EUROPEAN
COMMISSION

Brussels, 28.4.2017
SWD(2017) 138 final

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

IMPACT ASSESSMENT

Accompanying the document

Commission Implementing Decision

on a Delegation Agreement with the European Chemicals Agency on the European Union Observatory for Nanomaterials and the European Union Chemical Legislation Finder in the framework of the COSME programme

Disclaimer: This report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

{C(2017) 2628 final}

Table of Contents

1 Context

1.1 Definition of Nanomaterials

According to Commission Recommendation 2011/696/EU[1], a nanomaterial is:

> "*A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm.*

Due to their small particle size, some nanomaterials show different mechanical, electrical, optical and other properties than the same material in bigger size. This effect can be used to increase the performance of materials in products or achieve entirely new functions.

Nanomaterials need to be distinguished from the broader term 'nanotechnology', which in addition to nanomaterials refers to other nanostructured materials, including larger materials with surface or internal structures at the nanoscale. A big part of nanotechnology innovation is on such nanostructured materials, e.g. nanoelectronics. However, the health and safety discussion focuses on nanomaterials because the small size of nanoparticles means they can pass membranes and body cells where larger particles cannot. One implication of this is that tests of materials made up of particles in larger size in some cases will not identify hazards of the nanoforms of a substance.

The 2011 Commission Recommendation on the definition of nanomaterial is currently undergoing a review[2]. This may result in a revision of the Commission Recommendation in late 2016. Based on the current analysis and feedback from stakeholders, this review will most likely only concern clarification of details and will not alter the current definition in a way that would lead to substantial differences for this impact assessment[3].

1.2 Uses of nanomaterials and size of the market

Most nanomaterials on the market in terms of volume are commodity materials, some of them having been in widespread use for decades. In 2012, the total annual quantity of nanomaterials on the market at the global level was estimated at around 11 million tonnes, with a market value of roughly 20 billion EUR[4]. This estimate, however, excluded most pigments, cosmetics ingredients and plant protection products. In one way or the other,

---

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

[2] The Joint Research Centre (JRC) performed compiled an extensive amount of information concerning the experience with the definition, including a targeted survey and a stakeholder workshop. It then performed an assessment of the collected information concerning individual elements of the definition. In this context, three reports were published:
a) Compilation of information concerning experience with the definition (EUR 26567 EN)
b) Assessment of collected information concerning the experience with the definition (EUR 26744 EN)
c) Scientific-technical considerations to clarify the definition and to facilitate its implementation (EUR 27240 EN). Links to report accessible from the review webpage: http://ec.europa.eu/environment/chemicals/nanotech/faq/definition_en.htm

[3] The main effect of the possible changes to the definition would be that possible provisions in revised annexes to REACH would apply to a few more or a few lessnanoforms but it would not affect the nature of those provisions and the costs or benefits per affected nanoform.

[4] Communication on the Second Regulatory Review on nanomaterials, COM(2012) 572 final, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012DC0572&from=EN; and Staff Working Paper on Types and Uses of Nanomaterials, including Safety Aspects, SWD(2012) 288 final, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012SC0288&from=EN

nanomaterials are contained in a very large number of manufactured products, certainly reflecting a market value of trillions[5] of euros.

Among the commodity materials, carbon black (e.g. in tyres) and synthetic amorphous silica (used in a wide variety of applications including food additives, paper, plastics, detergents, toothpaste, inks, paints, adhesives, insulation materials in construction etc.) represent by far the largest volume of nanomaterials currently on the market. There are many pigments, cosmetics ingredients and substances used in plant protection products which fulfil the nanomaterial definition. They have been produced and marketed in high volumes[6] and for a long time, without having been intentionally designed as nanomaterials[7].

Some nanomaterials are the subject of intensive and worldwide research and development with a view to creating breakthrough innovations, e.g. in medicine, information technology, energy (e.g. batteries), environment (e.g. water treatment), transport, security, space etc. The benefits of innovation in nanomaterials range from saving lives, enabling new applications or reducing environmental impacts to improving the function of everyday commodity products. A number of different nanoforms[8] may be developed from the same chemical substance by modifying shape, physical or particle-surface characteristics of the substance at nanoscale.

Typical nanomaterials where such nanoforms have been developed include certain carbon allotropes (e.g. carbon nanotubes, fullerenes, graphene), nanotitanium dioxide, nanozinc oxide and nanosilver. Some of those materials have experienced strong growth in the past up to a certain market size. Nevertheless, none of those has so far created major disruptive innovation, as this was predicted in the past. Still, there are nanomaterials such as graphene that are currently under development and are seen as having high innovation potential.

There is a range of available information sources on nanomaterials markets and uses[9], including various market studies, national registries, research projects etc. Nevertheless, this information is incomplete, and not easily accessible to non-experienced users. Part of this information is confidential.

1.3 Hazards and risks of nanomaterials

Nanomaterials may not only have unique technical properties but also their toxicological profile and their interaction with the environment may differ significantly from the same material in bigger particle size. There is a wide range of available scientific studies on effects of nanoparticles[10]. The OECD has produced a number of publications on the properties of selected nanomaterials[11] and is in the process of adjusting existing Test Guidelines and developing new ones as well as specific Guidance Documents.

---

[5] The estimate is based on studies by Lux Rearch referred to in the Second Regulatory Review on Nanomaterials, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52012DC0572. That estimate suggested a market value of 2 trillion € for products containing nanomaterials in 2015. Nevertheless, this number does not reflect the fact that a wide range of pigments are nanomaterials. Due to the widespread use of pigments in products, the likely range of products containing nanomaterials will be substantially higher.

[6] However clearly lower than those of carbon black and silica

[7] In fact, they employ and improve certain manufacturing processes that also lead to particles with size in the nanoscale range.

[8] For the purpose of this impact assessment and the parallel impact assessment for a possible amendment of Annexes to REACH for registration of nanomaterials, a nanoform shall be understood as a form of a substance that fulfils the definition of a nanomaterial.

[9] For an over view see Staff Working Paper on Types and Uses of Nanomaterials, including Safety Aspects, SWD(2012) 288 final, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012SC0288&from=EN

[10] For a critical review of several thousands of publications, see e.g. Harald Krug, Nanosafety Research—Are We on the Right Track?, http://onlinelibrary.wiley.com/doi/10.1002/anie.201403367/abstract

[11] http://www.oecd.org/env/ehs/nanosafety/publications-series-safety-manufactured-nanomaterials.htm

From the existing scientific information, it is clear that nanoparticles may to some extent pass body membranes, enter into blood circulation, reach body organs and cells, and cause impacts in these organs and cells. These impacts seem to be partly reversible, as the body is to a certain degree capable of eliminating nanoparticles but bioaccumulation may not be excluded. Under experimental conditions, the most commonly observed effects of exposure to nanoparticles, particularly following inhalation, are oxidative stress, inflammatory responses and in some cases genotoxic effects[12]. The nature and dimension of these effects suggests significant risks, especially in the context of worker protection, unless appropriate risk management measures are taken. However, beyond this specific context, there are no indications that nanomaterials are on average more or less toxic than other chemicals[13]. There is no evidence of widespread serious and acute human health incidents related to nanomaterials, despite the extensive use of many nanomaterials over decades. This said, for nanomaterials as for other chemicals, the link between them and their effects in human health and the environment is not easy to establish. Data on potential long-term impacts is limited to a few studies only (e.g. on carbon black[14]).

1.4 The EU regulatory framework for the risk assessment and risk management of nanomaterials[15]

The EU regulatory framework for managing the health and environmental risks of nanomaterials is made up of a mixture of requirements to identify and communicate chemical hazards and risks, as well as specific requirements for measures reducing chemical risks.

REACH is the main legal instrument assessing the risks of chemical substances, including their nanoforms, and requiring risk management measures to ensure their safe use[16]. Under REACH, chemical substances on their own, in mixtures or in articles manufactured or imported in the EU, meeting certain conditions (e.g. tonnage levels), must be registered with the European Chemicals Agency (ECHA). Before a substance is manufactured or placed on the EU market, its safe use must be demonstrated in registration dossiers. The registration dossiers of certain substances may be subject to evaluation[17]. Depending on their properties and the level of risks, substances may be subject to authorisation or restriction. REACH applies equally to substances for which all, some or no forms are nanoforms, i.e. nanomaterials.

Many substances exist in different forms (solids, suspensions, powders, nanomaterials, etc.). Under REACH, different forms can be considered within a single registration of a substance.

[12] There is a discussion on the validity of a significant part of the studies. The ongoing NANoREG project, financed under the EU´s 7th Research Framework Program, is currently assessing the regulatory usefulness of past studies and is developing a more reliable scientific framework for nanomaterial testing.

[13] Scientific Committee on Emerging and Newly Identified Health Risks, 'Risk Assessment of Products of Nanotechnologies', 19 January 2009: *"nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not, yet specific nanomaterials and specific uses of these nanomaterials may carry specific health and environmental risks."*

[14] Hodgson, J.T. and Jones, R.D. 1985, A mortality study of carbon black workers employed at five United Kingdom factories between 1947 and 1980, Archives of Environmental Health, vol. 40, pp. 261- 268; Sorahan, T., Hamilton, L., van Tongeren, M., Gardiner, K. and Harrington, J.M. 2001, A cohort mortality study of U.K. carbon black workers, 1951-1996, Am J Ind Med, vol. 39, pp. 158-170; those studies are inconclusive.

[15] Further details on the applicable legal framework are given in Annex 5 to this impact assessment

[16] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R1907:EN:NOT

[17] Either compliance check, i.e. verification of completeness by ECHA or substance evaluation, i.e. verification of scientific and technical content by Member States.

The registrant must always demonstrate safe use and provide adequate information to address all different forms in the registration, including the chemical safety assessment and its conclusions (e.g. through different classifications where appropriate). The information requirements of REACH registration apply to the total tonnage of a substance, including all forms. Beside this general obligation, there is no specific provision to undertake specific tests for each different form, or to spell out the way in which the different forms have been addressed in the registrations, although the REACH dossier structure allows this and the technical advice in the guidance provided by ECHA encourages it.

Although a wide range of commodity nanomaterials has been registered and tested, this has often been done without specific attention being paid to the effects at the nanoscale, as those materials were considered as normal chemical substances and assessed like any other substance. In practice, REACH registration dossiers often contain a variety of different studies, without clear explanation to which forms the information is related, and whether the information is relevant for other forms/nanoforms of the substance.

According to Article 9 of the Regulation on classification, labelling and packaging of substances and mixtures (the "CLP Regulation")[18], hazard classification of substances and mixtures must take 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". This in principle requires taking into account specific hazards of nanoforms. However, as testing is regulated under REACH, and the CLP Regulation on its own does not require testing of substances, this may be done on the basis of available information, which in turn might not be detailed enough to identify hazards specific to particular nanoforms.

Nanomaterials are also subject to a number of provisions in product-specific legislation. This includes the identification of the nanomaterials present in a cosmetic product in the pre-market notifications of cosmetic products to the Cosmetic Product Notification Portal (CPNP). In addition to this general notification, cosmetic products containing nanomaterials other than those used as colorants, UV-filters or preservatives (those must be explicitly authorized) must be notified in the CPNP, including the submission of toxicological and safety data of the nanomaterial, six months prior to marketing. A catalogue of nanomaterials on the EU market, due for publication in 2014, is under preparation and will be soon published after some delay due to numerous inaccurate notifications. The Scientific Committee for Consumer Safety may assess notified nanomaterials and identify relevant conditions to ensure their safe use in cosmetics.

The Biocidal Products Regulation requires specific risk assessments for nanoforms of biocidal substances. The Food Additives Regulation stipulates that a significant change in particle size of a substance requires a new entry in the list of authorised substances or a change in specifications. Other legal instruments such as the legislation for plant protection products and medicinal products have general authorisation requirements for the products within their scope, including nanomaterials, however without specific provisions on nanomaterials.

Ingredient lists are required for products for which the composition is most relevant for consumers. Labelling requirements in the form of '(nano)' after the substance name in the ingredient list are currently applied for cosmetics, food and biocides. The information '(nano)' is provided in a similar way as for other ingredients, thus not suggesting a specific difference from other ingredients. This form of labelling was in general supported by the Second Regulatory Review on Nanomaterials[19].

[18] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF

Conversely, the Second Regulatory Review did not propose nano-specific labelling requirements for products without ingredient lists because such requirements were considered disproportionate and potentially misleading. This is because such labelling might suggest specific risks even when there is no indication for such risks. As this was conclusively covered in the Second Regulatory Review, the question of product labelling was not further assessed in the present impact assessments.

Further relevant legislation includes worker protection legislation and if found warranted nanomaterials may be the object of specific workers protection provisions under the relevant EU legal instruments[20,21,22]. In the meantime guidance was published[23] on how to apply existing legal provisions to nanomaterials. Without specifically mentioning nanomaterials, 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.

1.5 Two impact assessments on nanomaterials

1.5.1 Scope and purpose of the two impact assessments

This impact assessment concerns transparency measures for nanomaterials on the market.[24] It is closely linked with a parallel impact assessment for a possible amendment of Annexes to REACH for registration of nanomaterials [insert cross-reference].

The overarching objective of the two impact assessments is to contribute to increasing trust in the safe use of nanomaterials (1) by providing transparent information on nanomaterials, their use and their safety, adapted to the needs of target audiences and (2) by improving risk assessment and risk management of nanomaterials through requiring more specific health and environmental information to demonstrate the safe use of nanoforms of substances.

The purpose of the impact assessment on transparency measures is to assess the most adequate way to provide information on markets and uses of nanomaterials and products containing nanomaterials to policy makers, consumers and workers.

The purpose of the impact assessment on REACH Annexes is to assess relevant regulatory options, in particular possible amendments of REACH Annexes, to ensure further clarity on how nanomaterials are addressed and their safety demonstrated in REACH registration dossiers. The scope is limited to measures that can be proposed via Committee procedure[25], i.e. restrained to certain amendments of the REACH Annexes for nanomaterials, as the Commission in the General Report on the REACH Review[26] concluded that "*Some needs for adjustments have been identified, but balanced against the interest of ensuring legislative stability and predictability, the Commission concludes that changes to the enacting terms of REACH will not be proposed*".

[20] Council Directive of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (89/391/EEC), OJ L 183, 29.6.1989, p.1

[21] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC), OJ L 131, 5.5.1998, p.11

[22] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC), (codified version), (Text with EEA relevance), OJ L 158, 30.4.2004, p.50

[23] Find the relevant links at EU-OSHA dedicated website: https://osha.europa.eu/en/themes/nanomaterials

[24] For all procedural aspects of this impact assessment, please refer to Annex 1

[25] In accordance with Article 131 of REACH

[26] General Report on REACH, COM(2013)49 (http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013DC0049&from=EN), p. 13.

1.5.2 The political discussion leading to the two impact assessments

In the late 1990's and early 2000's, nanotechnology and nanomaterials were increasingly seen as a major innovation opportunity[27]. At the same time, concerns arose that nanomaterials may be linked to hazards and risks which were not covered by existing risk assessment practices and regulation. Responding to those concerns, the Commission issued in 2008 a Communication on Regulatory Aspects of Nanomaterials[28], arguing in essence that existing legislation is sufficient to address regulatory concerns on nanomaterials. Following this Communication, the European Parliament issued a Resolution[29] calling on the European Commission, inter alia, to establish a definition of nanomaterials, to review relevant legislation on its applicability to nanomaterials, and to establish an inventory of nanomaterials, including aspects of their safety.

At that stage, nanomaterials were largely perceived as a limited number of innovative substances which so far had been untested, and which may exhibit unpredictable hazard properties and risks to consumers and workers. This perception was fuelled by a diffuse debate on the nature and definition of nanomaterials, and unsuccessful attempts to obtain more information on nanomaterials on the market via voluntary notification schemes, such as those developed in the United Kingdom[30] and Germany. Against this background, there were calls by some Member States and non-governmental organisations to set up mandatory registration schemes to provide information on products containing nanomaterials. In September 2010, following a high-level event on the regulatory framework for nanomaterials, the Belgian Presidency of the Council of the European Union recommended that action should be taken "to develop harmonised compulsory databases of nanomaterials and products containing nanomaterials" and that "such databases must be the base for traceability, market surveillance, gaining knowledge for better risk prevention and for the improvement of the legislative framework".[31] Later on, France, Belgium and Denmark introduced national nanomaterial notification schemes.

During the legislative process leading to the adoption of REACH, specific provisions on nanomaterials had not been included, as too little was known on nanomaterials to take this into account in the already very complex negotiations. However, soon after REACH was adopted, discussions started on its implementation for nanomaterials, and a subgroup of the REACH Competent Authorities expert group ("CASG Nano") was set up.

As a reaction to the Parliament Resolution, the Commission adopted the definition of nanomaterials in 2011[32] and a Communication on the Second Regulatory Review of Nanomaterials in 2012[33]. The Communication concluded that nanomaterials were much more common, widespread and, at least for many of the substances analysed in an attached Staff

[27] See inter alia: Towards a European Strategy for Nanotechnology, COM(2004) 338 final of 12 5 2004; and Nanosciences and nanotechnologies: an action plan for Europe 2005 – 2009; COM(2005) 243 final of 7 6 200.

[28] COM (2008) 366, 17.6.2008; https://ec.europa.eu/research/industrial_technologies/pdf/policy/comm_2008_0366_en.pdf

[29] European Parliament Resolution on Regulatory Aspects of Nanomaterials (2008/2208(INI), 24.4.2009

[30] Department for Environment, Food and Rural Affairs, 'UK Voluntary Reporting Scheme for engineered nanoscale materials', February 2008, http://archive.defra.gov.uk/environment/quality/nanotech/documents/vrs-nanoscale.pdf

[31] Belgian Presidency of the Council of the European Union, 'Conclusions of the High level event "Towards a regulatory framework for nanomaterials' traceability"', 14 September 2010, http://www.health.belgium.be/filestore/19064475_FR/fr_12129319.pdf

[32] Commission Recommendation of 18 October 2011 on the definition of nanomaterial, 2011/696/EU; see Annex 4 for a glossary of definitions

[33] Commission Communication on the Second Regulatory Review on Nanomaterials, COM(2012) 572 final, http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52012DC0572

Working Document[34], not classified as hazardous. The Communication reaffirmed the general applicability of REACH and other existing legislation to nanomaterials. In line with previous scientific opinions[35], it also confirmed that, while risk assessment methodologies were generally applicable to nanomaterials, a case-by-case approach was still warranted to provide the necessary information for different nanomaterials. It recognised that REACH was not clear enough to ensure sufficiently specific information on nanoforms in registration dossiers. As a follow-up and due to the expected significant impacts of the considered changes[36], the Communication on the Review of REACH in 2013 announced an **impact assessment for a possible amendment of Annexes to REACH for registration of nanomaterials**[37].

Concerning the calls for mandatory registration schemes, the Commission did not take a stance but announced an **impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight**. In addition, the Commission launched an online portal with available information on nanomaterials and their uses (the 'JRC Web Platform on Nanomaterials')[38].

1.5.3 Cross-relationship between the two impact assessments

The two impact assessments complement each other and provide responses on how to improve information on nanomaterials in their respective areas, as identified in the Second Regulatory Review. There are however important differences in the type of information concerned, the target audience, the degree and nature of the problem to be addressed, and the potential options that could be used (see Table 1 below).

The impact assessment on the REACH Annexes covers *scientific information necessary to improve risk assessment and risk management of nanomaterials*. This should, for the substances covered by the scope of REACH:

- provide clarity on which nanoforms of the substance are covered by the registration dossier
- identify relevant hazard properties
- show how the safe use of the nanoforms will be ensured
- identify the main use categories in general terms

However, this information will only cover part of the perceived lack of information and it will remain at a technical level that is understandable for specialists only. Its scope is limited to actions that can be undertaken by adaptations to technical and scientific progress under REACH.

The impact assessment on transparency measures is broader than REACH, and evaluates which information on *nanomaterial markets and uses* is needed for policy makers, enforcement authorities, consumers and workers. It excludes however scientific and technical information[39], which is assessed as part of the REACH Annex impact assessment. Hence, the outcome of the REACH Annex impact assessment is part of the baseline of the impact assessment on transparency measures. Due to its broad scope, new regulatory provisions on

[34] Staff Working Paper on Types and Uses of Nanomaterials, including Safety Aspects, SWD(2012) 288 final, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012SC0288&from=EN

[35] http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_023.pdf, p. 52 and p. 56.

[36] Review of REACH - Thematic studies - REACH contribution to the development of emerging technologies (http://ec.europa.eu/DocsRoom/documents/11897).

[37] Review of REACH, COM(2013)49, available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013DC0049&from=EN).

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

[39] With some exceptions which are explained in the impact assessment on transparency measures.

this matter would require different legislation, which would need to be adopted under the co-decision procedure.

Table 1: Differences between the impact assessments on REACH Annexes and transparency measures

	REACH Annexes	**Transparency measures**
Scope	Substances subject to REACH	Manufactured nanomaterials in general
Nature of information concerned	Substance properties for hazard and risk assessment and the safe use of nanomaterials	Markets and uses of nanomaterials and products containing nanomaterials[40]
Main target audience	Risk assessment specialists (public authorities, companies, etc.)	Policy makers, enforcement authorities, consumers, workers
Degree of problem	High degree of consensus on the problem as such and the need to address it by a possible amendment of the REACH Annexes	Possible add-on to REACH Annex revision; no consensus on the need for additional market information
Type of procedure required	Comitology (REACH)	Co-decision for the legislative option (beyond the scope and purpose of REACH)

1.6 The specific context of transparency measures for nanomaterials, including nanomaterial registries

In its resolution on the first Commission Regulatory Review of Nanomaterials, the European Parliament called on the 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"*. In addition, it called on the Commission to evaluate the need to review REACH concerning inter alia *"notification requirements for all nanomaterials placed on the market on their own, in preparations or in articles"*.[41] The Commission addressed these requests in the Second Regulatory Review on Nanomaterials,[42] and a detailed analysis of available information was presented in an attached Staff Working Paper on types and uses of nanomaterials, including safety aspects.[43]

The Staff Working Paper on types and uses of nanomaterials covered the most common nanomaterials identified at the time of publication, including their production volumes, the main uses and available safety information, without however mentioning exact products, or even product names. The range of products containing nanomaterials was too big to allow going into such detail. The Staff Working Paper also did not include other nanomaterials, including in particular pigments and other commonly used materials, which were suspected to be nanomaterials at the time but for which no data existed to confirm or dismiss their compliance with the nanomaterial definition. The Staff Working paper used available market

[40] in one option is also linked to safety information from available sources, including REACH dossiers; in others characterisation information will be required, however, there is no self-standing information generation on health and environmental hazards.

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

[42] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 'Second Regulatory Review on Nanomaterials', COM(2012) 572 final, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012DC0572&from=EN

[43] Commission Staff Working Paper, 'Types and uses of nanomaterials, including safety aspects', SWD(2012) 288 final, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0288:FIN:EN:PDF

studies[44], a research project[45] and a German database[46] as the main sources. The Staff Working Paper also gives an overview of available product databases in Appendix 8. These product databases however only cover a very small part of the real market, and many of their entries do not seem to be correct[47]. Therefore, those product databases were of limited usefulness for the Staff Working Paper.

Following the publication of the Second Regulatory Review, the Commission has launched an online portal with available information on nanomaterials and their uses (the 'JRC Web Platform on Nanomaterials').[48] The Web Platform on Nanomaterials links to a range of information sources, and is being updated as part of an ongoing study.

Nevertheless, Austria, Belgium, the Czech Republic, Denmark, France, Italy, Luxemburg, the Netherlands, Spain, Sweden and Croatia have subsequently asked the Commission to "propose legislation on registration or market surveillance of nanomaterials or products containing nanomaterials"[49,50].

At the same time, three Member States have launched initiatives for mandatory national registries for nanomaterials. A French decree established a registry for substances in nanoform, including such substances contained in a mixture without being linked to it and in articles if intentionally released, entered into force in January 2013.[51] In the French system, the notification obligation applies to manufacturers, importers and downstream users. Information to be notified includes the substance identity of the nanomaterial, quantity of the nanomaterial placed on the market, use of the substance and names and contact information of the clients (professional users). The information generated by the French Notification System was evaluated in detail in a study supporting this impact assessment.[52] A Belgian decree on a notification scheme for nanomaterials was adopted on 27 May 2014.[53] The first notifications were due by 1 January 2016 for substances in nanoform. For mixtures containing nanomaterials, the first notifications will be due by 1 January 2017. A Danish order establishing an inventory for nano products for mixtures and articles that contain nanomaterials and are intended for sale to the general public (with a high number of exemptions) was adopted on 13 June 2014.[54] The first notifications were due by June 2015[55].

---

[44] Stefan Schlag, Bala Suresh, Masahiro Yoneyama and Vivien Yang, http://www.sriconsulting.com/SCUP/Public/Reports/NANOT000/; except for carbon black: Chemical Economic Handbook report on carbon black http://www.sriconsulting.com/CEH/Public/Reports/731.3000/; Source: IHS Inc. The use of this content was authorized in advance by IHS. Any further use or redistribution of this content is strictly prohibited a without written permission by IHS. All rights reserved.

[45] http://cordis.europa.eu/project/rcn/87963_en.html

[46] http://nanopartikel.info/en/projects/current-projects/dana-2-0

[47] Many of the product databases use search functions to the term 'nano' but do not verify whether the product indeed contains nanomaterials.

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

[49] Ministry of Infrastructure and the Environment, 'Note on the safety of nanomaterials', 6 July 2012

[50] This was reiterated in a letter from the Austrian, Belgian, Danish, Dutch, French, German, Swedish and Norwegian Ministers of Environment to Commissioners Vella and Bieńkowska on 12 November 2014

[51] Decree no. 2012-232 of 17 February 2012 on the annual declaration on substances at nanoscale in application of article R. 523-4 of the Environment code; Ministerial Order of 6 August 2012 on the content and the conditions for the presentation of the annual declaration on substances at nanoscale, in application of articles R. 523-12 and R. 523-13 of the Environment code.

[52] RPA *et al* (2014) Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market, Evaluation Report for DG Enterprise and Industry, November 2014, Loddon, Norfolk, UK *(henceforth cited as "**Evaluation Report**")*

[53] Evaluation Report, p. 5

[54] Evaluation Report, p. 9

In addition to these proposals, in 2013 Norway mandated the notification of nanomaterials in its Norwegian Product Register, which is the central register for hazardous chemical products in Norway and contains about 25,000 registered products.[56,57] Lastly, in the United Kingdom, the Environment Agency's Chemical Compliance Team has compiled a nanomaterials database for internal use based on voluntary phone interviews with companies (no notification requirement).[58] More details on each of the existing national schemes can be found in the Evaluation Report.[59]

Overall, this has led to a considerable body of information on nanomaterials and products containing nanomaterials. This information however also shows that listing all products containing nanomaterials, all manufacturers, downstream users and distributors of nanomaterials and products containing nanomaterials is an elusive task. Despite all this information, anecdotal evidence indicates that the perception of the nanomaterials, their uses and their risks as new, unknown and potentially very toxic persists in many circles. This perception is clearly not accurate for a wide range of nanomaterials on the market. Providing adequate information on all nanomaterials, including both well-established nanomaterials and new materials engineered at nanoscale, as well as their potential risks, in a relevant level of detail, will be essential to creating trust in the safety of all nanomaterials. The difficulty will be to differentiate between well-established applications and new applications, and to find appropriate and cost-effective ways of identifying relevant information.

Stakeholders' opinions on transparency measures are diverse: non-governmental organisations have called for a "publicly accessible inventory of nanomaterials and consumer products containing nanomaterials […] at European level"[60], 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"[61], while the chemicals industry argues that "additional reporting schemes, whether national or European, beyond existing data requirements, will not improve transparency"[62].

2 Problem definition

2.1 The problem that requires action, its size & its underlying drivers

Policy makers, consumer and environmental organisations and trade unions have expressed concerns that:

- **existing information on nanomaterials on the market is insufficient to allow appropriate risk assessment, risk management and enforcement**

[55] Due to the timing, the results could not be taken into account in the studies supporting this impact assessment but an assessment by the Danish EPA is available on: http://www2.mst.dk/Udgiv/publications/2015/12/978-87-93435-09-4.pdf

[56] Evaluation Report, p. 23

[57] Information online: http://www.miljodirektoratet.no/no/Tema/Kjemikalier/Produktregisteret/The_Product_Register/

[58] Evaluation Report, p. 24

[59] Evaluation Report, pp. 5-37

[60] EEB, CIEL, ClientEarth, ECOS, ANEC, HCWH, BEUC (2014) European NGOs position paper on the Regulation of nanomaterials

[61] 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

[62] 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

- **consumers do not have sufficient access to information on which products contain nanomaterials**
- **workers do not have sufficient access to information to which nanomaterials they are exposed at the workplace**

The starting point of the impact assessment was evaluating whether an EU nanomaterials registry was necessary, and if yes what form it should take. In analysing the above concerns, it became clear that the bottleneck to address those concerns lies in *communicating relevant* information on nanomaterials on the market rather than in a lack of general knowledge on nanomaterials and their applications. In particular, there is a significant amount of information showing that, contrary to common misperceptions, most (though not all) nanomaterials are widespread commodity materials that have been on the market for a long time. There are also no indications that those are more (or less) dangerous than other chemicals, even though this does not exclude specific risks of certain nanomaterials. It is therefore necessary to communicate in a clearer and balanced way to consumers, workers and policy makers what nanomaterials are, in which broad product categories they are commonly used, and what the presence of a specific nanomaterial in a product means in terms of potential risks.

At the outset of the impact assessment, **the establishment of national registration and notification systems for nanomaterials or products containing nanomaterials** was also seen as one of the problems with an EU dimension**, as it was assumed that this would cause internal market fragmentation and hamper trade within the internal market.** This market fragmentation would be mainly due to different obligations for downstream users and differences in exemptions for certain nanomaterials between the established systems in France, Belgium and Denmark.

Like the concerns on lack of information, this hypothesis was further investigated as part of the impact assessment work. Obviously, the co-existence of different national registration schemes may increase the administrative burden for companies operating in different Member States, in particular if those schemes have different scope and requirements. Also, there were strong views from respondents to the public consultation that national registries and notification schemes cause market fragmentation. Nevertheless, there is currently no evidence that the French notification system[63] has indeed led to market fragmentation or has hampered trade within the internal market (for further explanations see section 6.5 under the heading "Internal market and competition"). Moreover, as the markets for products containing nanomaterials are likely to be very similar, a certain divergence in scope and requirements is not necessarily a disadvantage but may lead to complementarity of otherwise rather repetitive information. Therefore, the co-existence of different national registers should not be seen as a major internal market problem, and should in itself not be the reason to justify one of the registry options if not otherwise justified on substance.

2.2 The concerns expressed in the public consultation

As part of the impact assessment, a public consultation was held between 13 May and 5 August 2014. Its results are published on the Commission's website[64] and referred to in the relevant parts of the impact assessment.

The public consultation showed that many authorities are concerned that they have insufficient details on what nanoforms of substances/nanomaterials are on their market, not enabling them to assess what risks are related to those nanoforms/nanomaterials and to

[63] There is no *ex post* information from the Belgian and Danish notification system so far.
[64] http://ec.europa.eu/growth/sectors/chemicals/reach/nanomaterials/index_en.htm

enforce risk management measures on companies.[65] More than 80% of NGOs and citizens responding to the public consultation considered the level of available information on nanomaterials on the market to be insufficient for an adequate response to health and environmental risks and for informed consumer choice. Consumers and their associations have questions on which nanomaterials are in the products consumers buy and what their presence means for their health.[66] NGOs have underlined that EU citizens have the right to know which products contain nanomaterials as well as the right to know about their risks to health and environment and overall level of exposure.[67] Workers and trade unions are concerned that they do not get relevant information on the presence of nanomaterials at the workplace and that workers are not able to protect themselves against risks of nanomaterials. Furthermore, various EU Member States expressed concern that *"current information on nanomaterials is insufficient to identify risks or safe use"*.[68]

Some of those concerns can be addressed through existing information and information that will or may be generated through other existing or planned tools. This includes, inter alia, the information of the Commission Staff Working Document on Types and Uses of Nanomaterials, including Safety Aspects[69]. For risk assessment, risk management and enforcement, much relevant information may be generated through possible amendments of the REACH Annexes. REACH will however not cover substances manufactured/imported in quantities below 1 tonne and will only to a limited extent contain information on downstream users (i.e. companies using nanomaterials in their products). In so far as they trigger notifications, scientific opinions and specific risk assessments, additional information is expected to come from the Cosmetics and Biocides Regulations. For consumers, more information may become available through product ingredient labelling (see section 0). For workers, more information may be generated through better Safety Data Sheets resulting from data generated through possible amendments of the REACH Annexes. Moreover, existing information on the hazards and risks (nanomaterials are not more or less toxic than other chemicals; absence of acute incidents with nanomaterials) needs to be taken into account.

Therefore, the dimension of the problem needs to be put in perspective. It will also be necessary to take into account whether and to what degree additional information on top of the sources mentioned above may indeed contribute to resolving the problem, and what the most efficient ways to gather, use and communicate this information will be. Notably, it should be considered whether and what key information for the purpose of risk assessment and risk management remains lacking that could be generated through transparency measures. Furthermore, in terms of information for consumers and workers, it should be considered to what degree there is a need (and an interest) for consumers and workers to get more information on nanomaterials in products on top of the existing labelling and safety data sheet

[65] RPA *et al* (2014) Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market, Options Assessment Report for DG Internal Market, Industry, Entrepreneurship and SMEs, November 2014, Loddon, Norfolk, UK *(henceforth cited as "**Options Assessment Report**")*, pp. 106-107

[66] According to the NanOpinion study, only one fifth of consumers in our study had never heard of nanotechnology. Nevertheless, less than half of the respondents could answer more than half of five questions on a nanotechnology knowledge quiz correctly. Therefore, the level of knowledge among consumers remains low. Furthermore, according to the study, Europeans generally do not feel sufficiently informed. See Nanotechnologies, a Subject for Public Debate, Policy Recommendations on Public Engagement (2015), online: http://results.nanopinion.eu/download/nanopinion_booklet.pdf

[67] EEB, CIEL, ClientEarth, ECOS, ANEC, HCWH, BEUC (2014) European NGOs position paper on the Regulation of nanomaterials

[68] Letter from the Austrian, Belgian, Danish, Dutch, French, German, Swedish and Norwegian Ministers of Environment to Commissioners Vella and Bieńkowska on 12 November 2014

[69] E.g. Commission Staff Working Paper, 'Types and uses of nanomaterials, including safety aspects', SWD(2012) 288 final, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0288:FIN:EN:PDF

obligations, what type of information is needed and how this information can be best communicated to consumers and workers. These considerations played an important role in determining the most appropriate and proportionate instrument to increase transparency on nanomaterials on the market.

2.3 Who is affected, in what ways and to what extent?

Public authorities may face limitations of information on nanomaterials on the market that may to an extent be relevant for decisions on the risk management of certain substances to prevent health and environmental damage, or their enforcement. Downstream user industries and workers may not be aware that they deal with nanomaterials and therefore may take suboptimal decisions on risk management measures in the working environment. Consumers and workers may, in so far as they are interested in information on nanomaterials, feel that they do not have sufficient information on nanomaterials and their specific risks as well as the products containing nanomaterials, preventing them from making informed choices on such products or assess the adequacy of risk management measures in their work environment. Although only a small part of consumers and workers are actively seeking information on nanomaterials, they are part of the target audience. On the one hand, those consumers and workers who are interested should be provided with relevant information in an objective and understandable way. On the other hand, information clarifying the implications for consumers and workers will also enable policy makers and stakeholder organisations to better assess the adequacy of policy responses to nanomaterials.

2.4 What is the EU dimension of the problem?

Nanomaterials and products containing nanomaterials are traded by companies and used by workers and consumers throughout the EU. Harmonised requirements for the hazard and risk assessment and risk management of chemicals have already been introduced by the REACH and CLP Regulations, as well as product-specific EU legislation.

As explained in section 2.1, concerns about internal market effects of national registries have been at the origin of calls for an EU registry on nanomaterials. Although there are no elements that would prove that such registries indeed create barriers to trade, gathering, evaluating and communicating information in a non-coordinated way at national and regional level will certainly create duplications. This will be less efficient than co-ordinated action at all levels with a tool at EU level to increase information flow and harness synergies in gathering, evaluating and communicating information.

2.5 How would the problem evolve, all things being equal?

In the absence of new measures on the transparency of nanomaterials, additional information will come from a number of existing or planned tools. This would be less systematic than under the policy options 1 to 4 analysed below but would nevertheless complement and further improve the overview given in the Staff Working Paper on Nanomaterial Types and Uses[70] and existing information sources such as the JRC Web Platform on Nanomaterials[71].

For **risk assessment**, the REACH and CLP Regulations on chemicals and product-specific legislation such as the Cosmetics Regulation will create a large part of the needed information. The REACH Regulation has already introduced harmonised information requirements for chemicals, including nanomaterials, and requires manufacturers to ensure the safe use of all chemicals. CLP requires classification and labelling, including notification of

[70] Commission Staff Working Paper, 'Types and uses of nanomaterials, including safety aspects', SWD(2012) 288 final

[71] The web platform is a website acting as a single-entry point to categorised web links with information relevant to nanomaterials. It can be accessed at: https://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials.

hazardous substances to ECHA (please refer to Annex 5 for a full overview of current legislative requirements). Nevertheless, there is currently a lack of clarity on which information concerns nanomaterials, as there are no requirements to indicate whether a dossier concerns a nanomaterial or not. Options to remedy these shortcomings are being assessed in a parallel impact assessment on possible amendments to the REACH Annexes.

The French Notification System (FNS) required manufacturers and downstream users for the first time to identify whether their material is a nanomaterial. It appeared that a majority of substances notified under the FNS is already subject to REACH registration: in 2013, 159 out of 258 substances notified under the FNS (62%) were registered under REACH[72]; in 2014, this concerned 171 out of 287 substances (60%)[73]. Moreover, there are clear indications that the vast majority of nanomaterials covered by the scope of REACH and the FNS will be registered by 2018 as there will be at least one manufacturer in the EU that manufactures them in quantities exceeding one tonne.

Therefore, if the REACH Annex review introduces a requirement to identify nanomaterials and to provide relevant information for nanoforms of a substance, much of the relevant information for the purpose of risk assessment will become available in this way. Although REACH provides information on uses according to the same codes as the FNS, REACH however does not require notification of nanomaterials at the level of individual downstream users, except where the uses of hazardous nanomaterials are not covered by the registration dossier of the manufacturer/importer.

For cosmetics, there is also a requirement to notify such ingredients to a central database, the Cosmetics Notification Portal (CPNP). 6% of FNS notifications concerned nanomaterials used in cosmetics[74].

For **consumer information**, interested consumers will be able to benefit from product labelling for cosmetics, food and biocides, which was recently introduced. There are also a number of other existing information sources that can be used to obtain information on nanomaterials. Some of those sources (especially product databases[75] which typically pick out single products from a mass of products containing nanomaterials and often also include products not containing nanomaterials) may be, despite the provided disclaimers, highly misleading. Moreover, there is a lack of reliable and understandable information on what the presence of nanomaterials means for them.

For **worker protection**, companies and workers will have to rely on information from REACH dossiers, safety data sheets and the application of worker protection legislation to optimise risk management measures (possibly benefiting from improved information resulting from the REACH Annex review).

For **policy makers**, there is a risk that, in the absence of clearer and more understandable information on nanomaterials, some common misunderstandings on nanomaterials (e.g. the view that nanomaterials are new or more dangerous than other chemicals) might continue to prevail in the policy discussion. This could hinder trust in nanomaterials and take-up of innovative applications. Policy makers might also see the need to further expand potentially divergent national or local responses.

For **companies trading nanomaterials** or products containing nanomaterials in several Member States, the co-existence of several national notification schemes may to an extent create additional administrative burden and duplication.

[72] Evaluation Report, Table 6-5
[73] Options Assessment Report, Table 3-4
[74] Evaluation Report, Table 3-4
[75] For examples, see Staff Working Paper on Nanomaterial Types and Uses, Appendix 8, section 2, p. 95-103.

For the moment, **national notification schemes** have been decided in three Member States. It cannot be excluded that further Member States will follow, but so far only one additional Member State is concretely considering whether a mandatory notification scheme should be introduced at national level.[76]

In this context, it is relevant to highlight that the existence of national notification schemes is not necessarily an internal market barrier, even if they may be incoherent and generate additional administrative burden to companies. This question was investigated by the Commission during the analysis of the notifications of the draft national schemes before their adoption, in the framework of notification of technical standards under Directive 98/34/EC. The Commission concluded that the requirements as e.g. specified in the French notification system do not constitute a relevant internal market barrier, in particular if the information requirement is not a pre-marketing condition for the products. Also, there is no evidence so far that the French notification system had a significant impact on trade flows between France and the other EU Member States.

On the other hand, as the markets for most products containing nanomaterials are rather homogenous, it should also be taken into account that information gathered at national level will largely be representative for the EU market as a whole and can be used also for policy purposes in other Member States. In the same line of thought, differences in national notification requirements should not only be seen as creating additional administrative burden but may also generate synergies by providing complementary information rather than duplicating efforts.

Finally, even in the absence of new legislation further information may become available from non-legislative instruments (e.g. UK voluntary industry surveys, Wissensplattform Nanomaterialien[77] etc.) and new market studies.

3 EU right to act

TFEU Article 169 stipulates that *"in order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests."* Furthermore, TFEU Article 191 foresees that EU policy contributes to preserving, protecting and improving the quality of the environment and protecting human health.

National notification and registration schemes for nanomaterials may impose divergent obligations. While the data requirements in the French, Belgian and Danish notification schemes are to an extent similar, there are significant differences concerning the trigger for a notification (per substance or per application) and the list of exemptions. Although those national measures so far have not led to noticeable impacts on the free flow of goods within the internal market, future possible legislation, especially if containing substantially higher obligations than current schemes, could at least in principle be relevant for the internal market. Article 26 (1) of the Treaty on the Functioning of the European Union (TFEU) foresees that "the Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market". Moreover, Article 114 requires that in the proposals for these measures the Commission ensures a high level of health, safety, environmental protection and consumer protection, "taking account in particular of any new development

[76] The Swedish Chemicals Agency is currently investigating possibilities for establishing a registry for nanomaterials in products, http://www.esv.se/Verktyg--stod/Statsliggaren/Regleringsbrev/?RBID=16493

[77] http://nanopartikel.info/cm

based on scientific facts". Harmonised requirements for chemicals have already been introduced by the REACH and CLP Regulations.

It should also be noted that the impact assessment itself assesses the option of leaving action to the national level.

4 Objectives

The overall objective of the impact assessment is to identify the best way to inform consumers, workers and policy makers on nanomaterials, their uses and their risks. The information to be gathered and communicated should objectivise the debate on nanomaterials and contribute to an adequate response to human health and environmental risks, consumer and worker protection, competitiveness and innovation, avoidance of undue internal market barriers and limiting costs and administrative burden of potential instruments to what is necessary and justified by corresponding benefits.

That objective thus goes beyond gathering the necessary safety information on nanoforms of substances to ensure their safe use, which is a matter for the parallel impact assessment on the REACH Annexes, for the substances manufactured or imported in volumes above 1 tonne annually and registered under REACH. However, REACH dossiers are used as one of the relevant information sources, along with many others, such as market studies, research projects, scientific studies outside the REACH dossiers, etc. In order to inform the public debate, this scientifically and technically complex information needs to be communicated in a clear and understandable way. Information on nanomaterial uses may also support risk assessment by improving understanding of exposure patterns (nevertheless to a limited degree, as shown in the impact assessment).

Table 1: Policy objectives

General policy objectives	**Specific policy objectives**
Protection of human health and the environment; consumer and worker protection in relation to nanomaterials on the market	On the basis of REACH registration dossiers and other relevant information, 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 interested consumers with relevant information on products containing nanomaterials on the market and hence contribute to consumer trust Better inform the public policy debate and facilitate responsible uptake of nanotechnology by providing objective and relevant information on nanomaterials and their uses in a clear and understandable way
Competitiveness and innovation of businesses marketing nanomaterials; level-playing field within the internal market	Proportionality of information requirements, associated costs and administrative burden Protect confidential business information Where relevant, avoid trade barriers within the internal market Build trust in nanomaterials and their applications

5 Policy options

The following policy options will be considered in the assessment:

0. Baseline scenario
1. Recommendation to Member States on national measures (a "best practice model" based on elements of national systems) (soft law approach)
2. Structured approach to collect and present 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/product (maximum scenario, including mixtures and articles containing nanomaterials without intended release)

For options 3 and 4, a number of variants, taking into account specific substances, mixtures or articles, shall be considered (see below). Some policy options may be combined (see below).

0. Baseline scenario

The baseline option consists of the existing EU legislative framework for nanomaterials and non-legislative tools, such as the JRC Web Platform and other information sources on nanomaterials, their markets and risks. The EU legislative framework includes the existing labelling requirements, the general registration and notification duties under the REACH and CLP Regulations and specific notification obligations for nanomaterials under the Cosmetics legislation (for more details see section 2.5 and Annex 5). Together, these sources already contain a certain level of information providing transparency on nanomaterials on the market, though not necessarily well structured, complete or easily understandable for the non-specialised reader.

As explained in section 1.5.3, it is also assumed that any measures clarifying REACH registration duties will be taken, subject to the outcome of the parallel impact assessment on the REACH Annexes. The contribution of possible measures under REACH would be to improve the information base on risk assessment and risk management but would not address market and use information, as well as the need to structure and communicate the information in an easily understandable way.

Therefore, the baselines of the two impact assessments are largely independent. The only exception is characterisation costs for nanomaterials which are covered by REACH registration obligations. Characterisation data are necessary to describe the exact identity of the registered nanomaterials, both for the registry options (1, 3, and 4) of this impact assessment and for requirements assessed under the REACH Annex impact assessment. Where not available, characterisation costs are a significant part of costs to prepare notifications/registrations. Depending on the scenario and exact purpose of characterisation, the impact assessment on REACH Annexes assumes those costs to be between 2000 and 24000 €[78]. This impact assessment assumes that for nanomaterials subject to REACH registration, characterisation will be available as a result of the envisaged amendments to the REACH Annexes and thus those characterisation costs are considered part of the baseline of the transparency impact assessment. For nanomaterials not subject to REACH registration (low tonnage, substances exempted from REACH), characterisation costs between 3000 and 10000 €[79] are taken into account in the registry options (1, 3 and 4) of the transparency impact

[78] See impact assessment on REACH Annexes, appendix XII, p. 132-133 [check page number in final version]
[79] See also more detailed considerations in section 6.5, p. 32-33 [check page number in final version]

assessment. Therefore, those characterisation costs are part of the baseline of this impact assessment. Should, for whatever reason, the REACH Annexes not be revised, additional characterisation costs would have to be added to the costs of options 1, 3 and 4[80], as they would not be available under the baseline.

Given the recent establishment of national registries for nanomaterials in a number of Member States, a baseline analysis would not be complete without considering the current French, Belgian and Danish notification systems. On the one hand, the existence of national schemes allowed extrapolating known costs and benefits associated with the existing schemes (in particular the French notification scheme for option 3) or estimating costs and benefits based on the impact assessments carried out for those schemes (in particular for the Belgian and Danish notification schemes), to assess impacts of a possible European system. On the other hand, this also required deducting both the costs and the benefits of the existing national systems wherever national schemes would overlap with a possible future EU measure. In particular with respect to the Belgian and Danish schemes, this however involves uncertainties, as there were no ex-post data available at the time of the assessment.

While more Member States may decide to establish a national registry, these decisions remain uncertain and cannot be taken into account in the baseline scenario. The expected evolution of the baseline is further described in Section 2.5.

1. **Recommendation on how to implement a "best practice model" for Member States wishing to establish a national system (soft law approach)**

This option would recommend a particular registry model to be implemented at a national level for those Member States who wish to have one. Based on the analysis of the various schemes, the Commission would identify a best practice model of a registry. Additionally, the recommendation could also cover 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 the EU. At the same time, it would leave Member States the leeway to opt out and/or take their own national approaches.

[80] Characterisation data are less relevant for option 2, as this option does not aim at completing the basic information on nanomaterials on the market but rather aims at improving the overview and communication on nanomaterials, their markets and risks.

2. **Structured approach to collect information ("Nanomaterials Observatory")**

This option proposes to establish a Nanomaterials Observatory that would contribute to increasing transparency on nanomaterials by providing well-structured overview information on nanomaterials, their markets and risks, including tools to present information in a way understandable to the broad public. In particular the Nanomaterials Observatory would be tasked to (a) collect relevant information on nanomaterials on the market, (b) undertake case studies and review questions on nanomaterials of particular importance and/or concern and (c) present targeted information in a clear and user-friendly way to the public online, adapted to the different audiences (general, regulators, consumer/worker organisations, etc.). The existing European Commission Web Platform on Nanotechnology and Nanomaterials[81], hosted by JRC and currently under further development, would be used as a starting point for this initiative.

The Observatory would contain both existing data collected from other information sources such as REACH, existing databases and registries, and, possibly, from curated links available on the Internet, as well as new studies and surveys to be launched by the Observatory.

Compared to a registry, this option would not reach the same level of completeness of information on nanomaterials and products containing nanomaterials on the market. However, it would allow prioritisation on the most relevant information on nanomaterials, making the link to hazard and risk information as well as making available clear and easily understandable information for policy makers, consumers and workers.

This option was supported in the public consultation by most industry stakeholders as well as one trade union organisation.

(a) Collection of data from other information sources

The Nanomaterials Observatory would systematically extract information on nanomaterials, their markets and safety from available information sources, verify it and validate it (e.g. through peer review) and present it in a structured manner, in particular by linking releasable data from the systems mentioned earlier. This could use, inter alia, data already collected through REACH registration dossiers (for substances with nanoforms 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 through national registration or notification systems. It could also build upon examples, such as the nanomaterial registry by RTI International[82] and the Wissensplattform Nanomaterialien.[83] Collaboration (sharing data or interlinking) with other international initiatives may also be sought.

In this way the Nanomaterials Observatory would continue and expand the ongoing work on the JRC web platform. The above information sources as well as the information in REACH registration dossiers would be systematically checked and links to the original information sources provided. A Nanomaterials Observatory will also allow harvesting the results of existing and ongoing scientific studies and research projects[84], by hosting relevant databases,

[81] As described on the JRC website, *"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."*. Online: http://ihcp.jrc.ec.europa.eu/our_databases/web-platform-on-nanomaterials

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

[83] http://nanopartikel.info/cms

[84] In particular of the projects funded under the 7th EU Research Framework Programme and Horizon 2020 (see www.nanosafetycluster.eu)

where feasible updating them, and maintaining the information beyond the end of the research project. This information will be summarized and evaluated with a view to giving a clear and objective picture on hazards, uses and risks of particular nanomaterials and their applications.

(b) Launching new case studies and reviews

The Observatory could complement available information by launching or buying relevant market studies and scientific information analyses (curating data) on nanomaterials. Such studies should allow filling identified knowledge gaps, in any area that is considered to be relevant for the public debate on nanomaterial safety. However, in line with the Nanomaterials Observatory's role of linking data and giving overview information, it will make sense to conceive studies at a meta-level, rather than doing fundamental research. Possible[85] subjects for studies could e.g. cover: analysis of the emerging market on graphene; analysis of producers and uses of nanosilver; sector analysis of uses of nanomaterials; literature analysis of key scientific issues such as bioaccumulation of nanoparticles in cells; etc.

(c) Communication of results to target audiences

Finally, the Nanomaterials Observatory would be tasked with aggregating, evaluating and interpreting the gathered information, and with communicating the results to decision-makers, authorities and the general public in a user-friendly, understandable and targeted way.

Due to its specific experience in managing REACH dossiers and providing communication tools about chemical substances, the European Chemicals Agency is a good candidate to host the Nanomaterials Observatory.

It should be noted that the employed measures under this option do not exclude its coexistence with either of options 1,3 or 4, using registry(ies) as one of the inputs under point a) and optimising b) and c) accordingly.

Sub-option

In addition to new data collected on an EU level, Member States could opt to collect data at national level, similarly to the voluntary industry surveys conducted by the United Kingdom authorities (DEFRA). This could complement the existing information by ensuring regular contact with nanomaterial manufacturers to identify new developments, which could then be fed into the EU Nanomaterials Observatory (provided that it does not concern confidential business information). For calculation purposes, this is considered as a sub-option of option 2, even though there is little doubt that it will make sense to request contributions from Member States in case option 2 is chosen.

3. Regulation creating an EU nanomaterial registry with one annual registration per substance for each manufacturer/importer/downstream user/distributor

Under this option manufacturers and importers will be required to submit relevant substance identity information in line with REACH registration dossiers for any substance with nanoforms the annual production volume of which exceeds a certain threshold, i.e. 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) will need to be submitted by manufacturers and importers of such substances at nanoscale, 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

[85] The subjects mentioned are for illustrative purposes only, and do not represent any concrete plan of launching such studies.

reasonably foreseeable conditions of use, as well as distributers selling such products to professional users (excluding retailers). This would contribute to transparency by collecting complete information on nanomaterial manufacturing and use within the scope of the registry. This information would be available for authorities, could be communicated in summary form to consumers and citizens, and would help to raise awareness among downstream users of nanomaterials. For simplicity of scenario definition, this option follows the choices made in the French notification scheme. Nevertheless, several parameters could be modified in case the option is chosen as preferred option.

This option would provide a relatively complete set of information on nanomaterials on the EU market, and, to a certain extent, information on the uses in products along part of the supply chain. It would require downstream user companies to identify whether they deal with nanomaterials and may therefore lead to awareness raising and possibly better risk management measures. Data analysis and communication are limited to summarising and presenting a statistical analysis of the registration results.

Information requirements as compared to the baseline scenario

A notification dossier would contain 49 entries, divided in 6 categories as it is the case for the French notification system: identity of the notifier, information on the notification, substance identity, quantities, uses and users. The requirements would vary for each of the duty holders:

- **Manufacturers and importers** would need to submit 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.

As outlined in section 2.5, the majority of substances will also be subject to REACH registration or CPNP notification requirements and thus apply in addition to the existing requirements (option 0: baseline).

Compared to the existing REACH requirements, this option would expand obligations in three dimensions:

Firstly, it would impose additional information requirements for all duty holders, including additional information on the notifier (role in the supply chain, business sector, public research organisation), on the notification (NACE code of clients/professional users, R&D status, NACE code for R&D activities, national defence interest), substance identity (state of the mixture, crystalline state and other information which could contribute to better distinction of nanoforms in risk assessment), distribution quantities, commercial names of mixtures and materials and user (client) information. [86] As requirements for substance characterisation are assessed in the impact assessment on the REACH Annexes, those are considered to be part of the baseline, and only considered as additional in so far as they concern nanomaterials which are not covered by REACH registration requirements[87].

[86] Options Assessment Report, Table 8-4
[87] See explanations given in section 0, baseline scenario

Secondly, option 3 would apply to substances that are not yet covered by the existing requirements, e.g. substances with nanoforms manufactured at volumes higher than 100 grams but below thresholds under the REACH Regulation.

Thirdly, it would apply to additional duty holders. The REACH registration requirements apply mainly to manufacturers and importers. Option 3 would expand the obligation to downstream users, including distributors. In the FNS, manufacturers and importers only make up a minority of the notifiers (29% in 2013[88] and only 15% in 2014[89]). Furthermore, it should be noted that the importers counted above also include importers of mixtures or articles containing nanomaterials, which are not usually subject to REACH registration duties.

The requirements of option 3 overlap to a large extent with requirements under the Cosmetic Products Notification Portal (CPNP). Only a few percent of nanomaterials that would be covered by option 3 are however subject to the CPNP requirements.

This option is a possible variation of an EU registry on nanomaterials that was called for by a number of Member States and representatives of the European Parliament (for details see section 1). It is in principle also supported by environmental organisations and one trade union association, although they expressed preference for option 4.

Sub-options

For option 3, exemptions for the following categories of nanomaterials have been assessed. These take into account the exemptions in existing notification schemes, as well as the outcome of discussions of in the sub-group of competent authorities on REACH and CLP (CASG Nano) (see Annex 1).

- Nanomaterials only used in scientific research and development or in product and process oriented research and development
- Nanomaterials only used as pigments and dyes
- Nanomaterials only used as fillers
- Nanomaterials for which the parental substance has been registered or will be registered under REACH
- Nanomaterials in mixtures or articles covered by existing registration requirements (cosmetics, medicinal products, plant protection products, biocides and food additives)

4. Regulation creating an EU nanomaterial registry with one annual registration per use/product (including substances, mixtures and articles)

This option is the most ambitious one. It is based on the combined Belgian and Danish registries, but has a broader scope. While the information requirements are similar to option 3, the annual registration is not made per manufacturer/importer/downstream user/distributor but per product (nanomaterial used on its own, or in a mixture or article). The scope is also wider as it also covers articles without intended release and it applies additionally to retailers. This option would require downstream users to submit a new declaration for each new nanomaterial-containing mixture or article that they put on the market. The approach would allow for full traceability of a nanomaterial across the supply chain.

Compared to option 3, this option would provide a similar contribution to transparency on nanomaterials, with a more complete set of information of nanomaterials and products containing nanomaterials on the EU market. It would allow individual consumer products to

[88] Evaluation Report, Table 3-1
[89] Anses (2014) Figure 3, p. 21

be identified but would not be directly accessible to consumers for confidentiality reasons. Otherwise it would be similar to option 3.

This option is a possible variation of an EU registry on nanomaterials that was called for by a number of Member States and representatives of the European Parliament (for details see section 1). Whereas Member States mostly would not include articles without intended release and possibly exempt some materials, environmental organisations and one trade union association have expressed preference for full coverage of all articles, including those without intended release. This is why this option was assessed, although the Commission services had doubts on its practicality from the outset of the work.

Sub-options

For option 4 the exemptions have been assessed. The last exemption apart, these are the same as for option 3 and take into account the exemptions in existing notification schemes, as well as the outcome of discussions of in the sub-group of competent authorities on REACH and CLP (CASG Nano) (see Annex 1).

- Nanomaterials only used in scientific research and development or in product and process oriented research and development
- Mixtures and articles containing pigments and dyes
- Mixtures and articles containing fillers
- Mixtures and articles containing nanomaterials that have been registered or will be registered under REACH
- Mixtures and articles covered by other regulations (cosmetics, medicinal products, plant protection products, biocides and food additives)
- Mixtures and articles without intended release

6 Analysis of impacts

6.1 Descriptions of impacts and their corresponding assessment criteria

Based on the hypotheses on the problem definition and the policy objectives identified above, a number of criteria have been identified to assess the impacts of the policy options. These criteria cover economic, social and environmental impacts. They have been selected from among the key questions listed in the Impact Assessment Guidelines, as well as from additional criteria in line with the policy objectives (e.g. protection of confidential business information).

Transparency measures for nanomaterials on the market can have significant economic effects in different areas. The most relevant areas, in which economic impacts will be considered, are internal market and competition, specific sectors, operating costs of businesses and administrative burden, public authorities, innovation and research, and consumers. Social impacts will occur through public health and safety issues for workers and consumers; governance, participation and good administration. Lastly, environmental impacts are relevant with regard to environmental consequences for firms and consumers. The specific criteria in each of these areas are listed below.

A special emphasis will be given to the impacts on SMEs.

Cost and administrative burden

- **Criterion 1**: Will the option impose costs (e.g. compliance costs) and administrative burden on businesses?
- **Criterion 2**: Does the option have significant effects on certain sectors?
- **Criterion 3**: Does the option have budgetary consequences for public authorities?

Public health and safety and the environment

- **Criterion 4**: Does the option allow authorities to respond more effectively to potential health or environmental risks? Does this decrease the likelihood of health risks due to substances harmful to health or the environment?

Worker safety

- **Criterion 5**: Does the option affect workers' health and safety?

Governance and enabling consumers

- **Criterion 6**: Does the option make the public better informed about a particular issue? Does the option affect consumer trust in products containing nanomaterials?

Internal market & competition

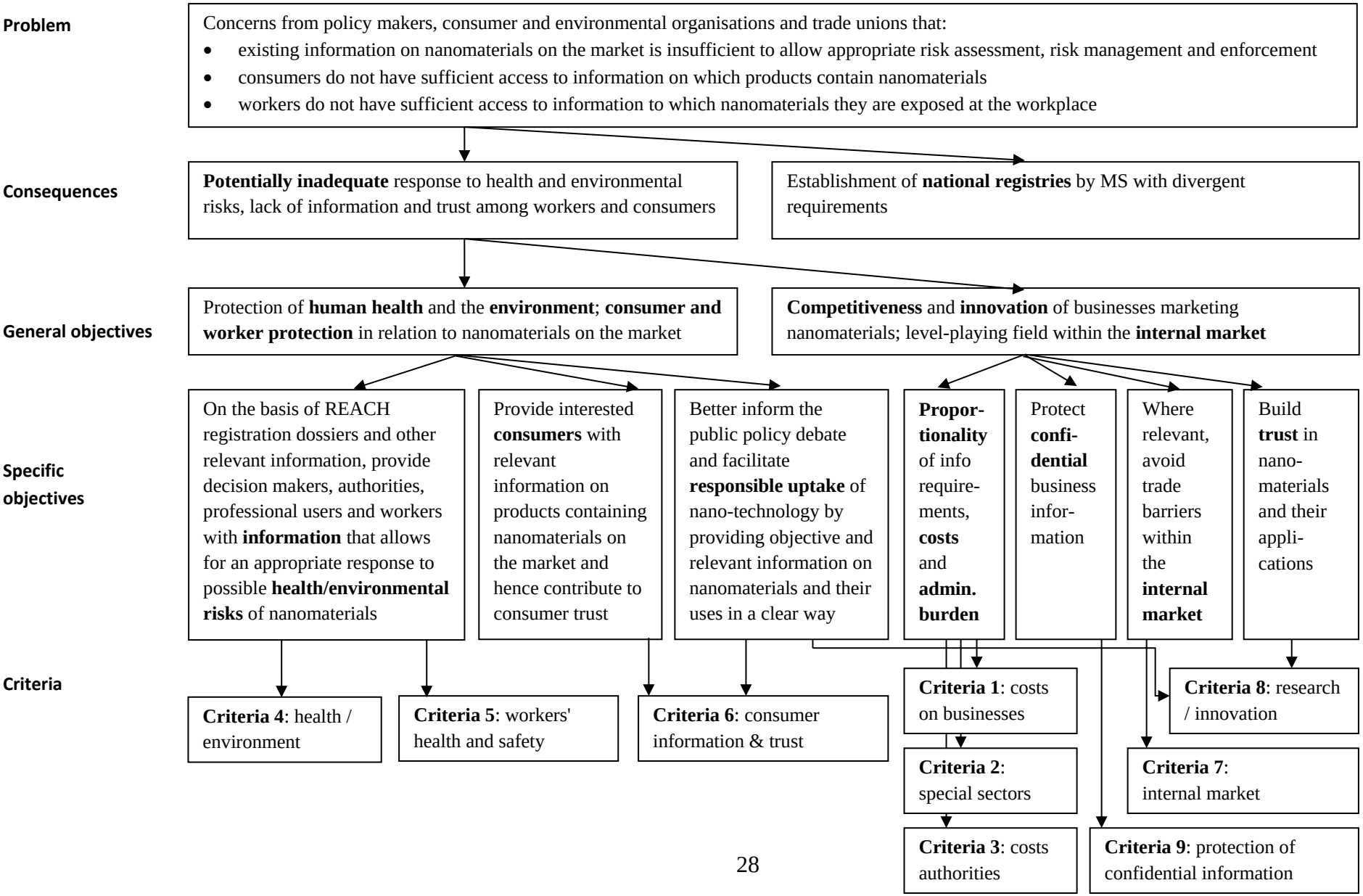
- **Criterion 7**: What impact does the option have on the free movement of goods, i.e. nanomaterials and products containing nanomaterials?

Innovation & research

- **Criterion 8**: Does the option stimulate or hinder R&D and innovation?
- **Criterion 9**: Does the option affect the protection of confidential business information (CBI)?

The problem tree below demonstrates the links between problems, their consequences, objectives and the corresponding criteria.

Figure 1: Problem tree



6.2 Option 0: Baseline scenario

The baseline scenario comprises the existing EU legislative framework for nanomaterials, as described in Sections 0 and 2.5 (for more detail on the legislative framework, please refer to Annex 5). The expected evolution of the status quo is described in Section 2.5.

6.3 Option 1: Recommendation (soft law)

This option involves a Commission Recommendation to implement a particular registry model at national level, either in line with the French notification scheme (corresponding to Option 3) or similar to a combination of the Danish and Belgian schemes (corresponding to Option 4). In the absence of a registry at EU level, a Commission Recommendation for a particular best practice model could be an alternative preserving part of the synergies of applying the same model in different Member States, while leaving the choice of implementing a registry or not to Member States in the spirit of subsidiarity.

The costs and benefits of this option depend on which of the two options 3 or 4, or which of the additional sub-options that have been identified under those options would be chosen for the recommendation. Moreover, the impacts will also depend on (a) whether Member States with existing notification schemes will abandon them in favour of an EU scheme and (b) whether and how many Member States without an existing notification scheme would introduce a new scheme in line with the Recommendation. For these reasons assumptions will need to be made.

As the main costs will be the similar whether applied at EU or national level, no separate calculations were made for each of the possible models that could be retained in a Commission Recommendation. Nevertheless, there are possible duplications and synergies arising from applying requirements at the level of one Member State, in the same or different way at the level of a number of Member States, or in a harmonised way at EU level.

Therefore, the assessment of option 1 builds on the results of the impact assessment on options 3 (section 6.5) and 4 (section 6.6). It then extrapolates the costs of the scheme to a certain EU level and assesses duplication or synergy effects that might occur as a result of a Commission Recommendation.

The below assessment needs to be read together with the corresponding parts of the assessment of options 3 and 4 (sections 6.5 and 6.6). It will therefore make sense for the reader to first read sections 6.5 and 6.6 and only return to this section thereafter.

Costs and administrative burden

Criterion 1: Will the option impose additional costs (e.g. compliance costs) and administrative burden on businesses?

The costs and administrative burden per notification will be in principle the same whether a notification goes to a national registry or to an EU registry. The total cost will be the sum of the costs of the expected number of notifications in the Member States participating in the registry. Nevertheless, there will be some synergies, especially for the first year of implementation, where the main cost will be linked to characterisation of nanomaterials (where this has not yet been done) and to familiarisation with the new obligations. Companies operating in several Member States can use the data prepared for one Member State to comply with the same requirements in the other Member States implementing the Recommendation. Therefore, the higher the number of participating Member States will be, the lower the relative cost per notification will be. On the other hand, this will be less relevant for the annual costs which are more related to annual collection of data of manufactured/sold

quantities. As the annual data collection is a much larger share of costs under option 4, the synergies and savings from applying the same requirements in different Member States will be much more relevant for option 3 than for option 4.

Criterion 2: Does the option have significant effects on certain sectors?

The relative impacts between different sectors will be the same as under options 3 and 4.

Criterion 3: Does the option have budgetary consequences for public authorities?

The budgetary costs per Member State are likely to be similar as for the French Notification Scheme (implementation costs of 250.000 euros and annual operational costs of 30.000 euros, excluding staff costs).

Furthermore, Member States would face enforcement costs which would be a proportional share of the € 3,3 million estimated for all Member States for a Recommendation of a model under option 3, and a proportional share of the € 160 million estimated for all Member States for a Recommendation of a model under option 4.

Public health and safety and environment

Criterion 4: Does the option allow authorities to respond more effectively to potential health or environmental risks? Does this decrease the likelihood of health risks due to substances harmful to health or the environment?

As outlined for options 3 and 4, a nanomaterial registry will contain information on nanomaterials on the market and their uses but no information on the hazards of nanomaterials as such. Therefore, a nanomaterial registry cannot be used directly as a means to reduce health and environmental risks. Consequently any reduction of health and environmental risks would be rather indirect through the use of information on potential exposure to carry out risk assessment and risk management.

As most nanomaterials are likely to be rather widespread and marketed in most Member States, the value added of gathering the same information in different Member States will however be limited for the purpose of overall risk assessment and the identification whether a particular nanomaterial application has specific risks or not. In this context, it may even be advantageous to use different notification frameworks with different scopes and requirements in different Member States as the information gathered may be complementary and avoid duplication. Therefore, from the perspective of reducing health and environmental risks through overall risk assessment and risk management, a Recommendation for a particular best practice is likely to be counterproductive, or close to neutral at best.

Worker protection

Criterion 5: Does the option affect workers' health and safety?

With regard to improving risk management at company level through raising awareness of companies dealing with nanomaterials (for more explanation see corresponding parts of sections 6.5 and 6.6 on criterion 5), the format of a registry is irrelevant. The same is true for possible benefits related to better enforcement. Therefore, the value added of a Commission Recommendation compared to the baseline scenario will be limited.

Governance and enabling consumers

Criterion 6: Does the option make the public better informed about a particular issue? Does the option affect consumer trust in products containing nanomaterials?

As outlined in corresponding parts of sections 6.5 and 6.6 on criterion 6, the usability of a registry for consumers is limited. This holds true for both national and EU level registries. Consequently, impacts on consumer trust are expected to be neutral.

Internal market and competition

Criterion 7: What impact does the option have on the free movement of goods, i.e. nanomaterials and products containing nanomaterials?

As outlined in corresponding parts of sections 6.5 and 6.6 on criterion 7, there are no indications so far that the French Notification Scheme had an impact on trade within the internal market. Therefore the differences in scope and obligations of national notification schemes do not seem to cause major problems in terms of free movement of goods. Those differences may however create additional administrative burden for companies operating in different Member States and reduce the synergies that could be gained from applying the same obligations in different Member States. In this sense, a Recommendation could have a slightly positive effect on reducing administrative burden for companies operating in several Member States that apply a registry according to the Recommendation.

Innovation and research

Criterion 8: Does the option stimulate or hinder R&D and innovation? *Criterion 9: Does the option affect the protection of confidential business information?*

Compared to the baseline, a recommendation of a best practice model is expected to have a slight positive impact on research and development due to the alignment of existing registries. The impact on confidential business information is expected to be neutral, as confidentiality concerns can be addressed in an appropriate way as described for options 3 and 4.

6.4 Option 2: Nanomaterials Observatory

Cost and administrative burden

Criterion 1: Will the option impose additional costs (e.g. compliance costs) and administrative burden on businesses?

A Nanomaterials Observatory would not involve additional information requirements for companies. In case of the UK Environment Agency Survey, the UK authorities contact companies on a confidential basis and enquire about the manufacture or use of nanomaterials. Collaboration may require some limited resources to respond to the enquiries, yet it can be assumed that the requested information is already readily available in the company. Therefore, this option does not lead to any significant increase in costs or administrative burden on businesses.

Criterion 2: Does the option have significant effects on certain sectors?

As a Nanomaterials Observatory would not lead to any new information requirements, the cost impact on industry is negligible across sectors.

Criterion 3: Does the option have budgetary consequences for public authorities?

This option would *a priori* only generate budget consequences at European level (for additional national contributions see sub-option below). The JRC web platform could form a starting point for the Nanomaterials Observatory. A re-development of the web platform would be needed, broadening its scope and redefining its objectives. This would require further IT activities and is estimated to cost € 335.000 for the first year and € 270.000 for annual maintenance and operating costs, amounting to € 605.000 for the first year.[90]

Table 2: Cost Estimates for the JRC Web Platform (source: Options Assessment Report, p. 31)

Cost estimates for a re-development of the JRC Web Platform		
	One-off costs, first year	**Recurring annual costs**
Maintenance (software, hardware/consumables, energy, bandwidth, security)		≈€23.000
Maintenance (IT staff)		≈€90.000
Operating Commission staff, including overheads		≈€157.000
Total recurring costs		**≈€270.000**
Development hardware and software	≈€15.000	
Development IT staff	≈€320.000	
Total one-off costs	**≈€335.000**	
Total	**≈€605.000 for the first year** **≈€270.000 per annum thereafter**	

In addition to this amount, a budget for specific work on top of this upgrade should be foreseen to undertake specific studies, analysis and communication tools (for example, such work could cover: analysis of the emerging market on graphene; analysis of producers and uses of nanosilver; literature analysis of key scientific issues such as bioaccumulation of nanoparticles in cells; analysis of REACH registration dossiers; development of fact sheets and overviews for citizens and consumers). The exact amount budgeted for such work will depend on further discussions and planning, including also the exploration of synergies with ongoing or planned work under the 7th Framework Programme for Research, Horizon 2020, available market studies etc. However, initially an amount of € 200.000 may be a good starting point, bringing the total budget for the first year to around € 800.000. Recurring costs would exclude IT development costs, but would include additional costs for projects, such as market studies, and are estimated to amount to € 600.000. The European Chemicals Agency (ECHA) has specific experience in analysing data on chemicals, including REACH registration dossiers, and in communicating information on chemicals in a clear and understandable way. Therefore, synergies could be exploited by attributing the task of hosting the Nanomaterials Observatory to ECHA.

The cost estimates are in line with previous experiences with observatories in other sectors: the Observatory for the Construction Sector[91] (including annually updated national reports, fact sheets and analytical reports on key issues, regularly updated web pages directed at interested parties) was budgeted at € 400.000 per year.[92] The European Risk Observatory (ERO), managed by the European Agency for Safety and Health at Work (EU-OSHA) and aimed at gathering and analysing information and communicating it to target audiences, generates annually recurring costs of approximately € 1 million.

Sub-option with surveys at national level

[90] Options Assessment Report, Table 5-2, based on cost estimates provided by the Joint Research Centre

[91] http://ec.europa.eu/easme/en/tender/9/competitiveness-eu-construction-sector-%E2%80%93-observatory

[92] Options Assessment Report, pp. 30-31; European Observatory on Infringements of Intellectual Property Rights Work Programme 2013

This sub-option involves the work of national authorities for the purpose of data collection through voluntary industry surveys (similar to those currently conducted by the UK authorities). This would take place on the basis of an invitation by the Nanomaterial Observatory to contribute on a voluntary basis, on the budget of the concerned Member State. As it is difficult to know which Member States would contribute, it was necessary to make assumptions on participation by Member States, in order to illustrate possible additional costs for national authorities. For this purpose, it was assumed that half of the EU-28 countries would actively participate. Based on information provided by the UK authorities, the associated resource costs (based on a € 45 hourly rate) was estimated at about € 20.000 for the first year, with recurring annual costs of around € 7.000 thereafter per participating MS.[93] Although there would be variations in resources committed by Member State authorities to assist with providing information to the Observatory, this was taken as an average value. Based on those assumptions, the additional cost to Member States would be € 280.000 for the first year with recurring annual costs of approximately € 100.000 thereafter.

Public health and safety and the environment

Criterion 4: Does the option allow authorities to respond more effectively to potential health or environmental risks? Does this decrease the likelihood of health risks due to substances harmful to health or the environment?

Similarly to other proposed transparency measures, the primary purpose of a Nanomaterials Observatory is not to directly decrease risks related to hazardous substances in a nanomaterial form. Rather, an Observatory would collect all relevant information about the presence of nanomaterials on the market, as well as link this information to available hazard and risk information. There is a broad range of data available, yet data is contained in various databases, ranging from national inventories to international market studies, and is not always easily accessible and interpretable to authorities, even if linked through a web portal like the existing one managed by the JRC in its current state. In order to create added value and provide more synthetic and user-friendly information for public authorities, a Nanomaterials Observatory would therefore have to systematically screen, verify and interpret information. Focused market research through phone calls, or through consultancy market studies could complement and deepen this information wherever existing information indicates potential hazards or other particular public interest.

In this way, information in a Nanomaterials Observatory can create a better overview of nanomaterials on the market and identify critical developments that may require further attention and prioritisation by policy makers. The main advantage of an Observatory is that it allows focused and flexible research on particularly relevant subjects. Illustrative examples for possible focused research work could be: analysis of the emerging graphene market; analysis of producers and uses of nanosilver; literature analysis of key scientific issues such as bioaccumulation of nanoparticles in cells; analysis of REACH registration dossiers of substances identified in the French Notification System. The public consultation showed that public authorities also expect the Observatory to be a useful resource of information on research projects (e.g. research under the Seventh Framework Programme[94]).[95]

Like a registry, a Nanomaterials Observatory is however not a focused tool to address risks related to specific nanomaterials. Such risks can be much better identified and managed through risk assessment, registration dossiers, substance evaluation and scientific opinions. Therefore, like a registry, a Nanomaterials Observatory should rather be seen as an accessory

[93] Options Assessment Report, p. 32
[94] http://cordis.europa.eu/nanotechnology/home.html
[95] Options Assessment Report, p. 120

tool, which to an extent can contribute to better risk assessment and management, and thus indirectly contribute to reducing health and environmental risks related to nanomaterials. Contrary to a registry, which will also contain a large amount of information with limited value for policy making, risk assessment and risk management, a Nanomaterials Observatory could focus its attention on particularly relevant information and market developments, and also make a direct link with hazard information. Its main disadvantage is the less systematic approach. This may result in the Observatory missing out certain (emerging) nanomaterials that are not known in relevant literature, that are not captured by existing registries or that could not be identified by studies to gather market data. The likelihood of this happening is a matter of debate (see also section on option 3 on advantages of such an approach).

Worker safety

Criterion 5: Does the option affect workers' health and safety?

Like a registry, this policy option could raise awareness about nanomaterials and thus contribute to better risk management at the workplace. However, the Observatory would not provide full company-specific data as a registry does and, therefore, it would not have the effect of obliging companies to reflect on whether they are dealing with nanomaterials. On the other hand, a Nanomaterials Observatory could be used flexibly to deepen information on issues that have been found to be particularly critical for worker protection. It could also be used to summarise and disseminate recommendations for appropriate risk management measures, e.g. on the basis of the Commission guidelines on nanomaterials and worker safety[96], the ECHA guidance on SDS, information available in the EU-OSHA website[97], etc.

Governance and enabling consumers

Criterion 6: Does the option make the public better informed about a particular issue? Does the option affect consumer trust in products containing nanomaterials?

A Nanomaterials Observatory would present information about nanomaterials on the market in a user-friendly way. This can build on the JRC Web Platform that already provides a single-entry point to categorised web links with information relevant to nanomaterials, and which can be used by consumers to become better informed about the topic. In addition to the current activities of the JRC Web Platform, the Nanomaterials Observatory would synthesise, analyse and evaluate information from existing databases. An Observatory can also be tasked with preparing tailor-made summary information in a language that is understandable for citizens and consumers who do not have specialised knowledge. The public consultation demonstrated that citizens and NGOs, as well as public authorities, would expect the Observatory to have a broad scope, including information on the use of nanomaterials, products containing nanomaterials and on hazards and risks posed by them.[98]

Providing well-researched information in an easily understandable format can create trust among interested consumers. Nevertheless and realistically, even with the best possible explanation, reaching consumers who are not a priori interested in the subject will remain elusive. Therefore, the actual effects on consumer trust might be more indirect, i.e. by fostering a more informed discussion on nanomaterials at policy level, which in turn could lead to increasing the quality of information flowing to the public debate and the media.

Internal market & competition

[96] http://ec.europa.eu/social/main.jsp?catId=716&langId=en
[97] https://osha.europa.eu/en/themes/nanomaterials
[98] Options Assessment Report, p. 119

Criterion 7: What impact does the option have on the free movement of goods, i.e. nanomaterials and products containing nanomaterials?

A Nanomaterials Observatory would be neutral as regards the free movement of goods as it does not impose obligations on companies trading with nanomaterials or products containing nanomaterials.

Innovation and research

Criterion 8: Does the option stimulate or hinder R&D and innovation?

Criterion 9: Does the option affect the protection of confidential business information?

A Nanomaterials Observatory would be mostly neutral towards research and development, although the creation of trust in nanomaterials and their uses may to some extent improve the climate for research, development and innovation in Europe. The Nanomaterials Observatory may also trigger market and safety research on questions it identified as relevant. Although a Nanomaterials Observatory will collect less confidential business information than alternative options, such information will still need to be analysed, where available to the Observatory, with a view to giving non-confidential summaries to the public. It will therefore also be necessary to apply appropriate security measures and procedures to avoid the release of confidential information beyond authorised officials.

6.5 Option 3: EU nanomaterial registry with an annual notification per substance

Costs and administrative burden

Criterion 1: Will the option impose additional costs (e.g. compliance costs) and administrative burden on businesses?

The results of the French notification system suggest that the costs to businesses of a notification dossier according to option 3 will differ largely between the first year of notification and the following years, where normally only an update of the quantities is necessary. Administrative costs are related to the following responsibilities: understanding legal requirements (estimated at €1050 per manufacturer/importer or €875 per distributor), gathering information (€350 per notification), submitting the information (€35 per notification), responding to enquiries (€70 per notification) and adapting product databases (€350 per notification).[99]

There is a substantial discussion on whether characterisation costs (roughly 3.000 to 10.000€ for a full characterisation or 3.000 to 5.000 for a partial characterisation)[100] should be assigned to the registry or whether they should not be assumed as available, be it for product quality reasons, be it for other legislative requirements such as REACH registration. In this context, it is assumed that the envisaged amendment of the REACH Annexes will set the appropriate level of physico-chemical characterisation requirements, and when implemented, lead to the availability of relevant characterisation information. Therefore, characterisation information is considered to be available for substances with nanoforms registered under REACH, as well as those notified to the existing national schemes.[101] Depending on the

[99] Options Assessment Report, p. 52
[100] Evaluation Report, p. 70
[101] Options Assessment Report, pp. 52-53

scenario and exact purpose of characterisation, the impact assessment on REACH Annexes assumes those costs to be between 2000 and 24000 €[102]. This is largely consistent with the numbers used for this impact assessment.

Moreover, the choice of the values also takes into account the following factors:

Some characterisation data seem to be available for product quality reasons for some nanomaterials, in particular for those where the particles in the range between 1 and 100 nm are critical for the product quality. Nevertheless, for a clear majority of substances at nanoscale, the product quality is not linked to the presence of nanoparticles. Rather, for those substances the presence of nanoparticles is an inevitable result of the production process. Therefore, without legal requirements, it is not assumed that the relevant characterisation data for nanomaterials is available for the majority of notifications (RPA assumes this to be the case for 70% of notifications)[103].

When taking into account the availability of characterisation data where required under other pieces of legislation, the remaining characterisation costs are mainly related to low volume substances. Those will therefore have a relatively higher impact per quantity manufactured/imported/used/sold and will affect SMEs to a relatively higher degree.

Finally, it should be taken into account that characterisation costs mainly concern manufacturers and importers rather than users and traders of substances.

The costs for familiarisation and data management could also vary from actor to actor. Measuring number-based particle size distribution to assess compliance with the Commission Recommendation on the nanomaterial definition is often very challenging, and for many materials it is all but straightforward to assess whether they are nanomaterials or not. As most of the concerned companies are unfamiliar with the concept and definition of nanomaterials, there is a high risk of misunderstandings and erroneous notifications (to be 'on the safe side'). There will also be companies assessing their substances, and finally deciding that their materials do not meet the nanomaterial definition. For these reasons, the study assumes that for every 10 substances subject to notification, there is one that results to be outside the definition.[104] All this adds up to familiarisation costs, which might be relatively more important for users and traders of substances who are not necessarily specialists in nanomaterials chemistry. On the other hand, there will be a certain learning curve where companies can use the experience and guidance provided by administration, other companies or their internal knowledge in other branches of the companies.

The public consultation showed that the nanomaterials market is complex: half of industry respondents indicated that they handle more than 1.000 articles containing nanomaterials; 78% of respondents reported having more than 100 customers.[105]

Companies consider the administrative burden of a registry to be significant. When asked to compare the burden posed by the FNS with other pieces of legislation, the notification system ranked second just after the REACH Regulation.[106] 47% of surveyed companies indicate that a part or all of the information required for the FNS needed to be generated for the purpose of the notification. A large proportion of industry stakeholders consider the information

[102] See impact assessment on REACH Annexes, appendix XII, p. 132-133 [check page number in final version]

[103] *"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"*, Evaluation Report, p. 51.

[104] Options Assessment Report, p. 53

[105] Options Assessment Report, pp. 100-101

[106] Evaluation Report, Table 5-11, p. 67

requirements on substance identity (54%) and on users/customers (43%) the most burdensome.[107]

Based on an extrapolation of numbers in the French notification scheme, the number of companies in the EU28 that would be subject to notification duties under this option is estimated at 14.720, with a total of 98.760 expected notifications[108]. Under the above assumptions, the **total cost to the concerned companies in the first year is expected to be between € 60 and 145 million** (please refer to Annex 3 of this report for the key calculation tables and Annex 2 of the Options Assessment Report for a detailed overview of all calculation steps).[109,110]

In the following years, the **annual costs of updating and completing information is estimated at around 3,9 million €** (i.e. an average cost of around € 40 per notification)[111]. This said, experience with the French notification scheme shows that also after the first year many companies discover that the materials they deal with are nanomaterials, while others that notified in the past come to the opposite conclusion.

Sub-options with possible exemptions

Exempting substances only used in scientific research and development or in product and process oriented research and development would reduce the number of notifications by more than a third. However, those notifications will require only limited additional information, since most of these nanomaterials are already characterised for research purposes. Therefore, the first year costs will only be reduced by around 3 million € (roughly 3%) and recurring costs by around € 0,7 million (roughly 18%).[112]

Exempting substances only used as pigments and dyes would reduce first year costs by around € 25-77 million (roughly 50%) and recurring costs by around € 1,3 million (roughly 34%).[113]

Exempting substances only used as fillers would reduce first year costs by around € 8-23 million (roughly 15%) and recurring costs by around € 0,4 million € (roughly 10%).[114]

Exempting nanomaterials for which the parental substance has been registered or will be registered under REACH would reduce first year costs by around € 18 million (roughly 18%) and recurring costs by € 1,6 million (roughly 40%).[115]

Exempting nanomaterials in products covered by existing registration requirements (cosmetics, medicinal products, plant protection products, biocides and food additives) would reduce first year costs by around € 18-21 million (roughly 19%) and recurring costs by € 1,5 million (roughly 39%).[116]

[107] Evaluation Report, Table 5-12, p. 67
[108] Options Assessment Report, Table 6-10, p. 54
[109] See Annex 3, Table A3-2 for further details
[110] Options Assessment Report, Table A2-23, p. 150
[111] Options Assessment Report, Table 6-10, p. 54
[112] Options Assessment Report, p. 56
[113] Options Assessment Report, p. 57; Table 6-14, p. 59
[114] Options Assessment Report, p. 57; Table 6-15, p. 60
[115] Options Assessment Report, p. 58; Table 6-16, p. 61
[116] Options Assessment Report, p. 58; Table 6-17, p. 62

Overview of the costs

Table 3: Cost estimates for all potential exemptions under Option 3

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**

Criterion 2: Does the option have significant effects on certain sectors?

Nanomaterials occur throughout different sectors. Nevertheless, certain sectors would be more affected by notification requirements than others (unless specific exemptions are granted). Out of the 14.720 companies with notification duties, an estimated 3780 would fall into the category "research and experimental development on natural sciences and engineering", followed by 3600 companies in the paints and varnishes sector, 1920 wholesalers of pharmaceutical goods, 1390 wholesalers of chemical products, 990 wholesalers of perfume and cosmetics, and 590 manufacturers of dyes and pigments.[117] Among the product categories, in the French notification system, the highest number of notifications concerns coatings and paints (631), followed by cosmetics (605) and plant protection products (575).[118] Among the end-use sectors, agriculture, forestry and fishery accounts for 58% of total end uses, followed by formulation of preparations (19%).[119] Distributors account for 57% of all notifications, followed by professional users and distributors[120] (24%) and importers (12%). Manufacturers account for only 3%.[121]

As indicated in the description of possible exemptions, roughly 50% of first year costs would be related to pigments and dyes (34% of recurring costs).[122] Other uses with important cost impact concern fillers (15% of first year costs and 10% of recurring costs), cosmetics, medicinal products, plant protection products and biocides and food additives. In all sectors that potentially work with nanomaterials, on average between 5 and 8% of firms are affected. In contrast, in the sector of coatings and inks, between 90 and 95% of firms are estimated to

[117] Options Assessment Report, Table 6-7, p. 45
[118] Options Assessment Report, Table 6-3, p. 39
[119] Options Assessment Report, Table 6-2, p. 38
[120] i.e. actors who are users and distributors at the same time, following the classification used in the FNS.
[121] Evaluation Report, Figure 3-2, p.48; Options Assessment Report, Figure 6-1, p. 42
[122] Options Assessment Report, p. 57; Table 6-14, p. 59

be affected; in rubber products this is between 75 and 90%, while between 60 and 80% of firms in cosmetics and paper products are estimated to be impacted.[123]

Industry respondents of the public consultation indicated that they expect a particularly significant impact on certain sectors: according to them, more than 500,000 mixtures would be affected annually within the paint and printing ink sector in Germany alone. Dental materials and materials in the automotive industry were also cited as specifically affected sectors.[124]

Sub-options with possible exemptions

As research and development would benefit from a relatively simple notification, an exemption of substances only used in scientific *research and development* or in product and process oriented research and development would have a relatively small impact on absolute costs, compared to exemptions for other nanomaterials (cost reduction of 3% in the first year and 18% in recurring costs, see above in the description of possible exemptions)[125] . However, as those lower costs compare to smaller volumes and profits, the impact of exempting research and development may still be substantial for the concerned companies and uses. The beneficiaries of the exemption are more likely to be SMEs and companies in innovative areas.

Exempting substances only used as *pigments and dyes* would significantly reduce the burden for pigments, dyes, paints, varnishes and related sectors, including a wide range of companies using and trading those mixtures.[126]

Exempting substances only used as *fillers* would also lead to significant reductions in many sectors. However, as those are high volume substances this will probably affect rather bigger than smaller companies.[127]

Exempting nanomaterials for which the parental substance has been registered or will be *registered under REACH* would exempt a very wide range of nanomaterials and uses in different sectors. However, the remaining obligations would then disproportionately affect smaller volumes and smaller companies, as well as sectors benefitting from REACH exemptions.

Exempting nanomaterials in products covered by *existing registration requirements* (cosmetics, medicinal products, plant protection products, biocides and food additives) would reduce the burden and partly duplication of information requirements for the concerned sectors.

Criterion 3: Does the option have budgetary consequences for public authorities?

Option 3 would involve the establishment of a nanomaterial registry at an EU level, managed by the European Commission. Costs include administrative costs for running the registry, as well as the acquisition of the necessary hardware or software. The latter involves the in-house development of a database or the licensing of an external database system. In addition, the development and maintenance of an online portal would be included.

[123] UBA (2014) Table 2, p. 71
[124] Options Assessment Report, p. 115
[125] Options Assessment Report, p. 57; Table 6-14, p. 59
[126] Expected reductions of 100% of the notifications for manufacturers of dyes and pigments, 75% for manufacturers of paints, varnishes and similar coatings and 50% for the wholesale of perfume and cosmetics and the wholesale of chemical products (see Options Assessment Report, p.57).
[127] Reduction of 25% of the number of affected companies and notifications among manufacturers of paints, varnishes and similar coatings, printing ink and mastics and for other inorganic basic chemicals (see Options Assessment Report, p. 57)

The FNS led to implementation costs of € 250.000 and annual operational costs of € 30.000, excluding staff costs. The Cosmetic Product Notification Portal (CPNP) is estimated to generate operational costs of € 402.000 per year.[128]

The development costs for an EU registry are estimated to be similar to those of the FNS, i.e. € 250.000. However, due to the large number of notifications, operational costs will be substantially higher in line with the CPNP estimates. Taking into account translation costs, the annually recurring costs are estimated to amount to € 450.000.

Furthermore, Member States would face enforcement costs. Based on the assumptions that 5% of the submitted notifications is verified, this would generate € 2.6 million of enforcement costs.[129] If inspectors test for 5% of the companies whether one of its products contains a nanomaterial, an additional € 750.000 is incurred.

In conclusion, first-year costs for public authorities amount to € 700.000 on an EU level; annual costs amount to € 450.000 on an EU level and € 3,3 million on a national level for enforcement purposes.

Public health and safety and the environment

Criterion 4: Does the option allow authorities to respond more effectively to potential health or environmental risks? Does this decrease the likelihood of health risks due to substances harmful to health or the environment?

A nanomaterial registry, as proposed by option 3, will contain information on nanomaterials on the market and on their uses, including detailed physico-chemical information, but no information on the hazards of nanomaterials. Therefore, it cannot be used directly as a means to reduce health and environmental risks. Rather, the additional information on nanomaterials on the market will in a first step only contribute to better identifying potential exposure situations. This information needs to be combined with relevant hazard information, in order to serve the purpose of assessing likelihood and likely dimension of potential health and environmental benefits through improved risk assessment and risk management.

Additional information on the presence of certain nanomaterials on the market

Experience from the French notification system shows the additional information created by a nanomaterial registry concerns innovative nanomaterials only to a small extent. Rather, the bulk of the additional information relates to materials which have been on the market for a long time, and which companies were forced to assess against the nanomaterial definition for the first time.

In 2014, the French authorities identified 319 different substances that were notified in the FNS.[130] Of these 287 were sufficiently clearly defined to allow further cross-checks by the consultant.[131] The real number of nanomaterial substances on the French and European markets may still be significantly higher, as many companies may still not have checked their materials against the nanomaterial definition.

Around 80% of the substances that were notified to the FNS have EC (EINECS) numbers, indicating that they were already on the market before 1981. More than half of all substances notified to the FNS are only used as pigments and dyes. It is true that the reported materials

[128] Evaluation Report, pp. 50-51
[129] Options Assessment Report, p. 65
[130] Ministère de l'Ecologie, du Developpement durable et de l'Energie (2014) p. 38
[131] Options Assessment Report, Table 6-1, p. 37

could be new nanoforms of previously known substances (in bigger particle size) but information from industry rather suggests that most of those substances are not new developments but have been produced in the same form for decades.

Among the previously known high volume nanomaterials (such as silica, carbon black, carbon nanotubes, titanium dioxide etc.), the reported quantities are roughly in line with previously known information (with some exceptions).

Nanomaterials which are known to be on the cutting edge of innovation such as graphene are partly present (e.g. graphene), partly absent from the results of the French registry (e.g. quantum dots including the substances typically used in quantum dots, dendrimers, fullerenes, many rare earth oxides). The quantities of such innovative nanomaterials reported are low, and below the amounts to be expected on the basis of scientific and market literature. Other known nanomaterials (e.g.) such as nanosilver hardly appear in the results, mainly because they are imported in products from which they are not expected to be released, and thus are not captured by a registry excluding nanomaterials in articles from which they are not released.

In conclusion, a registry will rather serve to assess traditional materials against the nanomaterial definition than to identify truly innovative nanomaterials. Innovative nanomaterials will not be easy to identify among the large number of notifications, and some will not be notified as they are imported in articles without intended release.

The value added of a registry compared to information requirements under REACH and other EU and national legislation

Currently, REACH does not clearly oblige companies to identify whether or not the substances they register are nanomaterials, and whether or not the submitted information relates to a nanoform of the substance. In REACH IT, the central IT system for the submission and processing of registration dossiers and data, there is only a voluntary tick box. So far, only 13 different substances were identified as nanomaterials in this way (though covering a much higher number of individual submissions).

Nevertheless, on the basis of the results from the FNS it is evident that a much higher number of nanomaterials or substances with nanoforms has been registered or will be registered by 2018[132]. The consultant has concluded that 171 substances in the French notification system have already been registered under REACH. This corresponds to 60% of all substances in the French notification system (see Figure 2). 48 further substances are covered by exemptions from REACH registration. This means that according to those data only 68 substances (of which 58 pigments and dyes) are below the current 100 tonnes threshold of REACH registration. This number is likely to further decrease substantially, as there is a high likelihood that many of those substances will have at least one manufacturer or importer in the EU with annual quantities above one tonne per annum.

[132] Date by which the current registration threshold of 100 tonnes per annum will be lowered to 1 tonne per annum

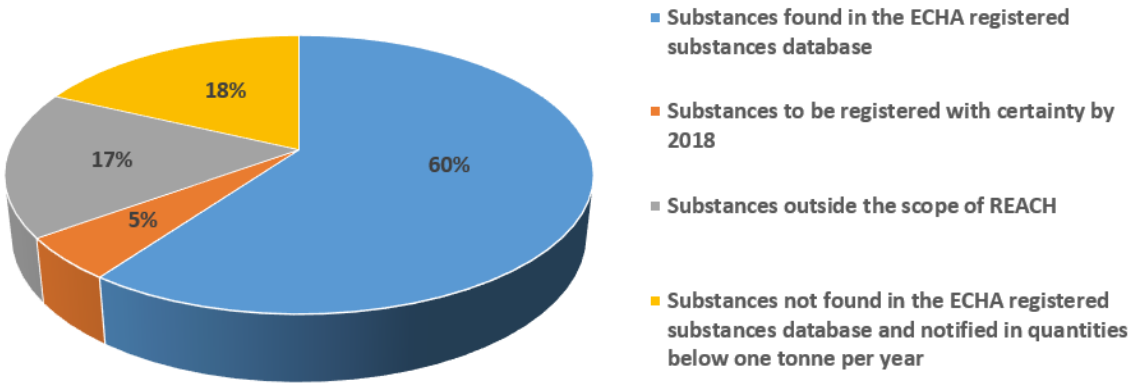


Figure 2: Results of the comparison between the list of substances notified to the FNS in 2014 and the ECHA registered substances database[133]

This means that:

Following the amendment of the REACH Annexes, to the extent requiring such information will be justified in the parallel impact assessment report, a significant amount of additional data on nanomaterials is expected to become available, covering the majority of characterisation data that could be expected from a registry according to option 3.

Only few substances are likely to be under the one tonne threshold. For these substances, additional characterisation data would be generated through a registry.

Nevertheless, it should be taken into account that:

- Many individual companies will still be below the one tonne threshold, thus they will not be subject to a REACH registration obligation but would nevertheless be subject to a registry. In the French notification system, 65,3% of notifications were in quantities below 1 tonne, including notifications from distributers and downstream users.[134] In terms of number of substances, 42,8% of substances were notified with a volume below 1 tonne in 2013; this percentage increased to 50,4% in 2014 (see Table 4 below)[135].

- There may be specific nanoforms of registered substances that are only produced in quantities below one tonne, and thus would not be covered by the registration dossier for the substance.

On top of the additional characterisation information, a registry as proposed under option 3 would also provide additional information on uses of nanomaterials. Nevertheless, REACH IT and the French notification system apply the same use categories. Therefore, a registry is unlikely to provide much more detailed information on uses. However, a registry will provide more information on the actors in the supply chain, which in turn may generate a better understanding of the uses concerned.

Compared to the information already required under the Cosmetics and Biocides Regulation, the additional information for nanomaterials with relevant uses under those Regulations will be relatively limited. In addition information in the context of product labelling under those regulations as well as the Food Information to Consumers Regulation will be much more

[133] Options Assessment Report, p. 20
[134] Ministère de l'Ecologie, du Développement durable et de l'Energie (2014) Table 9, p. 24
[135] Options Assessment Report, p. 18

specific for the uses, and thus much more visible and accessible for consumers than a central database. On the other hand, information from labelling obligations will be less searchable and usable for authorities.

Table 4: Number and percentage of substances in nanoforms per notified quantities to the FNS in 2013 and 2014[136]

Notified quantities	Number of substances 2013	% of the total number of substances 2013	% of the 206 substances w/ reported quantities 2013	Number of substances 2014	% of the total number of substances 2014	% of the 246 substances w/ 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

The link between the additional information and potential health and environmental risks

As mentioned before, a registry considered in option 3 will not generate much specific[137] information on **hazards**[138] of nanomaterials but will be limited to information that can be used to improve knowledge on potential exposure[139] to nanomaterials. In order to allow statements on possible benefits of a registry to reduce health and environmental risks, it is therefore necessary to link information on hazards of nanomaterials with information on potential exposure. Hazard information can be either taken from existing sources (e.g. in REACH registration dossiers, scientific opinions, scientific literature outside legal frameworks) or generated in separate processes (e.g. through REACH substance evaluation, new studies).

In general, existing information indicates that nanomaterials, as other chemical substances, may or may not be hazardous. Among the general patterns, most importantly, nanomaterials

[136] Options Assessment Report, Table 3-3, p. 19
[137] In a very large interpretation, characterisation data could contribute to identifying nanoforms which are likely to have specific hazard properties. Therefore, the term "not much specific" information is used, although the information gain on hazards is likely to be very small.
[138] Hazards are intrinsic or functional properties of a substance, i.e. the degree of damage a substance can cause *if* an organism or the environment is exposed to the substance.
[139] The likelihood/degree that an organism or the environment will indeed be exposed in a particular application or use

like other fine powders can provoke irritation, inflammation and in certain cases genotoxicity or even carcinogenicity[140]. In general, those effects seem to occur only at high doses. As confirmed by the study and the public consultation[141,142], there are hardly any reports on acute incidents with nanomaterials in practice, suggesting that if any effects occur, they are likely to be linked to chronic exposure rather than to acute incidents.

It is also known that some nanoparticles may pass body membranes, enter into blood circulation and reach body organs and cells. Their impacts seem to be partly reversible, as the body is to an extent capable to eliminate nanoparticles. Nevertheless, it remains to be researched to which extent uptake happens in real exposure situations and whether there are de facto adverse effects or bioaccumulation (e.g. in the organs of workers with long term exposure). For many nanomaterials that have been used for a long time, such studies should not pose major methodological problems. Nevertheless there is only a limited number of available epidemiological studies, which in addition tend to be inconclusive[143]. Some hazard patterns of individual nanomaterials seem to be more related to the specific chemistry of the substance rather than their particle size (e.g. at the current exposure levels the aquatic toxicity of zinc oxide seems to be linked to the toxicity of the zinc ions).

Although a registry may collect more specific information on companies using nanomaterials, and thus allow or improve epidemiological studies, it has to be noted that there is already sufficient information allowing identification of companies that could be asked to participate in such studies. Also, the general use patterns of (most) nanomaterials are known (e.g. for pigments and dyes this will include brushing and spraying of paints). This should allow the development of relevant exposure scenarios even in the absence of registry information. Many of the exposure patterns are very simple and some already include a high potential exposure (e.g. food additives)[144], thus maximal exposure (covering a wide range of individuals that have been exposed for a long time) can be assumed for these cases. Therefore, a particular detail on exposure information will at least for those cases provide little added value.

The added value of a registry for exposure information will therefore be limited to the company level, resulting in more awareness about nanomaterials used, potentially improved risk management and possibly more focused enforcement. This will however depend on a number of factors which are discussed in more detail in the section on worker protection (criterion 5).

A registry according to option 3 would also contain characterisation information, which could potentially be used in differentiating between different nanoforms. However, such information would still need to be combined with hazard information before it could be used in risk assessments, and thus create a value-added in terms of potential health and environmental benefits. Moreover, subject to the outcome of the envisaged revision of REACH Annexes, it can be expected that relevant data requirements will be included into the REACH Annexes. Therefore, the main value added of a registry in this respect would be to

[140] For an overview of relevant study results see e.g. Harald F. Krug, Nanosafety Research—Are We on the Right Track? http://onlinelibrary.wiley.com/doi/10.1002/anie.201403367/full

[141] There are a number of reported cases which could possibly be linked to the specifics of nanoforms but which could also be linked to the chemistry of the substances and generally poor worker protection, cf. RPA *et al* (2014) Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market, Building Blocks Report for DG Internal Market, Industry, Entrepreneurship and SMEs, November 2014, Loddon, Norfolk, UK *(henceforth cited as "**Building Blocks Report**")*, pp. 11-14

[142] Options Assessment Report, p. 109

[143] Hodgson, J.T. and Jones, R.D. 1985, A mortality study of carbon black workers employed at five United Kingdom factories between 1947 and 1980, Archives of Environmental Health, vol. 40, pp. 261-268.; Sorahan, T., Hamilton, L., van Tongeren, M., Gardiner, K. and Harrington, J.M. 2001, A cohort mortality study of U.K. carbon black workers, 1951-1996, Am J Ind Med, vol. 39, pp. 158-170.

[144] Building Blocks Report, p. 17

extend this requirement to more nanomaterials where they are not already covered by REACH. It might however be preferable to get a better understanding of the drivers of toxicity of particular nanoforms, and the value added of such characterisation data before setting wide-ranging characterisation requirements, in particular if they are not backed up by any relevant hazard data.

Specific aspects related to traceability

One of the objectives of the FNS was to obtain the traceability of the nanomaterials on the market, from the manufacturers or importers via the distributors to the final professional users. Notifiers provide information on their clients, while downstream users refer to the dossier number of their nanomaterial suppliers. This makes it possible to follow nanomaterial through the value chain to some degree, although this will necessarily stop as soon as further downstream tracing is no more obligatory (e.g. in the FNS/option 3 when a product is sold to final consumers or when it is integrated into an article from where it is not released under normal or foreseeable conditions). The commercial name of the mixture/article containing the nanomaterial can be provided in the notification, but this is not required if the name is not yet known at the time of notification. In the case of the FNS, the system keeps track only of the nanomaterials, in themselves or contained in mixtures without being bound to them or where the possibility of release cannot be excluded, for the professional users market.[145] The FNS does not require any information on nanomaterials contained in mixtures and articles for the consumers' market.

Traceability has in the past mainly been proposed as a tool to faster identify similar products in case acute incidents occur, allowing rapid withdrawal of concerned products. Given existing experiences (e.g. few RAPEX notifications and long scientific debates rather than acute incidents), the speed of identification of products containing specific nanomaterials is unlikely to be critical. Moreover, most of the concerns surrounding nanomaterials refer to potential chronic rather than acute effects.[146] The added value of traceability constitutes therefore the better overview of trade flows and raising awareness on nanomaterials in products among distributors and downstream users.

Sub-options with possible exemptions

Information on substances only used in *scientific research and development* or in product and process oriented research and development might be a major part of the value added of a registry over alternative information sources. Therefore, exempting those substances might also considerably reduce the information gain, in particular on innovative nanomaterials. On the other hand, as this is likely to concern materials which are not marketed or only at small amounts, the relevance of this information for health and environment, at least in the short term, is also likely to be limited.

Exempting substances only used as pigments and dyes would mostly affect information on rather traditional materials which have been in use for a long time. Although this does not mean that there could not be any (mostly chronic) health and environmental issues, the value added of registry information for risk assessment and management at EU level is probably limited, as this does not depend on company specific information. There are also a number of pigment and dye applications which are developed with specific considerations of nano-effects but it will be difficult to define objective criteria that would distinguish them from traditional pigments and dyes, and there is also no a priori argument why those should be more hazardous than other pigments and dyes.

[145] Evaluation Report, p. 103
[146] Evaluation Report, p. 104

Exempting substances only used as *fillers* would probably affect mainly rather traditional materials, and the loss of relevant information for assessing unknown effects is therefore likely to be rather limited.

Exempting nanomaterials for which the parental substance has been registered or will be *registered under REACH* would eliminate duplication with REACH and thus the loss of information would be limited and mostly concern company and supply chain specific information (specific use and volume).

Exempting nanomaterials in products covered by *existing registration requirements* (cosmetics, medicinal products, plant protection products, biocides and food additives) would eliminate duplication and thus the loss of information would be limited. However, the degree of nano-specific information that would be concerned differs between the concerned legal instruments.

Conclusion

The relevance of additional information from a registry as proposed under option 3 for reducing health and environmental risks is if at all rather indirect through a more detailed identification of potential exposure points to nanomaterials and raising awareness in companies that they are dealing with nanomaterials. Also, the more specific information may be used by enforcement authorities to target and verify the appropriateness of risk management measures for workers. For the purpose of studying health and environmental effects of nanomaterials, as well as overall risk assessment and management, existing information is probably sufficient to allow further work, e.g. substance evaluation, epidemiological studies etc. Moreover, much of the potential information in a registry is likely to be or become also available through existing specific legislation, through the amendment of the REACH Annexes or through the already existing national notification schemes. The possible exception is low volume substances not covered by REACH registration. However, the number of concerned substances is likely to be low, and there is no indication that those present more risks than the high volume nanomaterials.

Worker protection

Criterion 5: Does the option affect workers' health and safety?

A notification obligation will require companies to identify whether the materials they deal with are nanomaterials. This may lead to a better knowledge about potential exposure and higher awareness among downstream users and distributors, which may in turn lead to better risk management measures where they are not yet in place. As downstream user companies will only get a notification number, this will require companies to actively inquire about the nanomaterial and the appropriate risk management measures when not be provided already. If companies communicate the information to their workers, this may also lead to a better dialogue on risk management within the company.

Company specific information from a registry would also allow enforcement authorities to better focus their activities on companies dealing with nanomaterials, where the information in REACH registration dossiers or CLP notifications is unclear, incorrect or incomplete. This could allow identification of risk management deficits in manufacturing companies and safety data sheets.

An improvement of current risk management will also result to some extent from the possible amendment of the REACH Annexes. This is also assumed to lead to further clarification on which substances/forms of substances are nanomaterials. Compared to a pure notification scheme, the possible amendment of the REACH Annexes will also have the advantage that

for hazardous nanomaterials not only the name but also appropriate risk management measures will be communicated to downstream users via safety data sheets.

Sub-options with possible exemptions

Information on substances only used in scientific research and development or in product and process oriented research and development would probably affect mainly work environments which are familiar with the substances they are dealing with. On the other hand, specific novel effects, if they occur, are likely to appear first in research and development activities.

Exempting substances only used as pigments and dyes would affect a substantial number of work environments. The impact will depend on whether the sector already applies appropriate risk management measures and if not whether companies trigger additional risk management measures if they become aware that their substances are nanomaterials.

Exempting substances only used as fillers would probably affect a more limited number of work environments, though dealing with large volumes of nanomaterials.

Exempting nanomaterials for which the parental substance has been registered would eliminate duplication with REACH and thus the impact on work environments would be limited for REACH registrants, especially if information on hazardous nanomaterials is correctly reflected in safety data sheets. Nevertheless, an exemption of REACH registered substances would also apply to companies manufacturing the same substance in lower volumes, thus not subject to registration, and exempt downstream users, thus part of the positive effect of a notification scheme on worker protection would be foregone.

Exempting nanomaterials in products covered by existing registration requirements (cosmetics, medicinal products, plant protection products, biocides and food additives) would eliminate duplication. The impact on work environments depends on the legal requirements under the concerned legal instrument but at least part of the positive effect of a notification scheme on worker protection would be foregone.

Governance and enabling consumers

Criterion 6: Does the option make the public better informed about a particular issue? Does the option affect consumer trust in products containing nanomaterials?

The establishment of an EU nanomaterial registry will generate information about nanomaterial substances on the market and their use in mixtures and articles. Indeed, the French authorities have made a report available to the general public on the notified substances, including a listing of their general use and their volume band.[147] Nevertheless, the public availability of notification data remains limited due to the confidentiality of business information. Information from individual dossiers, such as information about the notifier or commercial names of mixtures and articles, are not accessible to public. To an extent, those limitations could be overcome by combining a with other communication tools such as a Nanomaterials Observatory. This would make information more understandable and could put the data in the relevant context (e.g. by linking market data to relevant information on the hazards and risks of the concerned nanomaterials). Nevertheless, it would still not identify individual products, and it also debatable whether the additional detail of information compared to existing data would make a major difference for the purpose of consumer information.

[147] Ministère de l'Ecologie, du Developpement durable et de l'Energie (2014) Eléments issus des declarations des substance à l'état nanoparticulaire, rapport d'étude, online: https://www.r-nano.fr/

Whether and how a registry as such[148] will directly affect consumer trust, is debatable. Like all other options, a nanomaterial registry is unlikely to reach out to the broad public, beyond an informed circle of interested consumers and consumer organisations. Moreover, it is also questionable whether the information is at all useful for individual consumers, as it neither gives information on individual products containing nanomaterials, nor any assessment on whether the use of the product represents any risk to the consumer.

Indeed, in the case of the FNS consumer and environmental organisations, although welcoming regulatory action in this area, are disappointed that the system does not allow the identification of consumer products containing nanomaterials. It is also unclear whether the FNS led to additional consumer trust in nanomaterials, or whether it gave any incentive to buy products with nanomaterials, as the fact that a nanomaterial is mentioned in a registry does not have any bearing on its safety.

The public consultation provided mixed results on the impact on consumer behaviour: responses ranged from considering 'nano' as a selling point to considering the presence of nanomaterials in a product as negative due to negative preconceptions associated with nanomaterials. However, overall, there was a consensus that the provision of information concerning nanomaterials in products would not lead to consumers being more inclined to purchase those products.[149]

The FNS may also have indirect effects on the behaviour of companies who might react in a similar way to the notification duty and to the presence of a certain substance on the list of notified nanomaterials. In fact, there were reports that clients of companies demanded "nano-free" products. As much as such a move may be irrational, a nanomaterial registry may have, at least at present and without additional communication effort, distortional effects on the market.

In this context, it should also be taken into account that labelling of products with ingredient lists, where such exist, are a much more effective way of informing consumers than a registry. Such product labelling on nanomaterials has already been implemented for cosmetics, food and biocides.

Sub-options with possible exemptions

Information on substances only used in scientific research and development or in product and process oriented research and development would normally concern consumer products only to a limited extent.

Exempting substances only used as pigments and dyes would probably affect a large range of consumer products. On the other hand, given the above considerations on limited consumer access, the exemption would not have a major impact on consumer information.

Similarly, an exemption for substances only used as fillers would probably have limited impacts, as consumers would not have direct access to the information.

Apart from the above considerations concerning the limited access of consumers to a registry, exempting nanomaterials for which the parental substance has been registered would probably have an even smaller effect on consumer information and trust, as relevant information would still appear in REACH IT.

Apart from the above considerations concerning the limited access of consumers to a registry, exempting nanomaterials in products covered by existing registration requirements

[148] The following considerations do not take into account the potential benefits of a linked Nanomaterial Observatory as those are assessed separately in chapter 6.4.

[149] Options Assessment Report, p. 110

(cosmetics, medicinal products, plant protection products, biocides and food additives) would have different effects on consumer information, depending on the legislation concerned. Where labelling is applied, the information on the packaging will in any case be much more accessible to the consumer than a registry could be.

Internal market and competition

Criterion 7: What impact does the option have on the free movement of goods, i.e. nanomaterials and products containing nanomaterials?

A registry may have a certain harmonising effect and reduce the cumulative administrative burden of companies operating in Member States with a national registration scheme. Nevertheless, there are currently no indications that the existing national schemes had an impact on the free movement of goods. Therefore, the impact on the free movement of goods within the internal market is likely to be neutral or positive to very limited extent at best. It might have a similarly limited negative impact on external trade, as some companies might avoid notification obligations and rather manufacture and market their nanomaterials outside the EU.

Sub-options with possible exemptions

In general, there are no reasons to assume that exemptions would lead to specific considerations concerning effects on the internal market and the free movement of goods, except from changing the dimension of any possible effects, e.g. for external trade. However, any internal market effects of diverging national systems, should they exist, would affect large volume substances to a higher degree than low volume substances.

Innovation and research

Criterion 8: Does the option stimulate or hinder R&D and innovation?

Criterion 9: Does the option affect the protection of confidential business information?

In France, 52% of responding companies indicated that the requirements of the FNS have a negative or very negative impact on research and development. A negative or very negative impact is expected on intra-EU competitiveness and on extra-EU competitiveness by 50% and 41% of companies, respectively.[150]

In the public consultation, a negative impact on intra-EU competitiveness and on extra-EU competitiveness is expected by 44% and 92% of companies, respectively, although these expectations are not shared by other respondents (only 20% of public authorities and 6% of citizens and NGOs expect a negative impact on extra-EU competitiveness).[151] 85% of industry respondents were concerned that providing information about the presence of nanomaterials in a product would negatively impact nanotechnology innovation.[152] Some respondents 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. Some respondents suggested that this could deter the further development of the sector in the EU. According to respondents, the impact notification requirements for nanomaterials in mixtures would be most significant[153].Results from the

[150] Evaluation Report, p. 73; based on a survey among 46 companies; please see Evaluation Report, pp. 59-64 for a characterisation of respondents
[151] Options Assessment Report, p. 114
[152] Options Assessment Report, Table A1-18, p. 112
[153] Options Assessment Report, Table A1-20, p. 114

SME panel are similar (35% of SMEs expects a small or medium impact; 33% expect a considerable or significant impact; 15% expects no impact), although respondents are divided over the effect of a registry on their competitiveness; most respondents are not able to estimate these effects (see Annex 2). There have also been claims that a registry could increase research and development on nanomaterials. Notably, 71% of NGOs and 60% of public authorities responding to the public consultation expect a positive impact on innovation (this expectation is shared by only 2% of industry respondents).[154] However, at least in the short term it would be difficult to identify concrete reasons to invest in research and development, *as a result of* a notification obligation.

In any case, these claims are hard to substantiate in practice, and so far it is difficult to identify any particular effects on nanomaterial research and development beyond anecdotal reports. The effects on research and development might also be different between the majority of nanomaterials which are rather well-established medium to high volume substances, and for which registry obligations are unlikely to result in delocalisation of research and development, and less established new developments at low volume, for which regulatory attention may indeed influence localisation decisions.

With regard to the protection of confidential business information, 98% of industry respondents indicated that a disclosure of notified information would conflict with the confidentiality of business information.[155] However, in the FNS, all information submitted is considered confidential with the exception of the chemical name and uses of the nanomaterial notified. The notifiers have the possibility to claim confidentiality also for these data, providing a justification. Therefore, it is expected that, if similar provisions were to be applied at EU level, confidentiality concerns could be addressed in an appropriate way.

Overall, it is considered that neither impacts on research and development nor particular arguments related to confidential business information would be clear enough to justify or discourage the establishment of an EU registry.

Sub-options with possible exemptions

Exempting substances only used in scientific research and development or in product and process oriented research and development would eliminate a large part of possible negative effects on research and development a possible registry might have. Similarly this might be the sector most sensitive to issues related to confidential business information.

Exempting substances only used as pigments and dyes or as fillers would probably have limited impacts on research and development.

Exempting nanomaterials for which the parental substance has been registered would rather affect the higher volume substances and might leave the more sensitive low volume (< 1 ton annually) substances for registration. Thus, if there are any effects hampering research and development of a registry, they would probably be particularly severe under this sub-option which would favour the more established higher volume substances.

Exempting nanomaterials in products covered by existing registration requirements (cosmetics, medicinal products, plant protection products, biocides and food additives) would probably have a rather limited effect, as those sectors are covered by specific legislation. Nevertheless, there may be sensitive research and development activities in these areas, which might be displaced outside the EU in case a registry is introduced. Such effects could be avoided in case of an exemption for these product categories.

[154] Options Assessment Report, p. 112
[155] Options Assessment Report, p. 115

6.6 Option 4: EU nanomaterial registry with an annual notification per use

Costs and administrative burden

Criterion 1: Will the option impose additional costs (e.g. compliance costs) and administrative burden on businesses?

As part of the supporting study, the compliance costs for option 4 were calculated on the basis of the Belgian and Danish impact assessments, which use an estimate of notification cost per company in a particular sector. This avoids estimating the number of concerned products, which, due to the very high number of concerned products (perhaps in the hundreds of millions of different products) is very challenging. Moreover, it will not be straightforward to identify whether a nanomaterial bound in a matrix is still present as a nanomaterial or has been transformed, let alone checking the number size distribution of the particles in such complex products. Therefore, the number of companies with notification duties was estimated at approximately 1.617.000 companies (i.e. 47% of all EU companies in the concerned sectors) that would be affected by a notification duty.[156] As an average value, the compliance cost per company subject to the notification duty is estimated at between € 1.750 per company and per year in the textiles sector and € 5.250 in the coatings and inks sector.[157]

As the administrative burden of notification per product is significantly higher than under option 3 where the notification is per substance, the recurring costs are relatively more important than under the French scheme where one-off costs (characterisation, familiarisation) are dominant.

The first year costs are estimated at € 5,3 billion, and the recurring costs at € 2,5 billion per annum (please refer to Annex 3 of this report for the key calculation tables and Annex 2 of the Options Assessment Report for a detailed overview of all calculation steps).[158,159]

The results of the Danish Nanoproductregister could not be taken into account in the study work supporting the impact assessment. Nevertheless, the first report on the administrative burden of the Nanoproductregister[160] was analysed in the last phase before submission of this impact assessment. Overall, extrapolation of costs and administrative burden to a registry covering all products is impossible, as the vast majority of products containing nanomaterials were exempted under the Danish scheme. Therefore, the overall estimates made during the study phase of the impact assessment were not modified. Nevertheless those estimates remain plausible, in particular as the report on the administrative burden of the Nanoproductregister confirms that without exemptions a very wide range of products would be subject to notification[161].

[156] Options Assessment Report, Table 7-1, p. 70
[157] Options Assessment Report, Table 7-4, p. 75
[158] See Annex 3, Table A3-3 for further details
[159] Options Assessment Report, Table 8-1, p. 81; Table A2-35, p. 166
[160] Assessment of the administrative burdens on businesses with a reporting obligation to the Danish Nanoproductregister, Ministry of Environment and Food of Denmark, Environmental project No. 1804, 2015 http://www2.mst.dk/Udgiv/publications/2015/12/978-87-93435-09-4.pdf.
[161] See the following quotes from the Assessment of the Danish Nanoproductregister: "Are materials wrapped around consumer articles (i.e. packaging) […] integral parts of the articles? The latter may ultimately result in an obligation to report almost all consumer articles due to their content of pigments in printing ink"; [if plastics is not considered to be a fixed matrix and thus exempted, this] "would lead to an obligation to report a very high number of plastic products"; "basically all consumer textiles would be subject to reporting due to their use of colouring agents containing pigments"; "basically all paints and adhesives would be subject to reporting", p. 30-31.

Probably, the most important lesson from the Danish scheme is that companies dealing with consumer products (including those who eventually conclude that they are not concerned or exempted) have major difficulties to assess whether their products contain nanomaterials and whether they are subject to notification[162]. Despite the very extensive exemptions in the Danish legislation, the costs to businesses were assessed to be between € 2.9 and 6.6 million, of which less than 1% (€ 46.900) was for companies that reported to the register. The rest of the cost was for other companies to check their obligations but ultimately deciding not to register[163].

Sub-options with possible exemptions

Due to the very widespread use of nanomaterials, any registry based on notifications per application can probably only realistically be implemented if a significant number of applications are exempted, as this is also the case in the Belgian and Danish notification schemes.

Exempting products which are the object of research and development would have a relatively minor effect on overall cost, as the vast majority of products containing nanomaterials are well-established applications. The savings for exempting R&D related applications compared to the costs of a scheme without exemptions are estimated at € 70 million (1,3%) of first-year costs and at € 39 million (1,5%) of annual recurring costs.[164]

A very large number of notifications would be linked to the presence of both pigments/dyes and fillers which are in a very high number of products, and which would trigger a high number of notifications. Exempting pigments/dyes and fillers from option 4 would reduce first year costs by around € 2,7 billion (around 50%) and recurring costs by around € 1,5 billion (around 59%).[165]

A similarly high cost reduction could be achieved by exempting mixtures and articles containing nanomaterials or nanoforms of substances registered under REACH. This would reduce first year costs by around 2.3 billion € (around 43%) and recurring costs by around € 1,3 billion (around 50%).[166]

Exempting nanomaterials in products covered by other existing registration requirements (cosmetics, medicinal products, plant protection products, biocides and food additives) would reduce costs by a much smaller amount (around € 284 million - 5% - in the first year and 86 million € in annual costs – 3%), as those products are already end-products and will not be integrated in the wide range of other products containing nanomaterials.[167]

The biggest possible cost reduction would however be by generally exempting mixtures and articles without intended release of nanomaterials. This would reduce the number of companies with obligations from 1.617.000 to 53.000 (i.e. almost 97%).[168] Under this option, the first year costs are estimated at € 310 million (less than 6% of the costs of a registry covering all products containing nanomaterials), with annual recurring costs of 66 million € (less than 3% of the costs of a registry covering all products containing nanomaterials). Still,

[162] See following comment from the assessment of the Danish Nanoproductregister: "knowledge and understanding of nanomaterials and nanoproducts are restricted to very few businesses. Paradoxically this makes some businesses spend many resources on checking various issues whole others give up understanding the order and ignore it.", p. 14.
[163] idem
[164] Options Assessment Report, Table 8-6, p. 77; Table A2-36, p. 167
[165] Options Assessment Report, Table 8-6, p. 77; Table A2-39, p. 170
[166] Options Assessment Report, Table 8-6, p. 77; Table A2-40, p. 171
[167] Options Assessment Report, Table 8-6, p. 77; Table A2-41, p. 172
[168] Options Assessment Report, Table 8-6, p. 77; Table A2-42, p. 173

the cost of a registry per application would be around threefold in the first year compared to a registry per substance (option 3) and around fifteen times the cost in the following years.

Criterion 2: Does the option have significant effects on certain sectors?

A nanomaterial registry per application without exemptions would affect a very wide range of sectors, including a big share of all finished products (including cars, electronics, machinery, textiles, paper and wood, food health care) and affect a wide range of distributors. The biggest number of companies affected would concern the category "complex products", i.e. manufacturers, wholesalers and retailers of e.g. cars, refrigerators, furniture etc., which would sustain over 70% of the total administrative burden.[169]

Sub-options with possible exemptions

Like for option 3, the burden could be shifted from certain sectors covered by exemptions. However, the most significant shift could be achieved by exempting articles and mixtures without intended release, which would exempt most complex objects from notification duties, next to many other sectors which would not be affected by a registry limited to articles and mixtures with intended release.

Criterion 3: Does the option have budgetary consequences for public authorities?

Similarly to Option 3, Option 4 would involve the establishment of a nanomaterial registry on an EU level managed by the European Commission. Costs include administrative costs for the running of the registry, as well as the acquisition of the necessary hardware or software. The latter involves the in-house development of a database or the licensing of an external database system. In addition, the development and maintenance of an online portal would be included.

The first-year development and establishment costs are expected to be similar to the estimates for Option 3 and the costs of the FNS development, i.e. € 250.000. With regard to the annually recurring costs, the larger number of notifications that would be received under Option 4 would cause an increase in administrative costs of the registry, in particular in terms of dedicated staff for the purpose of 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. Taking into account translation costs for the aforementioned documents, this would result in recurring costs of € 825.000 per year.[170] The first year of operations is therefore estimated to cost € 1,1 million.

As for Option 3, enforcement costs for national authorities should also be considered. Based on the assumption that 2% of companies that might manufacture, import or commercialise nanomaterials or mixtures and articles containing nanomaterials are inspected, enforcement costs amount to € 91,7 million. The testing of one product in each company inspected would cost around € 70 million every year.[171]

In conclusion, first-year costs for public authorities amount to € 1,1 million on an EU level; annual costs amount to € 825.000 on an EU level and € 160 million on a national level for enforcement purposes.

[169] Options Assessment Report, p. 76; Table A2-35, p. 166
[170] Options Assessment Report, pp. 78-79
[171] Options Assessment Report, p. 79

Public health and safety and the environment

Criterion 4: Does the option allow authorities to respond more effectively to potential health or environmental risks? Does this decrease the likelihood of health risks due to substances harmful to health or the environment?

A registry according to option 4 would increase the information about products containing nanomaterials very significantly. In particular, it would provide information about a large number of articles containing nanomaterials without intended release. 86% of NGO and citizen responses are in favour of including articles without intended release. This is not shared by the majority of industry respondents (10% in favour) and public authorities (36% in favour).[172] Some respondents to the public consultation suggest that information on articles containing nanomaterials without intended release could be relevant for workers. Moreover, it could provide relevant information on articles containing nanomaterials that are only released in the waste phase (e.g. during recycling).

Nevertheless, covering articles and mixtures without intended release would have a much smaller benefit in terms of reducing health and environmental risks than covering substances, mixture and articles with intended release, as for the former much less release and thus exposure can be expected.

Sub-options with possible exemptions

The most relevant possible exemption in this context is limiting notification obligations to articles and mixtures with intended release. In this context, the main remaining difference to option 3 will be structuring the data per application rather than per use. A registry per application could help better identify particular uses. However, it would not provide much added value in terms of risk assessment and reducing health and environmental risks, as there will be no information on whether the application is linked to risks.

For other possible exemptions, similar considerations as for the corresponding exemptions under option 3 will apply. These possible exemptions are therefore not further analysed here.

Worker protection

Criterion 5: Does the option affect workers' health and safety?

A registry covering all articles and mixtures containing nanomaterials would concern many more working environments than a registry limited to articles and mixtures with intended release. Nevertheless, workers (e.g. those working on finished products) are unlikely to get into direct contact with the nanoparticles contained in a matrix. Therefore, compared to the risk of inhalation of nanopowders during substance manufacturing or use in formulating mixtures, the risks of presence of nanoparticles in matrices is much smaller, and therefore the possible benefit for worker protection is much more limited.

Sub-options with possible exemptions

The most relevant possible exemption in this context is limiting notification obligations to articles and mixtures with intended release. Compared to a registry per substance, a registry per application will lead to an information gain on the detail of the use. However, the importance of this information gain will be relatively smaller for worker protection than for

[172] Options Assessment Report, p. 118

consumer information, as workers are more likely to deal with substances or unfinished products than final applications.

For other possible exemptions, similar considerations as for the corresponding exemptions under option 3 will apply. These possible exemptions are therefore not further analysed here.

Governance and enabling consumers

Criterion 6: Does the option make the public better informed about a particular issue? Does the option affect consumer trust in products containing nanomaterials?

A registry covering all articles and mixtures containing nanomaterials would lead to the collection of a much wider range of information than a registry limited to articles and mixtures with intended release, and thus the main argument for moving to a registry covering all nanomaterial applications could be informing the public. On the other hand, most of this information will still remain confidential, and the most likely outcome would be that nanomaterials are, though not in all products, in a very significant share of all manufactured products. Therefore, the value added of the information for consumer information and trust will still remain limited.

Sub-options with possible exemptions

The most relevant possible exemption in this context is limiting notification obligations to articles and mixtures with intended release. Although this would reduce the amount of information generated significantly, in practice it would probably not make a major difference for consumers, as due to confidentiality they will anyhow not have access to information on individual products.

Internal market and competition

Criterion 7: What impact does the option have on the free movement of goods, i.e. nanomaterials and products containing nanomaterials?

For a registry covering all articles and mixtures containing nanomaterials, the same considerations on the free movement of goods would apply as for a registry according to option 3, only that the effects on external trade might be much more significant. In particular, there may be very significant problems with identifying the presence of nanomaterials in the matrix of complex products imported from third countries. As this would be virtually impossible to verify, enforcement would be very difficult. This may also make countries outside the EU more attractive for producers wishing to avoid the notification burden.

Sub-options with possible exemptions

In general, there are no reasons to assume that exemptions would change the overall assessment on effects on the internal market and the free movement of goods, apart from changing the dimension of costs and administrative burden.

Innovation and research

Criterion 8: Does the option stimulate or hinder R&D and innovation?

Criterion 9: Does the option affect the protection of confidential business information?

As the vast majority of products containing nanomaterials are well-established applications, the wider scope of application of option 4 compared to option 3, is likely to be *relatively* less critical for R&D intensive products than for other products. On the other hand, much of the concerned information will be confidential business information, as it will contain very wide information on supply chains, markets and uses that, if published, could significantly advantage non-European companies. This would make measures to protect confidential business information and to ensure IT-safety against industrial spying more critical than for simpler versions of a registry.

Sub-options with possible exemptions

The most relevant possible exemption in this context is limiting notification obligations to articles and mixtures with intended release. The more limited scope of the information for this and other exemptions may reduce the criticality of protecting confidential business information and IT security.

7 Comparison of options

7.1 Comparison in terms of effectiveness, efficiency and coherence

Table 5: Overview of the assessment according to the used criteria

Criteria	Baseline scenario	Option 1 Commission Recommendation	Option 2 Nanomaterials Observatory	Option 3 EU registry (notification per substance; FR model)	Option 4 EU registry (covering all nanomaterial uses)
Criterion 1: costs/burden for businesses[173]	**0** No additional cost for businesses (except for additional measures that might be decided at Member State level)	**-/--/---** The costs of option 1 depend on which of options 3 or 4 or any of their sub-options is chosen, and on how many Member States would implement the Recommendation.	**0/-** No additional business costs, except for answering specific requests from the Observatory (on a voluntary basis).	**-/--** Business costs in the order of € 60 to 145 million in the first year, thereafter around € 3.9 million annually.	**--/---** Business costs in the order of € 5.3 billion in the first year, thereafter around € 2.5 billion annually. Option 4 only seems realistic if substantial exemptions are foreseen, similar to those of the Belgian and Danish notification systems.
Criterion 2: specific sectors	**0** No additional impact on specific sectors (except for additional measures that might be decided at Member State level)	**-/--/---** Additional impact on specific sectors depends on which of options 3 or 4 or any of their sub-options is chosen, and on how many Member States would implement the Recommendation.	**0/-** No additional impact on specific sectors, except for answering to specific requests from the Observatory (on a voluntary basis).	**-/--** A majority of notifications will relate to pigments and dyes. In articles, pigments and dyes are very often combined with fillers.	**--/---** In addition to the sectors mentioned under Option 3, Option 4 will also have a very significant impact on wholesalers and retailers dealing with complex articles. The specific impact on sectors could be reduced by exempting those sectors from notification duties (see exemptions below).
Criterion 3: costs for authorities[174]	**0** No additional costs for authorities (except for additional measures that might be decided at Member State level).	**--** No costs for EU public authorities. Additional costs for Member States depend on which of options 3 or 4 or any of their sub-options is chosen.	**-** Costs for EU public authorities € 800.000 in the first year, thereafter € 600.000 annually (for Observatory); support from national authorities first year € 280.000, then	**--** First-year costs for EU public authorities € 700.000, then annually € 450.000 (set-up and maintenance of registry); for Member States € 3,3 million annually	**--** First-year costs for EU public authorities € 1,1 million, then annually € 825.000 (set-up and maintenance of registry); for Member States € 160 million annually

[173] See the overview of costs for businesses in Table 6 below.
[174] See the overview of costs for public authorities in Table 6 below.

Criteria	Baseline scenario	Option 1 Commission Recommendation	Option 2 Nanomaterials Observatory	Option 3 EU registry (notification per substance; FR model)	Option 4 EU registry (covering all nanomaterial uses)
			100.000 annually	(enforcement).	(enforcement).
Criterion 4: health and environment	**0** Other measures such as the considered amendment of the REACH Annexes are likely to have a significantly higher impact on improving risk assessment and risk management than any of the options considered. Therefore any change resulting from the other options would be on top of the changes to be expected as a result of the evolving baseline.	**+/0/-** A Recommendation according as proposed in option 1 could provide some useful information for health and environment (see consideration on options 3 and 4). However, although reducing the differences between existing national notification schemes will alleviate administrative burden for companies operating in different Member States, it will also reduce the range of collected information compared to a baseline with different requirements. Therefore, from a health and environmental perspective, this option could also be slightly negative compared to the baseline.	**+** A Nanomaterials Observatory has the advantage that it could research information in a much more focused way, e.g. by gathering information on particularly toxic nanoforms, or by searching scientific literature on study results. Moreover, it could summarise and communicate information about health risks, and provide relevant recommendations on risk management measures in a way that is understandable for workers and consumers. It could also contribute in a more focused way on identifying knowledge gaps and advising public authorities in setting priorities on research, regulatory and enforcement issues.	**+/0** The option will lead to more systematic and complete data collection on companies dealing with nanomaterials. On the other hand, this information will not necessarily address the limiting factors for improved risk assessment (particular toxicity related to the nanoform, understanding the reasons for this toxicity, i.e. the drivers of toxicity, and studying bioaccumulation and chronic effects, e.g. through epidemiological studies). Such information could partly result from REACH (substance evaluation, amendment of Annexes, etc.) or would need to be generated through separate initiatives or studies. Therefore, the added value of additional information on possible exposure sources in comparison to existing information is considered to be low.	**+/0** The impact of option 4 is similar to option 3.
Criterion 5: worker safety	**0** Improvements of worker safety could also come from other measures such as revision of REACH	**++/+/0** Additional impact on worker safety depends on which of options 3 or 4 or any of their sub-options is	**+** A Nanomaterials Observatory (option 2) would probably not be as specific as option 3 but	**++** The main advantage of a registry according to option 3 would be to draw the attention of individual	**++** Compared to option 3, option 4 would collect additional information on articles containing

Criteria	Baseline scenario	Option 1 Commission Recommendation	Option 2 Nanomaterials Observatory	Option 3 EU registry (notification per substance; FR model)	Option 4 EU registry (covering all nanomaterial uses)
	Annexes, which in turn could result in improved Safety Data Sheets resulting from better data availability in REACH registration dossiers.	chosen, and on how many Member would implement the Recommendation.	could still gather and publish relevant information and recommendations on the most critical workplace situations.	companies, in particular downstream users, to the fact that they deal with nanomaterials. This in turn could lead to improved risk management for workers, in particular where nanomaterials are used as fine powders. Moreover, enforcement authorities could better focus their efforts on companies dealing with such nanomaterials. Nevertheless, this will depend on the degree companies and enforcement authorities will make use of the information.	nanomaterials. However, as those are less directly relevant for workplace exposure, the value added compared to option 3 will be limited.
Criterion 6: consumer information	**0** In this context, labelling on products will be much more efficient for informing consumers on the content of products than a central database. However, this is already implemented in EU legislation for many products with ingredient lists and therefore part of the baseline of this impact assessment.	**+/0/-** A Recommendation according as proposed in option 1 could provide some useful information for consumers, taking into account the constraints described for option 3. However, although reducing the differences between existing national notification schemes will alleviate administrative burden for companies operating in different Member States, it will also reduce the range of collected information compared to a baseline with	++ A Nanomaterials Observatory could be used as a tool to evaluate and summarise technical information and to communicate it to interested consumers in a clear and understandable way. In this way it is the only investigated option that would provide user-oriented information for consumers.	**+/0** Although a registry could be used by authorities to draw up reports which would indirectly inform consumers, the information in a registry would have to be largely confidential, in order to protect legitimate business interests. Moreover, raw information on the presence of particular nanomaterials in products would be of little value for consumers, as long as they do not get at the same time explanations on the implications for health and the environment.	+ As for option 3, confidentiality and the sheer amount of information to be expected will be a major barrier for usability by consumers. Nevertheless, compared to option 3, this option has the advantage of gathering more information on consumer products and is therefore rated slightly more positive than option 3 under this criterion.

Criteria	Baseline scenario	Option 1 Commission Recommendation	Option 2 Nanomaterials Observatory	Option 3 EU registry (notification per substance; FR model)	Option 4 EU registry (covering all nanomaterial uses)
		different requirements. Therefore, from a consumer information perspective, this option could also be slightly negative compared to the baseline.		Rather than generating trust in nanomaterials, raw information on individual applications in a registry may therefore lead to confusion and potentially avoidance of applications which are perfectly safe. Some of these limitations could be overcome by combining option 3 with option 2. Nevertheless, the value added of additional information generated under option 3 will still be limited, as the communication bottleneck relates rather to easily understandable aggregated information rather than additional detail.	
Criterion 7: internal market	**0** Although divergent national schemes have led/may lead to additional administrative burden for companies operating in several concerned Member States, there are no indications that the existing national notification systems have led to changes in the flow of goods containing nanomaterials.	**(+)/0** In line with the explanations given for the baseline scenario, it is unlikely that a recommendation would have a significant effect on the flow of goods within the internal market. A recommendation, if followed by Member States, would however have a harmonising effect by reducing divergences and administrative burden for companies operating in several concerned Member	**0** A Nanomaterial Observatory would not affect the free flow of goods, nor have a significant harmonising effect, apart from providing a common information source that can be used throughout the European Union (and beyond).	**+/0** In line with the explanations given for the baseline scenario, it is unlikely that option 3 would have a significant effect on the flow of goods within the internal market. A registry, if linked with an obligation to Member States to abandon national schemes, would however have a harmonising effect by eliminating divergences and reducing administrative burden for companies operating in several	**+/0** In line with the explanations given for the baseline scenario, it is unlikely that option 4 would have a significant effect on the flow of goods within the internal market. A registry, if linked with an obligation to Member States to abandon national schemes, would however have a harmonising effect by eliminating divergences and reducing administrative burden for companies operating in several

Criteria	Baseline scenario	Option 1 Commission Recommendation	Option 2 Nanomaterials Observatory	Option 3 EU registry (notification per substance; FR model)	Option 4 EU registry (covering all nanomaterial uses)
		States.		Member States.	Member States.
Criterion 8: research and innovation	**0** There may be a certain impact of public discussion on nanomaterial safety that might give an incentive to companies to relocate their research and innovation activities to countries and regions where such a discussion does not take place. Still, there is no evidence that the existing national notification schemes have led to displacement of research and innovation on nanomaterials, nor is there any evidence of attracting additional research and innovation. Therefore, it is assumed that overall effects will be relatively neutral, and that neither the notification cost nor the impact on the public opinion will have a major impact on deterring or attracting research and innovation activities.	**0/-** Explanation see baseline option and options 3 and 4.	**+/0** Explanation see baseline option. However, there could be a small positive impact through generation of a better understanding on the implications of nanomaterials, as well as better information on nanomaterial safety research that could be communicated through an Observatory. This in turn may possibly contribute to an extent to an improved climate for research and innovation on nanomaterials.	**0/-** Explanation see baseline option. However, there could be a small negative effect, mainly as a result of possible avoidance of researchers to be subject to notification obligations.	
Criterion 9: protection of confidential business information	**0** No particular impact or expected developments of the baseline (except possible effects of national schemes).	**0/-** Explanation see option 3	**0** A Nanomaterial Observatory would be selective in publishing information. Although it might analyse confidential business information to an extent, a Nanomaterials	**0/-** The exact composition of products is in many cases a very important part of confidential business information, and their release may cause severe losses for the companies	**0/-** Explanation see option 3

Criteria	Baseline scenario	Option 1 Commission Recommendation	Option 2 Nanomaterials Observatory	Option 3 EU registry (notification per substance; FR model)	Option 4 EU registry (covering all nanomaterial uses)
			Observatory would rather summarize information before publishing it. In this way, a Nanomaterials Observatory could be an elegant way to filter out relevant information for the public without jeopardizing business confidentiality. It is rated as overall neutral, rather than options 3 and 4, which have a higher risk of unintended data release as the amount of confidential information handled will be higher	concerned. Therefore, such information is in general protected, and neither any of the relevant existing EU pieces of legislation nor the relevant national notification schemes release this information. Therefore, overall the impact of the options is considered to be neutral. Nevertheless, the more information is collected, the more the confidentiality and the safety of the IT systems managing the information will be of relevance.	

Table 6: Overview of costs for businesses and public authorities

#	Costs for businesses		Costs for public authorities	
	First-year	**Annually recurring**	**First-year**	**Annually recurring**
1	N/A	N/A	N/A	N/A
2	€ 0	€ 0	€ 800.000	€ 600.000
3	€ 60-145 M	€ 3,9 M	€ 700.000	€ 450.000 + € 3,3 M [175]
4	€ 5.324 M	€ 2.546 M	€ 1,1 M	€ 825.000 + € 160 M [176]

[175] Enforcement costs on a Member State-level
[176] *Idem*

Possible variations of the options through exemptions

Exemptions will in general be relevant only for options 3 and 4, as for a Nanomaterials Observatory there is neither a need to define a specific scope nor a reason to exclude certain substances or applications from the scope of the Observatory. Rather, decisions on focusing the work of an Observatory to specific areas could be taken flexibly as the need arises.

While certain exemptions clearly will make sense if one of the registry options is chosen, the first and more fundamental decision will be whether at all one of those registry options would provide sufficient value added to justify its costs (see section 7.2).

Should any of those options be chosen, the clearest conclusion is that a full registry as outlined in option 4 will not be workable and that at least mixtures and articles without intended release should be exempted. Also it will make sense to exempt applications which are covered by other authorisation or notification schemes, probably also those covered by REACH registration (in particular for characterisation data that are available in the registration dossier), even though this may focus the impacts on small volume nanomaterials, thus disproportionately affecting SMEs and research and innovation. Concerning specific categories such as pigments/dyes, fillers, etc., there is no straightforward conclusion. These exemptions may indeed considerably reduce the overall burden and concern to a very large degree products which have been on the market for a long time without serious incidents. However, the same would also be true for most other concerned product categories. If all such categories were to be exempted, this could in the extreme case result in exempting all relevant applications, with the arbitrary exemption of products which for one or the other reason do not fall into one of the exempted categories. Moreover, the experience of the Danish system shows that even determining whether a company can benefit from an exemption causes significant administrative costs. In fact, 99% of the costs of the Danish system were for companies that ultimately did not register[177].

Effectiveness, efficiency and coherence with other EU policies

Table 7: Effectiveness, efficiency and coherence with other EU policies of the assessed options

	Baseline	Option 1	Option 2	Option 3	Option 4
Effectiveness	+/0/-	+/0	++/+	+	+
Efficiency	+/0/-	+/0/-	++/+	-	-/--
Coherence	+/0/-	+/0	+	0/-	0/-

Overall, all analysed policy options are an add-on to other means to generate information for the protection of human health and the environment. Amending the REACH Annexes and promoting risk assessment will be more effective to generate information specifically for risk assessment and management purposes. Labelling of products with ingredient lists will be more effective to inform consumers on products containing nanomaterials. Safety data sheets will be more effective to inform workers about risks related to hazardous nanomaterials in the work environment. The main information bottleneck identified in the impact assessment is the provision of clear and easily understandable information to policy makers, consumers and workers. This can be most effectively and most efficiently provided by the Nanomaterials

[177] Assessment of the administrative burdens on businesses with a reporting obligation to the Danish Nanoproductregister, Ministry of Environment and Food of Denmark, Environmental project No. 1804, 2015 http://www2.mst.dk/Udgiv/publications/2015/12/978-87-93435-09-4.pdf, comparing scenarios 1 and 3, p. 7.

Observatory, which is also the lowest cost option (the baseline option apart). For internal market, competitiveness and innovation, none of the analysed policy options plays a major role.

There are no particular concerns as regards the coherence of a Nanomaterials Observatory with other EU policies, as it is a research and communication tool rather than a separate policy tool. The registry options would also not have major impacts on other main European Union policies. Nevertheless, there is a certain overlap with REACH and other notification obligations such as under the Cosmetics Regulation.

7.2 Preferred option / Justification for not preferring the remaining options

Preferred option

Option 2 (Nanomaterials Observatory) has the advantage of providing clear and easily understandable information to interested policy makers, consumers and workers, as well as their organisations. In this way, it can contribute to creating more trust in nanomaterials and their safety and to objectivising the policy debate on nanomaterials. Contrary to the registry options, this will not only be based on market information on nanomaterials and their uses but also be linked to available information on hazards and risks of nanomaterials, including information from REACH IT, scientific studies and research projects. Available information can be completed in a focused way through additional studies. It also has the advantage of being the lowest cost option (the baseline option apart) and avoiding the need for new legislation and saving administrative burden. By requesting the European Chemicals Agency to host the Nanomaterials Observatory, synergies with their experience in analysing REACH registration dossiers and providing communication tools on chemical substances can be exploited. Although a Nanomaterial Observatory could in principle be combined with a registry, the value added of doing so would be limited, and the costs would be significant. Rather, synergies should be sought with a possible amendment of REACH Annexes to generate more information on characterisation and uses of nanomaterials. Therefore, preference is given in this impact assessment to option 2. National observatories can be a useful asset to provide information into an EU registry, and therefore will be welcome.

Justification for not preferring the remaining options

The costs and administrative burden of an EU registry per nanomaterial substance, if limited to the parameters required under option 3 (identical requirements as in the current French notification scheme) are of an order that is unlikely to create major impacts on markets. Nevertheless, these costs and administrative burden are still substantial. On the other hand, the value added of the generated information in terms of reducing health and environmental risks and informing consumers is limited, and much of the relevant information on nanomaterial characterisation and potential exposure to nanomaterials can be either found in available information or will be generated through the envisaged amendment of the REACH Annexes. A registry could benefit from a combination with option 2, thereby partly overcoming a registry's limitations for informing consumers. However, it remains unlikely that the more systematic data collection would make a major difference in the information a Nanomaterial Observatory would make available for consumers. This is because consumers will need simple and aggregated information rather than details. Moreover, the publicly available details in a registry would still not allow consumers to identify individual products, as most registry information remains subject to the protection of confidential business information. Although an EU registry could lead to improvements of company-level risk

management, this could also be achieved to an extent via improved safety data sheets, resulting from better REACH registration data. Therefore, the added value of this option is considered to be limited and not justifying the significant administrative burden and cost for companies.

Option 4 (registry per application containing nanomaterials) would generate more detailed information than option 3. However, as in option 3, the added value of the generated information in terms of reducing health and environmental risks and informing consumers would overall be limited for the same reasons. Furthermore, as most of the additional information under option 4 would concern final products, the added value added for workers of option 4 compared to option 3 would be limited. On the other hand, the costs and administrative burden will be substantially higher and implementing option 4 will only be realistic if a significant number of applications, in particular articles without intended release are eliminated from the scope of the registry. Exempting a large range of applications may bring down costs, but is difficult to justify from an objective point of view vis-à-vis those applications that are not exempted.

Option 1 was designed to achieve more harmonisation compared to the existing national registries while leaving the implementation of registries to Member States. It would however only make sense if registries as such are seen as cost-effective options, and if divergence of national systems would cause undue internal market barriers. As the same conclusions as for options 3 and 4 will apply, it would be difficult to justify recommending a registry at national level if this is not found to be the preferable option at EU level. Moreover, as shown above, there is no evidence of undue internal market barriers due to national systems.

7.3 Subsidiarity and proportionality of the preferred option

Option 2 (Nanomaterials Observatory) does not have an impact on the margin of Member States to take own actions within the framework of the Treaty and relevant internal market rules. However, it invites Member States to actively participate in the work of the Nanomaterials Observatory and to contribute by own information and active research. This option does not have any major cost impact other than the limited set-up and maintenance costs of the Observatory itself (European Union budget) and voluntary contributions by Member States and industry. On the other hand, it can significantly contribute to better information and understanding of nanomaterials on the market, as well as relevant safety aspects. Therefore, it is considered to proportionate to the objective sought.

8 Monitoring and evaluation

8.1 Practical arrangements of the evaluation:

It will be important for the Commission to evaluate the effectiveness of the chosen option three years after its implementation. The success of option 2 would depend on the usage by the main target groups, i.e. authorities, users, workers and consumers. The Commission will be responsible for checking usage data and collecting user feedback on a regular basis to ensure that the Observatory provides relevant data for its target groups. Potential monitoring indicators are shown in Table 8 below.

8.2 Monitoring indicators for the preferred option

Table 8: Potential monitoring indicators related to the objectives of the Nanomaterials Observatory

Objectives	Indicators
Provide decision makers, regulatory/risk assessment authorities and professional users with information that allows them to better understand the markets, uses and risks of nanomaterials, contributing to a more appropriate response to possible health or environmental risks of nanomaterials	• Relevant nanomaterial and use descriptions on the website of the Nanomaterials Observatory • Robustness, including appropriate validation, pertinence and detail of the provided information. • Number and relevance of links to other information sources • Usage statistics specific to different target group, i.e. authorities and professional users • Evaluation of feedback from users
Provide policy makers, consumers and workers, as well as their associations with relevant information on products containing nanomaterials on the market and hence contribute to trust in the safe use of nanomaterials	• Clarity and understandability of information in tools for non-experts • Originality of approaches and their capacity to attract the target audience • Correctness and balanced presentation of information • Usage statistics specific for policy makers, consumers and workers • Evaluation of feedback from users

9 Annexes

Annex 1: Procedural information

Identification

Lead DG: Internal Market, Industry, Entrepreneurship and SMEs

Other involved DGs: Environment, Research and Innovation, Joint Research Centre, Health and Food Safety, Communications Networks, Content and Technology, Employment, Social Affairs and Inclusion, Justice and Consumers, Secretariat-General

Agenda Planning/WP Reference: 2015/GROW/005

Organisation and timing

The Impact Assessment Steering Group met on 25 February 2014, 12 May 2014, 1 December 2014, 13 July 2015 and 28 September 2015. A number of additional inter-service steering group meetings were held to discuss the progress of the supporting study (described below); those meetings took place on 23 January 2014, 21 March 2014, 1 July 2014 and 13 February 2015.

External study

An external study was launched in December 2013 to gather available data with relevance to the impact assessment, in particular the experiences from the existing nanomaterials notification schemes and relevant data regarding the assessment of policy options. The key deliverables of the study were the following four reports[178]:

- Evaluation report, describing and evaluating existing nanomaterials registries, in particular the French notification system (RPA *et al* (2014): Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market, Evaluation Report for DG Enterprise and Industry, November 2014, Loddon, Norfolk, UK, *cited as "**Evaluation Report**")*

- Building blocks report, collecting data on hazards and risks of nanomaterials and specific impacts on the nanomaterials industry (RPA *et al* (2015): Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market, Building Blocks report for DG Internal Market, Industry, Entrepreneurship and SMEs, April 2015, Loddon, Norfolk, UK, *cited as "**Building Blocks Report**")*

- Options assessment report, providing quantitative data (e.g. cost estimates) in support of the assessment of the different policy options. This report also includes an analysis of the results of the public consultation (RPA *et al* (2015): Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market, Options Assessment Report, for DG Internal Market, Industry, Entrepreneurship and SMEs, April 2015, Loddon, Norfolk, UK, *cited as "**Options Assessment Report**")*

- Workshop report, describing the outcomes of the stakeholder workshop organised in June 2014 (RPA *et al* (2014): Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market, Workshop report for DG Enterprise and Industry, August 2014, Loddon, Norfolk, UK, *cited as "**Workshop Report**")*

[178] Available online: http://ec.europa.eu/growth/sectors/chemicals/reach/nanomaterials/index_en.htm

The evaluation report, an advanced draft of the building blocks report and an initial draft of the options assessment report were discussed at a stakeholder validation workshop on 30 June 2014, and submitted to written comments by workshop participants and CARACAL members. An advanced draft of the options assessment report was discussed at the CASG(Nano) meeting on 4 December 2014 and submitted to written comments by its members subsequently. The final reports of the study are available online.

Other relevant sources of information include the following reports from national authorities:

- Ministère de l'Ecologie, du Développement durable et de l'Energie (2014) Eléments issus des déclarations des substances à l'état nanoparticulaire, rapport d'étude, November 2014, online: https://www.r-nano.fr/
- Ministère de l'Ecologie, du Développement durable et de l'Energie (2013) Eléments issus des déclarations des substances à l'état nanoparticulaire, rapport d'étude, November 2013, online: https://www.r-nano.fr/
- UBA (2014) Assessment of Impacts of a European Register of Products Containing Nanomaterials, Texte 23/2014, online: http://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_23_2014_assessment_of_impacts_of_a_european_register_of_products_containing_nanomaterials-schwirn.pdf
- BiPRO *et al* (2013) Study of the scope of a Belgian national register for nanomaterials and products containing nanomaterials, report for the Federal Public Service Health, Food Chain Safety and Environment, online: http://www.health.belgium.be/filestore/19086003/BE%20Nano%20Register%20Report_final.pdf
- Miljøstyrelsen (2013) Anvendelse af nanoprodukter på det danske marked, Miljøprojekt nr. 1451, online: http://www2.mst.dk/Udgiv/publikationer/2012/11/978-87-92903-68-6.pdf
- Miljøstyrelsen (2013) Muligheder for reduktion af danske virksomheders administrative byrder ved indberetning til en nanoproduktdatabase, Miljøprojekt nr. 1462, online: http://www2.mst.dk/Udgiv/publikationer/2013/01/978-87-92903-84-6.pdf

Consultation of the Regulatory Scrutiny Board

The Regulatory Scrutiny Board (RSB) of the European Commission assessed a draft version of the present impact assessment and issued its opinion on 03/02/2016. The Board made several recommendations. Those were addressed in the revised IA report as follows:

RSB recommendations	Modification of the IA report
The report should more clearly set out the global policy context/issues relating to nanomaterials and explain the policy framework (existing and parallel initiatives). In doing so, it should clarify the link and consistency with the initiative on the possible amendment of annexes to REACH for registration of nanomaterials.	The global policy context/issues relating to nanomaterials are described in the new sections 1.1, 1.2 and 1.3. The policy framework is explained in section 1.4. The links and consistency of this impact assessment with the parallel impact assessment on REACH Annexes are described in section 1.5.
Against that background, the report should clarify the particular problem(s) that this initiative aims to address and their magnitude (i.e. what are the problems	The problem definition in section 2.1 was revised to work out more clearly the problems related to the lack of transparency.

related to lack of transparency). This should be complemented by an improved intervention logic, clarifying the coherence between the problem description, the baseline scenario, the objectives and options.	The intervention logic in sections 4 and 5 was adapted to give a clearer link between the problem description, the baseline scenario, the objectives and the options (including the justification of the preferred option).
The options should be redefined to more clearly address the problem of transparency. It should also be clarified what they are expected to achieve and what is their added value.	The options were partly redefined to work out their contribution to transparency more clearly. Paragraphs were added to describe their expected outcome and value added.
Given the link and complementarity between this initiative and the one on nanomaterials in REACH, full coherence should be ensured in the presentation of the policy context, the overarching problems, the policy objectives and the baseline scenario. To ensure this, the Board recommends considering a more unified presentation of these IAs.	The general policy context (sections 1.1 to 1.4), the presentation of the overarching problems and policy objectives, including the link between the two impact assessments in terms of the baseline scenario (section 1.5) are now part of a common chapeau. This chapeau is agreed with DG ENV and GROW D.1, which will also be used for the REACH Annex impact assessment. Moreover, the baseline option was amended to explain more clearly the contribution of possible measures under REACH to the baseline of this impact assessment.
Clarify the broader context. The report should outline upfront the global issues relating to nanomaterials. It should clarify what scientific evidence is available on the characteristics of nanomaterials, including their potential health and environmental implications. A systemic description should be provided of how information on nanomaterials is generated and acted upon by relevant parties and where the shortcomings are. Against this background, the report should explain the existing policy framework and how it relates to the parallel initiative on nanomaterials in REACH.	The global policy context/issues relating to nanomaterials are described in the new sections 1.1, 1.2 and 1.3. The policy framework is explained in section 1.4. The links and consistency of this impact assessment with the parallel impact assessment on REACH Annexes are described in section 1.5.
Improve the problem definition and develop a robust baseline scenario. Against a more developed explanation of the broader context, the report should focus in on the particular problem(s) that this initiative aims to address (i.e. what are the problems related to transparency, what is their magnitude, who is affected?). In doing so, it should be decided whether information for consumers or workers are problems to be addressed by this particular initiative or whether they are more global problems that are or will be addressed by other measures. This will then need to be reflected in	The problem definition in section 2.1 was revised to work out more clearly the problems related to the lack of transparency. Although only a minority of consumers and workers is likely to actively search for relevant information, the availability of easily understandable information for those consumers and workers, as well as their associations, is a key bottleneck for a better informed policy debate, and for generating trust in nanomaterials and their applications. This was highlighted in the revised sections 2.1 – 2.3.

the choice of options. Given that the preferred option of the REACH impact assessment is used as baseline scenario of this impact assessment, the report should clarify what the remaining issues to be tackled are as regards transparency once the REACH initiative has been implemented. The remaining transparency and information needs should be assessed against which relevant information for consumers or workers can possibly be generated and made available for them.	
Clarify the intervention logic and the policy options. The coherence of the problem description, baseline scenario, objectives and options needs to be improved both internally as well as vis-à-vis the parallel impact assessment. In doing so, the options should be redefined to more clearly address the problem of transparency. The report should also better explain the envisaged functionality of the observatory option – what new tasks are envisaged for the observatory compared to now and what structures will be applied to it? Finally, the report should better demonstrate the added value and impacts of the options, while taking better account of the experience gained with national registries.	The intervention logic in sections 4 and 5 was adapted to give a clearer link between the problem description, the baseline scenario, the objectives and the options (including the justification of the preferred option). The links with and differences to the parallel impact assessment on REACH Annexes have been clarified. The description of the observatory option in section 5 has been significantly expanded and includes a more detailed task description and identifies the European Chemicals Agency as envisaged host. The value added of the observatory over the registry option has been worked out more clearly in section 7.2. In addition, first experiences from the Danish registry, which have become available in the meantime, have been added in section 6.6.
The consistency between this initiative and the one on nanomaterials in REACH should be fully ensured in the presentation of the policy context, the overarching problems, the policy objectives and the baseline scenario. Moreover, given the link and complementarity between the initiatives, consideration should be given to merging the two IA reports into one. If this is not possible, the coherence should be ensured by applying a common 'chapeau' for both reports, which would clarify the links to the other report and make the report self-standing.	The context, the common overarching problems and objectives and differences between the issues addressed in the two impact assessments were highlighted in a common ‘chapeau’ for both reports. Where relevant, references to possible synergies, links, and differences to the parallel impact assessment on REACH Annexes were added in the remainder of this impact assessment report.

Annex 2: Consultation

Company survey

As part of the RPA/BIPRO study, an online survey was addressed to companies with relevant experience of the French National System (FNS) and/or the Cosmetic Products Notification Portal (CPNP) on 27 February 2014. The survey aimed to gather information on the costs and administrative burden that the notification obligations put on the enterprises with obligations under the FNS.[179]

Subsequently, a stakeholder meeting was organised on 10 March 2014 in Paris in conjunction with the session of the French Working Group on nanomaterials, hosted by the Ministère de l'Écologie, du Développement durable et de l'Énergie. Its purpose was to gather further information for the assessment of the FNS and to foster participation to the aforementioned survey and to the public consultation.[180] The cost figures from this survey and stakeholder meeting have been used as input to the cost calculations for the policy options in Section 6.

Expert group

The expert group of the Member States Competent Authorities for REACH and CLP (CARACAL) has been informed and invited to provide input to the supporting study on a regular basis. The plans for this impact assessment were first CARACAL at their meetings on 13 March 2013, 27 November 2013 and 3 April 2014. More detailed discussions took place in the CARACAL Subgroup on Nanomaterials (CASG Nano) on 20 March 2014 and 4 December 2014. Both groups include stakeholder observers who participated in the discussions. Where appropriate, written comments were invited and taken into account in the study reports.

Public consultation

A public consultation was held between 13 May 2014 and 5 August 2014. Its objective was to obtain stakeholder views on the currently available information on nanomaterials on the market, the problem definition that forms the basis of the impact assessment, as well as the potential positive and/or negative impacts of the aforementioned policy options. In total, 202 responses were received. 14 respondents requested that their contributions would not be published (see Table A2-1 below). All other contributions have been published online.[181] A summary of the results is annexed to the Options Assessment Report[182]. Furthermore, an SME panel, entailing a survey tailored to small and medium-sized enterprises, has taken place in parallel (see below).

[179] Evaluation Report, pp. 58-74
[180] Evaluation Report, pp. 52-58
[181] Available online: http://ec.europa.eu/growth/sectors/chemicals/reach/nanomaterials/index_en.htm
[182] Options Assessment Report, p. 89

Table A2-1: Number of responses to the public consultation

	Questionnaire for industry	Questionnaire for other stakeholders
Registered organisations*	48	19
Public authorities	0	11
Non-registered organisations and citizens	44	66
Responses not to be published	8	6
Total	100	102

* Registered organisations are included in the European Commission's Transparency Register and subscribe to its code of conduct.

SME Panel

An SME panel for this impact assessment was organised between 4 July and 15 September 2014. SME Panels are used to consult SMEs about EU legislation and policies. The Enterprise Europe Network (EEN) partners select suitable SME participants, run the SME panels and provide the Commission with the results.

A total of 63 responses were received from Denmark (2), France (15), Greece (1), Hungary (1), Netherlands (1), Poland (33), Romania (5), Spain (1), United Kingdom (2). Two responses were discarded as the respondents did not meet the criteria of the SME definition (headcount exceeding 250).

Different company sizes are covered by the group of respondents to the survey, i.e. micro-enterprises (61%), small enterprises (23%) and medium-sized enterprises (16%). Respondents represent a variety of sectors, including basic chemicals, paints and printing inks, perfumes, electrical equipment, machinery, ceramics, glassware, textile fibres, foodstuff and research and development.

While the number of respondents is relatively low and survey results are not statistically significant, the responses do provide an indication of the views of SMEs on currently available information on nanomaterials and on their expectations of potential transparency measures.

A majority of respondents (64%) only serves the domestic market; only 16% of respondents export to 5 or more Member States. Two-thirds of respondents report annual sales revenues for nanomaterials below €250.000, although the number of respondents is too low to estimate a percentage of total turnover. Most respondents (approximately 80%) report that they handle fewer than 6 nanomaterials (whether as substances in nanoform or in mixtures or articles).

With regard to the problem definition, a majority of respondents disagrees with the statement that the current level of information on the presence of nanomaterials or products containing nanomaterials prevents an adequate response to health and environmental risks (25% agrees, 51% disagrees, 25% is neutral). However, a majority of respondents does agree that it is insufficient for informed consumer choice (59% agrees, 21% disagrees, 20% is neutral). and potentially detrimental to consumer trust (51% agrees, 29% disagrees, 20% is neutral). Two-thirds of respondents also agree that available information is currently not presented in an effective way.

More specifically, various respondents report a lack of information on nanomaterials among customers or general public. However, one respondent points out that the average consumer is unlikely to be able to use the information on nanomaterials and expects the authorities to ensure adequate risk management. Another respondent suggests not generalising nanomaterials, but focusing on cases when a substance in nanoform truly shows different properties.

A majority of respondents consider that they currently receive sufficient information from suppliers (61% agrees; 33% disagrees; 14% is not able to judge this). Some respondents indicate that the information in the Safety Data Sheet (SDS) is sufficient.

Most SMEs expect a potential registry to have an impact on their companies (35% expects a small or medium impact; 33% expect a considerable or significant impact; 15% expects no impact), although the impact will depend on the exact information that would be required. As an illustration, one SME indicated that the profit margins on its nanomaterial products are low and that any additional burden may easily exceed these profits margins. However, the respondents are divided over the effect of a registry on their competitiveness; most respondents are not able to estimate these effects.

Some SMEs highlight that they do not have a dedicated department that could deal with such regulatory requirements. Two-thirds of respondents indicate that they do not have sufficient in-house expertise to meet the requirements of a potential registry. Some indicate that they expect larger competitors to be advantaged, as they may be better resourced to provide the required information.

Most respondents expect that the registry information will be useful to them (71%), although their expectations often exceed the possibilities of the registry (e.g. publicly available information on marketed products). Various SMEs express an interest in information on market sizes and market trends. However, it should be noted that only a Nanomaterials Observatory based on market studies could make such information available.

Overall, respondents consider the main advantage of transparency measures to be to educate the public and to increase customer confidence in nanomaterials.

Validation workshop

A validation workshop was organised on 30 June 2014 in Brussels. 59 representatives from Member State competent authorities, industry associations, trade unions, consumer associations, environmental NGOs and other relevant organisations attended the workshop. A full summary of the workshop proceeding and conclusions is provided in the *Workshop Report*.[183]

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

Annex 3: Key calculation tables

Detailed calculation tables for the administrative burden for companies are included in Annex II of the Options Assessment Report.

Table A3-1: Assumptions for cost calculation for Option 3 (Source: Options Assessment Report, Table A2-3, p. 128)

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 (Evaluation Report, p. 59), with the exception for the research institutes, which is based on assumptions by the authors of the Evaluation Report.			

Table A3-2: Cost calculation for Option 3 (Options Assessment Report, Tables A2-4 to A2-8 & A2-17 to A2-23, pp. 129-133 & 143-150)

Industrial sector (by NACE code)	1	2	3	4	5	6	7	Total costs (first year)
C20.12 - Manufacture of dyes and pigments	590	2.360	470 - 1.170	70%	30%	€1.410.000 - €9.950.000	€1.899.800	€3.310.000 - €11.850.000
C20.13 - Manufacture of other inorganic basic chemicals	270	1.080	200 - 520	70%	30%	€600.000 - €4.400.000	€869.400	€1.469.000 - €5.269.000
C20.14 - Manufacture of other organic basic chemicals	200	800	100 - 340	70%	30%	€300.000 - €2.900.000	€644.000	€944.000 - €3.544.000
C20.16 - Manufacture of plastics in primary forms	250	1.000	170 - 470	70%	30%	€510.000 - €4.000.000	€805.000	€1.315.000 - €4.805.000
C20.20 - Manufacture of pesticides and other agrochemical products	60	240	-	0%	0%	-	€193.200	€193.000
C20.30 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics	3.600	14.400	3.360 - 7.680	70%	30%	€10.080.000 - €65.300.000	€11.592.000	€21.672.000 - €76.892.000
C20.41 - Manufacture of soap and detergents, cleaning and polishing preparations	370	1.480	220 - 660	70%	30%	€660.000 - €5.600.000	€1.191.400	€1.851.000 - €6.791.000
C20.42 - Manufacture of perfumes and toilet preparations	460	1.840	-	0%	0%	-	€1.481.200	€1.481.000 - €1.481.000
C20.59 – Manufacture of other chemical products	430	1.720	360 - 880	70%	30%	€1.080.000 - €7.500.000	€1.384.600	€2.465.000 - €8.885.000
C21.10 – Manufacture of basic pharmaceutical products	90	360	-	0%	0%	-	€289.800	€290.000
C21.20 – Manufacture of pharmaceutical preparations	320	1.280	-	0%	0%	-	€1.030.400	€1.030.000
G46.45 – Wholesale of perfume and cosmetics	990	7.920	-	0%	0%	-	€4.816.350	€4.816.000
G46.46 – Wholesale of pharmaceutical goods	1.920	15.360	-	0%	0%	-	€9.340.800	€9.341.000
G46.75 – Wholesale of chemical products	1.390	11.120	-	0%	0%	-	€6.762.350	€6.762.000
M72.1 – R&D on nat. sciences and engineering	3.780	37.800*	-	0%	0%	-	€3.307.500	€3.308.000
Total	**14.720**	**98.760***	**4.880 - 11.720**			**€14.640.000 - €99.650.000**	€45.607.800	**€60.247.000 - €145.257.000**

1: Number of companies with notifications duties (Options Assessment Report, Table A2-2)

2: Number of notifications (Options Assessment Report, Table A2-4)

3: No. of notifications in the EU for which NM characterisation has to be done (Options Assessment Report, Table A2-17)

4: % of notifications for which all characterisation information had to be generated; cost estimated at €3.000-10.000 per notification (Options Assessment Report, Table A2-19)

5: % of notifications for which part of the information had to be generated, including negative results; cost estimated at €3.000-5.000 per notification (Options Assessment Report, Table A2-19)

6: Total Characterisation costs - low and high end (Options Assessment Report, Table A2-20)

7: Combined costs for understanding legal requirements, adapting product/account databases, costs for the gathering of the information, submission of the information, responding to enquiries (Options Assessment Report, Tables A2-21/A2-22)

Table A3-3: Cost calculation for Option 4 (Options Assessment Report, Tables A2-33/34/35, pp. 162-166)

Industrial sector (by product group)	1	2	3	4	5	6	Implementation costs	Annual costs
1. Substances	1,210	- *	- *	3.990	- *	- *	34,835,900 €[+]	435,600 €[#]
2. Cosmetics	1,450	3,850	875	22.950	175	525	17,631,250 €	5,285,000 €
3. Health Care	2,250	3,850	875	39.450	175	525	29,373,750 €	8,872,500 €
4. Food & Feed	17,960	3,850	875	341.240	175	525	248,297,000 €	75,432,000 €
5. Coatings & Inks	26,700	5,250	1,050	3.000	175	700	142,275,000 €	28,560,000 €
6. Cleaning & Disinfection	2,200	2,275	525	19.800	175	350	11,935,000 €	4,620,000 €
7. Tyres & Other Rubber Products	16,600	2,625	1,400	0	175	525	43,575,000 €	23,240,000 €
8. Plastic Products	52,500	2,625	1,400	8.050	175	525	142,038,750 €	74,908,750 €
9. Building & Construction	610	3,500	700	5.490	175	350	4,056,500 €	1,387,750 €
10. Textiles	21,400	1,750	1,050	192.300	175	700	172,060,000 €	56,122,500 €
11. Paper Products	9,300	2,625	1,400	9.200	175	525	29,242,500 €	14,630,000 €
12. Wood Products	35,700	2,625	1,400	106.995	175	525	149,884,875 €	68,704,125 €
13. Sporting Goods	1,505	3,500	1,750	2.795	175	350	6,245,750 €	3,122,875 €
14. Electronics	148,400	2,625	1,400	98.900	175	525	441,472,500 €	225,067,500 €
15. Complex Objects	1,274,100	2,625	1,400	849.400	175	525	3,790,447,500 €	1,932,385,000 €
16. Miscellaneous	5,100	2,625	1,400	90.900	175	525	61,110,000 €	23,047,500 €
Total	**1,617,000**	-	-	1.794.500	-	-	**5,324,500,000 €**	**2,545,900,000 €**

The NACE codes associated with each product group are listed in the Options Assessment Report, Table A2-33, pp. 162-164.

*: Substances costs are based on the results of the Option 3 and are an average of the ranges of NACE codes manufacturing substances

1: Number of companies with notifications duties (Options Assessment Report, Table A2-33)

2: Administrative costs (€) in the first year for companies with notification duties; values for substances (group 1) are based on the calculations for Option 3, values for other groups are based on Miljøstyrelsen (2013) Anvendelse af nanoprodukter på det danske marked, Miljøprojekt nr. 1451 (Options Assessment Report, Table A2-34)

3: Recurrent administrative costs (€) per year for companies with notification duties; values for substances (group 1) are based on the calculations for Option 3, values for other groups are based on Miljøstyrelsen (2013) Anvendelse af nanoprodukter på det danske marked, Miljøprojekt nr. 1451 (Options Assessment Report, Table A2-34)

4: Number of companies without notifications duties (these companies also incur administrative burden, as they may have to test their products to verify the absence of nanomaterials subject to notification duties) (Options Assessment Report, Table A2-33)

5: Administrative costs (€) in the first year for companies without notification duties; values for substances (group 1) are based on the calculations for Option 3, values for other groups are based on Miljøstyrelsen (2013) Anvendelse af nanoprodukter på det danske marked, Miljøprojekt nr. 1451 (Options Assessment Report, Table A2-34)

6: Recurrent administrative costs (€) per year for companies without notification duties; recurring administrative burdens for companies without notification duties estimated at 5 hours per company per year (Options Assessment Report, Table A2-34)

Annex 4: Glossary

Definitions

Nanomaterial: As defined in Commission Recommendation 2011/696/EU on the definition of nanomaterial, "'Nanomaterial' means a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. […] [F]ullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials".

Substance: The CLP and REACH Regulations define a substance as "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition".

Mixture: The CLP and REACH Regulations define a mixture as "a mixture or solution composed of two or more substances".

Article: The CLP and REACH Regulations define an article as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition".

Manufacturer: The CLP and REACH Regulations define a manufacturer as "any natural or legal person established within the Community who manufactures a substance within the Community".

Importer: The CLP and REACH Regulations define an importer as "any natural or legal person established within the Community who is responsible for import".

Downstream user: The CLP and REACH Regulations define a downstream user as "any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user.

Distributor: The CLP and REACH Regulations define a distributor as "any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties".

Abbreviations

CARACAL	Member States' Competent Authorities for REACH and CLP
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
CPNP	Cosmetics Products Notification Portal
ECHA	European Chemicals Agency
FNS	French Notification System
JRC	Joint Research Centre
R&D	Research and Development
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
SCENIHR	Scientific Committee on New and Emerging Health Risks
SME	Small and Medium-sized Enterprise
TFEU	Treaty on the Functioning of the European Union

Annex 5: Overview of the existing legislative framework on nanomaterials

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. Most notably, these requirements include the following:

- 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). Such a registration dossier contains the hazard information and, where relevant, an assessment of the risks that the use of the substance may pose and how these risks should be controlled.
- 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). The notification includes substance identity, the tonnage range of the substance and a description of the use of the substance in the article.
- 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 Annex IV (substances for which sufficient information is available indicating that they cause minimum risk) and Annex V (substances for which registration is deemed inappropriate or unnecessary).
- Provision of safety data sheets for any substance considered hazardous or dangerous or meeting certain other criteria (REACH Article 31).
- Hazard classification of substances and mixtures, taking into account "the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used" (CLP Article 9), as well as appropriate labelling and packaging, ensuring the communication of these hazards to downstream users.
- Notification of hazardous substances[184] (independently of tonnage) to the European Chemicals Agency.

An impact assessment on possible amendments of the Annexes to REACH is presented in parallel. This impact assessment aims at ensuring clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers of substances with nanoforms. In particular, it evaluates whether and what additional physico-chemical characterisation data should be required under REACH. For the purpose of the present impact assessment, it is assumed that these amendments of the REACH Annexes will establish the best balance between costs and value added for the substances with nanoforms in REACH registrations, and that this data will subsequently be available. Therefore, characterisation data for substances with nanoforms are considered to be available for the purpose of defining the baseline for the present impact assessment.

[184] A substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in Parts 2 to 5 of Annex I of Regulation No 1272/2008, is considered hazardous.

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. These are some of the most relevant requirements:

- The Cosmetics Regulation (No. 1223/2009) requires that all cosmetic products placed on the Union's market are notified to the European Commission through the CPNP. The information provided includes the identification of the nanomaterials present in the product. In addition to this general notification, cosmetic products containing nanomaterials[185] other than those used as colorants, UV-filters or preservatives (those must be explicitly authorized) must be notified to the European Commission, including the submission of toxicological and safety data of the nanomaterial, six months prior to marketing. Based on the CPNP notifications, 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). As described above in section 1.2, the labelling of nanomaterials is outside the scope of this impact assessment.
- Lastly, authorisation procedures exist for active substances in plant protection products (Regulation (EC) No 1107/2009) and medicinal products (Directive 2001/83/EC). Although not specifically designed for nanomaterials, those procedures will also cover risk assessment for nanomaterials falling under the scope of those pieces of legislation.

Some Member States have established national registries for nanomaterials and/or products containing nanomaterials on the market. France has introduced a notification system for substances in nano-form, including such substances in mixtures and in articles if intentionally released. Belgium and Denmark have adopted legislation requiring notification of nanomaterials in specific applications, including substances, mixtures and articles containing substances in nanoform.

[185] The scope under the Cosmetics Regulation is limited to intentionally manufactured nanomaterials. The following definition is currently used: *"an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm"*