the information had to be generated	Low end	High end	Costs – low end	Costs –high end
C20.12	1,530	830	20%	10%	30%	250 - 460	€3,000	€5,000	€750,000	€2,300,000
C20.13	700	380	20%	10%	30%	110 - 210	€3,000	€5,000	€330,000	€1,050,000
C20.14	520	280	20%	10%	30%	80 - 160	€3,000	€5,000	€240,000	€800,000
C20.16	650	350	20%	10%	30%	110 - 200	€3,000	€5,000	€330,000	€1,000,000
C20.20	-	-	0%	-	0%	-	€3,000	€5,000	€-	€-
C20.30	9,360	5,040	20%	10%	30%	1,510 - 2,810	€3,000	€5,000	€4,530,000	€14,050,000
C20.41	960	520	20%	10%	30%	160 - 290	€3,000	€5,000	€480,000	€1,450,000
C20.42	-	-	0%	-	0%	-	€3,000	€5,000	€-	€-
C20.59	1,120	600	20%	10%	30%	180 - 340	€3,000	€5,000	€540,000	€1,700,000
C21.10	-	-	0%	-	0%	-	€3,000	€5,000	€-	€-
C21.20	-	-	0%	-	0%	-	€3,000	€5,000	€-	€-
G46.45	-	-	0%	-	0%	-	€3,000	€5,000	€-	€-
G46.46	-	-	0%	-	0%	-	€3,000	€5,000	€-	€-
G46.75	-	-	0%	-	0%	-	€3,000	€5,000	€-	€-
M72.1	-	-	0%	-	0%	-	€3,000	€5,000	€-	€-
Total	**14,840**	**8,000**				**2,400 - 4,470**			**€7,200,000**	**€22,350,000**

Table A2-13: Characterisation costs					
	Characterisation costs of the notifications for which the information will have to be generated completely for the purposes of the notification		Characterisation costs of the notifications for which the information will have to be generated partially for the purposes of the notification		Total Characterisation costs - low and high end
NACE codes	Costs – low end	Costs –high end	Costs – low end	Costs –high end	
C20.12	€1,740,000	€10,700,000	€750,000	€2,300,000	€2,490,000 - €13,000,000
C20.13	€810,000	€4,900,000	€330,000	€1,050,000	€1,140,000 - €5,950,000
C20.14	€600,000	€3,600,000	€240,000	€800,000	€840,000 - €4,400,000
C20.16	€750,000	€4,600,000	€330,000	€1,000,000	€1,080,000 - €5,600,000
C20.20	€-	€-	€-	€-	-
C20.30	€10,590,000	€65,500,000	€4,530,000	€14,050,000	€15,120,000 - €79,550,000
C20.41	€1,080,000	€6,700,000	€480,000	€1,450,000	€1,560,000 - €8,150,000
C20.42	€-	€-	€-	€-	-
C20.59	€1,260,000	€7,800,000	€540,000	€1,700,000	€1,800,000 - €9,500,000
C21.10	€-	€-	€-	€-	-
C21.20	€-	€-	€-	€-	-
G46.45	€-	€-	€-	€-	-
G46.46	€-	€-	€-	€-	-
G46.75	€-	€-	€-	€-	-
M72.1	€-	€-	€-	€-	-
Total	**€16,830,000**	**€103,800,000**	**€7,200,000**	**€22,350,000**	**€24,030,000 - €126,150,000**

Table A2-14: Costs for understanding legal requirements and adapting product/account databases						
NACE codes	EU companies with notification duties	Understanding of the legal requirements (per notifier)	Understanding legal requirements	Adapting product/account databases (per notifier)	Adapting product/ account databases	Understanding legal requirements + Adapting product/account databases
C20.12	590	€1,050	€619,500	€350	€206,500	€826,000
C20.13	270	€1,050	€283,500	€350	€94,500	€378,000
C20.14	200	€1,050	€210,000	€350	€70,000	€280,000
C20.16	250	€1,050	€262,500	€350	€87,500	€350,000
C20.20	60	€1,050	€63,000	€350	€21,000	€84,000
C20.30	3,600	€1,050	€3,780,000	€350	€1,260,000	€5,040,000
C20.41	370	€1,050	€388,500	€350	€129,500	€518,000
C20.42	460	€1,050	€483,000	€350	€161,000	€644,000
C20.59	430	€1,050	€451,500	€350	€150,500	€602,000
C21.10	90	€1,050	€94,500	€350	€31,500	€126,000
C21.20	320	€1,050	€336,000	€350	€112,000	€448,000
G46.45	990	€875	€866,250	€350	€346,500	€1,212,750
G46.46	1,920	€875	€1,680,000	€350	€672,000	€2,352,000
G46.75	1,390	€875	€1,216,250	€350	€486,500	€1,702,750
M72.1	3,780	€175	€661,500	0	€-	€661,500
Total	**14,720**		**€11,396,000**		**€3,829,000**	**€15,225,000**

Table A2-15: Costs for the gathering of the information, submission of the information, responding to enquiries						
NACE codes	No. of notifications in the EU	Per notification	Gathering of the information	Per notification	Submission of the information, Responding to enquiries	Gathering of the information, Submission of the information, Responding to enquiries
C20.12	2,360	€350	€826,000	€105	€247,800	€1,073,800
C20.13	1,080	€350	€378,000	€105	€113,400	€491,400
C20.14	800	€350	€280,000	€105	€84,000	€364,000
C20.16	1,000	€350	€350,000	€105	€105,000	€455,000
C20.20	240	€350	€84,000	€105	€25,200	€109,200
C20.30	14,400	€350	€5,040,000	€105	€1,512,000	€6,552,000
C20.41	1,480	€350	€518,000	€105	€155,400	€673,400
C20.42	1,840	€350	€644,000	€105	€193,200	€837,200
C20.59	1,720	€350	€602,000	€105	€180,600	€782,600
C21.10	360	€350	€126,000	€105	€37,800	€163,800
C21.20	1,280	€350	€448,000	€105	€134,400	€582,400
G46.45	7,920	€350	€2,772,000	€105	€831,600	€3,603,600
G46.46	15,360	€350	€5,376,000	€105	€1,612,800	€6,988,800
G46.75	11,120	€350	€3,892,000	€105	€1,167,600	€5,059,600
M72.1	37,800	€35	€1,323,000	€35	€1,323,000	€2,646,000
Total	**98,720**		**€22,659,000**		**€7,723,800**	**€30,382,800**

Table A2-16: Total cost for businesses of an EU registry – First year of implementation and annual cost						
NACE codes	Total Characterisation costs - low and high end	Understanding legal requirements + Adapting product/account databases	Gathering of the information, Submission of the information, Responding to enquiries	Total cost – first year		Recurring costs
C20.12	€2,490,000 - €13,000,000	€826,000	€1,073,800	€4,390,000 - €14,900,000	€52.5	€124,000
C20.13	€1,140,000 - €5,950,000	€378,000	€491,400	€2,009,000 - €6,819,000	€52.5	€57,000
C20.14	€840,000 - €4,400,000	€280,000	€364,000	€1,484,000 - €5,044,000	€52.5	€42,000
C20.16	€1,080,000 - €5,600,000	€350,000	€455,000	€1,885,000 - €6,405,000	€52.5	€53,000
C20.20	-	€84,000	€109,200	€193,000	€52.5	€13,000
C20.30	€15,120,000 - €79,550,000	€5,040,000	€6,552,000	€26,712,000 - €91,142,000	€52.5	€756,000
C20.41	€1,560,000 - €8,150,000	€518,000	€673,400	€2,751,000 - €9,341,000	€52.5	€78,000
C20.42	-	€644,000	€837,200	€1,481,000	€52.5	€97,000
C20.59	€1,800,000 - €9,500,000	€602,000	€782,600	€3,185,000 - €10,885,000	€52.5	€90,000
C21.10	-	€126,000	€163,800	€290,000	€52.5	€19,000
C21.20	-	€448,000	€582,400	€1,030,000	€52.5	€67,000
G46.45	-	€1,212,750	€3,603,600	€4,816,000	€52.5	€416,000
G46.46	-	€2,352,000	€6,988,800	€9,341,000	€52.5	€806,000
G46.75	-	€1,702,750	€5,059,600	€6,762,000	€52.5	€584,000
M72.1	-	€661,500	€2,646,000	€3,308,000	€17.5	€662,000
Total	**€24,030,000 - €126,150,000**	**€15,225,000**	**€30,382,800**	**€69,637,000 - €171,757,000**		**€3,864,000**

A2.4 Option 3a compared with Baseline 0b

This Section (Tables A2-17 to A2-23) presents the calculation steps for the assessment of the marginal costs of the implementation of the EU wide nanomaterials registry by substance to baseline 0b, that is where no characterisation of the nanomaterials is necessary for those substances at the nanoform covered by the REACH Regulation and by the national registries already implemented (Belgian, Danish and French schemes).

Table A2-17: Number of notifications in the EU28 for which the characterisation of the nanomaterial will have to be done							
NACE	**No. of notifications in the EU not covered by REACH**		**No. of notifications in Belgium**	**No. of notifications in Denmark**	**No. of notifications in France**	**No. of notifications in BE, DK, FR**	**No. of notifications in the EU for which NM characterisation has to be done**
C20.12	1,530	830	40	40	240	240	470 - 1,170
C20.13	700	380	40	-	80	120	200 - 520
C20.14	520	280	40	-	80	120	100 - 340
C20.16	650	350	40	-	80	120	170 - 470
C20.20	-	-	-	-	40	40	-
C20.30	9,360	5,040	440	160	960	1,120	3,360 - 7,680
C20.41	960	520	40	-	160	200	220 - 660
C20.42	-	-	40	-	360	400	-
C20.59	1,120	600	40	-	120	160	360 - 880
C21.10	-	-	-	-	40	40	-
C21.20	-	-	40	40	120	120	-
G46.45	-	-	160	80	880	1,040	-
G46.46	-	-	560	240	1,280	1,840	-
G46.75	-	-	320	80	800	800	-
M72.1	-	-	500	500	3,600	4,600	-
Total	**14,840**	**8,000**	**2,300**	**1,140**	**8,840**	**10,960**	**4,880 - 11,720**

Notes: The number of notifications is calculated multiplying the number of companies with notification duties for the average number of notifications per notifier.
The cells highlighted present the number of notifications that will have to be done in Belgium and Denmark by the companies currently exempted under the national schemes.
The number of notifications in the EU28 for which the characterisation of the nanomaterial has to be done = The number of notifications in the EU28 – the number of notifications in Belgium, Denmark and France (considering the exemptions under the national schemes and 50% of notifications in Belgium, Denmark and France for which the notifiers will be able to use the characterisation data generated for the national schemes).

Table A2-18: Characterisation costs of the notifications for which the information will have to be generated completely for the purposes of the notification							
NACE	No. of notifications in the EU for which NM characterisation has to be done	% of notifications for which the information will have to be generated completely for the purposes of the notification	No. of notifications for which the information will have to be generated completely for the purposes of the notification	Low end	High end	Costs – low end	Costs –high end
C20.12	470 - 1,170	70%	330 - 820	€3,000	€10,000	€990,000	€8,200,000
C20.13	200 - 520	70%	140 - 360	€3,000	€10,000	€420,000	€3,600,000
C20.14	100 - 340	70%	70 - 240	€3,000	€10,000	€210,000	€2,400,000
C20.16	170 - 470	70%	120 - 330	€3,000	€10,000	€360,000	€3,300,000
C20.20	-	0%	-	€3,000	€10,000	€-	€-
C20.30	3,360 - 7,680	70%	2,350 - 5,380	€3,000	€10,000	€7,050,000	€53,800,000
C20.41	220 - 660	70%	150 - 460	€3,000	€10,000	€450,000	€4,600,000
C20.42	-	0%	-	€3,000	€10,000	€-	€-
C20.59	360 - 880	70%	250 - 620	€3,000	€10,000	€750,000	€6,200,000
C21.10	-	0%	-	€3,000	€10,000	€-	€-
C21.20	-	0%	-	€3,000	€10,000	€-	€-
G46.45	-	0%	-	€3,000	€10,000	€-	€-
G46.46	-	0%	-	€3,000	€10,000	€-	€-
G46.75	-	0%	-	€3,000	€10,000	€-	€-
M72.1	-	0%	-	€3,000	€10,000	€-	€-
Total	**4,880 - 11,720**		**3,410 - 8,210**			**€10,230,000**	**€82,100,000**

Table A2-19: Characterisation costs of the notifications for which the information will have to be generated partially for the purposes of the notification									
NACE codes	No. of notifications in the EU for which NM characterisation has to be done	% of notifications for which only part of the information had to be generated	Additional testing (negative results)		No. of notifications for which only part of the information had to be generated	Low end	High end	Costs – low end	Costs –high end
C20.12	470 - 1,170	20%	10%	30%	140 - 350	€3,000	€5,000	€420,000	€1,750,000
C20.13	200 - 520	20%	10%	30%	60 - 160	€3,000	€5,000	€180,000	€800,000
C20.14	100 - 340	20%	10%	30%	30 - 100	€3,000	€5,000	€90,000	€500,000
C20.16	170 - 470	20%	10%	30%	50 - 140	€3,000	€5,000	€150,000	€700,000
C20.20	-	0%	-	0%	-	€3,000	€5,000	€-	€-
C20.30	3,360 - 7,680	20%	10%	30%	1,010 - 2,300	€3,000	€5,000	€3,030,000	€11,500,000
C20.41	220 - 660	20%	10%	30%	70 - 200	€3,000	€5,000	€210,000	€1,000,000
C20.42	-	0%	-	0%	-	€3,000	€5,000	€-	€-
C20.59	360 - 880	20%	10%	30%	110 - 260	€3,000	€5,000	€330,000	€1,300,000
C21.10	-	0%	-	0%	-	€3,000	€5,000	€-	€-
C21.20	-	0%	-	0%	-	€3,000	€5,000	€-	€-
G46.45	-	0%	-	0%	-	€3,000	€5,000	€-	€-
G46.46	-	0%	-	0%	-	€3,000	€5,000	€-	€-
G46.75	-	0%	-	0%	-	€3,000	€5,000	€-	€-
M72.1	-	0%	-	0%	-	€3,000	€5,000	€-	€-
Total	**4,880 - 11,720**				**1,470 - 3,510**			**€4,410,000**	**€17,550,000**

Table A2-20: Characterisation costs					
	Characterisation costs of the notifications for which the information will have to be generated completely for the purposes of the notification		Characterisation costs of the notifications for which the information will have to be generated partially for the purposes of the notification		Total Characterisation costs - low and high end
NACE codes	Costs – low end	Costs –high end	Costs – low end	Costs –high end	
C20.12	€990,000	€8,200,000	€420,000	€1,750,000	€1,410,000 - €9,950,000
C20.13	€420,000	€3,600,000	€180,000	€800,000	€600,000 - €4,400,000
C20.14	€210,000	€2,400,000	€90,000	€500,000	€300,000 - €2,900,000
C20.16	€360,000	€3,300,000	€150,000	€700,000	€510,000 - €4,000,000
C20.20	€-	€-	€-	€-	-
C20.30	€7,050,000	€53,800,000	€3,030,000	€11,500,000	€10,080,000 - €65,300,000
C20.41	€450,000	€4,600,000	€210,000	€1,000,000	€660,000 - €5,600,000
C20.42	€-	€-	€-	€-	-
C20.59	€750,000	€6,200,000	€330,000	€1,300,000	€1,080,000 - €7,500,000
C21.10	€-	€-	€-	€-	-
C21.20	€-	€-	€-	€-	-
G46.45	€-	€-	€-	€-	-
G46.46	€-	€-	€-	€-	-
G46.75	€-	€-	€-	€-	-
M72.1	€-	€-	€-	€-	-
Total	**€10,230,000**	**€82,100,000**	**€4,410,000**	**€17,550,000**	**€14,640,000 - €99,650,000**

Table A2-21: Costs for understanding legal requirements and adapting product/account databases						
NACE codes	EU companies with notification duties	Understanding of the legal requirements (per notifier)	Understanding legal requirements	Adapting product/account databases (per notifier)	Adapting product/ account databases	Understanding legal requirements + Adapting product/account databases
C20.12	590	€1,050	€619,500	€350	€206,500	€826,000
C20.13	270	€1,050	€283,500	€350	€94,500	€378,000
C20.14	200	€1,050	€210,000	€350	€70,000	€280,000
C20.16	250	€1,050	€262,500	€350	€87,500	€350,000
C20.20	60	€1,050	€63,000	€350	€21,000	€84,000
C20.30	3,600	€1,050	€3,780,000	€350	€1,260,000	€5,040,000
C20.41	370	€1,050	€388,500	€350	€129,500	€518,000
C20.42	460	€1,050	€483,000	€350	€161,000	€644,000
C20.59	430	€1,050	€451,500	€350	€150,500	€602,000
C21.10	90	€1,050	€94,500	€350	€31,500	€126,000
C21.20	320	€1,050	€336,000	€350	€112,000	€448,000
G46.45	990	€875	€866,250	€350	€346,500	€1,212,750
G46.46	1,920	€875	€1,680,000	€350	€672,000	€2,352,000
G46.75	1,390	€875	€1,216,250	€350	€486,500	€1,702,750
M72.1	3,780	€175	€661,500	0	€-	€661,500
Total	**14,720**		**€11,396,000**		**€3,829,000**	**€15,225,000**

Table A2-22: Costs for the gathering of the information, submission of the information, responding to enquiries						
NACE codes	No. of notifications in the EU	Per notification	Gathering of the information	Per notification	Submission of the information, Responding to enquiries	Gathering of the information, Submission of the information, Responding to enquiries
C20.12	2,360	€350	€826,000	€105	€247,800	€1,073,800
C20.13	1,080	€350	€378,000	€105	€113,400	€491,400
C20.14	800	€350	€280,000	€105	€84,000	€364,000
C20.16	1,000	€350	€350,000	€105	€105,000	€455,000
C20.20	240	€350	€84,000	€105	€25,200	€109,200
C20.30	14,400	€350	€5,040,000	€105	€1,512,000	€6,552,000
C20.41	1,480	€350	€518,000	€105	€155,400	€673,400
C20.42	1,840	€350	€644,000	€105	€193,200	€837,200
C20.59	1,720	€350	€602,000	€105	€180,600	€782,600
C21.10	360	€350	€126,000	€105	€37,800	€163,800
C21.20	1,280	€350	€448,000	€105	€134,400	€582,400
G46.45	7,920	€350	€2,772,000	€105	€831,600	€3,603,600
G46.46	15,360	€350	€5,376,000	€105	€1,612,800	€6,988,800
G46.75	11,120	€350	€3,892,000	€105	€1,167,600	€5,059,600
M72.1	37,800	€35	€1,323,000	€35	€1,323,000	€2,646,000
Total	**98,720**		**€22,659,000**		**€7,723,800**	**€30,382,800**

Table A2-23: Total cost for businesses of an EU registry – First year of implementation and annual cost						
NACE codes	Total Characterisation costs - low and high end	Understanding legal requirements + Adapting product/account databases	Gathering of the information, Submission of the information, Responding to enquiries	Total cost – first year		Recurring costs
C20.12	€1,410,000 - €9,950,000	€826,000	€1,073,800	€3,310,000 - €11,850,000	€52.5	€124,000
C20.13	€600,000 - €4,400,000	€378,000	€491,400	€1,469,000 - €5,269,000	€52.5	€57,000
C20.14	€300,000 - €2,900,000	€280,000	€364,000	€944,000 - €3,544,000	€52.5	€42,000
C20.16	€510,000 - €4,000,000	€350,000	€455,000	€1,315,000 - €4,805,000	€52.5	€53,000
C20.20	-	€84,000	€109,200	€193,000	€52.5	€13,000
C20.30	€10,080,000 - €65,300,000	€5,040,000	€6,552,000	€21,672,000 - €76,892,000	€52.5	€756,000
C20.41	€660,000 - €5,600,000	€518,000	€673,400	€1,851,000 - €6,791,000	€52.5	€78,000
C20.42	-	€644,000	€837,200	€1,481,000 - €1,481,000	€52.5	€97,000
C20.59	€1,080,000 - €7,500,000	€602,000	€782,600	€2,465,000 - €8,885,000	€52.5	€90,000
C21.10	-	€126,000	€163,800	€290,000	€52.5	€19,000
C21.20	-	€448,000	€582,400	€1,030,000	€52.5	€67,000
G46.45	-	€1,212,750	€3,603,600	€4,816,000	€52.5	€416,000
G46.46	-	€2,352,000	€6,988,800	€9,341,000	€52.5	€806,000
G46.75	-	€1,702,750	€5,059,600	€6,762,000	€52.5	€584,000
M72.1	-	€661,500	€2,646,000	€3,308,000	€17.5	€662,000
Total	**€14,640,000 - €99,650,000**	**€15,225,000**	**€30,382,800**	**€60,247,000 - €145,257,000**		**€3,864,000**

A2.5 Calculations for Option 3b "With exemptions"

Tables A2-24 to A2-32 detail the calculation steps for the assessment of the total costs (first year) and recurring costs of an EU wide nanomaterials registry by substance with the different exemptions considered.

Table A2-24: Total cost for businesses of an EU registry – First year of implementation and annual cost with the exemption on nanomaterials only used in scientific research and development or in product and process oriented research and development							
NACE codes	**Number of notifications in the EU28**	**% of notifications exempted**	**Number of notifications exempted**	**Savings on total costs**	**Savings on recurring costs**	**Total costs (first year)**	**Recurring costs**
C20.12	2,360	2%	54	€20,646	€2,815	€3,289,000-€11,829,000	€121,000
C20.13	1,080	2%	25	€9,448	€1,288	€1,460,000-€5,260,000	€56,000
C20.14	800	2%	18	€6,999	€954	€937,000-€3,537,000	€41,000
C20.16	1,000	2%	23	€8,748	€1,193	€1,306,000-€4,796,000	€52,000
C20.20	240	2%	5	€2,100	€286	€191,000	€13,000
C20.30	14,400	2%	327	€125,975	€17,178	€21,546,000-€76,766,000	€739,000
C20.41	1,480	2%	34	€12,947	€1,766	€1,838,000-€6,778,000	€76,000
C20.42	1,840	2%	42	€16,097	€2,195	€1,465,000	€95,000
C20.59	1,720	2%	39	€15,047	€2,052	€2,450,000-€8,870,000	€88,000
C21.10	360	2%	8	€3,149	€429	€287,000	€19,000
C21.20	1,280	2%	29	€11,198	€1,527	€1,019,000	€65,000
G46.45	7,920	2%	180	€69,286	€9,448	€4,747,000	€407,000
G46.46	15,360	2%	349	€134,373	€18,324	€9,207,000	€788,000
G46.75	11,120	2%	253	€97,281	€13,266	€6,665,000	€571,000
M72.1	37,800	100%	37,800	€2,646,000[+]	€661,500	€662,000	€1,000
Total	**98,760**		**39,185**	**€3,179,293**	**€734,222***	**€57,068,000-€142,078,000**	**€3,130,000**

Notes:
Savings on total costs = Number of notifications exempted x €385 (11 work hours at €35/h for the gathering and submission of information)
[+] Savings on total costs = Number of notifications exempted x €70 (2 work hours at €35/h for the gathering and submission of information)
Savings on recurring costs = Number of notifications exempted x €52.5 (1.5 work hours at €35/h for the gathering and submission of information)
** Savings on recurring costs = Number of notifications exempted x €17.5 (0.5 work hours at €35/h for the gathering and submission of information)*

Table A2-25 – Number of companies and notifications considering the exemption on pigments									
NACE codes	EU companies with notifications duties	% of companies exempted	No. of companies after exemption	No. of notifications in the EU28	% of notifications exempted	No. of notifications in the EU28 after exemption	No. of notifications in the EU for which NM characterisation has to be done	% of notifications exempted	No. of notifications in the EU for which NM characterisation has to be done after exemption
C20.12	590	100%	-	2,360	100%	-	470 - 1,170	100%	-
C20.13	270	0%	270	1,080	10%	972	200 - 520	10%	180 - 468
C20.14	200	0%	200	800	10%	720	100 - 340	10%	90- 306
C20.16	250	0%	250	1,000	0%	1,000	170 - 470	0%	170 - 470
C20.20	60	0%	60	240	0%	240	-	0%	-
C20.30	3,600	100%	-	14,400	75%	3,600	3,360 - 7,680	75%	840 - 1,920
C20.41	370	0%	370	1,480	0%	1,480	220 - 660	0%	220 - 660
C20.42	460	0%	460	1,840	0%	1,840	-	0%	-
C20.59	430	0%	430	1,720	10%	1,548	360 - 880	10%	324 - 792
C21.10	90	0%	90	360	0%	360	-	0%	-
C21.20	320	0%	320	1,280	0%	1,280	-	0%	-
G46.45	990	0%	990	7,920	50%	3,960	-	50%	-
G46.46	1,920	0%	1,920	15,360	0%	15,360	-	0%	-
G46.75	1,390	0%	1,390	11,120	50%	5,560	-	50%	-
M72.1	3,780	0%	3,780	37,800	0%	37,800	-	0%	-
Total	**14,720**		**10,530**	**98,760**		**75,720**	**4,880 - 11,720**		**1,824- 4,616**

Table A2-26: Total cost for businesses of an EU registry – First year of implementation and annual cost – Exemption on pigments						
NACE codes	Total Characterisation costs - low and high end	Understanding legal requirements + Adapting product/account databases	Gathering of the information, Submission of the information, Responding to enquiries	Total cost – first year		Recurring costs
C20.12	-	€-	€-	-	€52.5	€-
C20.13	€540,000 - €4,000,000	€378,000	€442,260	€1,360,000-€4,820,000	€52.5	€51,000
C20.14	€270,000 - €2,550,000	€280,000	€327,600	€878,000-€3,158,000	€52.5	€38,000
C20.16	€510,000 - €4,000,000	€350,000	€455,000	€1,315,000-€4,805,000	€52.5	€53,000
C20.20	-	€84,000	€109,200	€193,000-€193,000	€52.5	€13,000
C20.30	€2,520,000 - €16,300,000	€-	€1,638,000	€4,158,000-€17,938,000	€52.5	€189,000
C20.41	€660,000 - €5,600,000	€518,000	€673,400	€1,851,000-€6,791,000	€52.5	€78,000
C20.42	-	€644,000	€837,200	€1,481,000-€1,481,000	€52.5	€97,000
C20.59	€990,000 - €6,700,000	€602,000	€704,340	€2,296,000-€8,006,000	€52.5	€81,000
C21.10	-	€126,000	€163,800	€290,000-€290,000	€52.5	€19,000
C21.20	-	€448,000	€582,400	€1,030,000-€1,030,000	€52.5	€67,000
G46.45	-	€1,212,750	€1,801,800	€3,015,000-€3,015,000	€52.5	€208,000
G46.46	-	€2,352,000	€6,988,800	€9,341,000-€9,341,000	€52.5	€806,000
G46.75	-	€1,702,750	€2,529,800	€4,233,000-€4,233,000	€52.5	€292,000
M72.1	-	€661,500	€2,646,000	€3,308,000-€3,308,000	€17.5	€662,000
Total	**€5,490,000 - €39,150,000**	**€9,359,000**	**€19,899,600**	**€34,749,000-€68,409,000**		**€2,654,000**

Table A2-27: Number of companies and notifications considering the exemption on fillers									
NACE codes	EU companies with notifications duties	% of companies exempted	No. of companies after exemption	No. of notifications in the EU28	% of notifications exempted	No. of notifications in the EU28 after exemption	No. of notifications in the EU for which NM characterisation has to be done	% of notifications exempted	No. of notifications in the EU for which NM characterisation has to be done after exemption
C20.12	590	0%	590	2,360	0%	2,360	470-1,170	0%	470-1,170
C20.13	270	25%	203	1,080	25%	810	200-520	25%	150-390
C20.14	200	0%	200	800	0%	800	100-340	0%	100-340
C20.16	250	0%	250	1,000	0%	1,000	170-470	0%	170-470
C20.20	60	0%	60	240	0%	240	-	0%	-
C20.30	3,600	25%	2,700	14,400	25%	10,800	3,360-7,680	25%	2,520-5,760
C20.41	370	0%	370	1,480	0%	1,480	220-660	0%	220-660
C20.42	460	0%	460	1,840	0%	1,840	-	0%	-
C20.59	430	10%	387	1,720	10%	1,548	360-880	10%	324-792
C21.10	90	0%	90	360	0%	360	-	0%	-
C21.20	320	0%	320	1,280	0%	1,280	-	0%	-
G46.45	990	0%	990	7,920	0%	7,920	-	0%	-
G46.46	1,920	0%	1,920	15,360	0%	15,360	-	0%	-
G46.75	1,390	25%	1,043	11,120	25%	8,340	-	25%	-
M72.1	3,780	0%	3,780	37,800	0%	37,800	-	0%	-
Total	**14,720**		13,362	**98,760**		91,938	**4,880-11,720**		**3,954-9,582**

Table A2-28: Total cost for businesses of an EU registry – First year of implementation and annual cost – Exemption on fillers						
NACE codes	Total Characterisation costs - low and high end	Understanding legal requirements + Adapting product/account databases	Gathering of the information, Submission of the information, Responding to enquiries	Total cost – first year		Recurring costs
C20.12	-	€ 826,000	€ 1,073,800	€3,310,000 - €11,850,000	€52.5	€ 124,000
C20.13	€480,000 - €3,300,000	€ 283,500	€ 368,550	€1,132,000 - €3,952,000	€52.5	€ 43,000
C20.14	€300,000 - €2,900,000	€ 280,000	€ 364,000	€944,000 - €3,544,000	€52.5	€ 42,000
C20.16	€510,000 - €4,000,000	€ 350,000	€ 455,000	€1,315,000 - €4,805,000	€52.5	€ 53,000
C20.20	-	€ 84,000	€ 109,200	€193,000 - €193,000	€52.5	€ 13,000
C20.30	€7,560,000 - €48,950,000	€ 3,780,000	€ 4,914,000	€16,254,000 - €57,644,000	€52.5	€ 567,000
C20.41	€660,000 - €5,600,000	€ 518,000	€ 673,400	€1,851,000 - €6,791,000	€52.5	€ 78,000
C20.42	-	€ 644,000	€ 837,200	€1,481,000 - €1,481,000	€52.5	€ 97,000
C20.59	€990,000 - €6,700,000	€ 541,800	€ 704,340	€2,236,000 - €7,946,000	€52.5	€ 81,000
C21.10	-	€ 126,000	€ 163,800	€290,000 - €290,000	€52.5	€ 19,000
C21.20	-	€ 448,000	€ 582,400	€1,030,000 - €1,030,000	€52.5	€ 67,000
G46.45	-	€ 1,212,750	€ 3,603,600	€4,816,000 - €4,816,000	€52.5	€ 416,000
G46.46	-	€ 2,352,000	€ 6,988,800	€9,341,000 - €9,341,000	€52.5	€ 806,000
G46.75	-	€ 1,277,063	€ 3,794,700	€5,072,000 - €5,072,000	€52.5	€ 438,000
M72.1	-	€ 661,500	€ 2,646,000	€3,308,000 - €3,308,000	€17.5	€ 662,000
Total	**€11,910,000 - €81,400,000**	**€ 13,384,613**	**€ 27,278,790**	**€52,573,000 - €122,063,000**		**€ 3,506,000**

Table A2-29: Number of companies and notifications considering the exemption on nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation							
NACE codes	**EU companies with notifications duties**	**% of companies exempted**	**No. of companies after exemption**	**No. of notifications in the EU28**	**% of notifications exempted**	**No. of notifications in the EU28 after exemption**	**No. of notifications in the EU for which NM characterisation has to be done**
C20.12	590	35% - 65%	207 - 384	2,360	35% - 65%	826 - 1,534	470-1,170
C20.13	270	35% - 65%	095 - 176	1,080	35% - 65%	378 - 702	200-520
C20.14	200	35% - 65%	070 - 130	800	35% - 65%	280 - 520	100-340
C20.16	250	35% - 65%	088 - 163	1,000	35% - 65%	350 - 650	170-470
C20.20	60	-	060 - 060	240	-	240 - 240	-
C20.30	3,600	35% - 65%	1,260 - 2,340	14,400	35% - 65%	5,040 - 9,360	3,360-7,680
C20.41	370	35% - 65%	130 - 241	1,480	35% - 65%	518 - 962	220-660
C20.42	460	-	460 - 460	1,840	-	1,840 - 1,840	-
C20.59	430	35% - 65%	151 - 280	1,720	35% - 65%	0,602 - 1,118	360-880
C21.10	90	-	090 - 090	360	-	360 - 360	-
C21.20	320	-	320 - 320	1,280	-	1,280 - 1,280	-
G46.45	990	-	990 - 990	7,920	-	7920 - 7920	-
G46.46	1,920	-	1,920 - 1,920	15,360	-	15,360 - 15,360	-
G46.75	1,390	35% - 65%	487 - 904	11,120	35% - 65%	3,892 - 7,228	-
M72.1	3,780	35% - 65%	1,323 - 2,457	37,800	35% - 65%	13,230 - 24,570	-
Total	**14,720**		7,648 - 10,912	**98,760**		52,116 - 73,644	**4,880-11,720**

Table A2-30: Total cost for businesses of an EU registry – First year of implementation and annual cost – Exemption on nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation						
NACE codes	Total Characterisation costs - low and high end	Understanding legal requirements + Adapting product/account databases	Gathering of the information, Submission of the information, Responding to enquiries	Total cost – first year		Recurring costs
C20.12	€1,410,000-€9,950,000	€826,000	€1,073,800	€3,310,000-€11,850,000	€52.5	€124,000
C20.13	€600,000-€4,400,000	€378,000	€491,400	€1,469,000-€5,269,000	€52.5	€57,000
C20.14	€300,000-€2,900,000	€280,000	€364,000	€944,000-€3,544,000	€52.5	€42,000
C20.16	€510,000-€4,000,000	€350,000	€455,000	€1,315,000-€4,805,000	€52.5	€53,000
C20.20	-	€84,000	€109,200	€193,000-€193,000	€52.5	€13,000
C20.30	€10,080,000-€65,300,000	€5,040,000	€6,552,000	€21,672,000-€76,892,000	€52.5	€756,000
C20.41	€660,000-€5,600,000	€518,000	€673,400	€1,851,000-€6,791,000	€52.5	€78,000
C20.42	-	€644,000	€837,200	€1,481,000-€1,481,000	€52.5	€97,000
C20.59	€1,080,000-€7,500,000	€602,000	€782,600	€2,465,000-€8,885,000	€52.5	€90,000
C21.10	-	€126,000	€163,800	€290,000-€290,000	€52.5	€19,000
C21.20	-	€448,000	€582,400	€1,030,000-€1,030,000	€52.5	€67,000
G46.45	-	€1,212,750	€3,603,600	€4,816,000-€4,816,000	€52.5	€416,000
G46.46	-	€2,352,000	€6,988,800	€9,341,000-€9,341,000	€52.5	€806,000
G46.75	-	€1,702,750	€5,059,600	€6,762,000-€6,762,000	€52.5	€584,000
M72.1	-	€661,500	€2,646,000	€3,308,000-€3,308,000	€17.5	€662,000
Total	**€14,640,000-€99,650,000**	**€15,225,000**	**€30,382,800**	**€60,247,000-€145,257,000**		**€3,864,000**

Table A2-31: Number of companies and notifications considering the exemption on nanomaterials in articles covered by existing registration requirements									
NACE codes	EU companies with notifications duties	% of companies exempted	No. of companies after exemption	No. of notifications in the EU28	% of notifications exempted	No. of notifications in the EU28 after exemption	No. of notifications in the EU for which NM characterisation has to be done	% of notifications exempted	No. of notifications in the EU for which NM characterisation has to be done after exemption
C20.12	590	0%	590	2,360	5%	2,242	470-1,170	5%	447 – 1,112
C20.13	270	0%	270	1,080	5%	1,026	200-520	5%	190 - 494
C20.14	200	0%	200	800	5%	760	100-340	5%	095 - 323
C20.16	250	0%	250	1,000	0%	1,000	170-470	0%	170 - 470
C20.20	60	100%	-	240	100%	-	-	100%	-
C20.30	3,600	0%	3,600	14,400	0%	14,400	3,360-7,680	0%	3,360 – 7,680
C20.41	370	25%	278	1,480	50%	740	220-660	50%	110 - 330
C20.42	460	100%	-	1,840	100%	-	-	100%	-
C20.59	430	0%	430	1,720	5%	1,634	360-880	5%	342 - 836
C21.10	90	100%	-	360	100%	-	-	100%	-
C21.20	320	100%	-	1,280	100%	-	-	100%	-
G46.45	990	100%	-	7,920	100%	-	-	100%	-
G46.46	1,920	100%	-	15,360	100%	-	-	100%	-
G46.75	1,390	0%	1,390	11,120	0%	11,120	-	0%	-
M72.1	3,780	0%	3,780	37,800	0%	37,800	-	0%	-
Total	**14,720**		**10,788**	**98,760**		**70,722**	**4,880-11,720**		**4,714 – 11,245**

Table A2-32: Total cost for businesses of an EU registry – First year of implementation and annual cost – Exemption on nanomaterials in articles covered by existing registration requirements						
NACE codes	Total Characterisation costs - low and high end	Understanding legal requirements + Adapting product/account databases	Gathering of the information, Submission of the information, Responding to enquiries	Total cost – first year		Recurring costs
C20.12	-	€826,000	€1,020,110	€3,166,000-€11,296,000	€52.5	€118,000
C20.13	€570,000-€4,250,000	€378,000	€466,830	€1,415,000-€5,095,000	€52.5	€54,000
C20.14	€300,000-€2,800,000	€280,000	€345,800	€926,000-€3,426,000	€52.5	€40,000
C20.16	€510,000-€4,000,000	€350,000	€455,000	€1,315,000-€4,805,000	€52.5	€53,000
C20.20	-	€-	€-	-	€52.5	€-
C20.30	€10,080,000-€65,300,000	€5,040,000	€6,552,000	€21,672,000-€76,892,000	€52.5	€756,000
C20.41	€330,000-€2,800,000	€388,500	€336,700	€1,055,000-€3,525,000	€52.5	€39,000
C20.42	-	€-	€-	-	€52.5	€-
C20.59	€1,020,000-€7,150,000	€602,000	€743,470	€2,365,000-€8,495,000	€52.5	€86,000
C21.10	-	€-	€-	-	€52.5	€-
C21.20	-	€-	€-	-	€52.5	€-
G46.45	-	€-	€-	-	€52.5	€-
G46.46	-	€-	€-	-	€52.5	€-
G46.75	-	€1,702,750	€5,059,600	€6,762,000-€6,762,000	€52.5	€584,000
M72.1	-	€661,500	€2,646,000	€3,308,000-€3,308,000	€17.5	€662,000
Total	**€14,130,000-€95,750,000**	**€10,228,750**	**€17,625,510**	**€41,984,000-€123,604,000**		**€2,392,000**

A2.6 Calculations for Option 4

The administrative burden for businesses has been estimated on the basis of the number of companies in different economic sectors with notification duties since this was considered the most reliable calculation method. The percentages of companies with notification duties for each sector is based on the figures used in two impact assessments carried out by the Danish Environmental Protection Agency and on the study of the proposed Belgium registry (BiPRO *et al*, 2013). Since the notification costs from the Danish impact assessment are available on a company basis (e.g. 150h/company) and not a notification basis, it was not necessary to estimate the number of products to be notified in order to estimate the administrative burden. Therefore, the emphasis on quantifying the impacts of Option 4 is placed on estimating the effects of different building blocks on the number of companies with notification duties.

The total costs to businesses resulting from the introduction of a mandatory EU Nanomaterial Registry by Application is calculated on a per company basis.

The costs for the notifications of the manufactured substances are based on the calculations for Option 3.

The costs for the articles and mixtures are calculated on a company basis according to the formulas used in the impact assessment by the Danish EPA.

$$Cost = No.\ of\ companies\ notifying * Cost_{Notification\ Duties} + No.\ of\ companies\ not\ notifying * Cost_{No\ Notification\ Duties}$$

As for Option 3, the basis for converting from hours to Euro is 35€/h.

The above formula reflects that companies will have to check their products and enquire up the supply chain (and respond to enquiries down the supply chain) to determine if they have notification duties, thus incurring costs. The implementation and annual costs per company are summarised according to product group.

The results are therefore a function of the following parameters:

- Number of companies in the EU28 per NACE code (Eurostat Structural Statistics database);
- Percentage of companies with notification duties per NACE code;
- Costs per company for complying with regulatory requirements per Product Group;
- Effect of each exemption on the percentage of companies with notification duties per Product Group;
- Percentage of companies with notification duties for each respective Product Group.

Tables A2-33 to A2-41 detail the calculation steps for the assessment.

Table A2-33: Number of companies with notification duties per NACE code and Product Group					
ID	Product Groups	Product Categories	No of companies in the EU 28 (from Eurostat)	Percentage of companies with notification duties	No. of companies in the EU with notification duties
1	1. Substances	Substances	5,200	23%	1,210
	C20.1.2 - Manufacture of dyes and pigments		590	100%	590
	C20.13 - Manufacture of other inorganic basic chemicals		1,086	25%	272
	C20.14 - Manufacture of other organic basic chemicals		1,980	10%	198
	C24.4 - Manufacture of basic precious and other non-ferrous metals		1,500	10%	150
2	2. Cosmetics	Mixtures	24,400	6%	1,450
	C20.4.2 - Manufacture of perfumes and toilet preparations		4,557	10%	456
	G46.4.5 - Wholesale of perfume and cosmetics		19,837	5%	992
3	3. Health Care	Mixtures	41,700	5%	2250
	C21.2 - Manufacture of pharmaceutical preparations		3,172	10%	317
	G46.4.6 - Wholesale of pharmaceutical goods		38,496	5%	1925
4	4. Food & Feed	Mixtures	359,200	5%	17,960
	C10.8 - Manufacture of other food products		9,172	5%	459
	G46.3 - Wholesale of food, beverages and tobacco		350,000	5%	17,500
5	5. Coatings & Inks	Mixtures	29,700	90%	26,700
	C20.3 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics		4,400	90%	3,960
	G46.7.3.311 Wholesale of paints varnishes		2,429	90%	2,186*
	G47.52 - Retail sale of hardware, paints and glass in specialised stores		22,827	90%	20,545*
6	6. Cleaning & Disinfection	Mixtures	22,000	10%	2,200
	C20.2 - Manufacture of pesticides and other agrochemical products		650	10%	65
	C20.4.1 - Manufacture of soap and detergents, cleaning and polishing preparations		3,700	10%	370
	G46.4.42 - Wholesale of cleaning products		17,585	10%	1,759
7	7. Tyres & Other Rubber Products	Articles	16,600	100%	16,600
	C22.11 - Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres		1,750	100%	1,750
	C22.19 - Manufacture of other rubber products		6,750	100%	6,750
	G46769* Wholesale of rubber products (part of 46769)		8,100	100%	8,100*
8	8. Plastic Products	Mixtures / Articles	60,550	87%	52,500
	C20.1.6 - Manufacture of plastics in primary forms		2,546	10%	255

Table A2-33: Number of companies with notification duties per NACE code and Product Group					
ID	Product Groups	Product Categories	No of companies in the EU 28 (from Eurostat)	Percentage of companies with notification duties	No. of companies in the EU with notification duties
	C22.2 - Manufacture of plastics products		58,000	90%	52,200
9	**9. Building & Construction**	**Mixtures / Articles**	**6,100**	**10%**	**610**
	C20.5.2 - Manufacture of glues		600	10%	60
	C23.2 - Manufacture of refractory products		900	10%	90
	C23.3 - Manufacture of clay building materials		3,500	10%	350
	C23.5 - Manufacture of cement, lime and plaster		1,100	10%	110
10	**10. Textiles**	**Articles**	**213,700**	**10%**	**21,400**
	C13 - Manufacture of textiles		53,000	10%	5,300
	C14 - Manufacture of wearing apparel		74,328	10%	7,433
	G46.4.1 - Wholesale of textiles		22,462	10%	2,246
	G46.4.2 - Wholesale of clothing and footwear		63,871	10%	6,387
11	**11. Paper Products**	**Articles**	**18,500**	**50%**	**9,300**
	C17 - Manufacture of paper and paper products		18,500	50%	9,250
12	**12. Wood Products**	**Articles**	**142,695**	**25%**	**35,700**
	C16.2 - Manufacture of products of wood, cork, straw and plaiting materials		142,695	25%	35,674
13	**13. Sporting Goods**	**Articles**	**4,300**	**35%**	**1,505**
	C32.3 - Manufacture of sports goods		4,300	35%	1,505
14	**14. Electronics**	**Articles**	**247,300**	**60%**	**148,400**
	C26 - Manufacture of computer, electronic and optical products		44,000	60%	26,400
	C27 - Manufacture of electrical equipment		52,000	60%	31,200
	G46.5 - Wholesale of information and communication equipment		60,718	60%	36,431
	G47.4 - Retail sale of information and communication equipment in specialised stores		90,540	60%	54,324
15	**15. Complex Objects**	**Articles**	**2123500**	**60%**	**1274100**
	C25 - Manufacture of fabricated metal products, except machinery and equipment		212,731	60%	127,639
	C28 - Manufacture of machinery and equipment n.e.c.		20,500	60%	12,300
	C29 - Manufacture of motor vehicles, trailers and semi-trailers		20,500	60%	12,300
	C30 - Manufacture of other transport equipment		14,300	60%	8,580
	C31 - Manufacture of furniture		130,000	60%	78,000

Table A2-33: Number of companies with notification duties per NACE code and Product Group					
ID	**Product Groups**	**Product Categories**	**No of companies in the EU 28 (from Eurostat)**	**Percentage of companies with notification duties**	**No. of companies in the EU with notification duties**
	G45 - Wholesale and retail trade and repair of motor vehicles and motorcycles		806,759	60%	484,055
	G46.4 - Wholesale of household goods		315,001	60%	189,001
	G46.6 - Wholesale of other machinery, equipment and supplies		169,421	60%	101,653
	G47.5 - Retail sale of other household equipment in specialised stores		434,194	60%	260,516
16	**16. Miscellaneous**	**Mixtures / Articles**	**96,000**	**5%**	**5,100**
	C20.5.9 - Manufacture of other chemical products n.e.c.		4,335	10%	434
	C23.1 - Manufacture of glass and glass products		17,247	5%	862
	G46.74 - Wholesale of hardware, plumbing and heating equipment and supplies		46,460	5%	2,323
	G46.7.5 - Wholesale of chemical products & 46769: chemical intermediary products		27,877	5%	1,394

Notes:
Values in light green cells are aligned with Option 3.
Values in light orange cells are equivalent to the upper range used in the Danish Impact Assessment study.
The remaining values are equivalent to the values used in the German Impact Assessment study.
** No Eurostat data are available for this NACE code. Confidential data from one MS was made available to the project team and was used to estimate the number of companies in the EU28 for this NACE code.*

Table A2-34: Values and assumptions for the assessment of the costs									
Product Groups	Notes	Implementation Administrative Burden [h/company/year]		Recurring Administrative Burden [h/company/year]		Implementation Administrative Burden [€/company/year] *		Recurring Administrative Burden [€/company/year] *	
		Company with notification duties	Company without notification duties	Company with notification duties	Company without notification duties, e)	Company with notification duties	Company without notification duties	Company with notification duties	Company without notification duties
1. Substances	a)	-	-	-	-	-	-	-	-
2. Cosmetics	c)	110	15	25	5	3,850	525	875	175
3. Health Care	c)	110	15	25	5	3,850	525	875	175
4. Food & Feed	c)	110	15	25	5	3,850	525	875	175
5. Coatings & Inks	b)	150	20	30	5	5,250	700	1,050	175
6. Cleaning & Disinfection	b)	65	10	15	5	2,275	350	525	175
7. Tyres & Other Rubber Products	d)	75	15	40	5	2,625	525	1,400	175
8. Plastic Products	d)	75	15	40	5	2,625	525	1,400	175
9. Building & Construction	b)	100	10	20	5	3,500	350	700	175
10. Textiles	d)	50	20	30	5	1,750	700	1,050	175
11. Paper Products	d)	75	15	40	5	2,625	525	1,400	175
12. Wood Products	d)	75	15	40	5	2,625	525	1,400	175
13. Sporting Goods	b)	100	10	50	5	3,500	350	1,750	175
14. Electronics	d)	75	15	40	5	2,625	525	1,400	175
15. Complex Objects	d)	75	15	40	5	2,625	525	1,400	175
16. Miscellaneous	d)	75	15	40	5	2,625	525	1,400	175

Notes:

a) The costs for the notifications of the manufactured substances are based on the calculations for Option 3. Substances costs are based on the results of the Option 3 and are an average of the ranges of NACE codes manufacturing substances

b) The values are from the Danish Impact Assessment 1451. If a range was provided in the Danish IA, the average value was used. The values for companies without notification duties were judged too high compared to the results from company interviews conducted in this study. Therefore 10h was estimated for sporting goods category.

c) The values are assumed on the Danish Impact Assessment 1451. Companies putting mixtures on the market have the average values of Coatings & Inks and Cleaning & Disinfection;

d) Average values assumed for Companies putting articles on the market have the average values of Textiles and Sporting Goods = 15h;

e) All recurring administrative burdens for companies without notification duties = 5

** Hourly wages used to convert "h" into "€" are: 35 €/h*

Table A2-35: Total costs and recurring costs for Option 4					
Product Groups	**No. of companies in the EU28**	**Share of companies with notification duties**	**No. of companies with notifications duties in the EU28**	**Implementation costs**	**Annual costs**
1. Substances	5,200*	23%*	1,210*	34,835,900 €[+]	435,600 €[#]
2. Cosmetics	24,400	6%	1,450	17,631,250 €	5,285,000 €
3. Health Care	41,700	5%	2,250	29,373,750 €	8,872,500 €
4. Food & Feed	359,200	5%	17,960	248,297,000 €	75,432,000 €
5. Coatings & Inks	29,700	90%	26,700	142,275,000 €	28,560,000 €
6. Cleaning & Disinfection	22,000	10%	2,200	11,935,000 €	4,620,000 €
7. Tyres & Other Rubber Products	16,600	100%	16,600	43,575,000 €	23,240,000 €
8. Plastic Products	60,550	87%	52,500	142,038,750 €	74,908,750 €
9. Building & Construction	6,100	10%	610	4,056,500 €	1,387,750 €
10. Textiles	213,700	10%	21,400	172,060,000 €	56,122,500 €
11. Paper Products	18,500	50%	9,300	29,242,500 €	14,630,000 €
12. Wood Products	142,695	25%	35,700	149,884,875 €	68,704,125 €
13. Sporting Goods	4,300	35%	1,505	6,245,750 €	3,122,875 €
14. Electronics	247,300	60%	148,400	441,472,500 €	225,067,500 €
15. Complex Objects	2,123,500	60%	1,274,100	3,790,447,500 €	1,932,385,000 €
16. Miscellaneous	96,000	5%	5,100	61,110,000 €	23,047,500 €
Total	**3,411,500**	**47%**	**1,617,000**	**5,324,500,000 €**	**2,545,900,000 €**

Notes:
** From table A2-33, first row.*
[+] No. of companies with notifications duties in the EU28 x (Administration costs per notifying company + (Administration costs per notification + Characterisation costs) x Number of notifications per company
[#] No. of companies with notifications duties in the EU28 x (Number of notifications per company x Recurring administration costs per notification)
Total costs are rounded to the nearest hundred thousand
Characterisation costs are based on an average value = €6,500; Administration costs per notifying company = €2,250; Administration costs per notification = €135
Number of notifications per company = 4
Recurring administration costs per notification = €90
*Implementation costs = Number of companies in the EU28 x (Implementation administrative burden per company with notification duties [Table A2-34] * Share of companies with notification duties) + (1- Share of companies with notification duties) x Implementation administrative burden per company without notification duties [Table A2-34])*
*Annual costs = Number of companies in the EU28 x (Recurring Administrative burden per company with notification duties [Table A2-34] * Share of companies with notification duties) + (1- Share of companies with notification duties) x Recurring administrative burden per company without notification duties [Table A2-34])*

Table A2-36: Total and recurring costs for Option 4 with the exemption of mixtures and articles containing nanomaterials object of research and development				
Product Groups	**Reduction in No. Of companies with notification duties**	**No. of companies with notifications duties in the EU28**	**Implementation costs**	**Annual costs**
1. Substances	4%	1,170	33,684,300 €	421,200 €
2. Cosmetics	2%	1,430	17,564,750 €	5,271,000 €
3. Health Care	2%	2,210	29,240,750 €	8,844,500 €
4. Food & Feed	2%	17,610	247,133,250 €	75,187,000 €
5. Coatings & Inks	2%	26,170	139,863,500 €	28,096,250 €
6. Cleaning & Disinfection	2%	2,160	11,858,000 €	4,606,000 €
7. Tyres & Other Rubber Products	2%	16,270	42,882,000 €	22,835,750 €
8. Plastic Products	2%	51,450	139,833,750 €	73,622,500 €
9. Building & Construction	2%	600	4,025,000 €	1,382,500 €
10. Textiles	2%	20,980	171,619,000 €	55,755,000 €
11. Paper Products	2%	9,120	28,864,500 €	14,409,500 €
12. Wood Products	2%	34,990	148,393,875 €	67,834,375 €
13. Sporting Goods	2%	1,480	6,167,000 €	3,083,500 €
14. Electronics	2%	145,440	435,256,500 €	221,441,500 €
15. Complex Objects	2%	1,248,620	3,736,939,500 €	1,901,172,000 €
16. Miscellaneous	2%	5,000	60,900,000 €	22,925,000 €
Total		**1,584,700**	**5,254,300,000 €**	**2,506,900,000 €**

Table A2-37: Total and recurring costs for Option 4 with the exemption of mixtures and articles containing pigments in nanoform				
Product Groups	**Reduction in No. Of companies with notification duties**	**No. of companies with notifications duties in the EU28**	**Implementation costs**	**Annual costs**
1. Substances	52%	590	16,986,100 €	212,400 €
2. Cosmetics	25%	1,090	16,434,250 €	5,033,000 €
3. Health Care	25%	1,690	27,511,750 €	8,480,500 €
4. Food & Feed	25%	13,470	233,367,750 €	72,289,000 €
5. Coatings & Inks	60%	10,680	69,384,000 €	14,542,500 €
6. Cleaning & Disinfection	25%	1,650	10,876,250 €	4,427,500 €
7. Tyres & Other Rubber Products	0%	16,600	43,575,000 €	23,240,000 €
8. Plastic Products	0%	52,500	142,038,750 €	74,908,750 €
9. Building & Construction	25%	460	3,584,000 €	1,309,000 €
10. Textiles	0%	21,400	172,060,000 €	56,122,500 €
11. Paper Products	0%	9,300	29,242,500 €	14,630,000 €
12. Wood Products	0%	35,700	149,884,875 €	68,704,125 €
13. Sporting Goods	0%	1,510	6,261,500 €	3,130,750 €
14. Electronics	0%	148,400	441,472,500 €	225,067,500 €
15. Complex Objects	0%	1,274,100	3,790,447,500 €	1,932,385,000 €
16. Miscellaneous	0%	5,100	61,110,000 €	23,047,500 €
Total		**1,594,300**	**5,214,300,000 €**	**2,527,600,000 €**

Table A2-38: Total and recurring costs for Option 4 with the exemption of mixtures and articles containing fillers in nanoform				
Product Groups	**Reduction in No. Of companies with notification duties**	**No. of companies with notifications duties in the EU28**	**Implementation costs**	**Annual costs**
1. Substances	3%	1,180	33,972,200 €	424,800 €
2. Cosmetics	35%	950	15,968,750 €	4,935,000 €
3. Health Care	35%	1,470	26,780,250 €	8,326,500 €
4. Food & Feed	35%	11,680	227,416,000 €	71,036,000 €
5. Coatings & Inks	0%	26,700	142,275,000 €	28,560,000 €
6. Cleaning & Disinfection	35%	1,430	10,452,750 €	4,350,500 €
7. Tyres & Other Rubber Products	0%	16,600	43,575,000 €	23,240,000 €
8. Plastic Products	0%	52,500	142,038,750 €	74,908,750 €
9. Building & Construction	0%	610	4,056,500 €	1,387,750 €
10. Textiles	0%	21,400	172,060,000 €	56,122,500 €
11. Paper Products	0%	9,300	29,242,500 €	14,630,000 €
12. Wood Products	0%	35,700	149,884,875 €	68,704,125 €
13. Sporting Goods	0%	1,510	6,261,500 €	3,130,750 €
14. Electronics	0%	148,400	441,472,500 €	225,067,500 €
15. Complex Objects	0%	1,274,100	3,790,447,500 €	1,932,385,000 €
16. Miscellaneous	0%	5,100	61,110,000 €	23,047,500 €
Total		**1,608,700**	**5,297,100,000 €**	**2,540,300,000 €**

Table A2-39: Total and recurring costs for Option 4 with the exemption of mixtures and articles containing pigments and fillers in nanoform				
Product Groups	**Reduction in No. Of companies with notification duties**	**No. of companies with notifications duties in the EU28**	**Implementation costs**	**Annual costs**
1. Substances	55%	550	15,834,500 €	198,000 €
2. Cosmetics	85%	220	13,541,500 €	4,424,000 €
3. Health Care	85%	340	23,023,000 €	7,535,500 €
4. Food & Feed	85%	2,700	197,557,500 €	64,750,000 €
5. Coatings & Inks	85%	4,010	39,035,500 €	8,706,250 €
6. Cleaning & Disinfection	85%	330	8,335,250 €	3,965,500 €
7. Tyres & Other Rubber Products	85%	2,490	13,944,000 €	5,955,250 €
8. Plastic Products	85%	7,880	48,336,750 €	20,249,250 €
9. Building & Construction	85%	100	2,450,000 €	1,120,000 €
10. Textiles	85%	3,210	152,960,500 €	40,206,250 €
11. Paper Products	85%	1,400	12,652,500 €	4,952,500 €
12. Wood Products	85%	5,360	86,170,875 €	31,537,625 €
13. Sporting Goods	85%	230	2,229,500 €	1,114,750 €
14. Electronics	85%	22,260	176,578,500 €	70,546,000 €
15. Complex Objects	75%	318,530	1,783,750,500 €	761,811,750 €
16. Miscellaneous	85%	770	52,017,000 €	17,743,250 €
Total		**370,400**	**2,628,500,000 €**	**1,044,900,000 €**

Table A2-40: Total and recurring costs for Option 4 with the exemption of mixtures and articles containing nanomaterials for which the parental substance has been registered/will be registered under the REACH Regulation				
Product Groups	**Reduction in No. Of companies with notification duties**	**No. of companies with notifications duties in the EU28**	**Implementation costs**	**Annual costs**
1. Substances	65%	430	12,379,700 €	154,800 €
2. Cosmetics	65%	510	14,505,750 €	4,627,000 €
3. Health Care	65%	790	24,519,250 €	7,850,500 €
4. Food & Feed	65%	6,290	209,494,250 €	67,263,000 €
5. Coatings & Inks	65%	9,350	63,332,500 €	13,378,750 €
6. Cleaning & Disinfection	65%	770	9,182,250 €	4,119,500 €
7. Tyres & Other Rubber Products	65%	5,810	20,916,000 €	10,022,250 €
8. Plastic Products	65%	18,380	70,386,750 €	33,111,750 €
9. Building & Construction	65%	220	2,828,000 €	1,183,000 €
10. Textiles	65%	7,490	157,454,500 €	43,951,250 €
11. Paper Products	65%	3,260	16,558,500 €	7,231,000 €
12. Wood Products	65%	12,500	101,164,875 €	40,284,125 €
13. Sporting Goods	65%	530	3,174,500 €	1,587,250 €
14. Electronics	65%	51,940	238,906,500 €	106,904,000 €
15. Complex Objects	65%	445,940	2,051,311,500 €	917,889,000 €
16. Miscellaneous	65%	1,790	54,159,000 €	18,992,750 €
Total		**566,000**	**3,050,300,000 €**	**1,278,600,000 €**

Table A2-41: Total and recurring costs for Option 4 with the exemption of mixtures and articles containing nanomaterials covered by existing registration requirements				
Product Groups	**Reduction in No. Of companies with notification duties**	**No. of companies with notifications duties in the EU28**	**Implementation costs**	**Annual costs**
1. Substances	11%	1,080	31,093,200 €	388,800 €
2. Cosmetics	100%	0	0 €	0 €
3. Health Care	35%	1,470	26,780,250 €	8,326,500 €
4. Food & Feed	100%	0	0 €	0 €
5. Coatings & Inks	0%	26,700	142,275,000 €	28,560,000 €
6. Cleaning & Disinfection	100%	0	0 €	0 €
7. Tyres & Other Rubber Products	0%	16,600	43,575,000 €	23,240,000 €
8. Plastic Products	0%	52,500	142,038,750 €	74,908,750 €
9. Building & Construction	0%	610	4,056,500 €	1,387,750 €
10. Textiles	0%	21,400	172,060,000 €	56,122,500 €
11. Paper Products	0%	9,300	29,242,500 €	14,630,000 €
12. Wood Products	0%	35,700	149,884,875 €	68,704,125 €
13. Sporting Goods	0%	1,510	6,261,500 €	3,130,750 €
14. Electronics	0%	148,400	441,472,500 €	225,067,500 €
15. Complex Objects	0%	1,274,100	3,790,447,500 €	1,932,385,000 €
16. Miscellaneous	0%	5,100	61,110,000 €	23,047,500 €
Total		**1,594,500**	**5,040,300,000 €**	**2,459,900,000 €**
Notes: *For categories covered by other legislation, companies have neither implementation nor annual costs. Product Groups 2, 4, and 6.*				

Table A2-42: Total and recurring costs for Option 4 with the exemption of mixtures and articles containing nanomaterials without intended release				
Product Groups	**Reduction in No. Of companies with notification duties**	**No. of companies with notifications duties in the EU28**	**Implementation costs**	**Annual costs**
1. Substances	0%	1,210	34,835,900 €	435,600 €
2. Cosmetics	0%	1,450	17,631,250 €	5,285,000 €
3. Health Care	25%	1,690	27,511,750 €	8,480,500 €
4. Food & Feed	0%	17,960	69,146,000 €	15,715,000 €
5. Coatings & Inks	0%	26,700	142,275,000 €	28,560,000 €
6. Cleaning & Disinfection	0%	2,200	11,935,000 €	4,620,000 €
7. Tyres & Other Rubber Products	99%	170	446,250 €	238,000 €
8. Plastic Products	99%	530	1,391,250 €	742,000 €
9. Building & Construction	50%	310	3,111,500 €	1,230,250 €
10. Textiles	99%	220	385,000 €	231,000 €
11. Paper Products	99%	100	262,500 €	140,000 €
12. Wood Products	99%	360	945,000 €	504,000 €
13. Sporting Goods	99%	20	70,000 €	35,000 €
14. Electronics	100%	0	0 €	0 €
15. Complex Objects	100%	0	0 €	0 €
16. Miscellaneous	99%	60	157,500 €	84,000 €
Total		**53,000**	**310,200,000 €**	**66,400,000 €**

Notes:
The formula for costs for product groups containing articles do not contain the costs for companies without notification duties (cells highlighted in green). It is assumed that it will be clear to companies in this product group that they do not need to notify and will have no incurred costs. All other product groups use the standard formula.

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