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IMPACT ASSESSMENT

Accompanying the document

Commission Regulation

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances

{C(2018) 7942 final} - {SEC(2018) 478 final} - {SWD(2018) 475 final}

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1 INTRODUCTION

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. Most 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 2018 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

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[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 less nanoforms 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-

pigments, cosmetics ingredients and plant protection products. In one way or the other, 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 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

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lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52012SC0288&from=EN. For updated information on nanomaterials, their uses, hazards and risks see European Union Observatory for Nanomaterials.

[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, just employing and improving certain manufacturing processes that also led to particles with size in the nanoscale range

[8] For the purpose of this impact assessment and the parallel impact assessment on transparency measures for 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

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.

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

[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

[12] There is a discussion on the validity of a significant part of the studies, as many studies have used high doses and have not been conducted at standard conditions allowing reproducibility. Work reassessing the validity of past studies and establishing a more reliable scientific framework for future studies is ongoing inter alia in the NanoREG project financed under the EU´s 7th Research Framework Programme. Nevertheless, it is beyond doubt that serious effects related to inhalation of nanoparticles can occur.

[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 Appendix XIV 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

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 the registration dossier. 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. 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 pre-market notification of nanomaterials which are cosmetics ingredients to the EU Cosmetics Notification Portal. A catalogue of such nanomaterials was due for publication in 2014 but was delayed until 2017 (see catalogue at http://ec.europa.eu/DocsRoom/documents/23861) due to numerous unclear and obviously wrong 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

[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.

[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

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].

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]. So far guidance has already been published[22] 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 the amendment of Annexes to REACH for the registration of nanomaterials[23]. It is closely linked with a parallel impact assessment on transparency measures for nanomaterials on the market.

The overarching objective of the two initiatives 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 this impact assessment is to assess relevant regulatory options, in particular possible amendments of REACH Annexes, to ensure further clarity on how nanomaterials are addressed and safety demonstrated in REACH registration dossiers. The scope is limited to

[20] 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

[21] 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

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

[23] For all procedural aspects of this impact assessment, please refer to Appendix XV

measures that can be proposed via the Committee procedure[24], i.e. restrained to certain amendments of the REACH Annexes for nanomaterials, as the Commission in the General Report on the REACH Review[25] 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*".

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 and closely linked with the present impact assessment. 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.

It is closely linked with a parallel impact assessment for a possible amendment of Annexes to REACH for registration of nanomaterials.

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[26]. 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[27], arguing in essence that existing legislation is sufficient to address regulatory concerns on nanomaterials. Following this Communication, the European Parliament issued a Resolution[28] 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[29] 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

[24] In accordance with Article 131 of REACH

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

[26] 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

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

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

[29] 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

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"[30]. 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[31] and a Communication on the Second Regulatory Review of Nanomaterials in 2012[32]. The Communication concluded that nanomaterials were much more common, widespread and, at least for many of the substances analysed in an attached Staff Working Document[33], less toxic than the public debate suggested. The Communication reaffirmed the general applicability of REACH and other existing legislation to nanomaterials. In line with previous scientific opinions[34], 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[35], 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**[36].

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')[37].

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

[30] 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

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

[33] 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

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

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

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

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

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 1-1 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 only understandable for specialists. Its scope is limited to actions which 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[38], which is assessed as part of the REACH Annex impact assessment, and thus 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 this matter would require different legislation, which would need to be adopted in ordinary legislative procedure.

Table 1-1: 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[39]
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	Comitology (REACH)	Co-decision for the legislative option (beyond the scope and purpose of REACH)

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

[39] One option is also linked to safety information from available sources, including REACH dossiers; however, it would not generate self-standing information generation on substance properties.

required		

2 PROBLEM DEFINITION

2.1 Policy context: the Registration process within REACH

The Registration, Evaluation, Authorisation and Restriction of Chemicals REACH Regulation replaced the previous legislation, with the aim to ensure the protection of human health and the environment from the risks of chemicals, including the promotion of alternative methods for assessment of hazards of substances (mainly in order to reduce animal testing), as well as the free circulation of the substances on the internal market while enhancing the competitiveness of the EU chemicals industry.

The overall purpose of the registration under REACH is that the registrant must ensure the safety of the intended uses of a chemical (in all forms)and provide sufficient information to this effect. In order to meet the objectives of the legislation, REACH imposes registration obligations on companies and at the same time provides for a tiered tonnage based information requirements, risk based approach to exposure assessment and staggered registration timelines in order to allow necessary flexibilities to companies to comply with REACH obligations. In other words, the depth and level of detail of the information requirements depend on the volume of the substance placed on the market and the risks it poses.

2.2 The problem requiring action and its drivers

2.2.1 The problem and its consequences

The Commission, in close collaboration with ECHA, assessed in 2011 how nanomaterials had been addressed in REACH registration dossiers submitted before December 2010. The assessment found that, in the absence of a definition of nanomaterial before October 2011 and of specific ECHA guidance (published only in April 2012), most registration dossiers for substances known to have nanoforms[8] do not mention clearly which forms are covered or how the provided information relates to the nanoform. As of August 2015, 13 substance registrations[40] and 108 CLP notifications[41] had selected "nanomaterial" as a form of the substance for at least one form documented in the registration dossier/notification. Only little information was specifically addressing safe use of the specific nanoforms supposed to be covered by the registration dossiers. The registration dossiers therefore did not document if and how registrants ensured the safe use of the substance with nanoforms covered by the registration.

In order to attain the aims of REACH[42], the Commission identified, based on the above mentioned assessment, a necessity for more specific requirements for the registration of

[40] 5 were registered in 2010, 4 in 2013 and 4 non-phase-in have been registered after 2013. Update as of March 2018: total number of registered substances with nanoforms: 21.

[41] The number of notifications in the C&L Inventory that have nanomaterial reported as the form of the substance (i.e. nanoform) has increased from 18 in June 2013 to 108 in August 2015; for comparison, during the same time the total number of notifications in the database increased from 3.2 to 6.4 million.

[42] According to its Article 1.1, the purpose of REACH is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

substances with nanoforms ensuring further clarity on how they are to be addressed and safety demonstrated in registration dossiers.

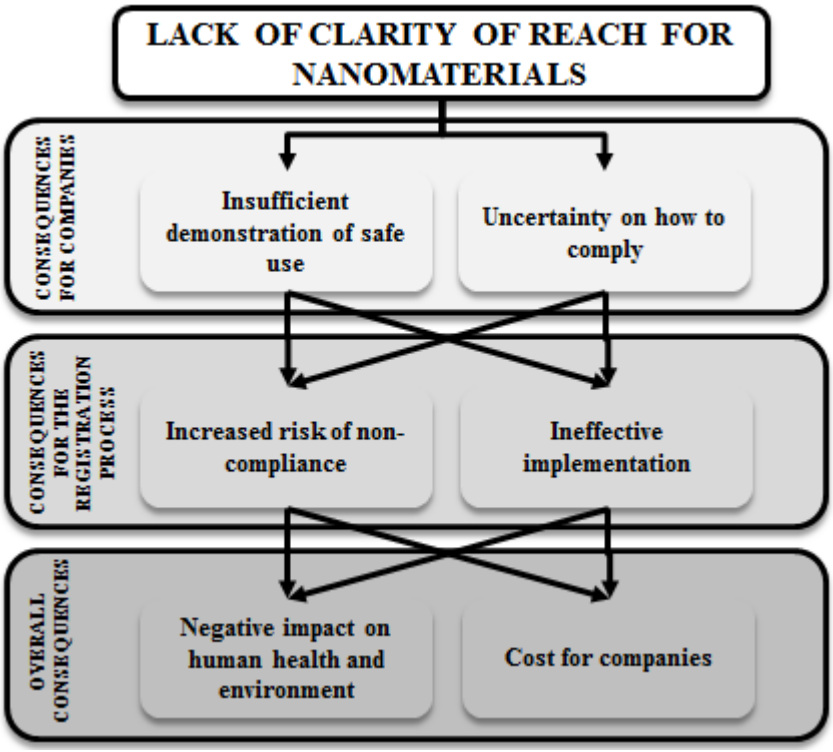
In case of inaction, the potential results can be:

i) Insufficient demonstration of safe use in the REACH registration dossiers, resulting in increased **risk for health and the environment**, due to potentially poor risk management and safety measures, ultimately leading to harmful use and negative economic consequences[43].

ii) Uncertainties for companies on what needs to be included in the REACH registration dossiers, resulting in ineffective implementation and consequently **increased costs**, affecting innovation, investment decisions and impaired competitiveness on global markets.

The problem and its consequences are illustrated in the figure below:

Figure 2-1: The problem and its consequences:



2.2.2 Magnitude of the problem

The magnitude of the problem can be determined by two factors: i) the extent of deficiencies in demonstration of safe use of nanoforms of a substance and the subsequent consequences, and ii) the size of the market of registered nanomaterials that is affected by the REACH provisions. Whereas the first factor, and in particular the deficiencies in the registration dossiers of substances containing nanoforms are qualitatively explained above, it is very difficult to quantify the magnitude of the problem due to the many variables and uncertainties involved. The figures related to the size of the market shown in section 1.2 *Uses of nanomaterials and size of the market* are very general. The exact size of the market at EU

[43] Potential accidents related to nanomaterials may affect the consumer confidence in products containing nanomaterials, and thus harming the sector overall.

level is not known with precision, even less the proportion between the part of the market subject to registration (i.e. quantities of the registered substances in nanoforms are above 1 ton per year) and the substances in nanoform that would not be subject to registration requirements.

Nevertheless, what is known is that 21 substances were registered as occurring (also) as nanoforms as of March 2018. The figures from the French notification system[44] (FNS) suggest that most of the nanomaterials may have been registered as substances already (in 2014, 171 out of 287 substances i.e. 60% notified under the FNS, with an additional 5% anticipated to be registered by 2018). It is therefore sensible to assume that most of the nanoforms are not being registered as such but have either not yet explicitly been indicated as being nanoforms in the registration, or are being registered jointly with bulk forms of the substance without yet declaring so.

The remaining 35% from FNS could be an indicator of the number of substances below the 1 tonne threshold, but does not indicate the proportion of the number of nanoforms of the non-registered substances with nanoforms to the total number of nanoforms on the market, or the proportion of the actual size of the market in volumes or in the value of products. In terms of volume, the information from the work on transparency measures (benefiting again principally from the FNS information) is that the vast majority can be attributed to nanoforms in some commodity products (e.g. pigments).

2.2.3 Initiatives undertaken

There have been important developments that have had an impact on the identified problem since the first registration round in 2010:

- Recommendation 2011/696/EU adopted by the Commission on October 2011 sets out a definition of the term nanomaterial. The definition clarifies terminology, but in itself does not provide clarity to the registrants on how to address nanomaterials in REACH registrations. The Commission is currently reviewing the nanomaterial definition. A three-part report addressing scientific-technical aspects of the definition has been published[45] by the Joint Research Centre and the Commission will consider these as input in the review of the definition, scheduled to be finalised in 2018. The Commission might conclude to revise certain aspects of the abovementioned Recommendation. Such a potentially revised Recommendation will be fully integrated in the changes to the REACH Annexes to ensure coherence with other Regulations. The potential changes might influence some of the assumptions used in this impact assessment. Based on the review performed so far, it is reasonable to assume that clarification of the definition of the text rather than changes in content would be taking

[44] R-Nano.fr Declaration of nanomaterials, https://www.r-nano.fr

[45] *Towards a review of the EC Recommendation for a definition of the term "nanomaterial - Part 1: Compilation of information concerning the experience with the definition"* from May 2014 http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/31515/1/lbna26567enn.pdf
Towards a review of the EC Recommendation for a definition of the term "nanomaterial" Part 2: Assessment of collected information concerning the experience with the definition" from September 2014 http://publications.jrc.ec.europa.eu/repository/bitstream/111111111/32544/1/jrc_nm-def_report2_eur26744.pdf
Towards a review of the EC Recommendation for a definition of the term "nanomaterial" – Part 3: Scientific-technical evaluation of options to clarify the definition and to facilitate its implementation" from June 2015 http://publications.jrc.ec.europa.eu/repository/bitstream/JRC95675/towards%20review%20ec%20rec%20def%20nanomaterial%20-%20part%203_report_online%20id.pdf

place. In any case, the revision of these assumptions would not affect the nature of the options in this impact assessment, but may impact the number of nanoforms to which the requirements of REACH (and the related changes to the Annexes) apply. If a material in a specific form is considered a nanoform before and after the revision of the nanomaterial definition, the REACH requirements introduced by the changes to the Annexes would apply in exactly the same way, whilst this would not be the case if a material was no longer a nanomaterial after the modification of the definition.

- The Commission conducted the comprehensive REACH Implementation Project on Nanomaterials (RIPoN) to provide advice on key aspects of the implementation of REACH with regard to nanomaterials concerning Information Requirements (RIPoN 2[46]) and Chemical Safety Assessment (RIPoN 3[47]). A third report of the RIPoN project relates to Substance Identity (RIPoN1[48]). In April and May 2012, ECHA updated with three new appendices the Guidance on Information Requirements and Chemical Safety Assessment (IR & CSA) and on registration, in order to take into account the recommendations from the RIPoN 2 and 3 projects. In February 2013, ECHA updated its advice on Nanomaterials in IUCLID from June 2010[49].
- ECHA established in May 2012 a nanomaterials working group (ECHA-NMWG) to discuss scientific and technical questions relevant to REACH and CLP processes and to provide recommendations on strategic issues. It is an informal advisory group consisting of experts from Member States, the European Commission, ECHA and accredited stakeholders organisations, with the mandate to "*Provide informal advice on any scientific and technical issues regarding implementation of REACH and CLP legislation in relation to nanomaterials.*"
- ECHA has finalised 13 decisions on the compliance of the registrations of 8 substances with nanoforms requesting further actions from addressed registrants in order to bring their registration dossiers into compliance with REACH information requirements. 5 out of these (concerning titanium dioxide, silic acid and aluminium sodium salt) have been appealed before the ECHA Board of Appeal[50]. These cases

[46] Specific Advice on Fulfilling Information Requirements for Nanomaterials under REACH (RIPoN2), 1 July 2011. http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon2.pdf

[47] Specific Advice on Exposure Assessment and Hazard/Risk Characterisation for Nanomaterials under REACH (RIPoN3), 7 July 2011. http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon3.pdf

[48] REACH Implementation Project Substance Identification of Nanomaterials (RIPoN1), March 2011. http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon1.pdf

[49] IUCLID 5 Guidance and Support – Nanomaterials in IUCLID 5, February 2013. http://www.google.lu/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CB8QFjAA&url=http%3A%2F%2Fiuclid.echa.europa.eu%2Fdownload%2Fdocuments%2Fusermanual%2FIUCLID_User_Manual_Nanomaterials_v2.0.pdf&ei=9XrCVN6mGIT6PISMgdgP&usg=AFQjCNHgLzwy9EbQ4fPdPZXcE4esI0T6uQ

[50] Appeal A-011-2014 against ECHA's Decision CCH-D-0000004804-72-03/F from 16 September 2014 for titanium dioxide. BoA decision published on 2 March 2017. https://echa.europa.eu/documents/10162/a3beed31-ab30-dcf1-1f86-7467f6b09a20
Appeal A-011-2015 against ECHA's Decision CCH-D-0000005201-89-02/F from 16 March 2015 for silicic acid, aluminum sodium salt. http://echa.europa.eu/documents/10162/13574/a_011_2015_announcement_en.pdf
Appeal A-008-2015 against ECHA's Decision CCH-D-0000005199-66-02/F from 16 March 2015 for silicic acid, aluminum sodium salt. http://echa.europa.eu/documents/10162/13574/a_008_2015_announcement_en.pdf

will provide valuable information regarding the interpretation of the current REACH information requirements in relation to the registration of substances with nanoforms. The first four closely related decisions of the Board of Appeal (regarding the cases A-008-2015, A-009-2015, A-010-2015 and A-011-2015)[51] were published on 12 October 2016. The Board annulled ECHA compliance check decisions and returned them to re-evaluation, as it found that the contested decisions are unclear regarding certain of the terminology used therein which gave ground to the appellant's claim that it is not clear how to comply with the decision. While the Board of Appeal decisions only refer to the specific drafting used by ECHA in these decisions, the Board of Appeal's observations also confirm the underlying problems as set out in section 2.3 that the measure accompanied by this impact assessment intends to address, i.e. that REACH information requirements are not clear enough for the registration of substances with nanoforms. The Board of Appeal's decision of 2 March 2017 on the appeal A-011-2014 regarding the compliance check on titanium dioxide annulled the ECHA compliance check decision, with the principal argument that under the current provisions in REACH, ECHA cannot request information on the characterisation of nanoforms as part of the substance identity information (Annex VI.2 of REACH), as the elements listed are exhaustive and adding new information requirements requires amending the REACH Annexes.

- Member States have started Substance Evaluation of some substances with nanoforms in the Community Rolling Action Plan (CORAP) due to concerns related to nanoforms. The Decision regarding silica has been agreed by consensus in the Member States Committee in December 2014 requiring information on physicochemical properties (including surface-treated nanoforms), additional toxicity studies for four specific forms (representing different ranges of characterisers of the registered forms), all toxicological information on surface-treated forms and the uses of the individual forms. The decision has been challenged by two groups of registrants in front of the Board of Appeal.[50]
- Further adjustment of the OECD Test Guidelines is currently being discussed by the OECD Working Party on Manufactured Nanomaterials (WPMN). Eight test guidelines have been identified as requiring adaptation.

It is reasonable to assume that the above mentioned initiatives, and in particular the RIPoNs and the subsequent nano-specific ECHA guidance as well as ECHA Decisions have addressed some aspects of the identified problem. Of the thousands of dossiers which were submitted by

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Appeal A-009-2015 against ECHA's Decision CCH-D-0000004724-72-03/F from 16 March 2015 for silicic acid, aluminum sodium salt.
http://echa.europa.eu/documents/10162/13574/a_009_2015_announcement_en.pdf
Appeal A-010-2015 against ECHA's Decision CCH-D-0000004722-76-03/F from 16 March 2015 for silicic acid, aluminum sodium salt.
http://echa.europa.eu/documents/10162/13574/a_010_2015_announcement_en.pdf
Substance evaluation:
Appeal A-014-2015 against Decision on substance evaluation for silicon dioxide of 11 March 2015
https://echa.europa.eu/documents/10162/13574/a_014_2015_announcement_en.pdf
Appeal A-014-2015 against Decision on substance evaluation for silicon dioxide of 11 March 2015
https://echa.europa.eu/documents/10162/13574/a_015_2015_announcement_en.pdf

[51] https://echa.europa.eu/about-us/who-we-are/board-of-appeal

the second registration deadline on 1 May 2013, only four indicated to cover nanomaterials[52] ECHA has not yet reviewed the many thousands new registrations in depths; by July 2017, 21 substances with nanoforms have however additionally identified nanoforms in the registration dossiers. The on-going review of the Nanomaterial definition has identified technical difficulties that may have partly influenced registrants' approaches in the registration dossiers.

Thus, the exact magnitude of the problem at present has multiple facets; assessing it in-depth would require significant additional resources and time. Nevertheless, it can be deducted that there is a need to further address the problem. Furthermore, the results[53] of the public consultation conducted for the purpose of this impact assessment indicated that the majority of the stakeholders considered the current provisions on information requirements for the registration of nanomaterials as not clear. Member States, NGOs as well as part of industry were of that opinion.

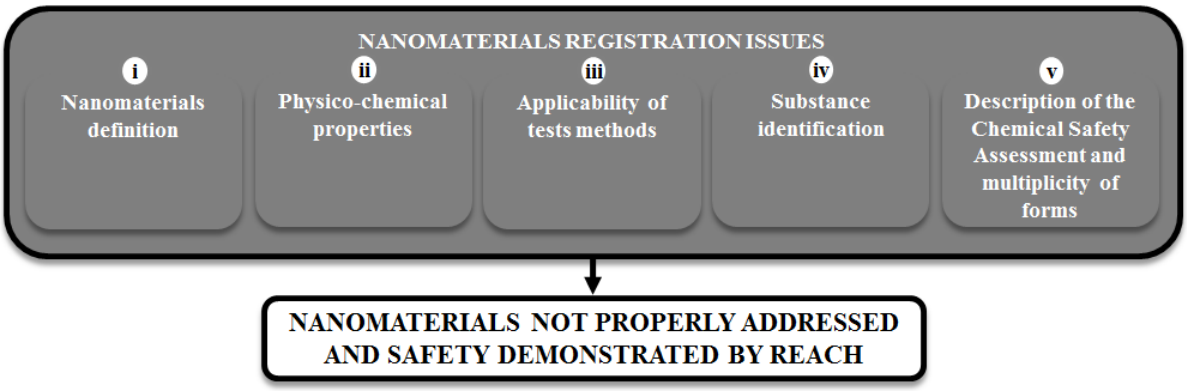
2.3 What are the underlying causes of the problem?

Preparation and handling of registration dossiers for substances with nanoforms requires expert knowledge as many obligations or specific information requirements are derived from more general obligations for substances in general. A registration dossier with one or several nanoforms requires a detailed knowledge of REACH, the comprehensive ECHA guidance and in some cases even familiarity with policy documents published by the Commission setting out the principles for the registration of nanomaterials.

While it is undisputed that REACH covers nanomaterials by virtue of its focus on 'substances', nanomaterials are not specifically mentioned and there are many factors that have led to a lack of understanding of how REACH should function for nanomaterials in the actual registration process.

In a simplified form, the most important causes to the problems can be illustrated by the following graph:

Figure 2-2: The causes to the problem:



The following key underlying causes have been identified explaining why the current system has not delivered as expected by the Commission:

i. No nanomaterial definition at the time of the registration

[52] The 5 registrations from 2010 and the 10 that registered by the 2013 registration deadline or after.
[53] Please refer to Appendix 10 of the Matrix report (Public consultation summary).

Until October 2011, there was no definition that could be used to distinguish nanomaterials as forms different from other forms of the same substance[54]. This made it open to each company to decide if their production also covered nanomaterials warranting specific attention when registered as a nanoform(s) together with other forms of the same substance. The cause for confusion or uncertainty is now partly resolved with the Commission Recommendation but it is a challenge in some cases to determine whether a material is or is not nanomaterial due to lagging progress in determination methods. However, the definition is still not an integral part of REACH and it does not provide an answer to how to distinguish between different nanoforms. Furthermore, for the registration dossiers submitted by the 2010 deadline, which were assessed by the Commission, the definition of nanomaterials was not available. Many substances were considered by registrants as bulk substances before the introduction of the nanomaterial definition. These companies did not explicitly identify registered substances (in their respective forms) as nanomaterials, and no major update of the dossiers has been observed folowing the introduction of the nanomaterial definition.

ii. The physico-chemical properties are not extensively listed

The physico-chemical properties of the substance must be described in the REACH registration dossier as they directly influence its toxicological and ecotoxicological properties, distribution and fate. For nanoforms, the relevance of some properties is limited, while other properties are not specifically listed, potentially leading to issues with the characterisation, as forms with importantly different risk profiles may have not even been differentiated at the onset of risk assessment. The same applies to the requirements to provide sufficient information on test materials, as it is the only way to assess the applicability of the test results.

Concrete examples of material characterisers, relevant in the nanoscale, are the size of particles, their shape and their surface coating/functionalisation. As the size gets smaller, the effects of particle surface and whatever might be attached to it become more prominent in comparison to the volume (mass)[55]. In addition, the scale of nanoparticles is in the same order of magnitude as the molecular tools driving the biological processes in organisms and more characteriser-selective binding of proteins to the surface (also known as corona) may influence biological recognition and signalling in cells.

These differences may lead to differences in risk assessment conclusions[56] or in the risk management recommendations[57].

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[54] In October 2011 the Commission published a Recommendation for the definition of nanomaterial.

[55] While volume and thus mass is reduced proportionally to the 3rd power of the particle size, surface area is reduced only by the 2nd power. So when particle size is reduced by a factor of 10, for example from a micrometer to 100nm particle size, the ratio between area and size increases by a factor of 10. Further quantum effects may occur in specific cases, usually at very small sizes or sharp-edged shapes.

[56] For example, SCENIHR 2014 on nanosilver identifies that "delivery route for Ag-NP that is different from what is known for dissolved species of silver …the release of ionic silver has been found to be the main cause of toxicity (in humans, in the environment and in hygienic applications), nevertheless an increasing number of studies found that this release cannot alone account for the toxic effects observed. ". http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_039.pdf

[57] Few examples:
- NIOSH recommendation for TiO_2 occupational exposure limit is 2.4 mg/m^3 while 0.3 mg/m^3 for ultrafine (i.e. nano) TiO_2, http://www.cdc.gov/niosh/docs/2011-160/pdfs/2011-160.pdf;
- IARC recommendation for classification of the particular carbon nanotube MWCNT-7 as "possibly carcinogenic to humans (Group 2B) while assigning Group 3 for other carbon nanotubes, https://monographs.iarc.fr/ENG/Classification/ClassificationsGroupOrder.pdf ;
- SCCS opinion on TiO_2 scopes its conclusion by defining TiO_2 purity, crystalline phases, range of particle

iii. There is uncertainty about the applicability of test methods to nanomaterials

The OECD notes that "*the approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials*." [58] Indeed, for many years it has been discussed and analysed whether nanomaterials (i.e. substances in nanoform) can be tested by using the test methods used for other substances. Both the EU's scientific committees and the OECD[59] have recommended that existing methods should be applied also for nanomaterials, while care should be given to how the nanomaterials are prepared and dosed in the test systems[60].

The scientific debate has also raised questions whether new additional endpoints[61], in particular in view of possible different modes of action may be needed for (certain) nanomaterials. In addition to on-going scientific and technical work in OECD-WPMN and internationally, several large scale research projects are on-going on the health and safety assessments. They will contribute to further adjustment of the current methods as well as for the further development of new approaches aiming at predictive, safe by design approaches for emerging nanotechnology products.

iv. There is insufficient guidance over the substance identification for substances with nanoforms and the scope of the registration dossier

From a generic perspective, REACH is simple: each substance must be registered in a dedicated registration dossier in accordance with the principle of 'one substance – one registration'. However, there are many variables that influence naming and determination of sameness of substances. The co-regulators therefore decided to leave the decision on how to distinguish between substances to the manufacturers and importers supported by ECHA in the enquiry process[62].

Detailed guidance to help this decision making has been prepared and is available on ECHA's website. However, by the time the guidance was made, not enough was known to advise on substances with nanoforms and on the potential additional physico-chemical properties (see above) that could be used for the purpose. Later attempts to bring more specific guidance was made with RIPoN1. Whilst it did not succeed in gathering consensus on all its recommendations, it clarified that nanoforms within a dossier can be addressed individually based on their differences. The differentiation would be triggered by the difference in so-called 'characterisers' in contrast to 'identifiers' that otherwise identify an individual substance and trigger a separate registration dossier. The final report of RIPoN1 was provided to ECHA, but given the impossibility to gather consensus, it has not been translated into guidance available to firms.

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sizes, list of shapes and coatings. It also conditions the use by the absence of photo-catalytic activity of the material and restricts its use for sprayable applications, http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf

[58] Six years of OECD work on the safety of manufactured nanomaterials, OECD, 2012 http://www.oecd.org/chemicalsafety/nanosafety/Nano%20Brochure%20Sept%202012%20for%20Website%20%20(2).pdf

[59] OECD Council conclusion, 2013

[60] OECD Guidance on Sampling and Dosimetry, 2012 http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV/JM/MONO(2012)40&docLanguage=En

[61] For further explanation on 'endpoints', refer to the Glossary.

[62] A process applicable for new firms entering the market helping the new firm to be associated with the correct registration dossier

Accordingly, nanoforms can be seen as forms of a substance or as distinct substances. In the latter case, the question arises whether they are treated as "new" substances and whether they would be subject to immediate registration[63]. When more experience from the evaluation of registrations is available, ECHA will provide guidance on treating nanomaterials as forms of a substance or as distinct substances with the aim of enabling effective data sharing. The results of RIPoN1 suggest, however, that some flexibility will be needed. Whether nanoforms have been addressed in one or several registrations, for the Commission the key issue remains whether the registration provides clear information on the safe use for all forms of the substance.

Regardless of how registrants organise their dossiers, it is expected that the scope of the registration is clear; it should be clear which nanoforms on the market are covered by the dossier. Any third party should also be in a position to verify whether a nanomaterial has in fact been registered, and relate it with corresponding demonstration of safety. Experience indicates that this has proven difficult so far.

v. There is uncertainty on how to deal with the multiplicity of forms in the chemical safety assessment (CSA)

As stated in the Second Regulatory Review on Nanomaterials (COM (2012) 572), the REACH approach to hazard assessment and risk characterisation, with its built-in flexibility, makes it overall suitable also for substances with nanoforms. Within the registration information requirements of the REACH Annexes VII-X and in the Chemical Safety Assessment that is to be conducted for the registration of substances at quantities of 10 tonnes or more per year, data for one form of a substance can be used to demonstrate the safety of another form (application of rules for grouping and read-across).

This requires a case-by-case scientific approach, implying: (i) clarity whether and which nanoforms of a substance are covered by a registration and that these nanoforms should be adequately characterised, with the user able to identify which operational conditions and risk management measures apply to them; (ii) information should be provided on which forms of a substance have been tested, with the test conditions adequately documented, and (iii) conclusions of a chemical safety assessment should cover all forms in a registration. Where data from one form of a substance are used in demonstration of the safe use of other forms, a scientific justification should be given on how, applying the rules for grouping and read-across, the data from a specific test or other information can be used for the other forms of the substance. Similar considerations should apply to exposure scenarios and the risk management measures.

The assessment indicates that the curent general REACH provisions (although complemented by ECHA guidance) have often not lead to an implementation that would follow such an approach in a situation where multiple forms of a substance are included in the registration. Unclear scope of the registration but also unjustified assumptions in application of relevance of data on one form to another[64] were frequent. As can be observed also from some concrete examples provided[55,56,57], these may lead to situations where risk is not adequately assessed and consequently managed.

[63] Any immediate registration requirement for a specific nanomaterial to be treated as a new substance could reasonably only apply from the moment that the interpretation of the REACH provisions was clear enough for registrants to exclude the interpretation that the nanomaterial is a form of an existing substance, potentially assumed due to the identical chemical composition.

[64] For example at the general level expected between substances, see REACH, Annex XI, section 1.5.

2.4 How will the problem evolve?

The Nano Support project[65] undertaken by the Commission suggested that almost all the reviewed registration dossiers contained insufficient information to be able to determine if safe use of the materials placed on the market as nanoforms of a registered substance has been demonstrated. ECHA has since then confirmed these observations as part of the formal evaluation procedures pursuant to REACH and has faced appeals to some of the decisions that attempt to address issues identified above.

It is thus assumed that the initiatives undertaken as referred to in section 2.2.3 *Initiatives undertaken:* the examination of testing proposals and compliance checks by ECHA, the RIPoN project, the definition and the revised definition of nanomaterials, ECHA's nanomaterials working group, the CoRAP and the adjustment recommendations by the OECD WPMN – will at least not efficiently solve the way REACH addresses nanomaterials and will therefore not suffice to solve the problem in the short term.

Based on existing evidence, the situation may develop as follows:

2.4.1 Nanomaterials as nanoforms of phase-in substances

Most nanomaterials have been registered so far as nanoforms of phase-in substances, meaning that they fall under the phase-in provisions (2010, 2013 and 2018 deadlines for registration). Since there is not enough clarity on the specific REACH information requirements for nanomaterials throughout the registration procedure, this means that the specificities in terms of how to handle them safely have most likely not been extensively described.

Based on current information, it is probable that this will continue to be the case, so that the registrations of substances with nanoforms in 2018 will also contain multiple nanoforms of substances without sufficient information for all forms covered.

2.4.2 Quality of the dossiers

In addition to the legal means foreseen by REACH to ensure the compliance of the submitted dossiers with the registration requirements – examination of testing proposals and compliance check, ECHA has undertaken a series of support actions with the aim to gradually bring the addressed dossiers into compliance according to ECHA's interpretation of the registration requirements[66].

Without further action, it is therefore reasonable to expect that, for the few current registration dossiers with often well-known nanomaterials included, the situation will improve over the next couple of years based on the on-going work of ECHA Committees and several decisions of the Board of Appeal on nanomaterials in 2016 and 2017 in the compliance checks and substance evaluations. The latter, annuling a number of decisions, had however showed limitations of what can be achieved.

However, some caveats are to be taken into account:

- Improvement via evaluation processes (compliance check, substance evaluation) is cumbersome, expensive (to both authorities and industry), will take years and

[65] Scientific technical support on assessment of nanomaterials in REACH registration dossiers and adequacy of available information, JRC, 12 March 2012. http://ec.europa.eu/environment/chemicals/nanotech/pdf/jrc_report.pdf

[66] Refer to Appendix VI for further information.

conflicts with the obligation that the burden of proof is with industry if the pertinent information is only made available upon request from the authorities.

- It is likely that dossiers that are not directly implicated within the scope of these actions may not change, with the associated risks it may have on safety.

- There continues to be ground for concerns that the root cause to the current problems, if unaddressed, will exacerbate due to the expected increasing number of dossiers and the growing number of companies involved.

2.4.3 Industry, SMEs and innovation

Information generated for the registrations provide inspiration for the innovative use of existing substances. As concluded by the REACH Review, REACH has had so far a positive impact on research into new substances.

Nanomaterials may be considered complex chemicals due to the potential increased complexity of dossiers (e.g. with multiple forms under one dossier) and to the importance of the relation between the individual nanoform and the specific use. Such relationship often requires a tailored risk management response as well as good communication along the value chain for the adequate risk assessment and risk management.

Consequently, when specifically referred to substances with nanoforms, it can be assumed that what needs to be included and how safety is demonstrated in the REACH registration dossiers for substances with nanoforms, may add to the compliance cost and affect industry investments and market decisions.

The REACH review studies highlighted that REACH compliance costs were considerably higher than estimated. Due to the burdensome processes and costs of information requirements, both nanotechnology and other companies, have shifted and may need to shift resources from R&D to REACH compliance. Accordingly, along with other constrains reported by nanotechnology companies, such as delays for the innovative products to market, high prices due to lack of investments in large scale processes, the way REACH registration deals with nanomaterials could form a challenge for the companies in the sector.

SMEs are of particular concern. Indeed, smaller firms represent a significant portion of manufacturers, importers or downstream users in the nanomaterials sector. Hence, concerns remain that the way REACH addresses nanomaterials may discourage SMEs from the nanotechnology sector to innovate.

Based on current knowledge, the situation will aggravate over time as it is anticipated that more small firms will be subject to registration obligations when substances in volumes at one or more tonnes will have to be registered in June 2018.

2.5 Who is affected and how?

Immediately affected is industry dealing with nanomaterials with an obligation to register substances with nanoforms (both EU manufacturers and importers) that are manufactured or imported over one tonne per year per manufacturer/importer. The effects will go from a possible change (positive or negative) of the administrative burden and a clearer legislative environment for fulfilling the obligations. External studies performed for the European Commission in the context of the REACH Review estimate the total number of European nanomaterial manufacturers in the range of 200 to 400. The numbers of importers or downstream users were not assessed in the study.

All stakeholders involved in the implementation of REACH and working with nanomaterials will be affected. Among them, ECHA, competent authorities and enforcement authorities, will be affected when performing their dedicated tasks in accordance with REACH.

By the provision of adequate information on safe use of registered substances with nanoforms there will also be positive effects on workers' health protection, on the environment and to a lesser extent on the health of the public at large.

Lastly, clarifying REACH information requirements will eliminate regulatory uncertainty and confirm the effectiveness of the regulatory system but might as well increase compliance costs; all this will influence investors' views on Europe as a site for innovation and manufacturing.

2.6 The EU's right to act and justification

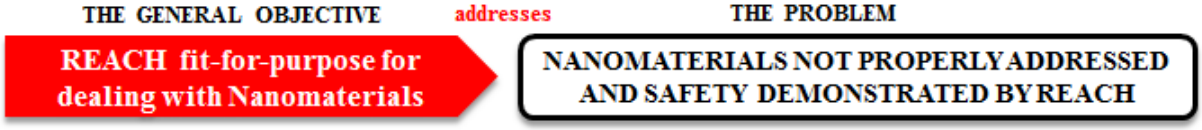
The current initiative concerns clarification of the existing provisions established in REACH Annexes. The legislation is based on Article 114 TFEU. According to the principle of subsidiarity established in Article 5 TFEU, the EU's right to act is justified based on the fact that the chemicals market is an important part of the internal market and that initiatives in Member States would be in breach of the freedom for firms to manufacture or use nanomaterials in the EU market. Any modifications to REACH including its annexes can legally only be made at the EU level. If the EU does not take action there will be continued uncertainty for companies producing (and using) nanomaterials about their legal obligations for registration and continued lack of information about those materials which are the basis for risk assessment and safe handling. Actions at national level to deal with the described problems would have to be taken outside the REACH framework. They would by their nature entail the risk of distorting and fragmenting the internal market. In addition, there are no indications that special national or regional conditions warrant different ways and levels of protection. Based on these considerations, there is a clear added value of action to be taken at the EU level.

3 OBJECTIVES – WHAT SHOULD BE ACHIEVED?

3.1 General objective

The aim of REACH, as provided for in its Article 1, is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances (mainly to reduce animal testing), as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. As identified in section 2.2.1, the registration dossiers of substances with nanoforms currently do not document how the registrants ensure safe use of those forms. In line with the aim of the legislation, the general objective of this initiative is therefore to ensure that REACH is fit for the purpose of dealing with substances with nanoforms.

Figure 3-1: The general objective and the problem:

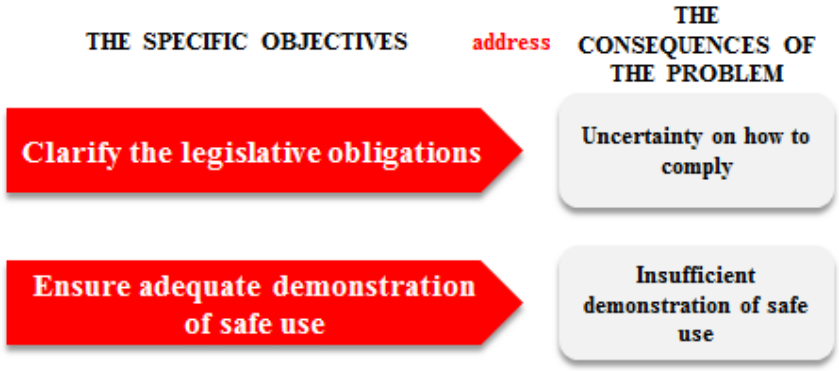


3.2 Specific objectives

In order to achieve the general objective and to address the two main consequences of the problem as identified above i.e. the uncertainty on how to comply and the insufficient demonstration of safe use, the following specific objectives have been established:

- **Clarify the REACH information requirements** for registrants on how substances with nanoforms must be registered pursuant to REACH;
- **Ensure adequate demonstration of safe use** of nanoforms in registration dossiers.

Figure 3-2: The specific objectives and the consequences of the problem:



3.3 Operational objectives

Furthermore, the following operational objectives are to be accomplished:

- Ensure that the registration dossiers clearly specify that they cover one or several nanoforms of a substance;
- Make sure that the registration dossiers contain justifications for using data/test results from non nanoforms or between nanoforms;
- Guarantee that the registration dossiers identify the uses of and the related exposure from nanoforms;
- Increase trust of downstream users/consumers in nanomaterials in order to facilitate market uptake and innovation;
- Speed up the process of achieving registration dossiers covering nanoforms that are of adequate quality.

4 POLICY OPTIONS

At the start of the impact assessment process, the Commission identified five different options grouping a large number of specific measures for analysis and stakeholder consultation. These are in addition to the 'no change scenario' as described in chapter 2.4 above on how the problem will evolve.

In identifying some of the individual measures considered, the Commission was supported by the Nano Support project and REACH Review studies, as well as contributions from EU Scientific Committees, OECD and ISO cooperation, expert networks and scientific literature on nanotechnologies and nanomaterials. Numerous measures were proposed based on a scientific assessment on the needed information to make a qualified assessment of the safe use of nanomaterials in addition to the information that the JRC – ECHA review team identified

in the concrete registration dossiers submitted up until December 2010. These were grouped under options 2 and 4. In addtion to those, the Commission has identified other possible measures that have been grouped in options 3, 5 and 6[67].

In most cases, the measures could be individually assessed in terms of effectiveness and efficiency addressing the general objective.

It is to be noted that the legal procedure this initiative is framed into does not allow to make changes to the enacting terms of REACH, but just to its Annexes; there is thus no possibility to modify the tonnage registration thresholds, explaining why the possibility to lower the threshold for substances with nanoforms below 1 tonne has not even been considered. Furthermore, there has been no evidence to indicate a need to change the tonnage thresholds structure as imposed by REACH specifically for substances with nanoforms, if it is on one hand understood that in most situations, nanomaterials will represent forms of the substance with identical chemical composition rather than be considered as substances by themselves, and on the other that REACH obligations pertain to the aggregated tonnage of all forms of the substance placed on the market by the economic operator.

4.1 Option 1: No change

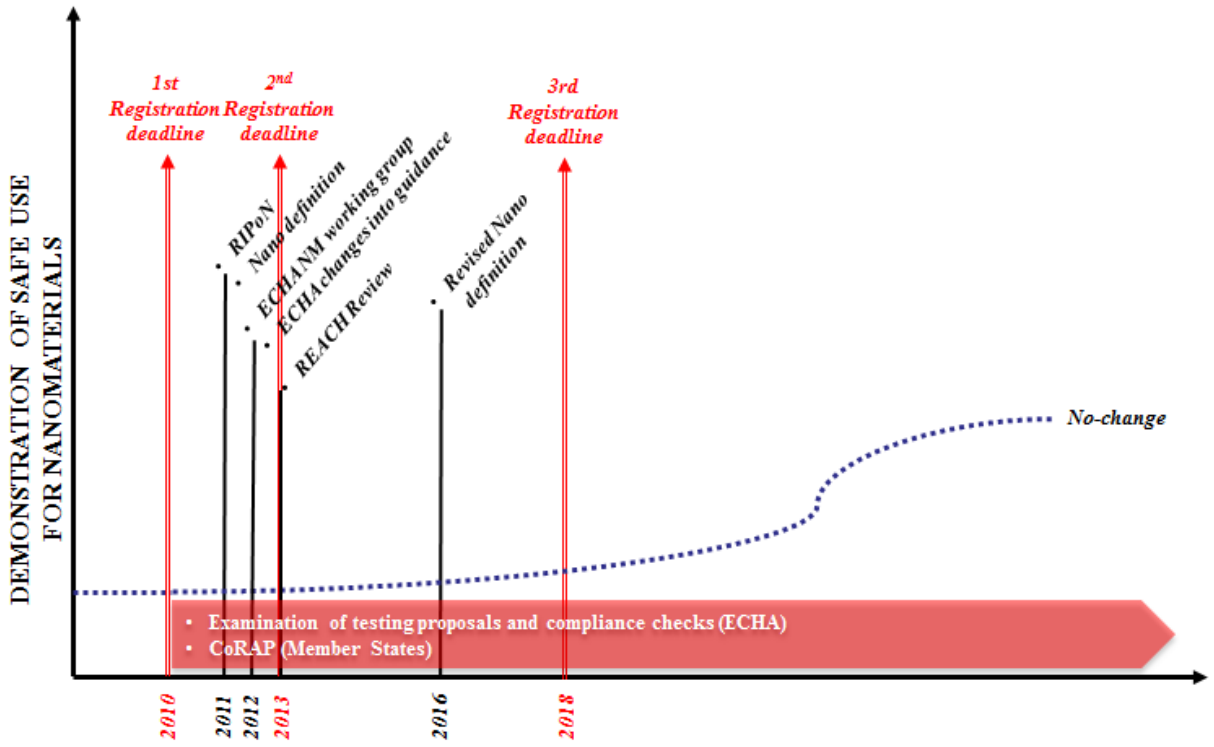
Option 1 is a continuation of the current situation under REACH assuming that there are no new policy actions and that the implementation is based on what currently is known i.e. including the guidance update from April and May 2012, the use of the Commission Recommendation on the definition of Nanomaterial and the updates of OECD Test Guidelines. The assessment of this option makes certain assumptions of how the current situation may develop over time when dossiers are brought into compliance.

Since the legal text allows for different interpretations of the REACH registration requirements vis-à-vis substances with nanoforms, the no-change scenario is set where Industry's current stance to the level of compliance is effectively maintained.

The figure below illustrates how the no-change scenario is expected to evolve along time in terms of demonstration of safe use as ECHA applies tools to improve compliance and Member States conduct substance evaluations.

[67] For a complete list of the measures, refer to Appendix I.

Figure 4-1: Evolution of the no-change scenario



4.2 Option 2: Clarifying the existing information requirements

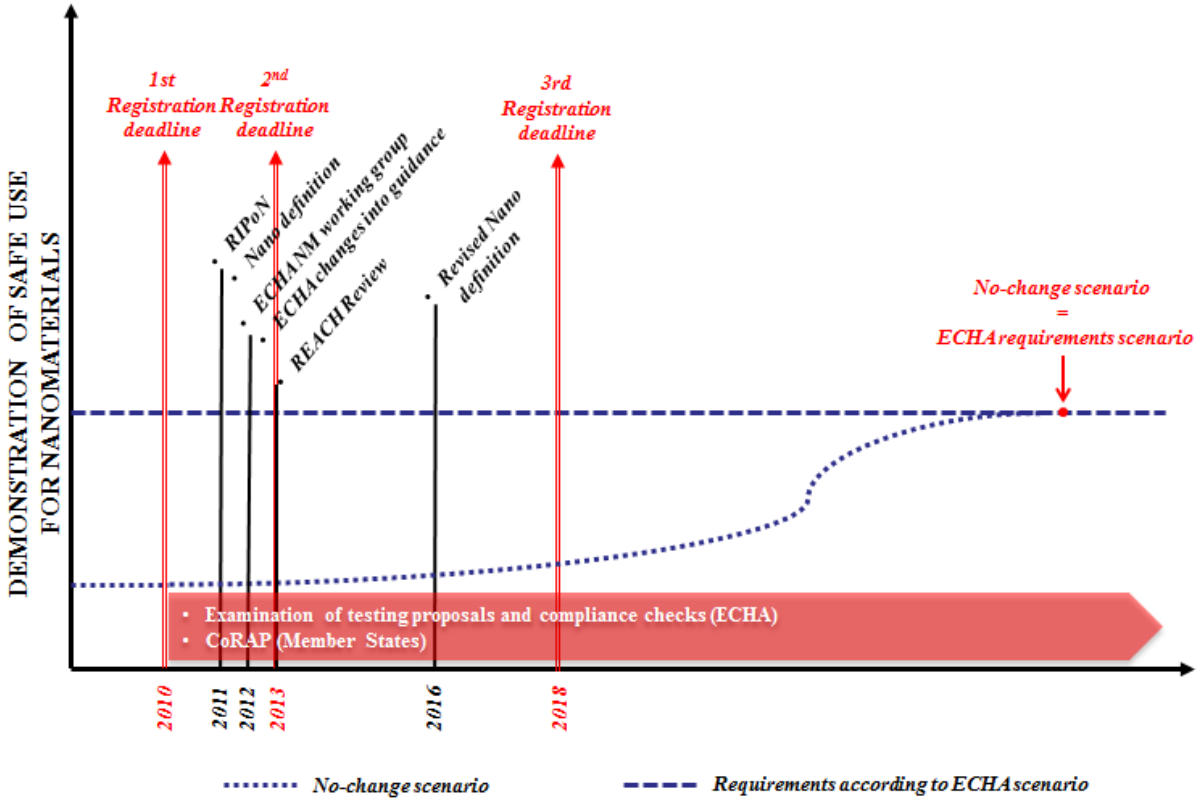
This option's aim is to clarify what companies are expected to do when registering nanoforms, by introducing changes to the description of certain information requirements in the REACH Annexes. The information requirements are in accordance with the registration obligations of REACH and the specific ECHA guidance, which takes into account CA/59/2008 Rev1[68] and the scientific-technical recommendations from RIPoN 2 and 3 reports from 2011. While ECHA's guidance still needs to be provided in some cases (the appropriateness of some available tests to substances in nanoform is still under discussion), these measures would outline necessities for an accurate information base to allow for a reasonable hazard assessment.

This option would therefore, according to ECHA, not change any existing obligations as they are understood to exist and these measures are/will be pursued as such in formal ECHA evaluation, but it would provide companies with a clearer understanding on what information they must provide in the registration dossier[69]. As a matter of fact, when asked in the framework of the Nano Support project, ECHA indicated that it considered that the measures listed in option 2 are derived from the general REACH requirements and are thus part of the baseline.

[68] Follow-up to the 6th Meeting of the REACH Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH), 15-16 December 2008 http://ec.europa.eu/environment/archives/chemicals/reach/pdf/1A%20CARACAL%2015-16%20DEC%2008.pdf

[69] For example: **Measure 1:** Explicitly require registrants to describe the scope of the registration dossier; for further details on the measures, refer to Appendix I.

The figure below illustrates where the current requirements of REACH for substances with nanoforms are in terms of demonstration of safe use, according to ECHA, compared to option 1.*Figure 4-2: Requirements according to ECHA compared to the baseline:*



4.3 Option 3: Soft law measures

Option 3 pursues the same goals as option 2 i.e. providing more clarity on the registration obligations for substances with nanoforms, but instead of amending the legal provisions in the REACH Annexes, this option would introduce measures of a non-legally binding nature.

Within the operation of REACH, already a wealth of different soft law measures are applied; of these, the following would also be applied to improve the clarity of obligations for registrants of substances with nanoforms:

- Development of further specific ECHA Guidance; presently there is only rather generic guidance on nanomaterials available to registrants and it is integrated in the general guidance on registration;
- Enhanced use of the Directors Contact Group[70] to further identify possible solutions for problems related to registration of substances with nanoforms;
- Initiatives to enhance information and dissemination at EU and Member State level; the overall understanding of how REACH applies to substances with nanoforms has

[70] In the run-up to the first registration dealdines in 2010, with a view to be able to address potential registration issues prior to these becoming a problem, the Commission established an informal group formed of key players (Industry associations, ECHA and Commission) in order to screen and identify possible problems in the registration process.

been shared between Member States and stakeholders that take part in the discussions in CARACAL; however, based on the empirical evidence on how companies have complied, much more communication is necessary in view of raising awareness.

The core difference between option 2 and option 3 is that option 3 is limited to the clarification of the current REACH requirements for substances with nanoforms through guidance, whereas option 2 imposes these clarified requirements by amending the REACH Annexes. As such the potential of option 3 is limited by the outcome of the cases before the Board of Appeal (and possibly subsequently the Court) on the interpretation of the current REACH requirements for substances with nanoforms. If the Board of Appeal confirms ECHA's interpretation, then option 3 and option 2 would impose virtually the same requirements, whereas if the Board of Appeal rules (partly) against ECHA's interpretation then some or most of the requirements under option 2 could not be demanded under option 3. Based on the Board of Appeal's decision of 2 March 2017, it is clear that some of the requirements under option 2 cannot be requested under option 3.

4.4 Option 4: Scientific-technical recommendations tailoring information requirements

At the time when information requirements in the Annexes to REACH were drafted, no consideration was given to nanomaterials and their specific properties. Thus this option's aim is, beyond the mere clarification of requirements pursued by options 2 and 3, to achieve demonstration of safe use in cases where the existing information requirements in REACH are not tailored for substances with nanoforms or where specific considerations are required. The measures this option proposes, such as limitation of the application of waivers[71], consideration of the most appropriate route of exposure or limitations of the applicability of test methods[72], are directly taken from the Nano Support project.

The option is assuming full implementation of option 2.

4.5 Option 5: Reduced information requirements

This option has a twofold aim: on one hand, to clarify a number of issues regarding how substances with nanoforms should be addressed when being registered; on the other, to alleviate the burden on companies, by reducing certain information requirements for nanoforms and by promoting the use of non-testing methods and exposure categorisation.

This double aim would be addressed by two sets of measures:

- First, measures providing clarity on how nanoforms are addressed and safety demonstrated under REACH by clarifying relevant provisions and specifying information requirements for nanoforms[73] with the aim to provide for specific solutions that increase predictability for registrants in the current regulatory framework.

[71] For example: **Measure 14** on water solubility-related waivers; for a further detail on the measures, refer to Appendix I.

[72] For example: **Measure 13:** Require non-bacterial in-vitro study; measures include revised or additional endpoints for substances with nanoforms, e.g. in low tonnages; most relevant route of exposure for acute toxicity and rep eated dose toxicity studies; and a non-bacterial gene mutation study (in vitro); in all REACH Annexes exclusion of waiving possibility on the basis of insolubility or lack of short term toxicity, and a priority for test on soil and sediment organisms; for a further detail on the measures, refer to Appendix I.

[73] For example: **Measure 21:** Specify that the granulometry concept in 7.14 of Annex VII includes also shape and surface area of nanoforms; for a further detail on the measures, refer to Appendix I.

- Second, measures reducing certain information requirements on nanoforms for the purpose of the registration[74] at 1 – 10 tonnes and 10 – 100 tonnes.

4.6 Option 6: Exhaustive information requirements

Option 6 goes beyond options 2, 3 and 4 by putting additional emphasis on the generation and documentation of further information. The objective of the option is to reduce uncertainty, considering that knowledge is still under development regarding the influence of particle and nanomaterial-specific properties on risk[75].

The option would contain three types of measures:

- More prescriptive rules as regards the organisation of the chemical safety assessment and its documentation for individual nanoforms and the influence of particle and nanomaterial-specific properties;
- Request specific information (e.g. toxicokinetics, repeated dose toxicity testing) in a targeted fashion and at lower tonnages;
- Address some remaining open questions regarding the scope of current REACH provisions, drafted without specific consideration to nanomaterials (e.g. coverage of new substances with nanoforms by phase-in provisions in Annex III of REACH, substance identification in Annex IV,V).

The option is assuming full implementation of options 2 and 4.

4.7 Interrelationship between options

It is useful to keep in mind that options 2, 4 and 6 are sequentially staggered, with option 4 adding further requirements to those contained in option 2 and option 6 adding again more to option 4.

Options 2 and 3 aim to achieve the same result (subject to confirmation that the interpretation that the measues in option 2 are already in line with the current REACH requirements), though option 2 does so through legislative adaptation and option 3 through guidance and other soft law measures.

Option 1 captures how most of the registrants have implemented the current legislative requirements – subject to possible updates as required by ECHA compliance decisions, and option 5 reduces certain information requirements for nanoforms.

The table and the figure below illustrate how the options are built and how they compare to one another and the REACH requirements according to ECHA:

Table 4-1: Underlying logic of the policy options, additional to the no-change scenario

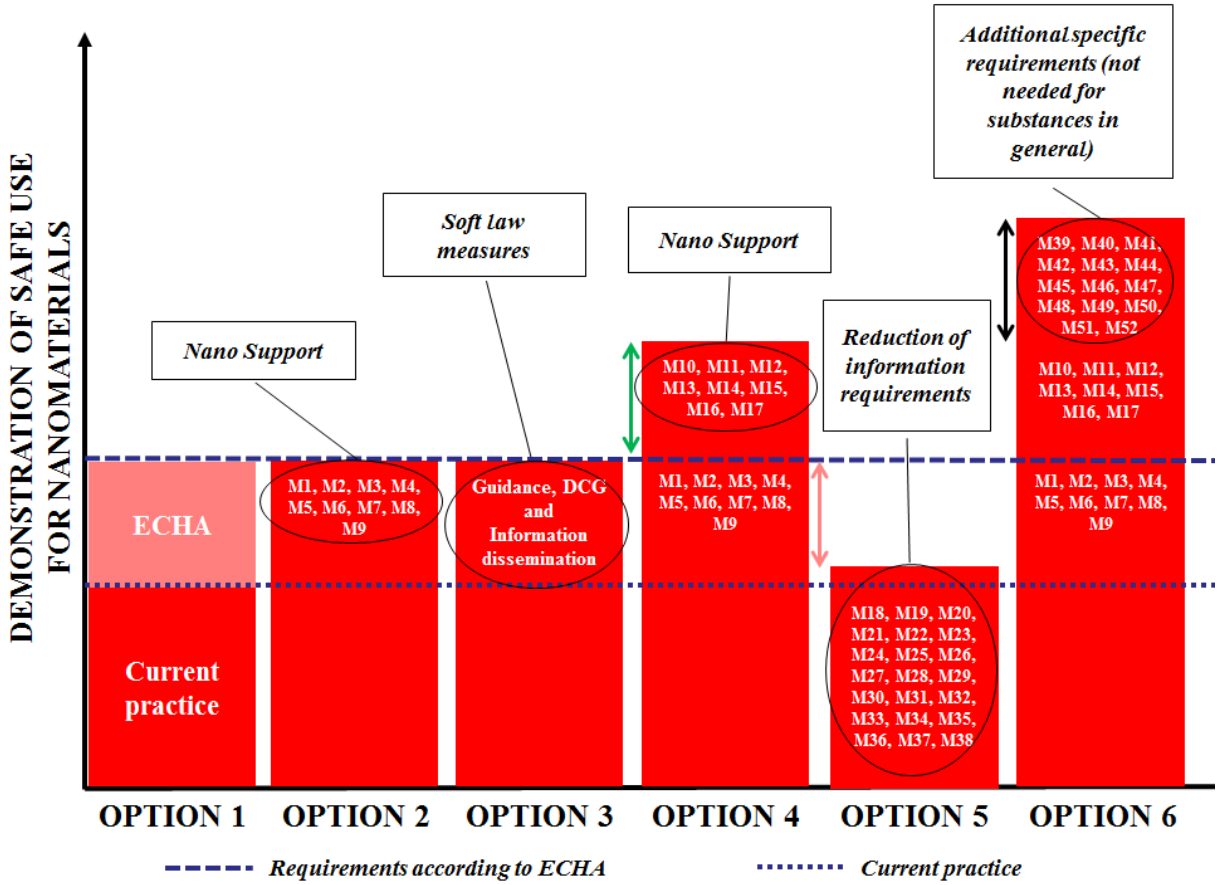
2	3	4	5	6
Clarifying the existing information requirements	**Soft law measures**	**Scientific-technical recommendations tailoring**	**Reduced information requirements**	**Exhaustive information requirements**

[74] For example: **Measure 28:** No specific obligations for nanoforms in 10-100 tonnage band; for a further detail on the measures, refer to Appendix I.

[75] For example: **Measure 40:** Introduce rules to ensure mandatory separation between nanoforms identified and addressed in the dossier whenever they differ in coating, shape, crystalline form or prescribed classes of particle size distribution; for a further detail on the measures, refer to Appendix I.

			information requirements		
Underlying logic of the options	Clarification of the existing information requirements (according to ECHA's interpretation), by changing the Annexes to REACH	Clarification of the existing information requirements, by implementing soft law measures (but no changes to the REACH Annexes)	On top of option 2, additional measures aiming to ensure the demonstration of safe use by changing the Annexes to REACH, in cases where the existing requirements are not specific for substances with nanoforms or where specific considerations are required	Clarification of existing information requirements and at the same time alleviating the burden on companies (and SMES in particular), by changing the Annexes to REACH	On top of options 2 and 4, requesting additional information specific to nanomateirals (not required for substances in general) in order to further reduce the uncertainty
Criteria for the measures therein	Measures proposed by Nano Support project, and considered by ECHA as currently (implicitly) required by REACH (derived from general REACH Requirements)	Further develop the ECHA Guidance, increase the involvement of Member States, ECHA and the Commission, raise awareness	Measures proposed by the Nano Support project, and considered by ECHA as not currently required by REACH	Increase clarity on information requirements for registrants while reducing information requirements for lower tonnages	Generation of additional information and its detailed documentation

Figure 4-3: The options compared to current practice and ECHA's interpretation of the current requirements



4.8 The Baseline

Establishing the baseline for this impact assessment as required by the guidelines is not straight forward. The current situation is set out as option 1 (current practice) in Figure 4-3. With time, assuming ECHA will fully implement compliance checks according to their own interpretation of current REACH requirements, the information generated under option 1 will eventually increase to that obtained by option 2. However, given the current pace of compliance checks by ECHA and the associated workload it is doubtful that ECHA will be able to conduct compliance checks for all substances possibly occuring in nanoforms. Furthermore, there are several compliance check decisions which through a Board of Appeal decisions further determine whether ECHA's interpretation of the current legal requirements is correct or not (see more in 4.9. *Industry appeals to ECHA decisions on registration of substances with nanoforms* below).

Similar considerations apply to option 3. The soft law option will explain what the information requirements are in ECHA's interpretation, but as registrants apply guidance in a more flexible manner than clear legal obligations, it is expected that the information generated under option 3 will eventually, but more slowly and with more efforts by ECHA to ensure correct application of guidance, increase to that of option 2 (again subject to confirmation by the Board of Appeal that the measures in option 2 are already in line with the current REACH requirements).

Therefore, for the purpose of this impact assessment, and without prejudice to the opinion of the Board of Appeal on the compliance check decisions, it has been assumed that ECHA's

interpretation of the legal requirements is correct and that consequently, the information requirements as set out in option 2 can be considered as the baseline for what should be provided for the registration of nanoforms in REACH. However, should the Board of Appeal decide against ECHA in the pending cases, the baseline would be closer to option 1, i.e. what industry has provided so far and without additonal data generation.

In the light of the dynamic character of the developments under options 1 and 3, for a precise calculation of costs and benefits it would be necessary to introduce a time dependence and appropriate discounts in the impact assessment. However, given the uncertainties of this timeline and of the speed by which ECHA could be expected to require data generation using the compliance check procedure, this impact assessment does not attempt to include this additional time variable. Instead, for simplicity reasons, the impact assessment will present the costs for option 1 without the data to be additionally generated, hence only looking at current practice, and for options 2 and 3 considering the full additional data. This has the following consequences:

- costing of option 1 does not include the cost (for registrants and for ECHA) of bringing the information content of registration dossiers to the level defined by option 2;
- options 2 and 3 will have the same cost because any use of ECHA administrative resources under option 3, and therefore also the likely higher effort and corresponding cost on ECHA of bringing the information content of registrations to the level defined by option 2, is not included in the costing model.

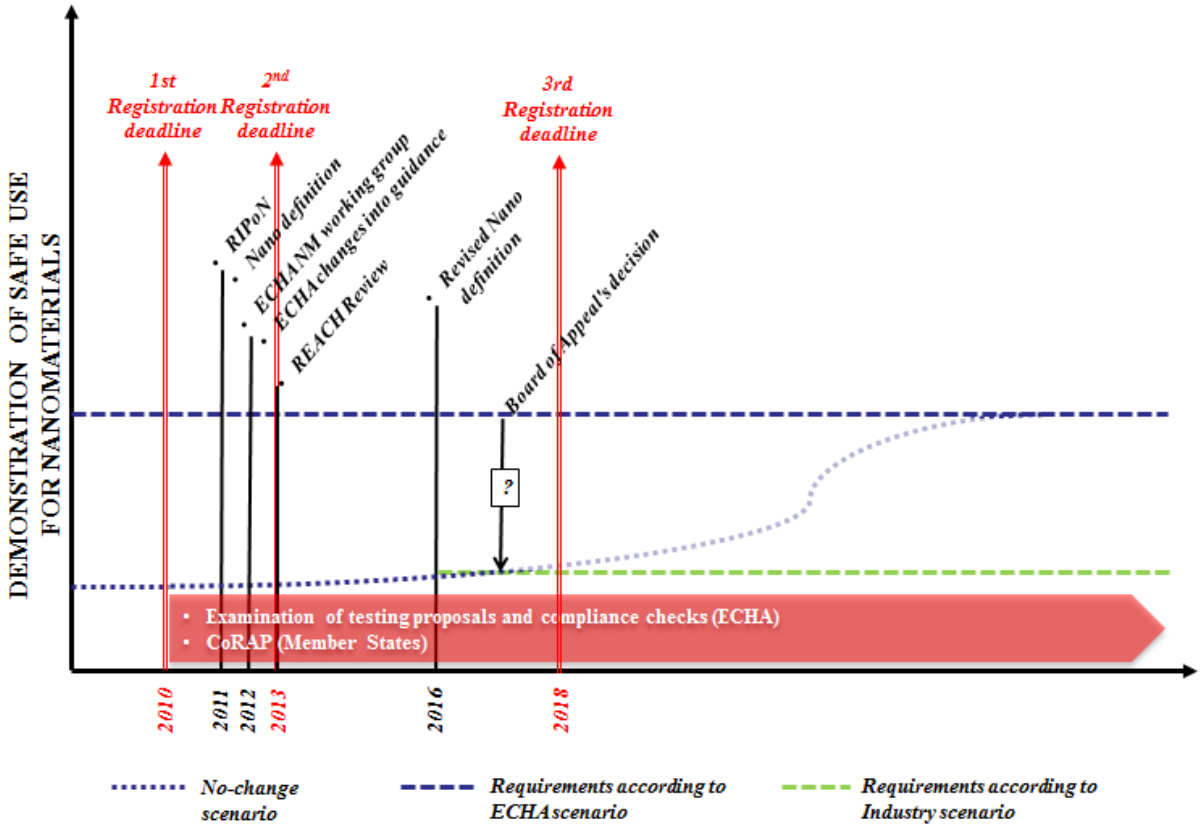
For the purpose of this impact assessment, conceptually, a similar logic as for costs explained above, can be applied to capture the benefits of each option for the same snapshots of time as for costs. The benefits would be expected only to the extent the underlying data is available (i.e. generated when required) and therefore an assumption can be made that safe use is demonstrated and applied. Option 1 can thus not be associated with the benefits that would evolve from the efforts by ECHA and competent authorities in a long run to bring the information content of registration dossiers to the desired level as defined by option 2. Thus, option 1 (under the current practice and without considering the developments in time) would not generate benefits. On the other hand, the benefits of option 3 can be considered comparable to that of option 2, based on the assumption that comparable underlying data is generated by the two options.

4.9 Industry appeals to ECHA decisions on registration of substances with nanoforms

As indicated above, ECHA's Board of Appeal[76] is presently considering several industry appeals against ECHA compliance check decisions requesting nanoform specific information in line with what would be required by option 2. While each case is specific, industry's arguments as well as ECHA's rationale are of more general nature, so the Board's decisions are expected to provide the Board's general views on information currently required in the registration dossier, thus outlining whether ECHA's or industry's interpretation of current REACH requirements for the registration of nanoforms is correct, or whether the requirements are somewhere in between. This is graphically presented in the figure below, marking the space in which the no-change scenario might evolve, should ECHA's position not be favoured:

[76] It should be noted that the Board of Appeal's decision may not be the last resort for resolving this dispute, as further appeal may be lodged with the European Court of Justice.

Figure 4-4: The no-change scenario and the decision by the Board of Appeal:



***Taking into account the Board of Appeal's decision on the appeal A-011-2014 regarding the compliance check on titanium dioxide, it should be emphasised that the requirements under the 'no change' scenario will never fully evolve to the requirements under the 'ECHA scenario'.**

The Board of Appeal's decisions will not affect the assessment of the options in absolute terms as presented in this report, but rather the relative change that each option represents compared to the baseline (which is therefore for transparency provided in relation to both options 1 and 2).

The Board of Appeal's decision of 2 March 2017 on the appeal A-011-2014[50] annulled the ECHA compliance check decision on titanium dioxide, with the principal argument that, under the current provisions of REACH the elements that are listed in Annex VI.2 are exhaustive so that the additional information on the characterisation of nanoforms requested by ECHA as part of the substance identity information is considered as new information requirements that fall under the exclusive competence of the EU legislator to establish by amending the REACH Annexes. In addition, the Board of Appeal confirmed that the registrant has the liberty to define the registered substance broadly. If he does so, then the hazards of all the possible forms of the substance covered by that substance definition must be addressed by the toxicological and ecotoxicological information provided in the registration dossier.

Consequently, as for the measures and scenarios of this impact assessment, the Board of Appeal's decision implies that the option 2 'ECHA scenario' (e.g. in particular characterisation under Annex VI.2. covered by measure 2 as explicitly addressed by Board of Appeal's decision) cannot be in its entirety considered as part of the baseline. Thus, it can be concluded

that the baseline (i.e. the 'no change' scenario) cannot fully bring the requirements to the level of requirements as set by option 2.

The robustness of the approach in finding an adequate overall conclusion was assessed. While any difference in the interpretation of the baseline leads to different evolution of the no-change scenario and would therefore also affect the relative impact of the implementation of the options compared to the no-change scenario, an approach using the total impact (e.g. total implementation cost) and the assessment of the impact of individual measures allows the comparison between the options and avoids excessive sensitivity to the evolution of the no-change scenario. This argument does not apply to option 3, that would for example remain bound by any potential legal constraint identified and that would in turn modify the assessment accordingly, including the estimation of costs and uses of animals. As the Board of Appeal Decision confirmed the lack of competences of ECHA to request under the current provisions of REACH nanoform-specific information to be submitted as part of the Annex VI.2, option 3 in itself cannot resolve all of the issues discussed under section 2.2 *The problem requiring action and its drivers*. Thus, there is need for further action beyond soft law measures.

5 ANALYSIS OF IMPACTS

This section introduces first a summary of the main findings of the Public Consultation and then develops a qualitative (and quantitative, where possible) analysis of the economic, social and environmental impacts of each of the options.

Quantified costs for each option will be presented based on data models utilising certain assumptions. It is important to note that quantitative estimates on costs from different studies vary due to different methodologies, assumptions and interpretations of the options, but are adequate to support qualitative grading and indicative of the magnitude of the impacts. In particular, the estimates are often built on the basis of assumptions and interpretations of the different measures.

As is often the case for health and environmental issues, as well as for innovation and competitiveness, it is impossible to establish a meaningful direct causal link between a single measure and the associated, often long term, benefit it may bring to society. This is not unique to the present impact assessment. In absence of better alternatives and for simplicity, it is generally assumed that correct risk management of nanomaterials will lead to health benefits similar to managing risks for bulk substances. For the same reason the benefits assessment as well as the assessment on innovation and competitiveness will be mainly qualitative.

5.1 Public Consultation

The results of the Public Consultation are presented in detail throughout the analysis of the impacts and in Appendix V.

Overall, when asked about their preferences for the options as a whole, a majority of the 142 respondents preferred option 5, closely followed by option 6; and then options 2 and 4, while option 3 had the lowest preference. Respondents can be grouped into three main categories, according to their preferences: industrial and trade associations and private companies, which preferred clearly option 5; government authorities, academic/research institutions, NGOs, consumer associations and individual citizens, which preferred option 6 followed by option 4;

and 'others',[77] for which the preference is more or less equally shared between options 6, 4 and 2.

When asked about the cost, the efficiency and the safety of each measure contained in the options, option 2 received the highest ranking for both efficiency and safety, option 5 the highest ranking for cost and the lowest for safety, and option 6 the lowest ranking for cost but only the third highest for safety. Option 4 ranked second, both for safety and efficiency and fourth for cost. Given the staggered interrelationship between options 2, 4 and 6, the outcome in terms of ranking of the three options for costs is coherent, while the ranking for safety is somewhat surprising. In response to a separate question regarding the efficiency of the options as a whole, option 4 received high appreciation by the majority of the respondents.

5.2 Economic impacts

5.2.1 Conduct of business

5.2.1.1 General considerations

Companies placing on the market substances with nanoforms (manufacturers and importers) would be directly affected by the measures under this proposal (downstream users of such substances will be indirectly impacted). A large part of how the conduct of business is affected by each of the options relies on the analysis of the testing costs and the administrative burden on registrants (understood as the costs linked to the information obligations placed on businesses, including the need to undertake tests). This section is mainly focused on the compliance costs for registrants (i.e. companies placing substances with nanoforms on the market).

Two supporting studies by BiPRO[78] and Matrix[79] have been conducted to support this impact assessment. Based on the information available from the two studies and the understanding of the possible applications of the different measures, the Commission services have made their own calculations[80].

Other impacts on the conduct of business, including that for SMEs and how the clarity/certainty of the regulatory requirements are going to be affected by each of the measures, are also explained, mostly in a qualitative manner.

It should be noted that the costs for business have been assessed from the perspective of cost incurred from registration requirements, while some of the information may be available from

[77] The category 'Others' groups all the respondents who did not identify themselves within any of the previous categories.

[78] BiPRO (2013) "Examination and assessment of consequences for industry, consumers, human health and the environment of possible options for changing the REACH requirements for nanomaterials", Final Report, prepared for the European Commission, Joint Research Centre, Institute for Health and Consumer Protection.

[79] A study to support the Impact Assessment of relevant regulatory options for nanomaterials in the framework of REACH, Matrix, 31 March 2014 http://ec.europa.eu/DocsRoom/documents/5826/attachments/1/translations/en/renditions/native

[80] The differences with the figures from the Matrix and the BiPRO studies reflect different interpretations of the measures, different assumptions and subsequent changes in the understanding of how the specific measures of each option would operate in practice (the cost calculations themselves led to refinements on assumptions, as did further discussion with experts and stakeholders). Clearly, changes in the assumptions of when and how many times a specific activity (e.g. test) will be required per company or substance for a specific measure will change the estimates of the costs of that specific measure and the option it is grouped under. Over the impact assessment process, the understanding improved considerably of how REACH and the specific measures would operate in practice and of when a measure would lead to cost-incurring behavioural change.

normal business operation (e.g. characterisation/reproducible product and functionality, safety information for investment) or from compliance with other legislation (e.g. sector specific legislation such as for Cosmetic Products).

5.2.1.2 Costs calculations

The cost calculations and related underlying assumptions are presented in detail in Appendix XIII.

In the tables below, the cost of registering a nanoform (or in grand total, all nanoforms estimated to be registered) is presented, as a function of the tonnage band to which the nanoform is associated, and the impact of the measures considerd to be applied under each option[81].

In accordance with the baseline narrative developed under section 4.8 *The Baseline*, presentation of costs under option 1 do not include compliance costs according to ECHA's interpretation of the current REACH requirements.

The total costs and not the incremental cost as compared to the baseline are presented in all the following tables. Some relative figures are however provided in the accompanying text assessing individual options under section 5.2.1 *Conduct of business*.

Most assumptions and estimations come within a certain range (e.g. minimum/maximum costs). Therefore, in most calculations a 'typical' value is used while individual ranges are used as specific examples to discuss the sensitivity of the results.

The resulting tables are presented below:

Costs of registration per nanoform

For the calculations in table 4-1, it has been assumed that it is possible to apply alternative methods to fulfil an information requirement (e.g. read-across between substances, grouping, QSAR, etc.) also for different forms of the same substance and to justify relevance of data on one form for the other or identify the worst form. Although currently the documented[82] use of such methods for nanoforms is limited, it is expected to increase with the development of the knowledge base. In the absence of better information, it is assumed that this leads to the same percentage of reduction for testing needs, as has been observed for conventional substances[83].

Within option 1, the costs are presented in two ways: one (1^a) indicating the cost for one information dataset for substance regardless of the number of forms, and the other (1^b) indicating the cost per nanoform/set of nanoforms calculated by dividing the first cost figure by an estimated average number of nanoforms or sets of nanoforms for a substance at a given tonnage band.

[81] There is a potential impact of the changes on the registration of other forms of the substance with nanoforms. Most of it is neutral (as the bulk form would be already registered) or reduces cost (application of read-across or worst case approach from nanoform to bulk). Such impacts were not quantified. Measure 41 may however lead to increased cost and use of animal and is thus addressed separately. See Appendix XIII for more details.

[82] One may argue that in cases where a single dataset is used for a number of (nano)forms, an implicit assumption on its relevance for each of those (nano)forms is made, with test material in another form serving either as an analogue or applying a worst case approach; as such claims are not explicitly documented and justified, this cannot be validated. See JRC: http://publications.jrc.ec.europa.eu/repository/handle/JRC106386

[83] See Appendix XIII for the table of applied percentages for each information requirement.

Table 5-1: Costs of options per nanoform and per tonnage band (use of alternative information considered possible, typical cost) (in thousand Euro):

	1[a]	1[b]	Estimated baseline[e]	2	3	4 (including 2)	5	6 (including 2 and 4)
>1000 tonnes	772	77	1049	1157	1049	1256	458	2256
100-1000 tonnes	538	77	770	814	770	939	375	1736
10-100 tonnes	183	37	334	359	334	471	40	869
1-10 tonnes[c]	49	12	91	116	91	137	12	466[d]
Weighted Average	**358**	**47**	**516**	**565**	**516**	**642**	**212**	**1254**

[a] *Costs per substance regardless of the number of forms – one test performed per substance per information requirement*

[b] *To calculate and present the cost per nanoform or set of nanoforms, the costs for conducting all tests according to the measures constituting option 1 are divided by an estimated average number of nanoforms or sets of nanoforms for a substance at a given tonnage band*

[c] *Weighted average: depending on applicable conditions of Annex III to REACH, the implications differ between registrants in the 1-10 tonnage band; more details in Appendix XIII*

[d] *Indirect impact of measure 41 on registration of bulk forms may bring an estimated additional cost of 10 K EUR per nanoform of substance otherwise benefiting from Annex III exemption. Relative additional contribution 2%. More details in Appendix XIII*

[e] *Estimated baseline consequent to Board of Appeal Decision 2 March 2017(see discussion in section 4.9). Option 2 cannot be considered baseline in its entirety.*

Grand Total costs

Multiplying the figures in table 4-1 by the estimated total number of nanoforms or sets of nanoforms and the number of substances with nanoforms per tonnage band provides an estimation of the total costs.

Table 5-2: Registration costs – Grand total per tonnage band (use of alternative information considered possible, typical cost) (in million Euro):

	1[a]	Estimated baseline[d]	2	3	4 (including 2)	5	6 (including 2 and 4)
>1000 tonnes	36	482	532	482	578	211	1038
100-1000 tonnes	43	426	450	426	519	207	960
10-100 tonnes	9	84	90	84	118	10	217
1-10 tonnes[b]	10	73	93	73	110	10	373[c]
Total	**97**	**1065**	**1165**	**1065**	**1325**	**437**	**2588[c]**

[a] *Note that in this grand total cost table only one number is used to represent option 1; it assumes that, whether sufficient for risk assessment or not, at most one test is performed per substance per information requirement, regardless of the number of nanoforms that the registration of that substance includes*

[b] *Weighted average: depending on applicable conditions of Annex III to REACH, the implications differ between registrants in the 1-10 tonnage band; more details in Appendix XIII*

[c] *Indirect impact of measure 41 on registration of bulk forms may bring an estimated additional cost of 6 M EUR. Relative additional contribution 1.6%. More details in Appendix XIII*

[d] *Estimated baseline consequent to Board of Appeal Decision 2 March 2017(see discussion in section 4.9). Option 2 cannot be considered baseline in its entirety.*

Additional scenarios are provided under Appendix XIII for costs of nanoform registration without alternative information available, costs per registration dossier and costs per company.

Interpretation, uncertainties and sensitivity analysis

Assessment of individual options is provided in the following chapters, but some broad features of tables 5-1 and 5-2 should be highlighted:

- Higher costs for nanoforms to be registered under higher tonnages reflect more extensive information requirements as set out in REACH ;
- Total costs rather than cost incremental to the baseline are presented;
- As explained in section 4.8, option 1 estimates present cost reflecting information found in many REACH dossiers of substances with nanoforms at present;
- As explained in section 4.8, option 3 will in time lead to costs as in the baseline – (see discussion in section 4.9 on the Board of Appeal decision in the case A-011-2014).

It should be emphasised that the costs presented above, in particular the Grand Total costs, are highly sensitive to several key assumptions, namely the number of substances with nanoforms subject to registration, the number of nanoforms within a substance, the extent to which use of alternative methods for providing information (read-across, ability to apply worst case approach etc.) can be applied between the substances and the nanoforms, testings costs, etc. As evident from Appendix XVI, where different scenarios are examined, the uncertainties of the average cost is likely to be in the order of at least +/- 50%.

Individual materials may present specific challenges when tested and the cost difference between them can correspondingly be significantly larger, within one order of magnitude of the average cost. The actual number of registrants sharing the costs of the information requirements for an individual nanoform will also influence proportionally the actual cost per registrant.

In the Grand Total, costs are directly related to the assumed number of nanoforms, i.e. the higher the number of forms, the higher the grand total cost. As the information related to the number of nanoforms covering nanomaterials on the market is highly uncertain, the assumptions are associated with significant uncertainty.

5.2.1.3 Option 1

As explained in section 2.4 *How will the problem evolve?*, it is reasonable to expect that the situation will improve over the next years and the issues stemming from the differences in understanding how REACH addresses substances with nanoforms at present will diminish due to the mechanisms foreseen in REACH, such as compliance checks by ECHA, continuous development of guidance, and the learning process within industry. However, the process would be cumbersome, take time and uncertainties for companies (on how to comply with the REACH registration requirements) would remain in the short to medium term. Many more companies will get involved by 2018 (1-100 tonnes) and as new nanomaterials make it to the market, many of the same issues will persist.

When preparing this initiative, it has also been shown that there exist clear discrepancies between the involved parties on what REACH entails when it comes to nanomaterials. As recalled above, there is indeed a certain grey area with regard to the interpretation of the current information requirements as applicable to substances with nanoforms, and thus different interpretation of the evolving baseline scenario. This leads to legal uncertainties that will not be resolved (or at least not quickly and not for all operators) with this option.

The assessment of this option makes the assumption that there will not be significant improvements in the short term of the information provided, and this is reflected in the cost estimation of the option in table 5-2.

5.2.1.4 Option 2

Public Consultation: 94% of respondents from industry report that costs of compliance would "significantly increase" under this option, whereas other stakeholders do not expect an impact.

Analysis

According to ECHA's interpretation, this option does not change any existing obligations, but explicitly explains what information companies must provide. Under this interpretation, option 2 would constitute the baseline.

Compliance cost (including administrative burden): The weighted average cost of providing information for a nanoform or set of nanoforms in accordance with option 2 is estimated to be 565 K EUR (depending on the tonnage band ranging from 116 to 1,157 K EUR - the higher the tonnage band, the bigger the cost). The most costly measures within this option are related to the characterisation of the nanoform (measure 2) and providing information on characterisation of test samples as a consequence of the insertion of clarifications in the REACH Annexes I and VI to X according to the OECD requirements (measure 4) [84]. These measures weigh more strongly in the low 1-10 t tonnage band (a 2.4 fold relative increase) and less at higher tonnages (1.5 fold increase for >1000t).

The Board of Appeal's decision on 2 March 2017 in the case A-011-2014 (see discussion in section 4.9) indicates option 2 in its entirety cannot be considered as baseline. It is estimated that the difference (per nanoform) is in the order of 25K to 108 K EUR (the higher the tonnage band, the bigger the cost). In the grand total, the cost of this measure amounts to approximately 100 M EUR (or 9.4% of the estimated baseline).

When comparing to option 1, the major cost increase comes from testing that might be required for individual nanoforms or sets of nanoforms and is therefore proportional to the number of nanofoms registered under one substance. Regardless of whether the registrants had not assessed different forms covered in the registration, or had perhaps just not included documentation of such assessment in the dossier, option 2 would cause additional costs that might be substantial compared to what they have incurred until now. In the medium/long term as ECHA progresses with evaluation, registrants are forced to upgrade the dossiers, the difference would eventually diminish, however, option 2 would still incur at least a total additional cost of 100 M EUR (as compared to the estimated baseline), with high relative increase in the lowest tonnage band.

[84] **Measure 2**: Explicitly require registrants to provide more detailed characterisation of nanoforms; **Measure 4:** Require detailed description of the test material/sample preparation; for further details on the measures, refer to Appendix I.

Regulation clarity/certainty: The option is expected to increase clarity and hence reduce regulatory uncertainties, which would permit firms to better plan business activities entailing the use of nanomaterials. Also, the increased knowledge base regarding the properties of nanomaterials is likely to reduce costs in the long run, also via increased trust for investors that there are no hidden liabilities and general demand side trust in the safety of nanomaterials.

5.2.1.5 Option 3

Public Consultation: For a large number of the respondents, option 3 would either increase the costs of compliance (44%), or have no impact on it (39%).

Analysis

Compliance cost (including administrative burden): Non-binding measures could have an impact on costs, e.g. specific guidance leading to different interpretations of the legislation can increase or decrease compliance costs. However, any cost changes will by definition not stem from a change of the obligations, but could stem from e.g. administrative cost of organising data differently or different testing costs. The compliance cost as well as the ability to address the problem in its entirety depends on the interpretation of the current information obligations. Pursuing the same objective as option 2, soft measures are effectively limited to those that might be pursued as current compliance. Assuming ECHA's interpretation is correct, it is thus expected that the costs for this option would be similar to those of option 2. It is worth noting however that the costs might potentially occur at different points in time, since compliance costs triggered by option 2 would occur immediately after implementation and that those triggered by soft law recommendations would likely take some time to occur. If interpretation of compliance is different (see discussion in section 4.9 on the Board of Appeal decision) and since the Board of Appeal ruled (partly) against ECHA's interpretation in terms that some of the requirements under option 2 cannot be considered as current REACH requirements) then the total cost of this option would differ, i.e. being lower that the total cost of option 2.

Regulation clarity/certainty: Since the measures contained in this option aim at providing explanations about what the obligations for companies are or where more information can be found, this option would increase clarity and reduce uncertainty for companies. The degree of clarity/certainty provided by changes solely in the guidance would, however, be weaker than that provided by changes in the legal text itself.

5.2.1.6 Option 4

Public Consultation: Option 4 is ranked fourth in terms of cost burden.

Analysis

Compliance cost (including administrative burden): A condition for option 4 to work properly is that the registrants provide correct data in accordance with option 2. With option 4, a few new tests are introduced or would be made compulsory for registrants at lower production levels than hitherto. The weighted average total cost of option 4 is estimated to be 642 K EUR (137 K EUR for 1-10t – 1,256K EUR for >1000t). The weighted average cost of the additional measures of option 4 compared to option 2 is 77 K EUR (14% increase), with higher impact on lower tonnage bands (18% and 33% for 1-10t and 10-100t, respectively). The most costly measure within this option relates to the prioritisation of testing on soil and sediments (measure 17, which requires data generation at lower tonnages than for conventional substances, thus having a maximum impact in the 10-100 tonnes registration

band) and additional justification further to water solubility for test waiving (measure 14). If compared to option 1, the cost increase is substantially higher (i.e. 14 fold).

Regulation clarity/certainty: While option 2 addresses the clarity in relation to legal requirements, this option includes additional requirements based on the scientific recommendation compiled by the JRC in the Nano support project. These should provide more certainty in the effectiveness in the regulatory requirements for this specific subgroup of chemicals.

5.2.1.7 Option 5

Public Consultation: This is the best ranked option in terms of cost (for 40% of the respondents this option would have no impact on the costs of compliance).

Analysis

Compliance cost (including administrative burden): The aim of this option being to reduce the cost of compliance, its implementation would indeed have a weighted average cost of 212 K EUR and entail savings of 62% for companies compared to option 2. Savings are in particular high for lower tonnages (92% and 90% for 1-10t and 10-100t, respectively). The estimated savings per nanoform, assuming they being registered together with a bulk form carrying the entire cost, has been estimated to range between -104 K EUR for the lower tonnage band to -699 K EUR for the upper one compared to option 2. In case of option 1 being the baseline, implementing option 5 would not cause any additional cost in lower tonnage bands but would cost 298 K EUR and 380 K EUR for 100-1000t and >1000t respectively.

There are two main reasons for such significantly lower cost:

- The specific requirements for a nanoform or set of nanoforms in terms of scope and characterisation under option 5 do not exist or are less demanding than the ones under option 2 (e.g. measure 18 versus measures 2 and 3[85]).
- The option would exempt the registrants from providing any ecotoxicological and environmental fate information for the nanoform or set of nanoforms and in addition assumes provision of information by alternative means rather than by testing[86].

This cost reduction does not affect the information supplied for the bulk or another (non-nano) form of a substance in the dossier. In general this option would not oblige data to be generated for the registered nanoform or set of nanoforms.

Regulation clarity/certainty: The option does provide further clarity to the registrants who will face easier tasks in fulfilling their requirements, imply savings and permit better planning. Essentially, the proposed option would reduce the standard information requirements for

[85] **Measure 2**: Explicitly require registrants to provide more detailed characterisation of nanoforms; **Measure 3**: Require that nanoforms are explicitly addressed in the endpoint sections; forms should be clearly addressed in study summaries; and **Measure 18**: Describe whether and which different nanoforms are covered in the chemical safety assessment, including a statement when and how information on one form is used to demonstrate safety of other forms; for further details on the measures, refer to Appendix I.

[86] **Measure 5**: Require scientific justifications for grouping / read across / QSAR and other non-testing approaches for different forms; **Measure 24:** Specify that the use of non-testing methods (e.g. read-across, grouping, categorisation etc. methods) is a priority for nanoforms; and **Measure 33**: Create presumption that non-testing methods are valid for nanoforms in all endpoints; for further details on the measures, refer to Appendix I.

nanoforms of a substance and change the legal situation for substances with nanoforms produced in quantities below 100 tonnes per year per company to a situation comparable to what was applicable to existing chemicals before REACH was adopted.

5.2.1.8 Option 6

Public Consultation: Option 6 was the worst ranked option in terms of impacts on costs (4 of the measures are particularly qualified as affecting or significantly affecting the costs of compliance[87]). Indeed, almost 90% of the respondents indicated cost increases, and half expected a "significant increase".

Analysis.

Compliance cost (including administrative burden): Option 6 would add further obligations to those established under options 4 and 2. It would add administrative requirements, e.g. presenting separate information for nanoforms of a substance that differ among themselves in terms of specific characteristics (coating, shape, form etc.). The option implies an average weighted cost increase by 121% compared to option 2. The total cost of this option is estimated to be 1,254 K EUR (466 K EUR for 1-10t and 2,256 K EUR for >1000t). Compared to option 1, the cost increase is 27 fold. There is also an estimated indirect additional cost of 10 K EUR per nanoform from measure 41 through registration of the bulk form of substances in 1-10t tonnage band, leading to (small in comparison to the impact of other measures) estimated total additional indirect costs of 5.8 million EUR (1.5% of the total cost in the 1-10t tonnage band, 0.2% in total). The highest costs come from the measures that effectively increase the number of nanoforms to be addressed (measures 41 and 49[88] addressing REACH Annexes III, IV and V) and those which reduce the availability of information via alternative means (measure 46). Further costs are incurred by requesting additional physico-chemical requirements from measure 44 and the toxicokinetic study from measure 51. However, it is to be noted that with better toxicokinetic information available, it can be reasonably assumed that at least some more tests can be waived (in particular in the higher tonnage bands) based on justifications referring to the toxicokinetic data or as the information is provided via alternative means; this means that despite more requirements being added, the general testing requirements (both new and existing testing) may be reduced so that the overall impact is lower than expected.

Regulation clarity/certainty: This option adds additional requirements. Because it is prescriptive and detailed, it supports the objective of providing clarity for the registration.

5.2.2 Impact on SMEs

5.2.2.1 Option 2

The costs for complying with option 2 are considerable, even more so in the lower tonnage bands (see above - the relative impact of the measures for the 1-10 t tonnage band is 1.6 times the one for > 1000t) where it is expected that more SMEs are active. However, the

[87] Refer to the Appendix V for more detail about these.

[88] **Measure 41:** Information requirements for substances covered by Annex III (b) must also apply to nanoforms; **Measure 44**: For nanoforms, require additional physico-chemical characterisation along the particle's fate when particle properties impacts on hazard; **Measure 46:** For nanoforms, explicitly limit the potential for use of non-testing approaches for hazard and exposure where science is not consolidated, but encourage its parallel application and documentation; **Measure 49:** Specify that list of substances in Annexes IV and V does not cover nanoforms of these substances; and **Measure 51**: Perform toxicokinetic screening; for further details on the measures, refer to Appendix I.

information gained through these measures is essential for demonstrating safe use of the nanoforms of the substance. In fact enhanced clarity is assumed to make it easier and more efficient also for small firms that are not lead-registrants to apprehend precisely and up-front what obligations REACH puts on them. However, the increase in the compliance cost may create a barrier for some SMEs and force them to exit the nanomaterial market.

5.2.2.2 Option 3

SMEs are the businesses least able to access information and the most likely to misunderstand how REACH works. As such, they stand to gain the most from soft law measures aiming at providing more clarity on the registration obligations. Other considerations apply as for part of option 2.

5.2.2.3 Option 4

The measures and their associated costs have proven to follow relatively closely the existing cost development between the different tonnages with the exemption for the tonnages 10 – 100 tonnes due to the expensive soil and sediment test that would be additionally required in that tonnage range. Assuming that SMEs have a higher relative representation in the lower production volumes, it is important to assess if the lower volumes are harder hit than the higher volumes. As shown in table 4-2, and comparing to option 2 this would be the case for the volumes 10-100 tonnes (mainly due to measure 17), but not that much for the volumes 1-10 tonnes, where it is expected more SMEs are active.

5.2.2.4 Option 5

Like for other company sizes, the short term savings on compliance cost will benefit SMEs. However, the continuous lack of relevant information on safety might impede the commercial success of the SME in the medium to long term.

5.2.2.5 Option 6

The impacts on the viability of SMEs explained under option 4 move in the same directions for this option, but their magnitude is much stronger. In particular for the lowest tonnage band (1-10 tonnes) the resulting cost increase, as compared to option 2, could be a challenge. SMEs involved in the manufacturing or importing of nanomaterials could see their viability severely affected.

5.2.2.6 General discussion on impacts on SMEs

The requirements for registration and generation of information under REACH are strictly company-neutral and related solely[89] to the tonnage of the substance placed on the market by a company. However, in particular through the tiered tonnage thresholds, REACH is already providing some relief for SMEs, for all chemicals, as a higher proportion of SMEs is registering low(er) tonnage substances under the less onerous standard information requirements for the lower tonnage bands. Furthermore, SMEs benefit from significantly reduced registration fees and dedicated implementation support by ECHA[90].

[89] There are a number of specific provisions (e.g. exclusion under Annex IV,V, polymers, intermediates) but they are all explicitly captured by the legal text. See Appendix XIV and REACH regulation for more details.

[90] Including dedicated events and webinars, webpages, helpdesk, SME ambassador, implementation support such as recent development of list of low tonnage chemicals likely to fulfil conditions under Annex III of REACH etc.

Any further adaptations (i.e. waivers for subgroups of chemicals) are based on scientific justification (generally available or demonstrated by registrants) and clear demonstration that such an adaptation does not impede the ability to safely manage the substance, but these cannot be dependent on the size of the registering company.

Measures addressing nanoforms, in all options apart from option 5, follow this same logic. SMEs seem to be proportionally affected more by the options, compared to the situation for conventional chemicals. That is principally because the nanoforms need to be characterised, a basic requirement to properly identify them, and thus defining the scope of the registration dossier, and subsequently enable better functioning of REACH[91]. At low tonnages, characterisation contributes, in relative terms, a higher proportion to the total costs (i.e. characterisation + testing), given that testing requirements are lower. The same 'disproportionate' effect is observed already in present REACH implementation e.g. for properly identifying a UVCB substance registered at low tonnage. The same argument applies to some of the related measures under options 2 and 4. Option 6 causes additional burdens for SMEs, but this has been clearly identified.

Option 5 includes several measures that attempt to mitigate impacts on SMEs also by further reduction of information requirements for lower tonnages via a generic waiver, applying to all nanoforms, of ensuring nanoform-relevant information and relying on data on whichever form of the substance that is available. A case by case assessment may in many cases eliminate need for further testing as relevant information for nanoforms may be available through alternative means (e.g. read across, worst-case approach), but a generic waiver applicable to all nanoforms of all low tonnage substances cannot be scientifically justified and thus represent a deviation from the REACH approach presented above.

5.2.3 Innovation and research

Drivers for innovation and research are manifold and not always equally well understood. In this particular case, it should be borne in mind that the measures all are to be introduced in context of already existing REACH registration obligations so isolated effects of the different options are even more difficult to identify. Overall the discussions have identified two general positions, those who argue that extra health and safety requirements adds compliance cost to companies that otherwise would have been spent on developing new products (the findings of the REACH review indicate that there has been indeed a shift of resources from R&D to compliance); and those who argue the opposite way claiming that research and innovation is (also) fuelled by legislative requirements and that compliance information is not passive knowledge but also an asset that can help further development.

The ‘de-regulation’ argument as voiced by some companies being part of the consultation assumes that regulation simply increases costs and erodes competitiveness and existing or future innovation; several answers of decision makers in companies showed that “data generation as such does not necessarily lead to conception of new ideas and innovative activity”. Fulfilling the requirements of the REACH Regulation requires scarce company resources otherwise needed for other purposes, e.g. goal-oriented research and development activities and/or gaining better position in the global markets. This is confirmed in a study

[91] In fact, the registrant is always registering the substance (with nanoforms) with other registrants of the same substance, also when he registers at different tonnages. Data sharing reduces total costs for testing and the number of animals required. However, failure to characterise nanoforms by all registrants would not allow the joint submission to function as desired.

monitoring the impacts of REACH on innovation, competitiveness and SMEs[92], where results show that about half of the companies have had to reallocate R&D staff to compliance activity.

The 'pro-regulation' argument builds e.g. on information gathered by the introduction of additional requirements in the options, addressing human health hazards and environmental fate and hazards may also help spark innovation as has been demonstrated by the effects of information generated thus far for the first registration dossiers. As soon as companies have performed the additional tests required, they gain additional information, on particular hazards and risks of these nanoforms, and also on relations between their characteristics and risks. Having this information early helps focus innovation to the more successful final solutions (i.e. 'safety by design') and helps secure investment. It may also induce further innovation, e.g. on alternatives with less hazards and risks. This does not apply only to the company's own development - harvesting the joined increased knowledge opens new innovation potential.

The impact assessment prepared in the run-up to REACH[93] forecasted no substantial changes related to REACH with regards to R&D investments by firms in the chemical sector. Similarly, the more recent CSES interim evaluation[94] mentions that there have been no significant effects in terms of innovation activities, which could however arise in the future. According to the preliminary findings in the same study cited above, in spite of forcing reallocation of resources to compliance for a significant share of companies, REACH has also increased activity in R&D for 26% of all companies. Indeed, an increase in knowledge of chemical substances and awareness of needs of upstream and downstream actors in value chains was reported by a significant share of respondents to a questionnaire, and about a fifth of respondents indicated that they had launched new products or services as a result of knowledge gained through the compliance process. Costs due to the registration process have resulted in withdrawal of substances for 30% of the respondents; however, among these, half have increased their R&D activity to identify alternative substances to use, and between 25 and 33% have changed their manufacturing processes in order to avoid the use of those substances. The REACH Review concluded that information generated for the registrations provide inspiration for the innovative use of existing substances and that REACH has had a positive impact on research into new substances. The survey of nanomaterial manufacturers and importers (ca. 15% with actual experience implementing REACH) highlighted REACH and CLP, alongside other reasons such as value chain readiness problems and lack of capital, to have negatively influenced time-to-market of nanomaterials, which might indicate shifts of resource allocations and loss of the momentum in gaining market shares for innovative applications[95]. The BiPRO study mentions that impacts on innovation from requirements related to substances with nanoforms could also arise in different directions, with increased

[92] Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs, CSES/RPA/Okopol, http://ec.europa.eu/DocsRoom/documents/14581/attachments/1/translations/en/renditions/native&usg=AFQjCNH4hu-0KJUtY0QyMvRSptk6jZnmow&sig2=xs3I5pBS91RMrXfBuNjvlw

[93] REACH – Further work on impact assessment. A case study approach, Final report, KPMG, July 2005 http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/kpmg_final_report_en.pdf

[94] Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU chemical industry, Final Report and Annexes, Centre for Strategy & Evaluation Services (CSES), 14 June 2012 http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/innovation_en.htm

[95] Study on REACH contribution to the development of emerging technologies, October 2012 http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/emerging_technologies_en.htm

knowledge as a possible driver of positive future impacts. Again, limitations in available data allow only a qualitative analysis.

Several measures aiming at improved clarity, especially in options 2 and 5, would allow better tailoring of the nanoform specific measures on the key aspects of hazard, exposure and risk assessment in REACH. Further measures reducing obligations for nanoforms, such as in option 5, might sometimes facilitate access to market for innovative SMEs; on the other hand, the reduced knowledge base or scientifically supported safety information could even impede innovation and market access.

Options implying an increase of requirements, such as options 4 and 6 (and depending on where the baseline is, also option 2), would entail both positive and negative impacts on innovation. On one hand, an increase in fixed costs could hamper innovation, as compliance costs would take away resources that could otherwise be devoted to R&D activities. This negative effect would be even stronger if costs would reduce the financial viability of a number of SMEs working with nanotechnologies. On the other hand, testing requirements would in the medium and long term increase the knowledge base in the sector with regard to the characteristics of nanomaterials, possibly facilitating their employment in new avenues for innovation in nanotechnologies. Please refer to Appendix XI for a table summarising an assessment performed by Matrix on the capacity to innovate under the different options.

To facilitate innovative SMEs developing nanomaterials would contribute to the long-term competitiveness and employment in Europe. However, given several indicators of drivers pulling in different directions and the general absence of data, a conclusive assessment of the effects of any of the options' impact on innovation cannot be made.

5.2.4 Competitiveness, trade and investment flows

The effects on the competitiveness of EU firms operating with nanomaterials could be twofold. On one hand, increments in costs would potentially harm the ability to compete in international markets. On the other, regulatory certainty, improvements in the knowledge and exchange of information could instead bolster competitiveness.

In the context of this assessment building on an established regulatory framework, EU based companies using nanoforms in the production of articles may be in disadvantage as compared to importers and non-EU companies, since these are not subject to the REACH registration obligation when the nanomaterial is integrated within an article (unless Article 7(2) of REACH[96] applies). EU based firms manufacturing nanomaterials will also be affected when competing with third country companies outside the EU territory. This is so because REACH is also applicable to the manufacture of products exported out of the EU territory. With the exception of Australia[97], the EU's main trading partners tackle nanomaterials through their existing chemicals legislation. Unlike in the EU, this most often means that new substances are subject to (limited) notification requirements prior to their placing on the market while existing substances are subject to measures only when the authorities have gathered enough evidence to introduce measures. For example, the US-EPA has interpreted that some

[96] If a substance is identified as being of very high concern, obligations apply as to the identification of its presence in products, including imported ones.

[97] Australia has introduced specific rules on the use of nanomaterials in cosmetics.

nanomaterials represent 'new uses' triggering in some cases further testing requirements for companies[98].

Given the general absence of data to underpin a quantitative conclusive assessment of the effects of either of the options' impact on competitiveness, trade and investment flows, this analysis is based upon the qualitative assessment provided by Matrix[99]. Accordingly, options 2 and 3 are likely to impact negatively in the short term in the cost of production and possibly affect manufacturers or downstream users of substances with nanoforms; however, the options would at the same time decrease the cost of capital in the long term due to reduced uncertainties and would increase the market shares of companies due to a higher confidence in the products containing their nanomaterials. By reason of a probable increment of the costs of production with regard to options 2 and 3, the negative impacts on competitiveness of option 4, and even more that of option 6, are likely to outweigh the increase in the confidence of the products containing nanomaterials. Finally, option 5 would, disregarding the negative impact of reduced confidence in products themselves, help decrease the cost of production, allowing the entry into the market of new operators, which would result in stronger competition and hence would presumably result in a reduction of prices of the final products; this would eventually allow improving the international competitiveness of EU firms.

5.3 Health impacts

5.3.1 Introduction

It is a challenge to estimate the health impacts associated with chemicals in general: their intrinsic properties are not a priori known for such an analysis (that is the purpose of testing under REACH); nor are they easily translated into dose-response functions, not least because exposure depends on the way in which they are used. Given this it is even more difficult to monetise the benefits.

The most direct health and safety impact affect the workers handling nanomaterials. Control of risks and exposures is dependent on the level of information available.

Most of the health benefits are expected to take place with significant delays after implementation of appropriate measures. This is also because enhanced protection of workers' safety will not automatically occur as a consequence of the measures taken with regard to the REACH registration requirements, but will only be achieved if appropriate risk reduction measures are implemented based on the information contained in the registration dossiers, which in turn can lead to additional costs.

There is a priori a lower risk for potential danger for the final consumer, in comparison with workers, because workers will experience higher levels of exposure during manufacturing processes involving nanomaterials. Health impacts are, therefore, likely to be smaller than in relation to occupational health.

More than 99% of the calculated health benefits of REACH refer to avoided cancer deaths[100]. However, for nanomaterials it may be relevant to refer to costs from other diseases, especially

[98] See http://www.epa.gov/oppt/nano/ for general approach, and https://www.federalregister.gov/articles/2015/02/02/2015-01721/significant-new-use-rules-on-certain-chemical-substances for an individual example of decision on premanufacture notice P-13-573 including carbon nanotubes, as restrictions are set on use prior to the submission and analysis of specific tox and ecotox information.

[99] Please refer to Annex XI for a table summarising the impacts on competiveness based on qualitative analysis.

[100] Assessment of the Impacts of the New Chemicals Policy on Occupational Health, RPA, June 2003

irritation, oxidative stress and genotoxicity. In any case, the majority of health benefits expected to be delivered by the measures discussed in the impact assessment will occur between 2022 and 2042, due to the latency of health risks and the consecutive extension of life years lost.

Two studies have recently been conducted and a third one is currently ongoing, which are not directly linked to nanomaterials or the assessed options, but rather to the assessment of benefits of better information on chemicals and the environmental legislation in general:

- A recent report by RPA and CSES on the potential extension of the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year[101] assesses the costs and the benefits of different options for the modification of the information requirements for substances registered in the 1-10t band. The study assesses the benefits, expressed in terms of damage costs avoided, on the basis of the avoidance of one incidence of 'disease' per year per substance identified with a human health classification and improvement in 1 km of waterbody for every substance identified with a classification for aquatic toxicity. The study concludes that the baseline scenario provides €10.02 benefits for every €1.00 of cost and that by increasing the information requirements, there is a roughly proportionate increase in benefit in terms of damage costs avoided. Note that the assessment of the baseline cost was made for bulk substances and concerns only the information requirements relevant for 1 – 10 tonnes per year, with similar assumptions regarding cost per bulk substance as done in the analysis above for the nanoform or set of nanoforms.
- Another study compared the costs and benefits of environmental regulation in the UK[102]. According to this study, the cost benefit of environmental regulation in the UK has increased, with every £1 spent on compliance and enforcement returning £3 to society through economic, environmental and health benefits, according to government research. The environment ministry quantified the costs and benefits of 428 of its regulations affecting UK businesses, just over half of which were derived from EU or international legislation. The total estimated direct cost to business between 2012 and 2021 will be £6bn, of which 86% is related to compliance and 14% to administrative burden. The estimated direct benefit to business is £2bn a year, giving an estimated net cost of £4bn. But the wider benefit of regulation to parties other than business is about £10bn a year. Chemicals legislation, almost exclusively based on EU regulation, provided the best cost benefit ratio of almost 1 to 20.
- The DG GROW study referred to in section 5.2.3 *Innovation and research* shows that around 53% of companies have improved their risk management procedures because of REACH, with personal protection equipment and new safety instruction indicated with more frequency. When distinguishing by the role of the company within the supply chain, 51% of manufacturers and 70% of formulators changed their risk management measures; these shares decrease going down the supply chain but still remain relatively high (from 48% for distributors to 27% for suppliers of articles).

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http://ec.europa.eu/environment/chemicals/reach/pdf/background/envhlthimpact.pdf

[101] Technical assistance related to the review of REACH with regard to the extension of the registration requirements for substances manufactured or imported between 1 and 10 tonnes per year (ENV.A.3/SER/2013/0057r)

[102] The costs and benefits of Defra's regulations, 2015 https://www.gov.uk/government/publications/the-costs-and-benefits-of-defra-s-regulations

This is an important finding and certainly constitutes a positive economic effect: various studies have concluded that expenditure on occupational safety and health is an investment that "pays off" and calculated the Return on Prevention (ROP) to be 2.2[103] or the Benefit-Cost Ratio to be between 1.04 and 2.70[104].

In summary, while there are many indications that health benefits are to be expected as a result of better information availability for registered substances with nanoforms, it has not been possible to quantify all the potential benefits that are expected to occur as a result of introducing the various options examined in this impact assessment. The analysis that follows is thus based mainly on a qualitative assessment of each of the options.

5.3.2 Option 1

Public Consultation: It can be deduced from the overwhelming majority of respondents indicating a need for change and the majority (51%) supporting the measures under option 2 (which are also part of options 4 and 6) leading to increased information on potential health hazard of nanoforms, that 'no change' does not score high in relation to safety.

Analysis: Even if it is expected that, depending on the outcome of the pending appeal cases concerning the ECHA compliance check decisions (see 2.2.3 *Initiatives undertaken*), over time the availability of information for substances with nanoforms will improve via the control mechanisms foreseen in REACH (i.e. moving towards a similar situation as under option 2 in the medium/long term), option 1 may entail risks for the health of workers and consumers in the short/medium term, leading to potential long term impacts (see discussion on cancer above).

5.3.3 Option 2

Public Consultation: In the public consultation, the majority of respondents (51%) considered the implementation of measures under option 2 (which are also contained in options 4 and 6) in their preferred option. Its measures also rank first in relation to the contribution to safety.

Analysis: Enhanced clarity can improve the effectiveness of current information requirements to generate relevant information leading to adequate risk management, delivering health benefits. This is the case, for instance, from the additional information about the nature of the nanoform being tested, established under measure 2, or the requirement that the nanoform is specifically addressed (measure 3), but especially from the requirement of identification of uses and exposure assessment for the nanoform (measure 9).

Overall, this option would entail positive impacts on occupational health safety.

5.3.4 Option 3

Public Consultation: In public consultation, this option ranked 4th in the safety category.

Analysis: Depending on the legal interpretation of present information requirements, the "soft law" approach would have similar health effects than those for option 2, although slightly lower, and with longer delays, similar to what has been described for option 1. This is expected to be so because, compared to option 2, guidance and the other accompanying soft

[103] Calculating the international return on prevention for companies. Costs and benefits of investments on occupational safety and health. DGUV. 2013 http://publikationen.dguv.de/dguv/pdf/10002/23_05_report_2013-en--web-doppelseite.pdf

[104] Socio-economic costs of accidents at work and work-related ill health, DG EMPL, EC, 2011 http://ec.europa.eu/social/BlobServlet?docId=7416&langId=en

law measures contained in option 3 are not as binding as formal requirements in the legal text, and therefore companies may not be as inclined to adapt their registration practices to nanomaterials specificities. Moreover, the ECHA evaluation process is assumed not to be sufficient on its own to ensure an immediate implementation by companies.

5.3.5 Option 4

Public Consultation: More than 40% of the respondents considered implementation of measures under option 4 (i.e. measures listed under options 2 and 4 combined) in their preferred option. Its measures rank second in relation to the contribution to safety.

Analysis: This option entails an important increase in requirements beyond option 2. Measures requiring data on dustiness (measure 10), route of exposure (measure 11) and non-bacterial in vitro gene mutation study (measure 13) could potentially entail significant improvements in occupational safety, especially in terms of prevention of lung cancer, as they would increase information on exposure to hazardous substances. Those health impacts would affect workers in the chemical sector but also those in downstream sectors using nanomaterials. Benefits would also indirectly affect employers, as they are legally responsible for workplace safety and have to conduct risk assessments for their workers, as specified by the European Framework Directive 89/391/EC.

5.3.6 Option 5

Public Consultation: this option ranked last in the safety category.

Analysis: This option could potentially entail a higher risk of disease for workers due to the fact that less information for risk assessment will be available. The considerations developed for option 4 in terms of reduction of risk, in particular in relation to lung cancer, are reversed here. While there is no clarity with regard to actual risks in relation to nanoformcompared to bulk chemical, this option could allow potential dangers to materialise. For instance, the omission of mutagenicity and acute toxicity tests in lower tonnages could result in missing the identification of adverse health impacts (e.g. cancer) and possibility of accidental death from acute exposure.

5.3.7 Option 6

Public Consultation: this option ranked third in relation to the contribution to safety, after options 2 and 4.

Analysis: As a consequence of its increased information requirements, option 6 further reinforces the prevention of occupational diseases. Additional requirements related to toxicokinetics (measure 51), physico-chemical characterisation (measure 44) and separate documentation for each nanoform (measure 45) can enhance the informational benefits of testing. Establishing inhalation as the appropriate route of exposure in repeated dose toxicity study unless such exposure can be excluded (measure 50) can help protect from cancer and respiratory diseases.

5.4 Environmental impacts

5.4.1 Introduction

The UK study mentioned above in section 5.3 *Health impacts*, also points to environmental benefits arising from the cost spent on environment legislation. A study conducted by a

consultant[105] identified several ways in which REACH can reduce the discharge of chemicals into the environment, which is confirmed by the provisional results from the study on impacts of REACH on innovation, competitiveness and SMEs (see section 5.2.3 *Innovation and research*), according to which around 39% of companies have improved their management of environmental emissions and waste due to REACH.

The impacts on the environment are however hard to quantify. This is mainly due to the lack of meaningful reference systems, i.e. ecosystems that are small enough to be useful while not being too simplistic to transfer the results to more commonplace, larger ecosystems. One way to assess the benefits of measures (and regulation in general) is to evaluate the ability to identify (and where necessary to manage) chemicals that are hazardous to the environment: aquatic toxicity and persistence, bioaccumulation and toxicity (PBT) are the most common indicators that have been picked also in the ESTAT REACH Baseline study[106] and recent RPA and CSES study[107].

Nanoforms should be considered as any other forms of chemical. Possible impacts range from: probably insignificant dissolution or immediate agglomeration and precipitation, to persistence in ecosystems and organisms with genetic and morphologic consequences as well as potentially different susceptibilities depending on species. There is already evidence of specific nanomaterials in the environment and their impact[108] and SCENIHR recently delivered an opinion which included an assessment of the environmental impact of one specific substance with nanoforms (nanosilver)[109]. More comprehensive work has recently been concluded[110], however it is considered that extrapolation from the scarce information on the few specific nanomaterials available at present is more appropriate than drawing conclusions from the environmental impacts of chemicals in general. The analysis is, however, limited to a qualitative discussion.

As regards the public consultation, the ranking on safety did not differentiate between health and environmental impacts and the conclusions summarised in the chapter on health above are not repeated. It should be noted that apart from the two more general measures related to environment (option 4, measure 14 on water solubility, option 6, measure 44 on consideration of modification of hazard along the life cycle), environmental measures scored marginally lower in importance to safety than those related to health.

5.4.2 Option 1

In analogy to consideration on health impacts and depending on the outcome of the appeal 11/2014 (see 3.2 *Specific objectives*), over time the availability of information for substances with nanoforms is expected to improve via the control mechanisms foreseen in REACH (i.e. moving towards a similar situation as under option 2 in the medium/long term), option 1 may

[105] DHI (2005): "The impact of REACH on the environment and human health", ENV.C.3/SER/2004/0042r, report to DG Environment

[106] For latest see "The REACH Basline Study, 5 years update" http://ec.europa.eu/eurostat/documents/3888793/5851097/KS-RA-12-019-EN.PDF

[107] See reference in 5.3.1.

[108] See for example " Environmental and health effects of nanomaterials in nanotextiles and façade coatings", March 2011 http://www.ncbi.nlm.nih.gov/pubmed/21397331

[109] See "Opinion on Nanosilver: safety, health and environmental effects and role in antimicrobial resistance", SCENIHR, 2014; http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_039.pdf

[110] See for example NanoFATE project under FP7 http://www.nanofate.eu

entail risks for the environment in the short/medium term with potential long term impacts in case of persistent nanoforms.

5.4.3 Option 2

Specification under this option improves the information derived from tests or alternative methods such as read-across, which will enable positive impacts in terms on environmental protection. This is the case, for instance, for measure 3 (and related measure 7) requiring that environmental endpoints are addressed specifically for nanoforms. More precise information related to nanoforms will generate more accurate information that can lead to a better functioning of the Regulation on Classification, Labelling and Packaging of Chemicals, which is the key legislation used to trigger action in downstream environment legislation on e.g. waste and water.

5.4.4 Option 3

The "soft law" approach would have similar effects than those for option 2, although slightly lower and with delay, similar to what has been described for option 1, and depending on the legal interpretation of the current REACH requirements. It is reasonable to assume that compared to option 2, some adverse impacts on the environment may occur as they will not be addressed immediately. Some companies will not follow guidance or voluntarily follow best practices identified by others and not all registration dossiers will be subject to ECHA evaluation.

5.4.5 Option 4

Similarly as for health impacts, requirements under option 4 provide further concrete measures in addition to also implemented option 2 clarification measures to adequately assess hazard to the environment and thus limit any potential risk. Measure 15 (specification that long term testing should not be waived based on lack of short term toxicity) contributes to preserve wildlife, measure 17 (requiring that testing on soil and sediment organisms is conducted already for low tonnages) and measure 16 (preventing the waiving of algae testing based on insolubility) help preventing harm for cases where nanoforms might end up in the aquatic environment, while measure 13 (requiring non-bacterial in vitro gene mutation study), provides information regarding toxicity to mammalian wildlife and agricultural animals.

5.4.6 Option 5

The reduced information required pertinent to nanoforms of a substance might generally increase the risk to the environment, in particular due to measure 32, which excludes an obligation to provide any ecotoxicological or environmental fate information specifc to the nanoform or set of nanoforms.

5.4.7 Option 6

This option provides limited additional protection to the environment, in comparison with option 4. Measures 42 and 44 increase test relevance as they augment knowledge on nanoform fate and transformation through the life-cycle, while measures 39, 40 and 45 help protecting environmental harm through imposing separate documentation for each nanoform.

5.5 Animal testing

The table 5-1 below includes a rough estimation of the cumulative number of animals used for the testing of one nanofom or set of nanoforms, using assumptions on the average animal use

per test from a report made by the JRC[111] and the same assumptions as in section 6.2 on the generation of information via alternative means. One can observe that the main impact stems from measures under option 2. The impact of additional measures under option 4 is marginal while under option 6 they are more significant. As expected, animal use is lower in option 5 as the obligation to have information relevant to the nanoforms or set of nanoforms is waived by several measures.

Table 5-3: Animal use per option per nanoform (or set of nanoforms), use of alternative methods considered possible, with default assumptions (see Appendix XIII):

	1	1[a]	Estimated baseline[d]	2	3	4 (including 2)	5	6 (including 2 and 4)
>1000 tonnes	118	1178	1178	1178	1178	1182	600	2463
100-1000 tonnes	154	1076	1076	1076	1076	1081	577	2195
10-100 tonnes	97	485	485	485	485	496	97	835
1-10 tonnes[b]	2	9	9	9	9	16	2	128[c]
Weighted Average	**80**	**613**	**613**	**613**	**613**	**619**	**301**	**1288**

[a] *The column represents animal use for bulk form registration, which can be directly compared with the other estimates under REACH*

[b] *For the 1-10 tonnage band animal testing is required only for phase-in substances that fulfil the Annex III conditions; therefore, for most substances no information requirements beyond physico-chemical properties are requested, apart from option 6 (due to measure 41)*

[c] *Indirect impact of measure 41: 8 additional animals. See Appendix XIII for details*

[d] *Estimated baseline consequent to Board of Appeal Decision 2 March 2017(see discussion in section 4.9).*

Table 5-4: Total estimated animal use per option (in thousands):

	1[a]	Estimated baseline[d]	2	3	4 (including 2)	5	6 (including 2 and 4)
>1000 tonnes	54	542	542	542	544	276	1133
100-1000 tonnes	85	595	595	595	598	319	1214
10-100 tonnes	24	121	121	121	124	24	209
1-10 tonnes[b]	2	7	7	7	12	2	102[c]
Total	**165**	**1266**	**1266**	**1266**	**1278**	**621**	**2658[c]**

[111] Numbers are primarily used from the JRC report: http://publications.jrc.ec.europa.eu/repository/bitstream/JRC29111/EUR%2021405%20EN.pdf.

[a] *Only one number is used to represent option 1, assuming that, whether sufficient for risk assessment or not, at most one test is performed per substance per information requirement, regardless of the number of nanoforms the registration of that substance includes*

[b] *Weighted average*

[c] *Estimated indirect impact of Measure 41: 4387 animals (4.3% of use in 1-10t tonnage band, 0.1% of total estimated use). See Appendix XIII for details*

[d] *Estimated baseline consequent to Board of Appeal Decision 2 March 2017(see discussion in section 4.9).*

5.6 Classification and Labelling (CLP)

Depending on the changes to be made in the Annexes of the REACH Regulation (in particular Annex VI), the changes would affect not only the registration requirements as analysed above, but also the requirements under the CLP Regulation and Annex II of REACH in relation to the communication in the supply chain via Safety Data Sheets for the registered substances or certain nanoforms thereof. As expected by the main objectives of REACH, the changes would have a 'domino effect' with impacts on the implementation of the CLP Regulation (and subsequent regulation relying on CLP), communication in the supply chain via Safety Data Sheets in general and even in view of companies operating with substances with nanoforms in volumes of less than 1 tonne per year, as well as to the chemical safety assessment by downstream users. This is because the provisions of the CLP Regulation require the notifiers of hazardous substances to the C&L Inventory to notify to ECHA the information on the identity of the substance as required under sections 2.1 to 2.3.4. of Annex VI to REACH, based on the available information and taking into account different classification for different forms. There are no requirements to generate information, but it is expected that any available information (that will become available as a consequence of the implementation of the options examined in this impact assessment) is acted upon also under CLP.

For the purpose of this impact assessment, none of these impacts are explicitly entered under cost, as they are considered 'business as usual', i.e. standard implementation of the CLP Regulation which relates to any increase in available information and is not nanomaterial or REACH Annexes modification specific.

5.7 Summary of the impacts

5.7.1 Option 1

With more companies and more specialised substances with nanoforms being subject to REACH registration in the coming years, maintaining the *status quo* is expected to give rise to further problems similar to those already identified in the submitted registration dossiers. Mitigating factors are ECHA's and the Member States' evaluation processes (note that legal interpretation of some important aspects of present information requirements or the ability to request certain information under REACH are presently under appeal) and the general learning process in the private sector on what REACH entails.

Overall it is expected that the no-action scenario will maintain uncertainties among companies which could reduce the appetite in innovating in the nanomaterial sector. Coupled with question marks about whether REACH provides an adequate answer to the safety assessment needed for nanoforms this option may not only lead to a suboptimal protection level but may also be bad for business, both at the micro economic level and viewed from a broader perspective on the ability to embrace new technologies and products. The public consultation also established very neatly that the current system is not clear, hence almost all actors agree on the need to do something.

5.7.2 Option 2

Under this option firms must register nanoforms and are expected to incur significant costs. The biggest cost in this option is associated with the 'characterisation' of the nanoforms and the characterisation of test samples used to fulfil information requirements for nanoforms. However, as explained in earlier parts of this impact assessment, without this information it is not possible to determine what is covered by the registration dossier, nor determine the relevance of the test results that have been used to claim the safe use of the registered substance with nanoforms. It is important to stress that the measures under option 2 are already considered as present compliance requirements by ECHA as an indispensable requirement in order to deliver the 'case-by-case' assessment broadly recommended by science. Based on the outcome of the appeal case on ECHA's compliance check decisions (see 2.2.3 *Initiatives undertaken and 4.9 Industry appeals to ECHA decisions on registration of substances with nanoforms*), some of the costs may thus be incurred also under option 1 through a lengthy and resource-intensive process of ECHA requesting additional information from registrants. A key benefit of option 2 is to shorten this process, make it more effective and providing upfront clarity to registrants on what needs to be included in the dossiers when assessing nanoforms of a substance. Although SMEs may be disproportionately affected as compared to larger companies, this option requires essential information for demonstrating safe use.

The clearest benefits compared to option 1 would come from the enhanced clarity in terms of which information is required for the registration of nanoforms and the correspondingly better, targeted and quicker information to protect human health and the environment. It could also help reduce the uncertainty amongst downstream users where information suggests some reluctance to accept nanomaterials where they can be avoided. Most importantly, the overarching aim of REACH registration of demonstrating safe use will be helped by the introduction of these measures.

Generating relevant information on nanoforms or sets of nanoforms may at present, as for substances in general, still require significant use of animals, even when assumptions on use of alternative information (QSAR, read-across, grouping) are made.

Overall, it can therefore be concluded that the introduction of the measures in option 2 represent a good trade-off between the costs and the potential benefits. It has been marked with the highest efficiency and safety score in the public consultation with a majority of respondents (51%) supporting the measures in their preferred option. Furthermore, the option is coherent with the tiered information requirements foreseen in REACH (i.e. the higher the volume for which a substance is registered, the more information has to be provided).

5.7.3 Option 3

REACH is already today supported by thousands of pages of guidance ranging from general ECHA guidance that has gone through a rigorous approval process involving all the stakeholders of relevance to the particular guidance to FAQs that can address very particular technical needs where doubt may arise.

Since April 2012, the ECHA guidance has already been complemented with appendices containing specific guidance of relevance to registration of nanoforms of substances, with the last update in May 2017. The foundation for this guidance was the comprehensive RIPoN that was initiated by the Commission in collaboration with ECHA in 2009, as well as further research work and implementation experience.

This impact assessment, largely backed by the views expressed by most stakeholders in the public consultation, supports the conclusion that, while better guidance always should remain a goal as such, only relying on these non-legislative initiatives may not deliver the objectives this project aims to achieve or, would only deliver with a certain delay. This being said, there will be a need for reviewing the existing guidance where it is relevant in function of the changes that may be introduced following this initiative. As has been the case before, this will be done in an inclusive manner to ensure broad consensus. This secondary introduction of revised guidance once REACH has been modified will obviously have beneficial effects on all the objectives. In terms of animal use and depending on the legal interpretation for current requirements (see discussion for option 1 and 2 above) this option would be in the range of option 2. The option is coherent with the tiered information requirements foreseen in REACH.

5.7.4 Option 4

The measures in this option would introduce additional obligations over and above option 2 and what today is possible to request pursuant to REACH in a normal registration dossier except for cases where a substance has been selected for substance evaluation where additional data can be requested.

The measures are based on scientific recommendations on what is relevant to pay special attention to as regards nanomaterials, in addition to the information that is already asked for in REACH. Most measures were already identified by the RIPoN as scientific/technical recommendations and later brought forward as proposals for measures under the Nano support project.

In REACH providing data for several endpoints can be waived based on 'water solubility'. As water solubility has been identified as an inappropriate basis for waiving for many nanoforms, the consequence in this option is that all current waivers building on that information may also not be appropriate and cannot automatically be used for nanoforms. This option will thus require that registrants generate more information than today either by developing additional justification why the already existing data is relevant and adequate, or performing the test.

Furthermore there are measures that will require additional tests in lower volume bands for nanoforms compared with option 2. This has cost implications that have a relative higher weight for lower volume registration dossiers, and as such impacts SMEs more strongly. At the same time these measures are addressing some of the key loopholes of the present hazard assessment when it comes to particulate nanoforms and thus also where some of the most important health / environment benefits can be achieved. In the public consultation, this option was ranked second in terms of safety as well as efficiency. Separately, the option received high appreciation by the majority of the respondents to a separate question with regard to its efficiency as a whole. Some increase in animal use is expected, however with the purpose of ensuring that all tests (including animal tests) contribute with genuinely relevant information for the safety assessment of nanoforms of a substance.

It is arguable whether the option is coherent with the tiered information requirements foreseen in REACH as some of the measures require tests currently only foreseen at higher tonnages already for lower tonnages, e.g. where a given tests foreseen at lower tonnages cannot be used for nanoforms.

5.7.5 Option 5

This option has been designed predominantly with a view to make it less costly to register substances with nanoforms, spur innovation and be of help to SMEs. This option contains two

sets of measures; measures aiming to provide clarity for registrants and measures reducing information requirements and thus compliance burden.

On the cost side asking for substantially less information for nanoforms reduces the registration cost for companies and will reduce the number of animals needed for testing. However, this may have an adverse impact on the demand side due to concerns of accepting a higher risk for nanomaterials, where already today there is information pointing to the avoidance of nanomaterials by European downstream users.

The option might increase the risks to human health and environment, as in particular the second set of measures exempts nanoforms of substances from requirements applicable to other chemicals, even beyond what can be supported scientifically, so any hazards specific to nanoforms will remain undetected. This will most likely lead to more public debate about the safety of nanomaterials and further pressures at national level in some Member States to take action. In the public consultation, while option 5 scored first in terms of cost, it ranked last in terms of safety and third in terms of efficiency.

It is arguable whether the option is coherent with the tiered information requirements foreseen in REACH, as some of the measures lower the requirements for nanoforms of substances registered in a given tonnage band compared to bulk substances without sound justification.

5.7.6 Option 6

In addition to the content of options 2 and 4 (for most measures), this option pushes further the separation between nanoforms and other forms of the substance in the registration dossier, which has impacts on the operation of the registration process under REACH.

On the cost side, the option will lead to significant compliance costs. The additional cost stems from significantly increased administrative cost in establishing the dossier in a way that effectively means that one dossier is a collection of two or more parallel dossiers. Additional costs are due to the need to generate more data by conducting also some specific tests on nanoforms which are not required for substances in general.

On the benefit side, the option will provide significantly more information for the protection of human health and the environment (note that much of the benefit is due to the implementation of all measures under options 2 and 4, which are also included in option 6) and thereby further reduce any doubt as to the completeness with which the conclusion of safe use has been made.

Due to the measure's comprehensive and prescriptive nature ruling out room for adaptation and thus adding substantial additional cost on firms, the efficiency of the option, with the exception of the three measures 41 (reducing the exemption possibilities for phase-in substances provided by Annex III), combined measures 42/44[112] (requiring consideration of modifications of the nanoforms during use) and 51 (requiring a toxicokinetic screening), is considered low which was identified also by the respondents in the public consultation.

[112] Measures 42 and 44 are considered complementary: M42 outlines documentation of considerations where transformation might occur (also for downstream users), while M44 includes cost of physico-chemical characterisation of potentially transformed nanoforms. While both are costed, in the text reference is made only to measure 42.

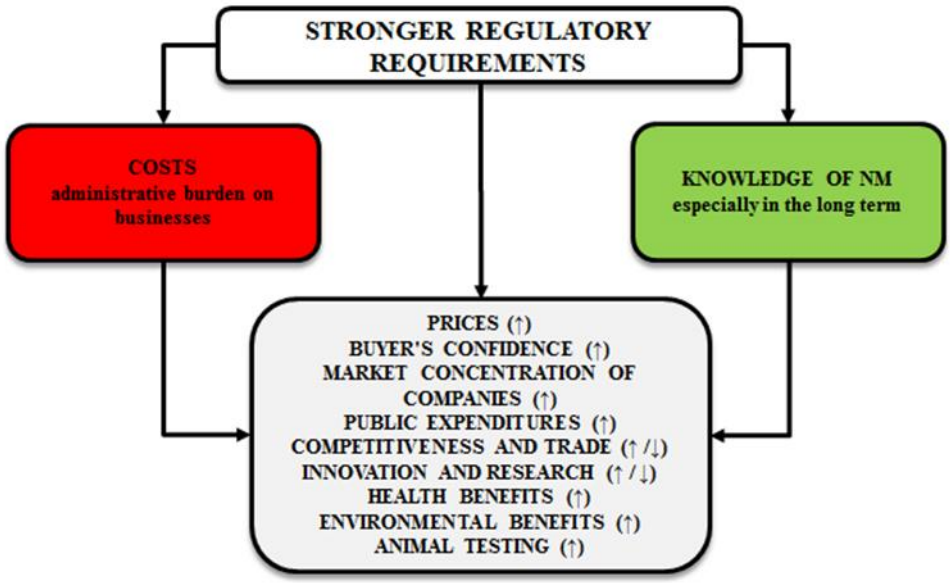
The additional measures under this option increase animal use significantly, in particular due to the identification of additional nanoforms requiring assessment and the reduced ability to rely on alternative information.

It is arguable whether the option is coherent with the tiered information requirements foreseen in REACH, as some of the measures require tests currently only foreseen at higher tonnages already for lower tonnages.

5.7.7 Schematic summary

The following figure illustrates in a schematic way the main impacts of the options:

Figure 5-1: The main impacts of the options:

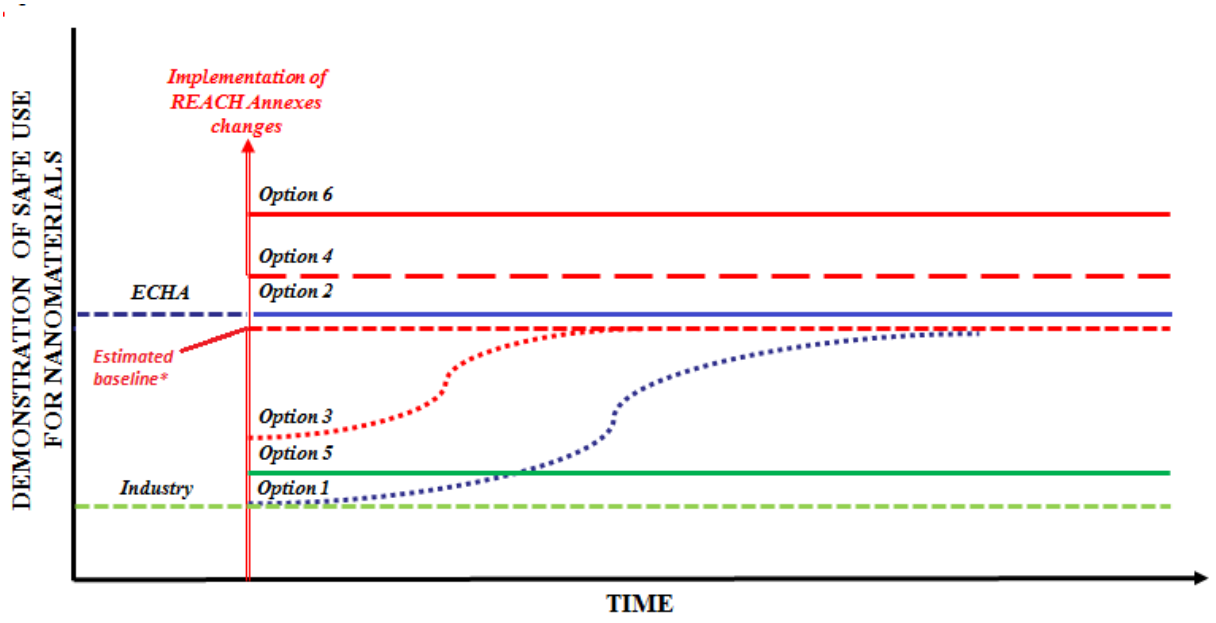


6 COMPARING THE OPTIONS

6.1 Qualitative comparison

The graph below illustrates how demonstration of safe use for nanoforms of substances would be achieved timewise by each of the options.

Figure 6-1: Demonstration of safe use by the different options:



***Taking into account the Board of Appeal's decision on the appeal A-011-2014 regarding the compliance check on titanium dioxide.**

As discussed in section 4.9, on the basis of the Board of Appeal's decision in case A-011-2014, option 2 cannot be considered as covered in its entirety by existing REACH information requirements. However, the Board of Appeal concludes in its decision in case the registrant defines the registered substance broadly, the hazards of all possible forms of the substance covered by the substance definition must be addressed by that relevant toxicological and ecotoxicological information. As already indicated before it is noteworthy that:

- Option 1 would eventually reach a similar level of demonstration of safe use (but still somewhat lower) as option 2, and this would take considerable time;
- Option 2 would achieve the level set rather quickly after its implementation;
- Option 3 would achieve the same level as option 1, with a somewhat shorter delay;
- Options 4 and 6 would go beyond that level rather quickly after their implementation;
- Option 5 would result rather quickly after its implementation in a higher level of demonstration of safe use than option 1, but lower than the rest of the options.

Table 6-1 below summarises schematically the results of the analyses in qualitative terms. The scores indicate whether the impacts are positive or negative compared to option 1.

Table 6-1: Qualitative summary of the main impacts of the options, per category:

	2	3	4	5	6
1. Economic impacts					
1.1 Conduct of business					
• Compliance costs *(including administrative burden)*	-	-	--	+	---
• SMEs	-	-	--	+	---
• Regulation clarity/certainty	++	+	++	+	++

	2	3	4	5	6
1.2 Innovation and research					
• Investment in R&D	0	0	0	0	0/-
• Knowledge	++	+	++	-	+++
1.3 Competitiveness, trade and investment flows	0/-	0	-	+	--
2. Health impacts	++	+	+++	--	+++
3. Environmental impacts	++	+	++	-	++
4. Animal testing	--	--	--	+	---

Key to the scores applied as compared to the no-change (current practice) scenario:

--- ... -	*decreasingly negative / undesirable*
0	*Neutral*
+ ... +++	*increasingly positive / desirable*
N/A	*not applicable*

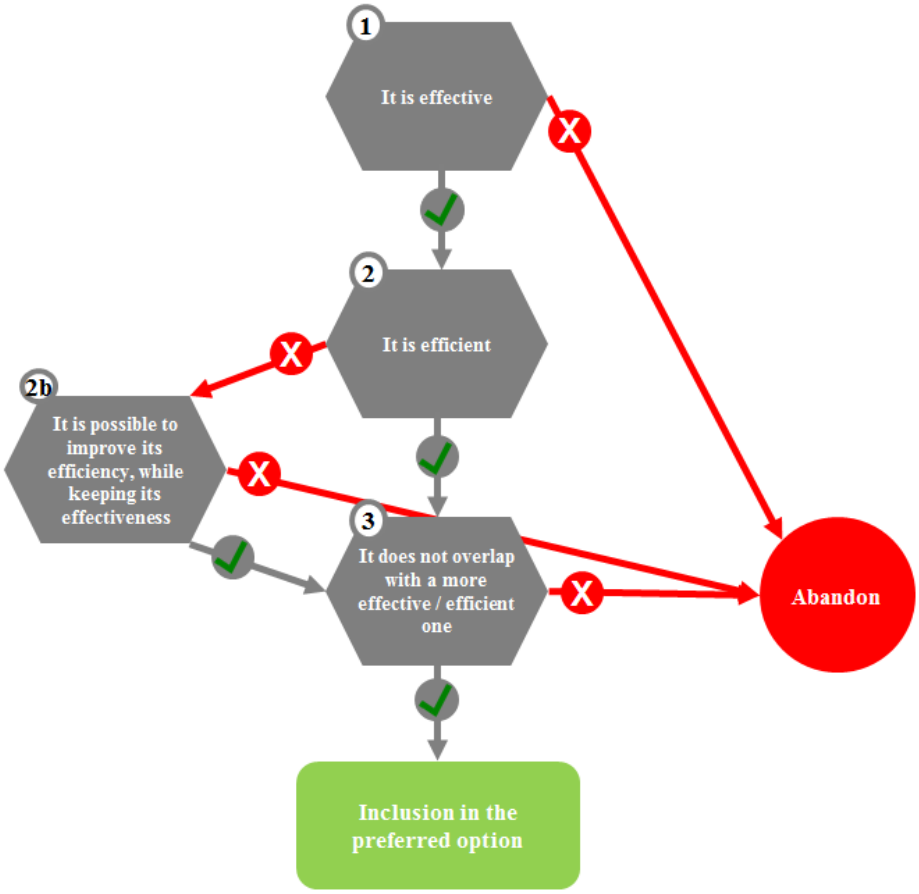
In conclusion, all options except option 5 would provide, in different degrees, higher protection of health and the environment than option 1 - in decreasing order: 6, 4, 2 and 3 -, but with an inverse effect on the conduct of business. Option 5 is the only option that, although having negative effects on human health and the environment, would have positive impacts on compliance costs and on SMEs; indeed, although the impacts on SMEs differ for each of the options, none of them includes specific mitigation measures, except for option 5 which provides for a reduction of the requirements for the lowest tonnage registrations where more SMEs are active. Advantages for smaller size companies are already embedded in the general tiered information requirements of REACH, which establishes different level of obligations depending on the tonnage level the substance is registered in, as well as in the fee structure that provides for lower registration fees for SMEs.

6.2 The choice of the preferred option

This impact assessment has led to a better understanding of the specific measures contained in the different options and of the practical implications that implementing them would have, based on repeated discussions with stakeholders, ECHA experts and Member States. Instead of a simple choice between the options as such, it has therefore been considered more appropriate to choose a combination from the underlying specific measures of different options.

The choice has thus been made taking into account how each of the measures addresses the causes of the problem (their effectiveness) and how much they cost (their efficiency). Some measures have been left out as they would not address (sufficiently) the causes of the problem, they would be too costly or they are already covered (partially or totally) by other measures. Furthermore, in order to increase their effectiveness and their efficiency, some of the measures have been slightly modified in the preferred option compared to what was proposed initially. These modifications have been considered in the assessment of the preferred option as set out in Appendix XII. Schematically, the approach to choose the measures within the preferred option can be illustrated as follows:

Figure 6-2: The 3-step decision process to choose the measures within the preferred option:



Combining the observations from the qualitative comparison in 6.1 above and the conclusion of the Matrix study[113] that, based on a multi criteria analysis, option 2 scored significantly higher than any other option, and that there were a number of measures contained within each of the other options that deserve attention, it follows that the preferred option needs to be built on option 2 by adding specific measures from the other options.

Considering the scientific and economic evidence at hand, the commitments already made by the Commission and the increased pressures from Member States to take action to address the concerns associated with the safety of nanomaterials balanced against the interest of ensuring a competitive chemicals sector with scope for innovation and growth, the preferred option is consequently a combination of different measures. In the **initial Commission proposal**, to which most of the information in the report refers to as 'the preferred option', these are: all measures of option 2, plus six measures of option 4 (measures 10,12,13,14,16,17) and three measures from option 6 (measures 41, 42 and 51). The reasoning behind the choice of each of the measures is explained in detail in Appendix XII; the summary of the justification for the inclusion of the measures within the preferred option is as follows:

- The preferred option is based on all measures from option 2, with some modifications as explained above.
- The six measures from option 4 have been retained in the preferred option due to their appropriateness in addressing the specific nature of nanoforms of a substance and

[113] See Appendix X.

considering their efficiency; measures 16 and 17 have been modified in order to optimise the way they address nanoforms, but without placing an excessive burden on companies, in particular those registering at lower tonnages, where also SMEs are more strongly represented.

- The three measures from option 6 have been chosen for the clearly identified cost effectiveness in addressing the objectives; measure 41 would close the potential loophole for nanoforms of phase-in substances while maintaining the prioritisation aspect of Annex III; measure 42 would ensure transparency and increased confidence in the safety assessment along more complex value chains of substances with nanoforms; measure 51 would provide data on toxicokinetics of nanoforms for the chemicals safety assessment (only registrations above 10 tonnes per year), while modification ensures that any need for additional testing would be scrutinised via testing proposal examination.

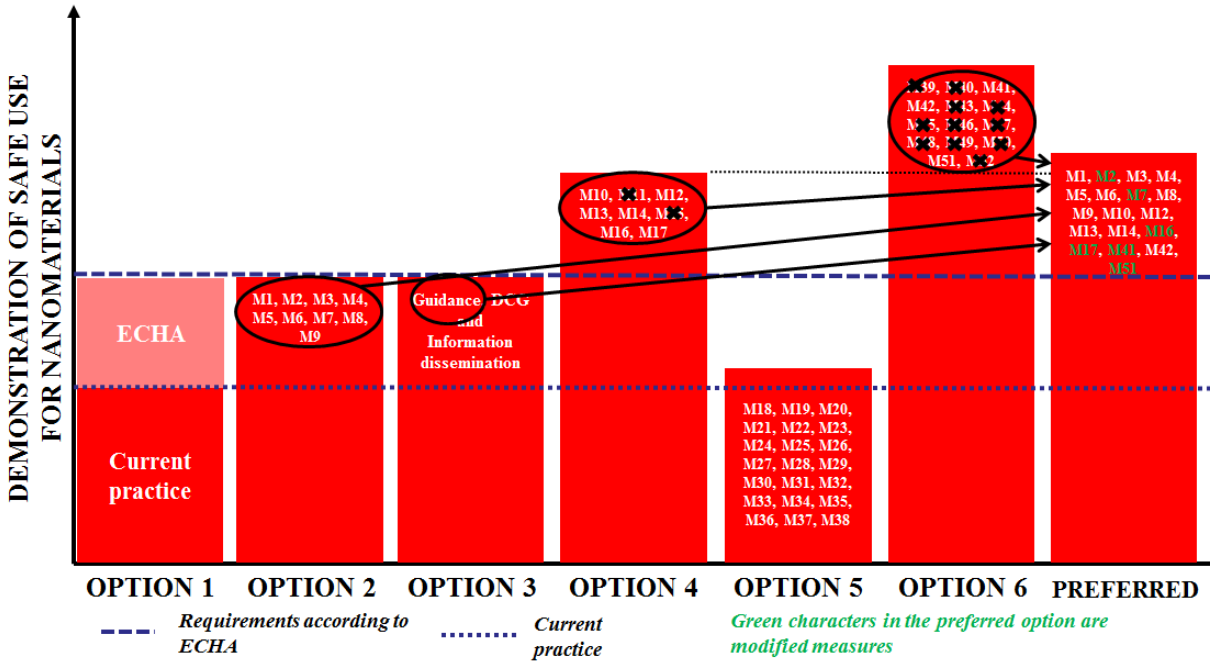
Based on the discussion in the REACH committee and some further concerns expressed by the Member States on the detail of the selection of measures, the Commission modified the initial proposal, following the same overarching objectives and the 3-step process described above. For detail, see table of changes in Section 9.15.3 in Appendix XV. Beside several changes to the drafting for increased clarity but non-measureable changes in impacts on cost or animal use, the **final Commission proposal** as voted in the REACH committee includes also the following measures:

- Dissolution rate and dispersion stability are considered as principal physico-chemical parameters of nanoforms and are as such explicity expected for all registered nanoforms (extended measure 2).
- For low volume registrations, testing of acute toxicity of nanoforms via inhalation route rather than the default oral route (measure 11) has been promoted from the recommendation to mandatory requirement.

Impacts on SMEs have been considered in selecting the measures in the preferred option. Some of the possible additional measures were fully excluded, some others modified, to minimise adverse impacts. Some measures or elements of them (in particular in option 5) were explored to further minimise impact on SMEs.

The figure below shows how the preferred option compares to the other options in terms of demonstration of safe use for nanomaterials.

Figure 6-3: The preferred option compared to the other options:



6.3 The costs of the preferred option

The assessed costs of the measures within the preferred option (both the initial and final Commission proposal) are reflected in the tables below[114], compared to the costs for options 1 to 6:

[114] *Following the submission of draft report to the Regulatory Scrutiny board and the REACH committee in October 2017, a minor calculation error has been identified in the calculation of the preferred option, In addition, the assumption on number of toxicokinetic studies that are triggered in addition to the available information as well as the newly adopted subchronic inhalation toxicity testing guidelines TG 412 and TG413 (with included consideration of biokinetics), if performed, has been conservatively reset to 50% of all nanoforms registered in volumes >10 tonnes. The numbers on cost and animal use are therefore deviating slightly from the tables provided at the time for the preferred option, with ca.3% in cost estimation, but do not qualitatively change the assessment.*

Table 6-3: Costs of options per nanoform, with the preferred option (per tonnage band, use of alternative information methods possible) (in thousand Euro):

	1[a]	1[b]	Estimated baseline[e]	2	3	4 (incl. 2)	5	6 (incl. 4)	Preferred Initial proposal (Oct 2017, corrected *)	Pre F pro (2
>1000 tonnes	772	77	1049	1157	1049	1256	458	2256	**1265**	
100-1000 tonnes	538	77	770	814	770	939	375	1736	**932**	
10-100 tonnes	183	37	334	359	334	471	40	869	**444**	
1-10 tonnes (Full Annex VII)	78	20	162	187	162	249	20	466	**240**	
1-10 tonnes (Only Phys-chem)	37	9	62	87	62	91	9	466[d]	**132**[d]	
1-10 tonnes[a]	49	12	91	116	91	137	12	466	**164**	
Weighted Average	**358**	**47**	516	**565**	516	**642**	**212**	**1254**	**649**	

[a] *The column represents the cost for a substance with one (bulk) form, which can be directly compared with the majority of REACH registration cost assessments for substances, as the usual assumption in those calculations is that one test is performed per substance per information requirement*

[b] *The costs of 1[a] are divided by an estimated average number of nanoforms or sets of nanoforms for a substance*

[c] *Weighted average*

[d] *Indirect impact of measure 41 on registration of bulk form may bring an estimated additional cost of 10 K EUR per nanoform of substance otherwise benefiting from Annex III exemption. Relative additional contribution 2.2% (option 6) and 8% (preferred option). More details in Appendix XIII*

[e] *Estimated baseline consequent to Board of Appeal Decision 2 March 2017(see discussion in section 4.9). Option 2 cannot be considered baseline in its entirety.*

Table 6-4: Grand total costs, with the preferred option (per tonnage band, use of alternative information methods possible) (in million Euro):

	1[a]	Estimated baseline[c]	2	3	4 (incl. 2)	5	6 (incl. 4)	Preferred Initial proposal (Oct 2017, corrected*)	I (
>1000 tonnes	36	482	532	482	578	211	1038	582	
100-1000 tonnes	43	426	450	426	519	207	960	515	
10-100 tonnes	9	84	90	84	118	10	217	111	
1-10 tonnes (Full Annex VII)	5	38	44	38	58	5	109	56	
1-10 tonnes (Only Phys-chem)	5	35	49	35	52	5	264[b]	75[b]	

1-10 tonnes[a]	10	73	93	73	110	10	373	131	
Total	**107**	**1065**	**1165**	**1065**	**1325**	**437**	**2588**	**1339**	

[a] *Note that only one number is used to represent option 1; it assumes that, whether sufficient for risk assessment or not, at most one test is performed per substance per information requirement, regardless of the number of nanoforms the registration of that substance includes*

[b] *Indirect impact of measure 41 on registration of bulk form may bring an estimated additional cost of 5.8M Euro for substances otherwise benefiting from Annex III exemption. Relative additional contribution 2.2% (option 6) and 8% (preferred option). More details in Appendix XIII*

[c] *Estimated baseline consequent to Board of Appeal Decision 2 March 2017(see discussion in section 4.9). Option 2 cannot be considered baseline in its entirety.*

Table 6-5: Registration costs for a substance with one nanoform/set per company and per tonnage band (use of alternative information considered possible, typical cost) (in thousand Euro):

	1[a]	**Estimated baseline**[d]	**2**	**3**	**4 (incl. 2)**	**5**	**6 (incl. 4)**	**Preferred Initial proposal (Oct 2017, corrected*)**	**P p (A**
>1000 tonnes	110	150	165	150	179	65	322	181	
100-1000 tonnes	179	257	271	257	313	125	579	311	
10-100 tonnes	102	186	199	186	262	22	483	246	
1-10 tonnes (Full Annex VII)	43	90	104	90	138	11	259	133	
1-10 tonnes (Only Phys-chem)	20	35	48	35	51	5	259[c]	74[c]	
1-10 tonnes[b]	27	51	64	51	76	7	259	91	
Weighted Average	**96**	**144**	**159**	144	**185**	**53**	**386**	**189**	

[a] *The column represents the cost for a bulk form, which can be directly compared with the majority of REACH cost assessments for substances, as the usual assumption in those calculations is that at most one test is performed per substance*

[b] *Weighted average: depending on applicable conditions of Annex III to REACH, the implications differ between registrants in the 1-10 tonnage band. More details above*

[c] *Following assumption on registration of nanoform only, no additional indirect cost of measure 41 through registration of bulk form*

[d] *Estimated baseline consequent to Board of Appeal Decision 2 March 2017(see discussion in section 4.9). Option 2 cannot be considered baseline in its entirety.*

Additional scenarios are provided in Appendix XIII, for costs per nanoform under different assumptions (depending on whether alternatives to testing exist or not and on different assumptions on the cost of testing) and for the Grand Total costs under different assumptions on the existence of alternatives and on the number of nanoforms).

The more comprehensive description of impact of the changes between the initial and final Commission proposal, also on animal use, is provided in the Section 9.15.3 of Appendix XV.

6.4 Conclusion

Based on the above evidence and analysis, a comparison of the options in terms of effectiveness, efficiency and coherence can be summarised in the following table 6-6:

Table 6-6: Qualitative comparison of options in terms of effectiveness, efficiency and coherence:

	EFFECTIVENESS[115]		EFFICIENCY	COHERENCE
	Clarify the legislative obligations acting on companies	Ensure adequate demonstration of safe use	*In terms of striking a balance between appropriate demonstration of safe use and the associated costs*	*With REACH - make REACH fit for nanomaterials as for other chemicals*
Option 1	0	0	0	0
Option 2	++	+	+	+
Option 3	+	+	+	+
Option 4	++	++	-	-
Option 5	+	--	-	--
Option 6	++	++	--	--
Preferred option	++	++	+	+

Magnitude of impact as compared with the baseline scenario (the baseline is indicated as 0): ++ strongly positive; + positive; – – strongly negative; – negative; ≈ marginal/neutral

Option 1 scores neutrally under the assumption that industry continues applying its current interpretation of the REACH registration requirements and no particular actions by ECHA or Member States are taken to require additional data.

Option 2 scores positively against all of the objectives. It is indeed a package of measures that shows a good ratio between what it demands and what it delivers in return.

Option 3 may deliver within the limits of the current legal obligations, but would not be as efficient as option 2, as it entails similar costs while the degree of clarity/certainty provided by the changes in the guidance would not be the same than that provided by changes in the legal text and it would take longer to implement.

Option 4 fares better in terms of effectiveness, but this comes at a cost that is not negligible. However, some individual measures display a good ratio between what they cost and what they deliver. For example, the substitution of mutagenicity test on bacteria by a test that works

[115] As regards the fulfilment of the Specific objectives stated in 3.2.

better for nanomaterials (measure 13) will deliver more reliable information on mutagenicity for nanoforms, while the costs are proportionate.

Option 5 induces savings but fails on demonstrating safe use and results in reduced human health and environmental protection. However, it contains measures that score high in terms of effectiveness on providing clarity on the information requirements for nanoforms of a substance and with lower costs especially for SMEs.

Option 6 would bring incremental improvements to the level of protection compared to options 2 and 4, but these improvements are, in general and in particular at lower tonnages, outweighed by the considerable extra costs imposed on firms, not least SMEs. However, it contains some individual measures that also display a good ratio between what they cost and what they deliver (for example measures 41, 42 and 51).

The preferred option (initial Commission proposal)

As evident from the above analysis, the preferred option is much more effective than options 1, 3 and 5, and it is more effective than option 2, as on top of clarifying the registration requirements, it adds specific considerations for substances with nanoforms. Its effectiveness is slightly higher than that of option 4, due to the generation of additional information specific to nanomaterials, and comparable to that of option 6. In terms of efficiency, considering that quantification and monetisation of benefits was not possible and bearing in mind the general objective of the initiative to ensure adequate demonstration of safe use for nanomaterials, in order to identify the most efficient policy option, the trade-offs between benefits and costs were assessed based on the cost-effectiveness of the most effective options. The effectiveness of options 1, 3 and 5 was considered insufficient to attain the objectives of the initiative, thus their cost-effectiveness is not further assessed. The cost of the preferred option is slightly higher than the cost of option 2 (15%), however as mentioned above, option 2 is less effective in terms of ensuring adequate demonstration of safe use. The cost of the preferred option is effectively the same as option 4 whereas its effectiveness is higher than that of option 4. Thus, the preferred option is more cost-effective than option 4. The cost of the preferred option is half that of option 6, whereas their effectiveness is comparable. Thus, the preferred option is more cost-effective than option 6. Based on this analysis, it can be concluded that the preferred option is the most cost-effective option that would attain the objective of the initiative to ensure adequate demonstration of safe use for nanomaterials.

It is to be noted that, compared to option 1, the cost increase of the preferred option would be significant (almost 14-fold). However, based on the decision of the Board of Appeal in case A-011-2014 (see discussion in section 4.9), it is not appropriate to compare the cost to option 1, even if that could be construed from many of the REACH dossiers as the level of information presently provided, but rather to what can be considered as the baseline. The average costs increase of registering a substance with one nanoform per company and per tonnage band compared to this estimated baseline is 26%. However, the cost increase in the low tonnage band is significant (79%).

The total additional cost of the preferred option as compared to the baseline is approximately 274 million EUR.

Three measures in the preferred option stand out as being mainly responsible for the cost increase compared to option 2: measure 41 addressing the exemption system introduced by REACH Annex III (essentially exempting any health and safety assessment below 10 tonnes unless a substance has already been identified as a CMR substance), measure 13 (i.e. requiring higher tonnage genotoxicity testing at lower tonnage due to the scientific

unsuitability of the test method foreseen), and measure 51 with the requirement to perform a toxicokinetic screening. The first two, in particular, affect costs for the lower tonnages where most SMEs are expected to be active.

Measure 41 aims at generating an equal amount of information for non-classified substances with nanoforms in volumes below 10 tonnes. The existing exemption in REACH Annex III for non-classified substances was introduced to ease the burden for firms producing substances with a longstanding well-recorded knowledge base in relatively modest volumes. Accepting that nanoforms (even newly generated and potentially without any recorded knowledge base) may be registered together with 'phase-in' bulk form of a substance rather than being registered as new substances makes it not compatible with such an understanding. Eliminating the waiver in Annex III for substances with nanoforms completely (measure 41 as foreseen originally under option 6) would subject 'existing' nanoforms of substances (including those which may have been with unchanged nanoforms on the market for a long time already) to the same requirements as new nanoforms as they would have to provide the full data package. A modified measure 41 as included in the preferred option is thus nuanced and would apply only to priority substances with nanoforms (see Appendix XII for details).

Measure 13 is justified, as the genotoxicity test currently foreseen at low tonnages is scientifically unsuitable for many nanoforms. In order to acquire for nanoforms the same knowledge as for general substances, another test must thus be used – the best option for nanoforms being a test currently foreseen for the next higher tonnage band.

Measure 51 on toxicokinetic screening could be justified for nanoforms of a substance because due to their small size they may translocate to other parts of the human body than bigger particles. By knowing where the specific types of particles translocate in organisms the measure offers in return enhanced access to reliable use of alternative and non-test methods for a range of other end-point tests (however, this would be limited mostly to those foreseen in the higher tonnage bands). It should be noted that additional toxicokinetic tests may often not be needed – relevant information may be generated when some tests e.g. 28-day repeated dose toxicity testing are perfomed. Applying the measure would however ensure that this information is always available for nanoforms of a substance. It is estimated that the additional stand-alone cost for a toxicokinetics study, when one is still required, is more than offset in the higher tonnage registration band by the increased ability to reduce the cost of other testing and the increased application of alternatives such as read-across, that often times presupposes in particular toxicokinetic information.

The total cost (Grand total) of the preferred option would be about 1.3 billion EUR, i.e. 174 million EUR in addition to the costs for option 2 (which itself creates costs of 1.17 billion EUR) and 1.2 billion EUR in addition to option 1 (which itself creates costs of 97 million EUR). Based on the decision of the Board of Appeal of ECHA in case A-011-2014 (see discussion in section 4.9), which sets the baseline between Option 1 and 2, the additional cost of the preferred option as compared to the baseline is approximately 274 million EUR (increase of 26%).

As already mentioned, it is not possible to make a comparably accurate calculation on the benefits side. Two benchmarks can be established for the purpose of comparison of the overall costs and benefits of the options:

- The 2003 Extended Impact Assessment of REACH estimated health benefit for all chemicals over 30 years from its entry into force to be **50 billion EUR**. The proposed

changes of the REACH Annexes for registration of substances with nanoforms would allow to fully achieve the benefit potential for these substances, which can, however, not be quantified.

- The estimated costs should be considered in the context of the size of the nanomaterial market. As noted in 1.2 *Uses of nanomaterials and size of the market*, the global nanomaterial market value is estimated to be of roughly 20 billion EUR, which, for the EU would mean ca. 4 billion EUR if one assumes that the share of sales of nanomaterials is comparable to the share of sales of chemicals in the EU compared to global sales (i.e. ca 20%). Considering the value of the products into which the nanomaterials are incorporated, the estimation goes up to 2 trillion EUR globally by 2015, i.e. **400 billion in the EU**.

The preferred option would also be the most coherent one with REACH, since it applies within the margins of the mandate and the scope of the legislation and ensures that the legislation is fit for nanomaterials as for any other chemical.

As regards the use of animals (see full Table in the Section 9.15.3 of Appendix XV), the preferred option is almost neutral (it is estimated that it uses 620 (612 + 8 due to indirect impact on registration of bulk by measure 41) instead of 614 animals per nanoform or set of nanoforms), in total 11,500(12,000-4,528 due to indirect impact on registration of bulk by measure 41) animals less than option 2. This is mainly due to the estimated positive impact of the measure regarding toxicokinetics. The use in lowest tonnages is marginally higher (16 instead of 9 animals).

Overall, the preferred option is the best ranked one among all assessed options.

The preferred option (final Commission proposal)

The qualitative analysis of the preferred option presented in the previous chapter remains. For detailed assessment and impact on cost and animal use of the changes made in the final Commission proposal please refer to Appendix XV.

Each of these changes aims at increasing the relevance of available information on nanoforms and is expected to bring benefit in the quality as well as effectiveness of safety assessment. It is however not possible to quantify this benefit.

The average cost per nanoform is estimated to be increased by EUR 31K, with a total additional cost estimate EUR 63M, a 4.5% increase as compared to the original Commission proposal. The highest relative increase (~20%) as compared to the original proposal is estimated for low tonnage registrants. The total cost for the registration of all nanoforms assumed to be on the market is estimated at 1.4 billion EUR, i.e. 337 million EUR in addition to the estimated baseline. Regarding the scenario of registration of bulk with 4 nanoforms, the cost of registration compared to baseline would increase by 27%.

In terms of animal use, on average an additional 8 animals per nanoform – 597 in total - are expected to be used under the final Commission proposal, leading to the estimated total additional use of 16 thousand animals (1.232 million, or +1.3% compared to original Commission proposal). This estimate is still within estimates for animal use under the baseline scenario, as additional animal testing is offset in the calculation by the increased ability to read-across, based on better and available non-animal supporting data.

7 MONITORING AND EVALUATION

For monitoring and evaluation, the existing provisions pursuant to REACH, apply, namely: Title VI on Evaluation, Article 117 on Reporting and Title XIV on Enforcement. Based on these already existing review mechanisms ECHA in the first place and then the Commission will be able to regularly follow the effectiveness and effects of the changes. These will be reported every five years, and every three years as regards the status of implementation and use of non-animal methods and testing strategies.

A standing ECHA expert group on nanomaterials will continuously monitor technical implementation and the impact the adaptations will have. On a policy level, CARACAL and as necessary its dedicated subgroup CASG Nano will follow the uptake of revised provisions by the industry and the perception of the wider stakeholder base, in particular the Member States and NGOs. This group would also help to maximize the impact of these REACH adaptations in pursuing objectives on transparency on nanomaterials, by facilitating dissemination of public nanomaterial-related registration information.

A simple indicator of whether the changes are performing adequately will be the number of registrations of substances with nanoforms, number of nanoforms documented in the dossiers and associated consequences (e.g. nanoform specific documentation of safe use, classification), where appropriate. Another indicator will be the the quality of the information provided. The reporting by Member States on the operation of the Regulation on their respective territories and on the enforcement, according to Article 117 will also be important.

Under Article 138, REACH registration requirements are also subject to a review by 1 June 2019, including registration requirements for nanomaterials.

8 GLOSSARY

Agglomerate: a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.

Aggregate: a particle comprising of strongly bound or fused particles.

Characterisation: substance characterisation is an analytical process through which the chemical identity and composition of a substance may be demonstrated. Every manufacturer or importer intending to undertake a registration dossier must characterise their substances fully. The nature of a given substance will determine which analytical tests are appropriate and clearly, technical expertise is essential at this stage.

Chemical Safety Assessment CSA: the chemical safety assessment is carried out to demonstrate that the risks from the exposure to a substance, during its manufacture and use, are controlled when specific operational conditions and risk management measures are applied.

Chemical Safety Report CSR: the chemical safety report documents the chemical safety assessment undertaken as part of the REACH registration process, and is the key source from which the registrant provides information to all users of chemicals through the exposure scenarios.

Classification, labelling and packaging CLP: CLP of substances and mixtures is the Regulation on classification, labelling and packaging of substances and mixtures. Its main objectives are to facilitate international trade in chemicals and to maintain the existing level of protection of human health and environment.

CMR: A substance classified in the hazard classes cancenogenicity, germ cell mutageneticity or reproductive toxicity.

ECHA: the European Chemicals Agency (ECHA), located in Helsinki, is the driving force among regulatory authorities in implementing the EU's ground-breaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness. ECHA helps companies to comply with the legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern.

EMA: European Medicines Agency (EMA)

Endpoint: a biological endpoint is a direct marker of disease progression - e.g. disease symptoms or death - used to describe a health effect (or a probability of that health effect) resulting from exposure to a chemical.

Exposure to a particular chemical may lead to a series of endpoints. The most sensitive endpoint (critical endpoint) is the one that occurs at the lowest exposure level.

The derivation of a tolerable daily intake (TDI) or an acceptable daily intake (ADI) is based on the NOAEL (no observed adverse effect level) of the most sensitive endpoint and will also ensure protection against all other adverse effects.

EFSA: European Food Safety Authority (EFSA)

Form: generally the term 'form' can be understood to identify the state of a substance e.g. granular, lamellar, sheets, but is usually (and in this document) applied more widely to allow differentiation when one or more intrinsic physico-chemical properties (i.e. characterisers) differ. Form would therefore include bulk(solid) in different crystalline forms, different powders etc. A form fulfiling the nano-definition is called nanoform (see below).

Identification: Unambiguous substance identification is a pre-requisite to most of the REACH processes. Actors in the supply chain must have sufficient information on the identity of their substance. The following information on the manufactured or imported substance shall be included in the dossier in order to unambiguously identify the substance:

- Substance name and related identifiers, molecular and structural formulae, if applicable;
- Information on the composition and purity of the substance;
- Spectral data and analytical information to verify the identity and composition of the substance;
- Clear and concise description of the analytical methods.

Measure: each of the proposed actions that compose the options included within this impact assessment.

Nanomaterial: a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm. In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a

threshold between 1 and 50 %. By way of derogation, some specific materials are always nanomaterials (graphene flakes, single wall carbon nanotubes, fullerenes), based on Commission Recommendation No 2011/696.

Nanoform: a form of a substance that falls within the scope of the definition of a nanomaterial (see above). There is a defined minimum list of characterisers that enable characterisation of (and differentiation between) nanoforms. Substance may be in many forms, include multiple nanoforms. As different nanoforms may exhibit very similar behaviour – a proposition that needs to be adequately justified – such **sets of similar nanoforms** can be approached jointly using same documentation requirements. Within this assessment, the term nanoform is often used to describe individual entities for which documentation requirements are considered in the different options. Such entities may be nanoforms, but may also be sets of similar nanoforms, providing that the range of characterisers for each set is well described, that the same information requirements datasets apply, and it can be assumed that if data generation is required at most one test would be required for the set.

Non-phase-in substances: all substances that do not fulfil any of the criteria for phase-in substances are considered as non-phase-in substances. Normally, non-phase-in substances have not been manufactured, placed on the market or used in the EU before 1 June 2008, unless they were notified under Directive 67/548/EEC.

Potential manufacturers and importers of non-phase-in substances have to submit an inquiry to ECHA and subsequently register the substance in accordance with REACH before they can manufacture or import the substance.

Options: in the framework of this exercise, it refers to possible amendments of REACH Annexes that will enable to ensure further clarity on how substances with nanoforms are addressed and safety of nanoforms demonstrated in registration dossiers.

Particle: minute piece of matter with defined physical boundaries.

Phase-in substances: substances which were already manufactured or placed on the market before REACH's entry into force. In accordance with REACH (Article 3(20)), phase-in substances must fulfil at least one of the following criteria:

- Substances listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);
- Substances that have been manufactured in the EU (including the countries that joined on 1 January 2007) but have not been placed on the EU market after 1 June 1992;
- Substances that qualify as "no-longer polymer".

Three distinct registration deadlines have been defined for these substances.

QSAR models: Quantitative structure–activity relationship models (QSAR models) are regression or classification models used in the chemical and biological sciences and engineering.

Read-across approach: “Read-across” is a technique of filling data gaps. To “read-across” is to apply data from a tested chemical for a particular property or effect (cancer, reproductive toxicity, etc.) to a similar untested chemical. The read-across technique is often applied within groups of similar chemicals assembled for assessment using either analogue approach (grouping based on a very limited number of chemicals) or category approach (grouping

based on a larger number of chemicals). In an analogue/category approach, not every chemical needs to be tested for every endpoint. REACH Annex XI, Section 1.5. sets out the requirements for the application of this strategy.

Set of similar nanoforms: See **nanoform** above

SCCS: Scientific Committee on Consumer Safety (SCCS)

SCENIHR: The Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) is one of three independent non-food scientific committees which give scientific advice on consumer safety, public health and the environment. It was set up by the European Commission to consider in particular emerging issues arising from new technologies. The Committee provides opinions on emerging or newly identified health and environmental risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk assessment bodies.

For further information on the SCENIHR see: http://ec.europa.eu/health/scientific_committees/emerging/index_en.htm

9 APPENDIXES

9.1 APPENDIX I: Detail of the measures

9.1.1 Overview of the measures in option 2

#	**Measure**	**What the measure aims to achieve**
1	Explicitly require registrants to describe the scope of the registration dossier	Without exact knowledge about what is covered by a registration dossier neither compliance check nor enforcement is possible. Accuracy is particular important when several nanoforms are in a single dossier. A clarification of Annex VI.2 is anticipated.
2	Explicitly require registrants to provide more detailed characterisation of nanoforms	Even small difference between nanoforms can have significant effects on properties. For that reason detailed characterisation is necessary. Also to enable data sharing this is a crucial point. Clarifications of Annex VI.2 and physico-chemical properties (Section 7 of Annexes VII-X) are anticipated.
3	Require that nanoforms are explicitly addressed in the endpoint sections	Due to the current need for a case-by-case assessment and the variety of properties the relevance of data provided for each end-point needs to be made for each nanoform. Does not automatically necessitate data generation as justified read across to existing data may be possible. Clarifications are required in Annexes I and XII, VI – X.
4	Require detailed description of the test material/sample preparation	Testing nanoforms requires an accurate description of the material, its dose in the test system and how the sample has been prepared. This is an OECD recognised requirement. Also to enable data sharing or read across this is a crucial point. Clarifications are required in Annexes I, VI – X.
5	Require scientific justifications for grouping / read-across / QSAR and other non-testing approaches for different forms	The rules of using non-testing approaches are set out in Annex XI. However, it is currently not clear that the same considerations must apply when results are used between different forms within a dossier. Clarifications are required in Annex XI but also Annex I and Annexes VI-X.

6	Require considerations of most appropriate/relevant metric with preferable presentation in several metrics	To guide the registrant (or downstream user) to give due regard to the best metric for each situation while ensuring that data can be compared. Clarifications are needed in Annex I, XII.
7	Require that bioaccumulation is addressed specifically for the nanoform	Specific case of measure 3, explicitly acknowledging that bioaccumulation potential of a nanoform could be different compared to the bulk form. Often assessment for those forms is waived on basis of predictors such as partition coefficient Kow that do not generally work well for nanomaterials. Clarifications are needed in Annex VII – X.
8	Specify that absorption/desorption behaviour of nanoforms should not be assessed based on Kd values derived from Koc and Kow	For nanomaterials, a number of deficiencies have been found in the implementation of methods to determine several indicators such as water-octanol partitioning coefficient Kow. In addition, the complexity of their interpretation (dispersed particles do not partition in equilibrium) reduces significantly their predictive powers for other properties related to fate in the environment and the bioavailability. Adaptations using such indicators should therefore be applied with caution and alternative information should be sought. Clarifications are needed in Annex VII – X.
9	Require identification of uses and exposure assessment of the nanoforms	Linked to measure 3. Properties of nanoforms often enable specific uses or variation/improvement in the use of the substance that should be appreciated in the dossier, while their state of agglomeration, surface functionalization or application within a matrix may significantly influence behaviour. Clarifications are needed in Annex I.

9.1.2 Overview of the measures in option 3

Development of further ECHA guidance	Guidance development is a continuous task of ECHA. Specific guidance for registration is already available that also includes concrete recommendations for nanomaterials.

Enhanced use of the Directors Contact Group	The Directors Contact Group was set up by the Commission in the run up to the first registration deadline and was used as an informal forum discussing and anticipating potential problems faced by firms.
Initiatives to enhance information and dissemination at EU and Member State level	ECHA, Competent Authorities of Member States and industry confederations all play an important role in dissemination information on what is expected by firms subject to REACH obligations.

9.1.3 Overview of the measures in option 4

#	**Measure**	
10	Include information on dustiness	Generally considered a very relevant parameter in particular in the manufacturing occupational safety context of any granular materials and could therefore be particularly relevant where nanoforms of a substance are manufactured and handled as dry powders with inhalation potential. Clarifications in Annex VII are needed.
11	Require acute toxicity data for the most relevant route of exposure	This is already a requirement for the substances above 10 tons. Below, an oral route is required as default while its results may not be relevant when e.g. inhalation is the most relevant route (which might be the case for many nanoforms). Clarifications in Annex VII are needed.
12	Change ‘particles’ to ‘(nano)particles’ for repeated dose toxicity studies (inhalation)	Measure addresses several considerations due to specificities of nanoforms that include justification for not considering inhalation as the most relevant route of exposure and extension of evaluation of the exposed animals. Clarifications in Annex VIII - X are needed.
13	Require non-bacterial in vitro gene mutation study	Bacterial testing is a first step in tiered mutagenicity testing. Unfortunately bacterial testing is not appropriate for many nanomaterials and may give false negative tests (i.e. a prediction of no adverse effect where this is not the case) thereby failing to trigger higher tier studies. For some nanoforms the current test in Annex VII

		must be replaced by test(s) with ability to address mutagenicity of substances in nanoform. Clarifications in Annex VII are needed.
14	Consider water solubility in relation to test waiving	Due to dispersion and additional mechanisms of uptake, the insoluble nature of some nanoforms does not automatically imply they are not bioavailable. Clarifications in Annex VII – X are appropriate where tests are waived due to low solubility in water.
15	Specify that long term testing should not be waived based on lack of short term toxicity	At present, long term testing may be waived in few specific situations if there is no evidence of toxicity in the short term. For nanomaterials in particular, there is very little evidence that short term toxicity might predict long term effects, also as lower concentrations delivering same dose over longer exposure as applied in long term testing often imply different bioavailability due to modified state of aggregation / agglomeration.
16	Specify that algae testing should not be waived based on insolubility	Specific case of more general measure 14 as same consideration applies.
17	Require that testing on soil and sediment organisms is prioritised	These environmental compartments are considered important sinks for substances in nanoform. REACH applies a tiered approach requiring an assessment for lower tonnages based on an equilibrium partitioning trigger that however may not work for nanomaterials. Prioritisation may be addressed by different modifications: requirement for testing of nanoforms already at lower tonnages or only modification of the trigger. Clarifications in Annex IX are needed.

9.1.4 Overview of the measures in option 5

#	**Measure**	
18	Describe whether and which different nanoforms are covered in the chemical safety assessment, including a statement when and	Clarifies the need to describe how substances with nanoforms are addressed in REACH Chemical Safety Assessment,

	how information on one form is used to demonstrate safety of other forms	including information about non-testing methods, e.g. read-acrosss between different nanoforms. Clarifications are needed especially for Annex I.
19	Specify that nanoform specific information is required only when an insoluble or poorly soluble nanoform put on the market is classified hazardous/ dangerous	Clarifies when nanoform specific information is required for the hazard and risk assessment in REACH. Clarifications are needed especially for Annexes I, VI-XII.
20	Specify that a coated nanomaterial is considered as a special mixture e.g. in classification and labelling as accepted e.g. alloys	Change current practices for forms of substances with coated nanoparticles, with an example from the registration of alloys and surface treated substances in REACH. Clarifications are needed especially for Annexes I, VI-XII.
21	Specify that the granulometry concept in 7.14 of Annex VII includes also shape and surface area of nanomaterials	Clarifies the scope of information requirement on granulometry as also described in ECHA guidance. Clarifications are needed for Annex VII.
22	Specify that the information on dustiness is required for nanoforms only where relevant for the worker safety assessment	Clarifies that the need for information on dustiness relates only to worker safety. Clarifications are needed for Annex VII.
23	Specify that waiving of endpoint specific information requirements for classified insoluble or poorly soluble nanoforms applies as for any other forms and also when nanoforms do not significantly differ from each other in specific endpoints	Determines that nanoforms are as any other forms of a substance, some toxic, some not, and waivers in REACH apply also to nanoforms allowing the necessary flexibilities in testing and cost savings. Clarifications are needed for Annexes I, VI-XII.
24	Specify that the use of non-testing methods (e.g. read-across, grouping, categorisation etc. methods) is a priority for nanoforms	Reiterates that the Commission strategy for non-testing methods as a priority applies also to substances with nanoforms in line with in recital 40 and Articles 13 and 25, reducing thus animal testing and testing costs. Clarifications are needed for Annexes I, VI-XII.
25	Specify and require explicitly that waiving of testing on the basis of exposure conditions and categories applies also for nanoforms, in particular when nanoforms are completely reacted (cured), incorporated or embedded into a completely cured matrix or permanent solid polymer forms, or otherwise used in	Clarifies that exposure conditions and categories, apply as waivers and should be used to reduce animal testing and the overall costs of REACH compliance. Clarifications are needed for Annexes I, VI-XII.

	closed systems or controlled conditions	
26	Specify that absorption/desorption behaviour of nanoforms can be based on biological surface adsorption index, affinity coefficient or other relevant parameters	Clarifies that the assessment of absorption/desorption behaviour in REACH may take place via other parameters than octanol-water partition coefficient which may not always apply for nanomaterials. Clarification is needed for Annex VIII.
27	No specific obligations for nanoforms in 1-10 tonnage band	This measure does not require nanoform specific information of the substance at the lowest tonnage and allows thus the companies to allocate resources to upscaling of innovative applications and gaining better market shares. Clarification is needed for Annex VII.
28	No specific obligations for nanoforms in 10-100 tonnage band	This measure does not require nanoform specific information of the substance at 10-100 tonnage and allows thus the companies to allocate resources to upscaling of innovative applications and gaining better market shares. Clarification is needed for Annex VIII.
29	No nanomaterial specific obligations for 2nd exposure route at 10-100 tonnage band for acute toxicity	This measure assumes that the oral acute toxicity represents well the dermal exposure (usual 2nd route) rendering additional dermal testing redundant. This prevents animal testing and burden to companies. Clarification is needed for Annex VIII.
30	Specify that information generated according to existing test guidelines and/or test methods is sufficient for the purposes of hazard assessment of nanomaterials under REACH	Clarifies that existing test guidelines apply for the hazard assessment of nanoforms in REACH recognising thus the earlier GLP compliant safety assessments cover nanoforms even when these were not considered. Clarifications are needed for Annexes I, VI-XII.
31	A nanoform consisting of aggregates is considered same as bulk form and the same endpoint information for (eco)toxicological and environmental fate apply	It is assumed that the primary particles are bound in aggregates so strongly that there is minimum chance that they could be released. Aggregates should be considered as indivisible particles (or constituent particles) in (eco)toxicological studies. Clarifications are needed for Annexes I, VI-XII.

32	No specific obligations for nanoforms to provide ecotoxicological and environmental fate information	This measure considers pragmatically base considerations of ecotoxicology and environmental fate on substance level data. Clarifications are needed for Annexes I, VI-XII.
33	Create presumption that non-testing methods are valid to apply for nanomaterials in all endpoints	This measure aims to spur innovation with application of non-testing methods, tools and instruments for hazards assessment and minimising the efforts under safety assessment. Clarifications are needed for Annexes I, VI-XII.
34	Amend the granulometry information requirements in Annex VII (1-10 tonnage band) for nanomaterials in line with Annex II, Section 9.1.a of REACH on Safety Data Sheet and respective ECHA Guidance on Compilation of Safety Data Sheets	This measure streamlines Annex II and VII information on granulometry. Clarification is needed for Annex VII.
35	Specify explicitly that coating agents of nanoforms are registered separately in line with practices already accepted for e.g. alloys	Changes current practise so that registration of the coating agent is in a separate dossier while risk assessment in the registration dossier of the substance will take into account the way how the coating agent is bound to nanoparticle of the registered nanoform. This is analogical to the risk assessment of the substances bonded in the alloys. Clarifications are needed for Annexes I, VI-XII.
36	Reduce the set of combined methods for nanomaterial determination (Nanomaterial definition, EU/2011/696) to only one (e.g. DLS)	This measure strives for more pragmatic identification of nanoforms and potential reduction of associated costs. Industry should have one standardized method in particular for the so called unintentional nanomaterials. Clarifications are needed for ECHA guidance on this matter.
37	For the purposes of REACH, consider aggregates as constituent particle (primary particle) in the nanomaterial definition (EU/2011/696)	The measure assumes that the primary particles are bound in aggregates so strongly that there is minimum chance that they could be released. Aggregates should be considered as indivisible particles (or constituent particles) in hazard assessment (see measure 31). Clarifications are needed for ECHA guidance on this matter.
38	Omit mutagenicity and acute toxicity tests in	This measure minimises the information

	lower tonnages; no skin irritation, skin corrosion or *in vivo* eye irritation information required for 10-100 t/y if the assessments in 1-10 t/y has been negative	requirements for skin irritation and corrosion as well as eye irritation and considers substance level information on mutagenicity and acute toxicity adequate for nanoforms of a substance. These reduce regulatory burden of lower tonnage manufacturers and importers of nanoforms in general. Clarifications are needed for Annexes I, VI-VIII.

9.1.5 Overview of the measures in option 6

#	**Measure**	**What the measure aims to achieve**
39	Apply clear rules on when nanoforms can be in one dossier or in separate ones based on possibility for data sharing	Rules are expected to improve level playing field, more effective enquiry, registration and evaluation process. While it may restrict flexibility and increase administrative cost (registration fee), it is not expected to increase testing requirements (read-across is possible between forms or between substances) and may in some cases reduce them (separation in different substances leads to registration of substances with lower tonnages). Measure is expected to be implemented via ECHA guidance, regularly updated with progress and experience.
40	Introduce rules to ensure mandatory separation between nanoforms identified and addressed in the dossier whenever they differ in coating, shape, crystalline form or prescribed classes of particle size distribution	An extension of the measures 1 and 2 (Option 2) by providing further clarification regarding administrative organisation of the dossier with multiple forms. Expected to provide transparency, easier implementation, evaluation and level playing field. Mandatory separation is not expected to increase testing requirements (read-across between separated nanoforms is possible, or implied grouping before such separation requirement would not be compliant) but may increase administrative cost for industry. Measure is expected to be implemented via ECHA guidance, regularly updated with progress and experience.
41	Information requirements for substances covered by Annex III (b) must also apply to	Annex III exemption to the requirement to document basic toxicological and ecotoxicological hazard is applicable to

	nanoforms	lowest tonnage phase-in substances. Allowing exemption to be applied to new nanoforms that happen to share substance identity (but not necessarily hazardous properties) with the legacy bulk or nano phase-in material may be seen as a loophole that creates unfair advantage to the legacy materials. Modification is required in Annex III.
42	For nanoforms, require all information on potential alterations of hazard due to operational conditions upstream the exposure situation is considered	It has been demonstrated that due to particle nature that most nanoforms share, their properties and transformation such as state of aggregation/agglomeration may strongly depend on the local environment as well as the history of the material in a life cycle. An explicit provision to acknowledge that operational conditions can affect the actual status of nanoform (through e.g. agglomeration), which can otherwise already be considered as an implicit requirement, may in practice lead to additional administrative costs related to documentation but should enable a higher degree of confidence for specific value chains. Clarification required in Annex I and XII.
43	For nanoforms, require all available information on the use is considered, even when the use would not be covered by the registration	When so much attention is put into the adequate delimitation between different nanoforms (see measures 1-3 of Option 2, 39-40 of Option 6), there is potential for the abuse or the mismanagement of the safety assessment approach by taking a very narrow view as to the relevance of the available information e.g. discarding warning signals from information generated on different yet similar (nano)forms or unrecognized uses for the particular nanoform. This measure aims to encourage consideration of innovation dimension in the dossier preparation and in particular minimize the potential abuse of rejecting available relevant information due to lack of adequate handle on the value chain. This will also facilitate proper SDS entry of 'uses advised against' where relevant.

		Clarification in Annex I and XII is required.
44	For nanoforms, require additional physic-chemical characterisation along the particle's fate when particle properties impacts on hazard	Following similar argument as for the measure 42, here related to the actual properties of the nanoform through its life cycle (and possibly in different value chains). Operational conditions modify physico-chemical properties that will in turn influence the actual hazard. Information should facilitate application of adaptation possibilities e.g. read-across. Clarification in Annex I and XII is required.
45	Physico-chemical, (eco)toxicological and CSA documented separately for each nanoform	While in principle not providing any difference in content, such administratively different approach to dossier preparation may in many cases provide additional transparency in dealing with substances with nanoforms. No extra testing can be implied. Additional cost is difficult to ascertain; while volume of the dossier is expected to increase, the work required may not, as the elaborations for grouping etc. are replaced by more straightforward copy/paste of information between different forms. Clarification required in Annex I, VI-XII but in particular via ECHA guidance also on IUCLID.
46	For nanoforms, explicitly limit the potential for use of non-testing approaches for hazard and exposure where science is not consolidated, but encourage its parallel application and documentation	There is still uncertainty as regards the use of individual non-testing methods for nanomaterials. This measure aims to facilitate the responsible work by the registrants, pointing in specific situations to the generation of information without the delay that may occur as the attempt to apply a non-testing method is eventually rejected by the evaluator and the test is required. The measure also still encourages that the adaptation approach is tried and documented in order to facilitate faster development and validation of non-testing methods. To be implemented via (regularly updated) ECHA guidance.
47	Require adapted DNEL setting based on different routes through the value chain /	See argumentation under measures 42 and 44; this may provide transparent and

	specific uses	potentially more cost-effective route to document safety of individual value chains with higher degree of confidence. While the aim of REACH remains a more general demonstration of safety of a substance and not just an individual process, it may require work via individual chains to generate enough understanding before the aim is achieved for substances with nanoforms.
48	Add to the SDS information relevant to Nano registries in Member States	SDS is an effective tool developed for international use that can serve to effectively cross any impediments to the internal market by exchange of the necessary information. It is expected to help users of SDS as well as the MS authorities compiling the inventories that will benefit from consistent information. An alternative is a parallel documentation (e.g. EU registry currently still being assessed for impacts). Modification in Annex II is required.
49	Specify that list of substances in Annexes IV and V does not cover nanoforms of these substances	Lists of substances in both Annexes were designed without consideration of potentially new nanoforms being developed with the same substance identity, benefiting perhaps inappropriately from the exemption. Modification to Annexes IV,V.
50	Choose inhalation as the appropriate route of exposure in repeated dose toxicity study unless such exposure can be excluded.	Experts suggest that in a lot of cases, the oral route may not be the most relevant route of exposure to nanomaterials. To provide the most relevant information with a single test, another route (e.g. inhalation) may be warranted. The limited knowledge on the uses may however make the argument for relevance difficult. The measure may serve to ensure generation of the most appropriate information not just for the present but also for the foreseeable future. Modification in Annex VIII is required.
51	Perform toxicokinetic screening	Toxicokinetics – an understanding of how materials are distributed between the organs in the body - is one of the most important information in determining whether

		additional mechanisms of toxicity may be expected, and whether it may be possible to apply grouping between the nanoforms or with the bulk counterpart for a variety of endpoints. Clarifications in Annex VIII are needed.
52	For nanoforms, request 28 day repeated dose toxicity in Annex VII	For the lowest tonnage, only acute toxicity testing is currently required. Some information on nanomaterials and their mode of action, but in particular the absence of the experience that we have with conventional chemicals, suggests that testing for an indication of 'chronic' toxicity at lower levels seem more indicative of potential hazard and should be explored. Modification in Annex VII is required.

9.2 APPENDIX II: Monitoring and evaluation

Concept	Relevant Article in the REACH Regulation	Referring to
Enforcement and Information		
Enforcement: Tasks of the Member States	Art. 125	Member States shall maintain a system of official controls and other activities as appropriate to the circumstances.
Enforcement: Penalties for non-compliance	Art. 126	Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.
Information: Reporting	Art. 117	Every five years Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement.
Enforcement: Report	Art. 127	This report shall include the results of the official inspections, the monitoring carried out, the penalties provided for and the other measures.
Evaluation		
Evaluation: Dossier evaluation	Art. 40, 41, 42	Examination of testing proposals, Compliance check of registrations
Evaluation: Substance evaluation	Art. 44, 45, 46, 47, 48	Criteria for substance evaluation, Competent authority, Requests for further information and check of information submitted
Evaluation: Intermediates	Art. 49	Further information on on-site isolated intermediates

9.3 APPENDIX III: Ex-post assessment of 2010 registration dossiers

We quote below the main conclusions of the JRC Nano Support report. To consult the full report, please refer to: Nano support project, JRC, 12 March 2012 http://ec.europa.eu/environment/chemicals/nanotech/pdf/jrc_report.pdf

The current REACH regulation, including information requirements, does not contain any specific provisions related to substances with nanoforms. Additionally, the current REACH guidance is not tuned to address the properties of nanomaterials. In this respect, it should be noted that a REACH Competent Authority document (CA/59/2008 rev1) has clarified that the REACH provisions apply to nanomaterials and that registrants should attempt to apply the existing guidance in their registrations. An additional complicating factor for registrants was the fact that there was no adopted EC Recommendation on the definition of nanomaterial at the time of the first registration deadline (December 2010). Moreover the REACH Implementation Projects (RIP-oNs), addressing how the REACH guidance could be updated, were not finalised by the time.

a) Identification of dossiers addressing substances with nanoforms:

According to the dossiers analysed in the report, registrants generally did not provide the constituent/primary particle size distribution needed to explicitly verify whether nanoform(s) is/are addressed by a given dossier. This is not unexpected as constituent/primary particle size distribution is not a REACH standard information requirement. On the other hand, given other information found in various places of the (…) [analysed] dossiers and expert judgment, it is believed that the 25 dossiers address (or with very high probability address) nanomaterials and/or nanoforms.

b) Analysing and assessing the information reported on 'nano' in those dossiers:

The information on identification/characterisation of the substances addressed by a given dossier was of varying level of detail. Some (…) explicitly mentioned that a nanoform was covered by the registration. In those dossiers a nanoform was described in a generic way.

Regarding information on other parameters relevant for identifying or characterising nanoforms/nanomaterials, it was found that about half of the dossiers reported information (in various places of the dossiers) indicating that the registered substance could be surface treated, but specific information (including analytical data) on the type and extent of such treatments was only indicated in one dossier.

Information on particle size (distribution) was given under the 'granulometry' endpoint and in some cases in the Substance Identity section (IUCLID section 1). The quality of the information on this endpoint varied among the different dossiers, but a number of issues with significant impacts on the assessment of nanomaterials were identified. First, the methods used were in several cases not appropriate for the measurement of particle size distributions of nanomaterials (e.g. the method does not detect particles in the 1- 100 nm range). Second, the results from several methods do not distinguish between primary particles, aggregates, and agglomerates, and registrants did not clearly and consistently make a distinction between these. Thirdly, members of a joint submission did not provide their own granulometry data. For joint submissions, normally one set of particle size data were given in the lead dossier. As particle size (distribution) depends on the manufacturing process, and is logically not amenable to read-across, the project suggests that members of a joint submission should submit their own individual granulometry data. It should be noted that under the current REACH regulation, submission of granulometry data individually by members of a joint

submission would require an ‘opt out’ for this endpoint, which has some consequences in relation to fees and the possibility for prioritisation of the dossier for compliance check.

About half of the dossiers provided some additional information on other possible characterisers such as density and surface area. However, typically the description of the method used to obtain the reported data was not included.

The ambiguity in relation to the scope and identification/characterisation of nanoforms addressed by the registrations generally cascaded through the dossiers. A few dossiers did distinguish between ‘bulk’ and ‘nano’. Though the purpose was to explicitly address different forms, this was done in varying level of detail between dossiers, as well for information (CSRs and endpoints) within those dossiers and did not go to a level beyond considering ‘nano’ as one form, i.e. differences in characteristics between nanoforms of the same substance were not addressed.

Further, it was found that test data provided for physico-chemical, human health and environmental endpoints generally did not describe the test material in great detail. Further, description of sample preparation, which is an important aspect known to influence the outcome of a given study, was varying and sometimes lacking. On a positive note it seems that this situation is improving for recent (eco-)toxicological studies of nanomaterials, probably supported by the fact that scientific journals continuously raise their requirements in this respect.

It is the outcome of this assessment that, in order to address the above mentioned ambiguities, it is essential to outline in a transparent manner what is registered in terms of nanoforms and how these are addressed in terms of information requirements and assessment.

The information that needs to be generated should be focussed on demonstrating safety of the different forms that are manufactured, imported and used on the EU market. To facilitate generation of specific information there is a strong need for developing nontesting methods and for creating stakeholder consensus on the use of non-testing data. An important prerequisite for this is a clear understanding of the characteristics of the nanoforms within the relevant registration dossiers. In any case, it is important that a transparent scientific discussion is made by the registrant when using such methods for nanoforms/nanomaterials.

9.4 APPENDIX IV: Ex-post assessment of the REACH impacts to companies

Large variations exist in the registrations costs of substances with nanoforms. The compliance costs are largely taken out of R&D resources in smaller companies, even if it should be noted that these costs are not fixed costs, hence after the registration has successfully been done only marginal costs will be incurred e.g. to keep the data up to date.

In cases where companies are unable to transfer the compliance cost to the product price - typically seen as a problem for SMEs - it may affect their competitiveness. This was one of the reasons why REACH changed the requirements for non-phase-in substances only to apply from 1 tonnes instead of the previous 10 kg. In addition, REACH offers a possibility for companies to apply for up to a five year registration exemption for Process and Product Oriented Research and Development. In 2012 there were only 4 SME companies out of overall 105 applications suggesting that this segment of companies may need extra help in this regard.

The nanotechnology companies were asked about potential changes to legislation. Although only 15% of those that responded had any experience with REACH, they considered, mainly due to administrative burden and time-to-market, the possible modifications of "Considering all nanomaterials as new substances", "Chemical Safety Report with exposure assessment for all registered nanomaterials" and "Notification requirement for all nanomaterials placed on the market on their own, preparations or in articles" mainly negative for the enhancement of competitiveness and innovation, while "Simplified registration also for nanomaterials manufactured or imported in quantities of less than one tonne" a third of manufacturers considered the effect negative and a fourth indicated no effect.

<u>REACH contribution to the development of emerging technologies</u>

The regulatory uncertainties (e.g. leading to additional testing costs and authorisation) and lack of capital were considered the main challenges in bringing nanomaterials to market in Europe. The main REACH and CLP impacts on products of emerging technologies were considered to be administrative burden and information requirements, as well as negative effect to time-to-market and marginal cost structure.

A set of six recommendations on key policy options put forward by the consultant were:

- I Reduce uncertainties related to regulatory aspects (e.g. testing costs, authorisation);
- II Streamline information/testing requirements between sectoral legislations;
- III Substances produced by emerging technologies should not be treated more stringently than any other substances (or forms of substance);
- IV Strengthen the integration of REACH provisions into the Research & Development & Innovation processes;
- V Enhance market uptake of safer chemicals;
- VI Ensure affordable means for financing REACH compliance in Research & Development & Innovation process.

9.5 APPENDIX V: Summary of the Public Consultation

9.5.1 Context

The Public Consultation exercise was a targeted process that sought to gather stakeholder views relating to the Problem Definition, the Baseline scenario and the five additional substantive options under consideration. The consultation ended on 13 September 2013. The results are not binding for the Commission's decision, but can affect the decision-making process, as they give an idea of what the perception of the European society is.

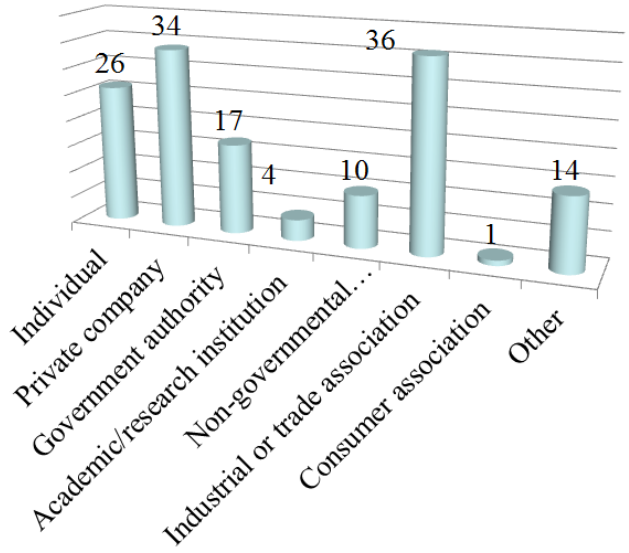
Given the current limited number of registrations of substances with nanoforms under REACH, it was unlikely that respondents would be able to do more than make an estimation of cost, efficiency and impact, as it relates to the measures and options under consideration. That having been said, it appears to be the case that respondents were able to give nuanced and considered responses and that as a result, the survey presents a detailed assessment of each option and the specific measures within them. Note: term nanomaterial (and not nanoform) is used below, in consistency with the terminology applied at the time.

9.5.2 Typology of respondent

A total of 142 questionnaires were submitted:

- A majority of respondents were representing an organisation (82%), the rest being individuals;
- Belgium[116], Germany and UK were the Member States where most responding organisations are located;
- 86% of the respondents considered that the current requirements for the registration of nanomaterials as unclear or very unclear.

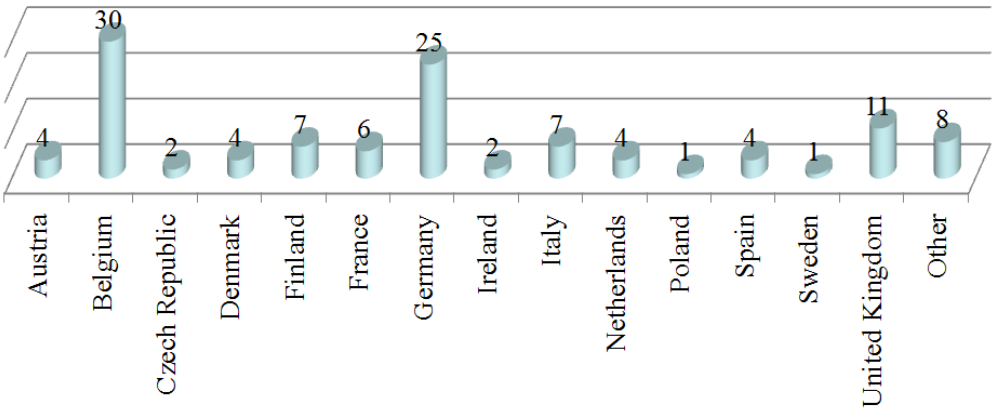
Graph 9.5-1: Profile of the respondents



[116] Most probably due to the fact that EU-wide associations and NGOs are located in Belgium

Organisations belonged to half of all Member States. In terms of geographic spread, a little over a quarter of the respondents were based in Belgium (most probably due to the location of organizations (NGOs, trade associations) representing interests of stakeholders in more than one or all MSs), with Germany being the second highest, the United Kingdom the third highest, Italy fourth and France fifth.

Graph 9.5-2: Nationality of the respondents



The organizational profile suggests that industrial/trade associations were the largest group, followed by private companies. NGOs made up one in ten respondents, with ten respondents stating themselves to be an environmental NGO. Government authorities made up 15% of respondents, with the remainder made up of consumer associations, academic bodies and other.

9.5.3 Main observations

9.5.3.1 Rankings

Respondents were asked a series of questions regarding the potential impact of the measures contained in each of the options on overall cost (increase or reduce the cost of compliance), efficiency (higher or lower overall efficiency of the regulatory process for nanomaterials within REACH in terms of striking the balance between appropriate demonstration of safe use and the cost to achieve it) and safety (increase or reduce the demonstration of safe use of nanomaterials). The table 9.1 below compares the overall summary results for each of the options when the assessment was done for each of the measures within the options.

Table 9.5-1: Ranking of Policy Options by Individual Measure

	COST	EFFICIENCY	SAFETY
Option 2	Third	First	First
Option 3	Second	Fifth	Fourth
Option 4	Fourth	Second	Second
Option 5	First	Third	Fifth

Option 6	Fifth	Fourth	Third

It needs to be stressed that respondents were not explicitly asked to rank options, but the summary table 9-1 provides interesting comparative insight. Notable points include option 2 receiving the highest ranking for both efficiency and safety, option 5 receiving both the highest ranking for cost and the lowest for safety, and option 6 receiving the lowest ranking for cost but only third highest for safety. Option 4 ranked second both for safety and efficiency and fourth for cost. Given the staggered interrelationship between options 2, 4 and 6, the outcome in terms of ranking the three options for costs is coherent, while the ranking for safety is somewhat surprising.

Table 9.5-2: Overall ranking of Policy Options

	OVERALL
Option 2	Fourth
Option 3	Fifth
Option 4	First
Option 5	Third
Option 6	Second

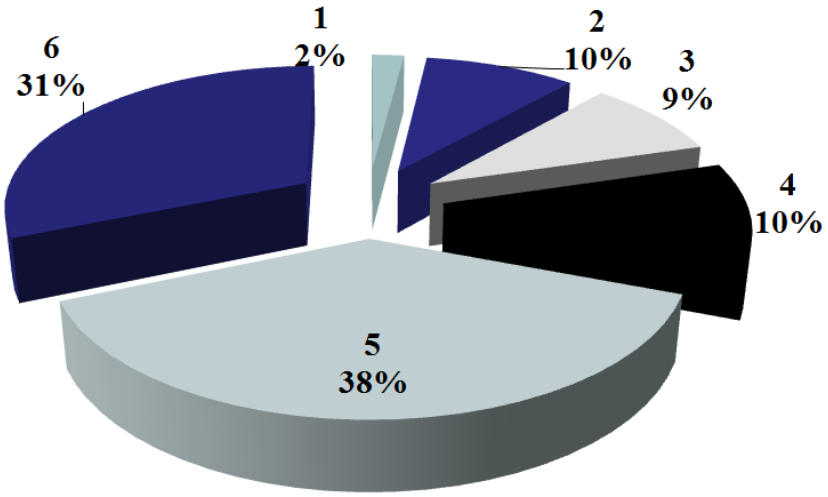
Based on a separate question regarding the efficiency of the options as a whole, option 4 received high appreciation by the majority of the respondents.

9.5.3.2 Preferences

When asked about their preferences, results are slightly different: respondents as a whole opt clearly for option 5, and then 6; options 2 and 4 are the next favoured ones, being option 3 the last preference.

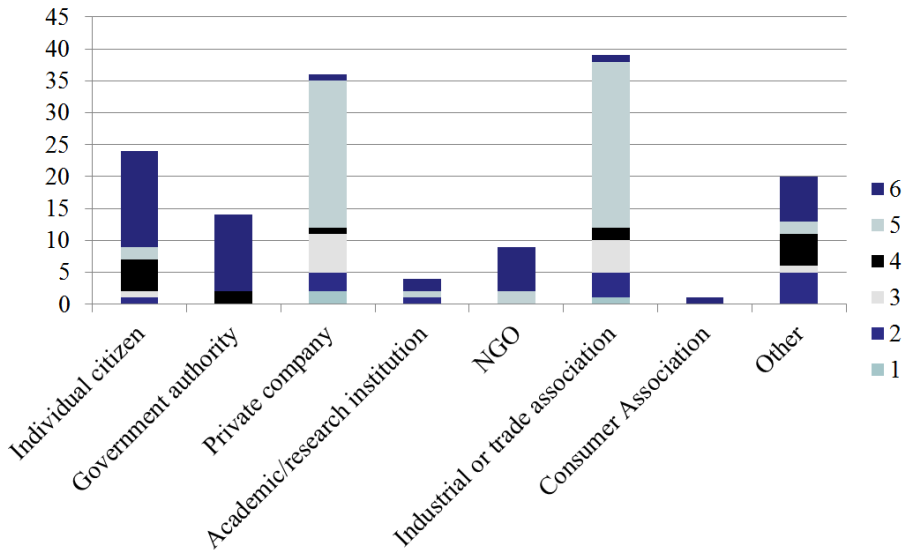
Considering that options 6 and 4 include measures of options 4 and 2 respectively, respondents as a whole have as a majority promoted measures under option 2 (51%), followed by measures included under option 4 (41%).

Graph 9.5-3: Options preferences



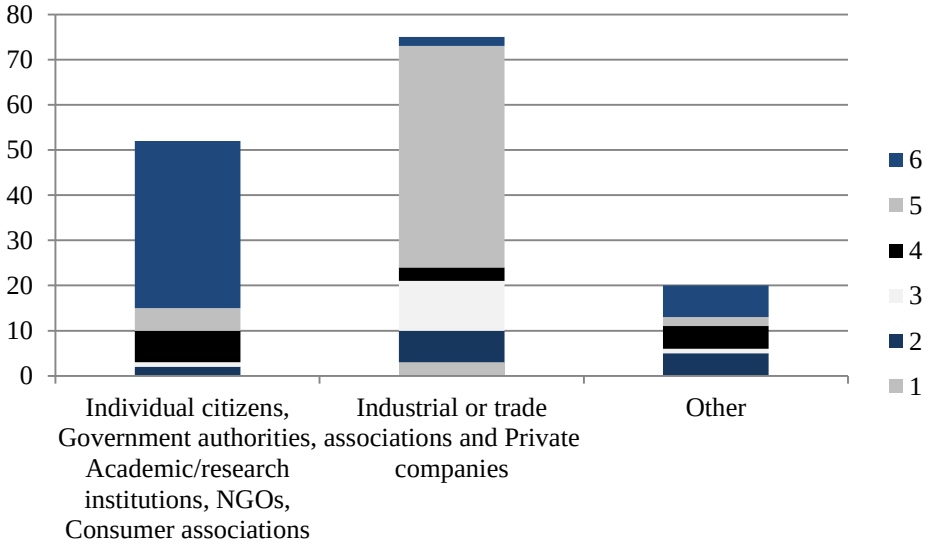
When narrowing down by type of respondent (eight different types), the results diverge as follows:

Graph 9.5-4: Options preferences by typology of respondent



By analysing the results, some common tendencies are noticed:

Graph 9.5-5: Options preferences by category



Overall, respondents can be grouped into three main categories, according to their preferences:

- Industrial and trade associations and Private companies, which opt clearly for option 5;
- Individual citizens, Government authorities, Academic/research institutions, NGOs, Consumer associations opt for option 6 followed by option 4;
- Others[117] for which the preference is more or less equally shared between options 6, 4 and 2.

9.5.4 Specific observations

We report here some specific observations that derive from the breakdown of the results per category (except for Option 3).

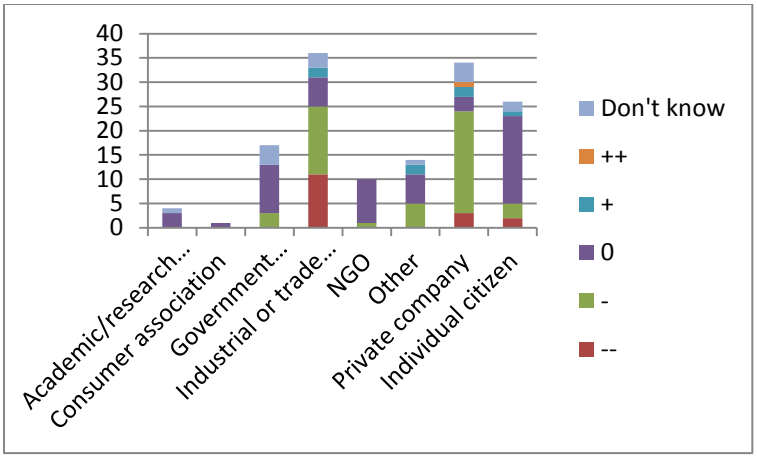
9.5.4.1 Option 2

Three measures outstand particularly among the 9 proposed ones that integrate this option with regards the negative impact they can have on costs; they refer to bioaccumulation, uses and exposure and endpoints specificities of nanomaterials. [118]

[117] The category 'Others' groups all the respondents who did not identify themselves within any of the previous categories.

[118] The three following measures are considered as having a negative impact on costs for more than 70% of respondents: g) Require that bioaccumulation is addressed specifically for the nanoform (77%); i) Require identification of uses and exposure assessment of the nanoform (76%); and c) Require that nanoforms are explicitly addressed in the endpoint sections (72%). For more detail about the Public Consultation, refer to Appendix V

Graph 9.5-6: Option 2 - Costs



Key to the scores applied as compared to the baseline scenario:

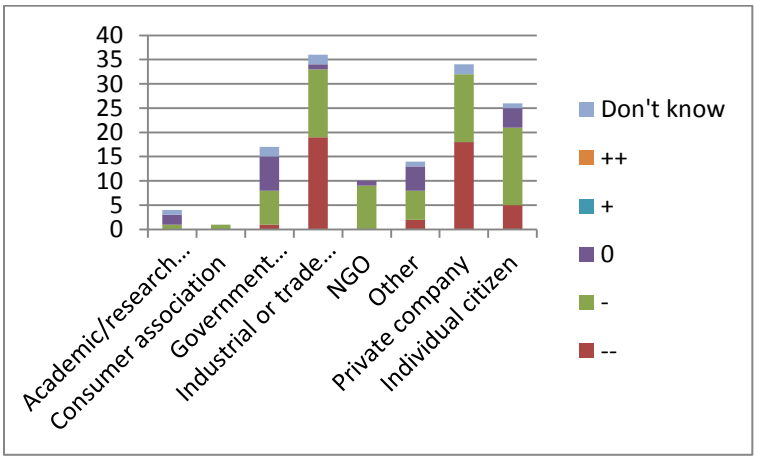
+ ... ++	*Positive impact*
0	*No impact*
-- ... -	*Negative impact*

When analysed by stakeholder category industrial associations as well as private companies believe that this option would increase the cost of compliance (94% in both cases), whereas for the rest of stakeholders the option would not have any impact on the costs.

9.5.4.2 Option 4

A vast majority of respondents to the public consultation (almost 80%) agree that costs of compliance with REACH regulation would increase under option 4. Industrial associations and companies see this option as particularly harmful for costs (9 out of 10 respondents consider that this option will increase costs, more than half of them believe that it will do so significantly). As for option 2, 3 of the 9 proposed measures are especially negatively perceived.[119]

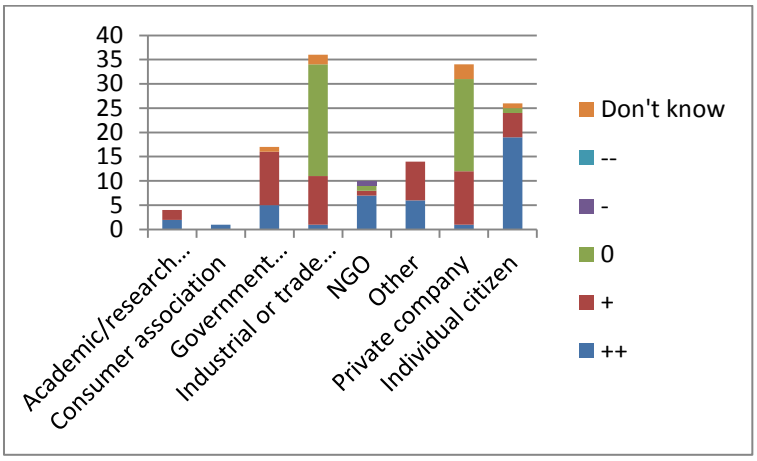
Graph 9.5-7: Option 4 - Costs



[119] The three following measures are considered as having a negative impact on costs for approximately 80% of respondents: **Measure 17:** Require that testing on soil and sediment organisms is prioritised (83%); **Measure 16:** Specify that algae testing should not be waived based on insolubility (81%); and **Measure 13:** Require non-bacterial in vitro gene mutation study (77%). For more detail about the Public Consultation, refer to Appendix V

In contrast, this option is considered as contributing to the safe use of nanomaterials (in 63% of respondents). There is here a clear difference of perception between industry and the rest of stakeholders: two thirds of the respondents from industry consider this option as not having any impact on safety, whereas among academic institutions, consumer associations, government authorities, NGOs and individual citizens, almost all the answers recognize that it increases or significantly increases safety. The remark for safety extends to the perception of how this option impacts on efficiency.

Graph 9.5-8: Option 4 - Safety



Special mention is to be made to the measure requiring the inclusion of information on dustiness[120], which is considered as having the most impact on safety (for 91% of the respondents) and as providing the highest increase in efficiency (74%).

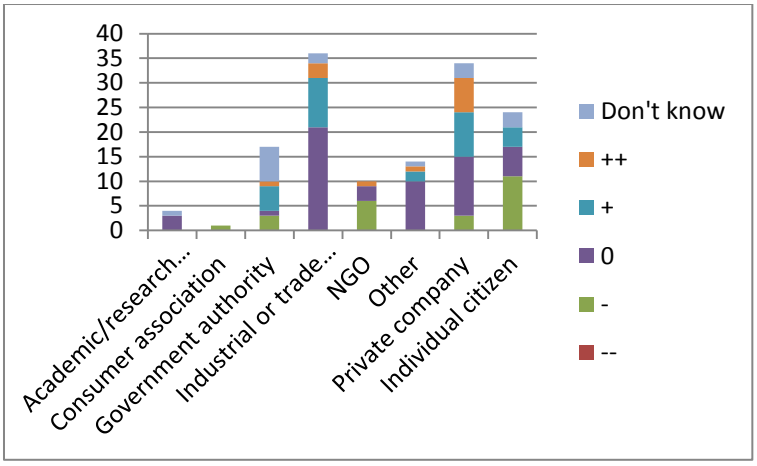
9.5.4.3 Option 5

For a large number of the respondents (40%), option 5 would have no impact on the costs of compliance.

The perception that this option will not have any impact on costs is especially true among industrial associations (58%). Moreover, an important percentage of these believe that the option will even help to reduce the costs of compliance (36% for Industrial associations and 53% for Companies).

[120] Reminder: **Measure 10:** Include information on dustiness; for a further detail on the measures, refer to Appendix I

Graph 9.5-9: Option 5 - Costs

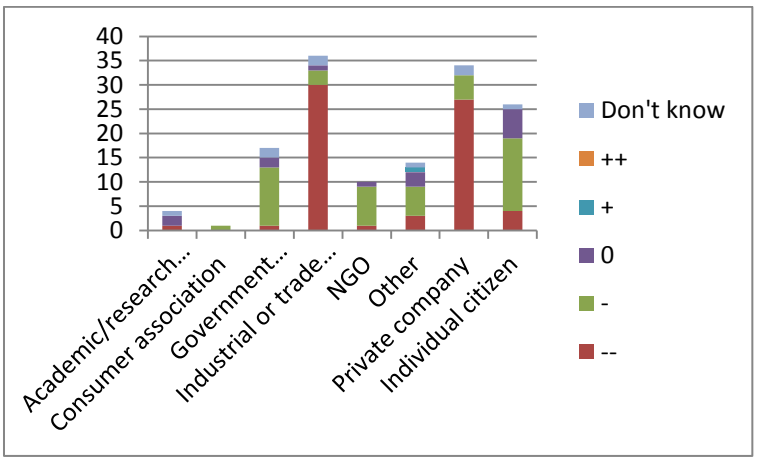


Three measures out of the 21 that are contained in this option stand out for stakeholders as impacting most positively on the cost of compliance, and these refer to the reduction of methods for nanomaterial combination, the consideration of aggregates as constituent particles and the omission of mutagenicity and acute toxicity tests for lower tonnages.[121]

However, the option is ranked as the lowest in terms of safety.

9.5.4.4 Option 6

Graph 9.5-10: Option 6 – Costs



This option comes on a second place in the overall assessment of options by the public.

The observations are similar to those already stated for option 4: high reluctancy from industrial associations and private companies, good acceptance from the rest of stakeholders regarding its impacts on safety and efficiency.

[121] Reminder: **Measure 36:** Reduce the set of combined methods for determination whether a material is a nanomaterial (Nanomaterial definition, EU/2011/696) to only one (e.g. DLS); **Measure 37:** For the purposes of REACH, consider aggregates as constituent particle (primary particle) in the nanomaterial definition (EU/2011/696); and **Measure 38:** Omit mutagenicity and acute toxicity tests in lower tonnages. No skin irritation, skin corrosion or *in vivo* eye irritation information required for 10-100 t/y if the assessments in 1-10 t/y has been negative; for a further detail on the measures, refer to Appendix I.

9.5.5 Assessment of the measures

9.5.5.1 Option 2: relation of answers per measure

Specific Measures	**Impact on Cost[122]**	**Impact on Efficiency**	**Impact on Safety**
a) Explicitly require registrants to describe the scope of the registration dossier	35%	54%	49%
b) Explicitly require registrants to provide more detailed characterisation of nanomaterials/nanoforms	67%	55%	57%
c) Require that nanoforms are explicitly addressed in the endpoint sections	72%	50%	57%
d) Require detailed description of the test material / sample and sample preparation	60%	52%	54%
e) Require scientific justifications for grouping / read-across / QSAR and other non-testing approaches for different forms	52%	48%	52%
f) Require considerations of most appropriate / relevant metric with preferable presentation in several metrics	57%	42%	49%
g) Require that bioaccumulation is addressed specifically for the nanoform	77%	45%	58%
h) Specify that absorption/desorption behaviour of nanomaterials should not be assessed based on K_d values derived from K_{oc} and K_{ow}	52%	40%	51%
i) Require identification of uses and exposure assessment of the nanoform	76%	64%	71%

9.5.5.2 Option 3: perception of the impact on safety according to companies

Business Respondents by Company Size	Total
Large: >250	23
Don't know	4
Have no impact on the safe use of nanomaterials	11
Increase the safe use of nanomaterials	8
Medium: <250	5
Don't know	1
Increase the safe use of nanomaterials	3
Significantly increase the safe use of nanomaterials	1
Micro: <10	2
Have no impact on the safe use of nanomaterials	1
Increase the safe use of nanomaterials	1
Small: <50	4
Have no impact on the safe use of nanomaterials	3
Significantly reduces the safe use of nanomatrials	1
Grand Total	34

9.5.5.3 Option 4: relation of answers per measure

Specific measures	**Impact on Cost**	**Impact on Safety**	**Impact on Efficiency**
a) Include information on dustiness	70%	91%	74%
b) Require acute toxicity data for the most relevant route of exposure	72%	68%	50%
c) Change 'particles' to '(nano) particles' for repeated dose toxicity studies (inhalation)	71%	54%	46%
d) Require non-bacterial in vitro gene mutation study	77%	75%	63%

[122] The higher the rating, the more the measure is considered as having negative impact on cost of compliance

e) Consider water solubility in relation to test waiving	35%	52%	58%
f) Specify that long term testing should not be waived based on lack of short term toxicity	72%	59%	43%
g) Specify that algae testing should not be waived based on insolubility	81%	56%	46%
h) Require that testing on soil and sediment organisms is prioritised	83%	53%	46%
i) Require consideration of most appropriate / relevant metric with preferable presentation in several metrics	65%	60%	47%

9.5.5.3 Option 5: relation of answers per measure

Specific measures	**Impact on Cost[123]**	**Impact on Efficiency**	**Impact on Safety**
a) Describe whether and which different nanoforms are covered in the chemical safety assessment, including a statement when and how information on one form is used to demonstrate safety of other forms	11%	62%	20%
b) Specify that nanoform specific information is required only when an insoluble or poorly soluble nanoform put on the market is classified hazardous/ dangerous	34%	53%	36%
c) Specify that a coated nanomaterial is considered as a special mixture e.g. in classification and labelling as accepted e.g. alloys	23%	30%	38%
d) Specify that the granulometry concept in 7.14 of Annex VII includes also shape and surface area of nanomaterials	7%	44%	29%
e) Specify that the information on dustiness is required for nanoforms only where relevant for the worker safety assessment -	21%	47%	38%
f) Specify that waiving of endpoint specific information requirements for classified insoluble or poorly soluble nanoforms applies as for any other forms and also when nanoforms do not significantly differ from each other in specific endpoints	32%	30%	40%
g) Specify that the use of non-testing methods (e.g. read-across, grouping, categorisation etc. methods) is a priority for nanoforms -	31%	44%	41%
h) Specify and require explicitly that waiving of testing on the basis of exposure conditions and categories applies also for nanoforms, in particular when nanoforms are completely reacted (cured), incorporated or embedded into a completely cured matrix or permanent solid polymer forms, or otherwise used in closed systems or controlled conditions	34%	39%	32%

[123] The higher the rating, the less the option is considered as having negative impact on cost of compliance

i) Specify that absorption/desorption behaviour of nanoforms can be based on biological surface adsorption index, affinity coefficient or other relevant parameters	17%	17%	32%
j) No specific obligations for nanoforms in 1-10 tonnage band -single choice reply- (compulsory)	24%	19%	50%
k) No specific obligations for nanoforms in 10-100 tonnage band	25%	14%	51%
l) No nanomaterial specific obligations for 2nd exposure route at 10-100 tonnage band for acute toxicity	24%	14%	39%
m) Specify that information generated according to existing test guidelines and/or test methods is sufficient for the purposes of hazard assessment of nanomaterials under REACH	30%	32%	39%
n) A nanoform consisting of aggregates is considered same as bulk form and the same endpoint information for (eco)toxicological and environmental fate apply	45%	44%	42%
o) No specific obligations for nanoforms to provide ecotoxicological and environmental fate information	27%	21%	48%
p) Create presumption that non-testing methods are valid for nanomaterials in all endpoints	34%	20%	64%
q) Amend the granulometry information requirements in Annex VII (1-10 tonnage band) for nanomaterials in line with Annex II, Section 9.1.a of REACH on Safety Data Sheet and respective ECHA Guidance on Compilation of Safety Data Sheets	11%	33%	31%
r) Specify explicitly that coating agents of nanoforms are registered separately in line with practices already accepted for e.g. alloys	17%	25%	33%
s) Reduce the set of combined methods for nanomaterial determination (Nanomaterial definition, EU/2011/696) to only one (e.g. DLS) -	53%	22%	47%
t) For the purposes of REACH, consider aggregates as constituent particle (primary particle) in the nanomaterial definition (EU/2011/696)	47%	45%	40%
u) Omit mutagenicity and acute toxicity tests in lower tonnages. No skin irritation, skin corrosion or in vivo eye irritation information required for 10-100 t/y if the assessments in 1-10 t/y has been negative	69%	46%	44%

9.5.5.4 Option 6: relation of answers per measure

Specific measures	**Cost - 'greatest increase in cost**	**Efficiency - 'greatest increase in**	**Safety - 'highest increase in**

	burden'	efficiency'	safety'
a) Apply clear rules on when nanoforms can be in one dossier or in separate ones based on possibility for data sharing	49%	49%	49%
b.) Introduce rules to ensure mandatory separation between nanoforms identified and addressed in the dossier whenever they differ in coating, shape, crystalline form or prescribed classes of particle size distribution	64%	42%	55%
c) Information requirements for substances covered by Annex III (b) must also apply to nanoforms	69%	39%	61%
d) For nanoforms, require all information on potential alterations of hazard due to operational conditions upstream the exposure situation is considered	69%	40%	62%
e) For nanoforms, require all available information on the use is considered, even when the use would not be covered by the registration	85%	39%	48%
f) For nanoforms, require additional physic-chemical characterisation along the particle's fate when particle properties impacts on hazard	53%	42%	76%
g) Phys-chem, (eco)tox and CSA documented separately for each nanoform	80%	42%	51%
h) For nanoforms, explicitly limit the potential for use of non-testing approaches for hazard and exposure where science is not consolidated, but encourage its parallel application and documentation	75%	38%	49%
i) Require adapted DNEL setting based on different routes through the value chain / specific uses -	62%	38%	56%
j) Add to the SDS information relevant to Nano registries in Member States	63%	40%	46%
k) Specify that list of substances in Annexes IV and V does not cover nanoforms of these substances	73%	42%	44%
l) Choose inhalation as the appropriate route of exposure in repeated dose toxicity study unless such exposure can be excluded.	61%	42%	67%
m) Perform toxicokinetic screening	82%	47%	63%
n) For nanoforms, request 28 day repeated dose toxicity in Annex VII	87%	40%	65%

9.5.5.5 Perception of the options in terms of: Cost, Safety and Efficiency, per category of respondent (number of received responses)

Option 2	COST (question #21.j)	SAFETY (question #22.j)	EFFICIENCY (question #23.j)

	--	-	0	+	++	Don't know	++	+	0	-	--	Don't know	++	+	0	-	--	Don't know
Academic/research institution	0	1	2	0	0	1	2	2	0	0	0	0	2	2	0	0	0	0
Consumer association	0	1	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0
Government authority	1	6	8	0	0	2	3	12	0	0	0	2	4	12	0	0	0	1
Industrial or trade association	23	10	1	0	0	2	1	13	20	0	0	2	1	5	19	9	0	2
NGO	0	2	7	1	0	0	8	1	1	0	0	0	8	1	0	1	0	0
Other	1	6	6	0	0	1	9	3	1	0	0	1	6	6	0	1	0	1
Private company	19	13	0	0	0	2	0	15	16	0	0	3	0	4	11	12	1	6
Individual citizen	5	6	14	0	0	1	17	8	0	0	0	1	14	7	2	2	0	1
Total	**49**	**45**	**38**	**1**	**0**	**9**	**40**	**55**	**38**	**0**	**0**	**9**	**35**	**38**	**32**	**25**	**1**	**11**
Option 3	COST (question #24.d)						SAFETY (question #25.d)						EFFICIENCY (question #26.d)					
	--	-	0	+	++	Don't know	++	+	0	-	--	Don't know	++	+	0	-	--	Don't know
Academic/research institution	0	0	3	0	0	1	0	1	1	2	0	0	0	1	1	2	0	0
Consumer association	0	0	1	0	0	0	0	0	1	0	0	0	0	0	1	0	0	0
Government authority	0	3	10	0	0	4	0	11	5	1	0	0	1	8	4	1	0	3
Industrial or trade association	11	14	6	2	0	3	0	14	19	1	0	0	0	9	19	6	0	2
NGO	0	1	9	0	0	0	0	1	7	2	0	0	1	1	0	3	5	0
Other	0	5	6	2	0	1	0	6	3	4	0	0	0	6	1	5	1	1
Private company	3	21	3	2	1	4	1	12	15	0	1	1	1	7	13	5	1	7
Individual citizen	2	3	18	1	0	2	3	7	12	2	0	3	4	4	6	1	9	2
Total	**16**	**47**	**56**	**7**	**1**	**15**	**4**	**52**	**63**	**12**	**1**	**4**	**7**	**36**	**45**	**23**	**16**	**15**
Option 4	COST (question #27.j)						SAFETY (question #28.j)						EFFICIENCY (question #29.j)					
	--	-	0	+	++	Don't know	++	+	0	-	--	Don't know	++	+	0	-	--	Don't know
Academic/research institution	0	1	2	0	0	1	2	2	0	0	0	0	2	1	1	0	0	0
Consumer association	0	1	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0
Government authority	1	7	7	0	0	2	5	11	0	0	0	1	2	12	1	0	0	2
Industrial or trade association	19	14	1	0	0	2	1	10	23	0	0	2	4	4	9	17	1	1
NGO	0	9	1	0	0	0	7	1	1	1	0	0	8	0	0	2	0	0
Other	2	6	5	0	0	1	6	8	0	0	0	0	6	1	4	2	0	1
Private company	18	14	0	0	0	2	1	11	19	0	0	3	0	6	6	14	4	4
Individual citizen	5	16	4	0	0	1	19	5	1	0	0	1	15	8	0	2	0	1
Total	**45**	**68**	**20**	**0**	**0**	**9**	**42**	**48**	**44**	**1**	**0**	**7**	**38**	**32**	**21**	**37**	**5**	**9**
Option 5	COST (question #30.v)						SAFETY (question #31.v)						EFFICIENCY (question #32.v)					
	--	-	0	+	++	Don't know	++	+	0	-	--	Don't know	++	+	0	-	--	Don't know
Academic/research institution	0	0	3	0	0	1	0	1	0	1	2	0	0	1	1	0	2	0
Consumer association	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	1	0
Government authority	0	3	1	5	1	7	0	1	0	5	10	1	0	1	1	6	7	2
Industrial or trade association	0	0	21	10	3	2	0	3	29	2	1	1	3	22	9	1	1	0
NGO	0	6	3	0	1	0	2	0	1	0	7	0	1	0	1	1	7	0
Other	0	0	10	2	1	1	0	0	2	4	7	1	0	2	0	4	7	1
Private company	0	3	12	9	7	3	0	10	17	4	1	2	3	17	10	2	0	2
Individual citizen	0	11	6	4	0	3	4	2	0	4	14	2	4	3	3	1	13	2
Total	**0**	**24**	**56**	**30**	**13**	**17**	**6**	**17**	**49**	**20**	**43**	**7**	**11**	**46**	**25**	**15**	**38**	**7**

Option 6	COST (question #33.o)						SAFETY (question #34.o)						EFFICIENCY (question #35.o)					
	--	**-**	**0**	**+**	**++**	**Don't know**	**++**	**+**	**0**	**-**	**--**	**Don't know**	**++**	**+**	**0**	**-**	**--**	**Don't know**
Academic/research institution	1	0	2	0	0	1	2	2	0	0	0	0	2	2	0	0	0	0
Consumer association	0	1	0	0	0	0	1	0	0	0	0	0	1	0	0	0	0	0
Government authority	1	12	2	0	0	2	10	6	0	0	0	1	10	6	0	0	0	1
Industrial or trade association	30	3	1	0	0	2	3	5	26	0	0	2	3	5	26	0	0	2
NGO	1	8	1	0	0	0	8	0	1	1	0	0	8	0	1	1	0	0
Other	3	6	3	1	0	1	7	5	1	0	0	1	7	5	1	0	0	1
Private company	27	5	0	0	0	2	0	11	16	0	1	6	0	11	16	0	1	6
Individual citizen	4	15	6	0	0	1	18	6	1	0	0	1	18	6	1	0	0	1
Total	**67**	**50**	**15**	**1**	**0**	**9**	**49**	**35**	**45**	**1**	**1**	**11**	**49**	**35**	**45**	**1**	**1**	**11**

9.6 APPENDIX VI: Undertaken actions to ensure the quality of the registration dossiers

The safe use of all substances under REACH, including substances with nanoforms, starts with compliant high quality registration dossiers. There are further tools provided under REACH to address deficiencies:

i. Request for complementing information

Sometimes, the lack of explicit provisions under REACH for substances with nanoforms may be dispelled by the application of Article 36 that enables ECHA and Member States Competent Authorities to request complementing information in the dossier by other available information. This procedure has already been used by ECHA, requesting clarity on the physico-chemical properties of the registered substances with suspected nanoforms, a precondition for adequate chemical safety assessment.

ii. Evaluation

Examination of testing proposal Highest tier testing under REACH requires pre-submission of a testing proposal that is examined by ECHA, which verifies whether it adequately covers the endpoint for the substance (in all its forms) and that may result in acceptance, amendment or rejection of the proposed tests. Such examination ensures that at least in highest tier testing any specificity required for nanoforms covered by the registration, even when potentially omitted by the registrant, is accounted for, provided that the scope of the dossier as regards their coverage is transparent to ECHA.

Compliance check In compliance check, ECHA determines whether or not the information submitted in the selected subset of registration dossiers is in compliance with standard (i.e. minimum) requirements of REACH. Such checks are able to address substance identity, information gaps, but also inappropriate use of adaptation possibilities such as waivers, weight of evidence or read-across that may represent challenges when applied to substances with nanoforms. Only a limited percentage of dossiers is however annually subject to this resource intensive scrutiny[124].

CoRAP Where there may be grounds for concern that a specific substance represents a risk for human health or the environment, but the concern still needs to be clarified before further measures are introduced, ECHA, in cooperation with the Member States, can add the substance to the Community Rolling Action Plan (CoRAP). This enables the substance to be evaluated under substance evaluation, where the potential request to the registrants to generate the necessary information is not restricted to the standard information requirements of Annexes VII-X under REACH.

[124] Compliance check strategy is multifaceted and complex: high percentage of dossiers may be investigated in a targeted fashion (only selected endpoints) and individual chemical families of known substances with nanoforms may be selected for particular scrutiny. Legal obligation is however limited to 5% of the dossiers annually. For a good overview of the activity see the ECHA Report Evaluation under REACH: Progress report 2017 that includes also a 10-year review.

Dossiers with substances with nanoforms have been selected for both dossier evaluation and substance evaluation[125].

iii. Other tools

In addition to these legal tools, ECHA has taken steps to support registrants' efforts to provide quality dossiers with substances with nanoforms also via other means, such as the standing Working Group on nanomaterials that discusses open sci-technical questions in relation to nanomaterials under REACH, and the Group Assessing Already Registered Nanomaterials (GAARN), established with a view to discuss and learn best practices. It is hoped that the participating firms, in liaison with their umbrella organisations involved in the general discussions, will help other firms to update their dossiers and that future dossiers will build on current best practise experiences. The same applies of course for the continuous commitment of ECHA to improve guidance and apply its communication strategies to raise awareness.

[125] By March 2018, 4 lead dossiers for substances with nanoforms have been subject to compliance check, while seven substances with nanoforms have been put on CoRAP or already in substance evaluation.

9.7 APPENDIX VII: 2013 BiPRO report: costs and benefits for industry of option 4

9.7.1 Costs of the measures

According to the 2013 BiPRO report, the total costs for implementing the measures which are foreseen in this option amount to between €11 million and €73 million as a cumulative effort for all concerned companies for a time period until 2022.

These cost calculations were made in 2012, predominantly based on previous figures used by the industry in 2011[126]. The industry estimated that between 500 – 2.000 nanomaterials would be subject to registration pursuant to REACH. These figures have not been validated, but based on the first two registration rounds the number of nanomaterials seems to be high. This can partly be explained by some assumptions about substance ID that were being discussed by the time the CEFIC study was commissioned, but since then have been (partially) clarified, leading to many nanomaterials now being regarded as forms of the very same substance.

The split of total costs on single measures shows big differences between options with high or medium efforts, and hence high or medium costs, and options with no or very little additional costs.

Overview of the measures costs in Policy Option 4[127]

#	Measure	Additional costs (€ 1.000)
10	Include information on dustiness	210 - 640
Human health hazards		
11	Require acute toxicity data for the most relevant route of exposure	1.280 – 9.400
12	Change 'particles' to '(nano)particles' for repeated dose toxicity studies (inhalation)	0
13	Require non-bacterial in vitro gene mutation study	2.000 – 9.600
Environmental fate & hazards		
14	Consider water solubility in relation to test waiving	5.090 – 29.540
15	Specify that long term testing should not be waived based on lack of short term toxicity	1.800 – 15.270
16	Specify that algae testing should not be waived based on insolubility	0
17	Require that testing on soil and sediment organisms is prioritised	770 – 7.660

[126] Impact Assessment of the REACH Implementation Project on Substance ID for Nanomaterials, RPA on behalf of CEFIC, March 2012

[127] Measure 21 has been withdrawn from the calculations, as it is not one of the measures finally included in Option 4

Resulting additional costs for industry	11.200 – 72.200

The assessed costs take into consideration an extensive grouping and read-across approach, as specified in the provisions of the REACH Regulation. Without this approach, the final costs would increase up to €100 million and €600 million.

9.7.2 Benefits of the measures

According to the same 2013 BiPRO report, the quantification of total benefits of the measures in monetary terms is hampered by considerable uncertainties. The dimensions of additional costs can be compared to expected revenues of concerned companies in that period of about €40 billion. The revenues are assumed and extrapolated on the basis of the current global turnover for nanomaterials (worth €20 billion per year) and the current share of European chemicals market to the global chemicals market. Related to health benefits, an average of €165 million (with a range between €83 million and €248 million) for cumulative savings for a period until 2042 could be calculated. It needs to be mentioned that, due to latency effects, most of the health benefits are expected to occur with significant delays after implementation of the measures. It needs to be further mentioned that health benefits do not automatically occur as a consequence of the measures but will be achieved only if appropriate risk reduction measures are taken, which in turn could lead to additional costs. It is estimated that the increase of health benefits per substance in average will amount to about 20% of the health benefits per substance to be obtained as the total potential of REACH. This share is based on a judgment of a plausibility range between 10% and 30%, estimated during a set of expert interviews.

Besides the quantifiable benefits, additional added value is expected through implementation of the proposed measures. This concerns in particular the reduction in uncertainty regarding potentially adverse effects on the environment and the increased ability to react promptly and appropriately in cases where risks are suspected or identified. Furthermore, increased knowledge is likely to stimulate innovation processes within companies searching for new and better solutions. Nanoforms identified as being hazardous to human health and/or the environment can be subject to substitution activities within the concerned companies. It will consequently help to improve the image of companies in the public view and provide options for concerned companies to communicate that non-hazardous nanoforms are used in the manufacturing process. The conclusion is that these non-quantifiable effects should not be neglected.

9.8 APPENDIX VIII: Nanoforms, sets of nanoforms and the importance of characterisation

The diagram describes the main terms used in the document, describing the relation between the substance, registration, **nanoform** and set of nanoforms used in the main text also as the unit in calculating impacts.

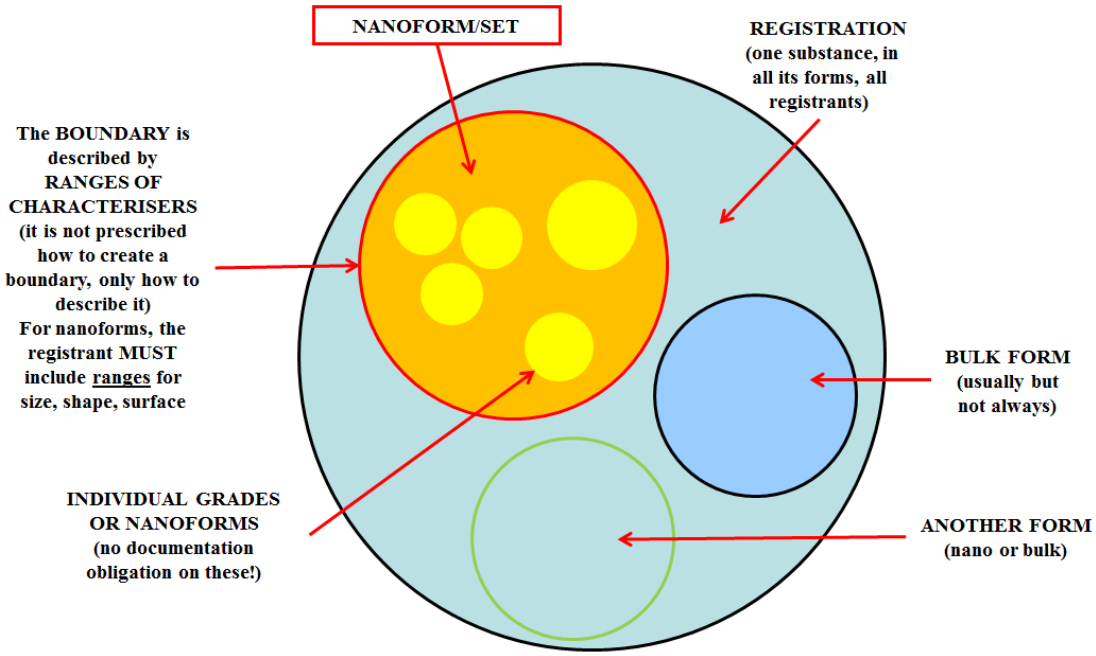
In a simple picture of one registrant registering a substance, the diagram represents the scope of the registration by outlining the different forms the registrant is putting on the market. The information in the dossier is expected to cover (eco)tox information of all forms. While forms are all the same substance, they differ in different ways that may affect hazard or risk of the form. To ensure that the relevant hazard information in the dossier (e.g. toxicology testing) is associated with the use, risk and risk management of the material on the market, the forms themselves need to be described so they can serve as 'assessment entities', linking the information.

Description is done by the use of **characterisers** – quantifiable properties that can be attributed to each nanoform, such as particle size or shape. As shown in the picture, a **set of nanoforms** can be unambiguously described by providing **ranges for the characterisers**; all nanoforms that fall within the ranges belong to the set. Ranges are not prescribed; the registrant is expected to define them in a way that any information requirement in a dossier can be effectively fulfilled for a complete set by a single piece of information.

There may be several non-overlapping sets in the single dossier – they are defined separately as it is expected that the corresponding hazard or risk information may differ between them. This makes the set a best possible unit for the assessment of impacts.

It is clear however that the difference in the properties between forms/sets may be only on a very specific information requirement and that for many if not most information requirements, the information may be shared between them or even with information for other substances (grouping). In the same manner, a 'worst case' form may often (but not necessarily always) be identified in advance of testing, reducing a necessary dataset required to cover all registered forms.

Graph 9.8-1: The nanoform/set registration



This picture applies to individual registration of a substance, but can as well apply to joint registrations and multiple registrants.

The difference is that in joint dossiers, the nanoform or set of nanoforms is used as the basis for the information requirements within a joint submission. In the adjoint individual dossiers, the sets are only used to describe the scope of the individual registration dossier, to indicate uses-per form, and to enable the link with the relevant information requirements in the joint dossier.

Hence not all forms/sets from joint registration are necessarily included in every individual registration, In contrast, the sets in the joint dossier are expected to cover all the individual forms/sets of the registrations in the joint submission.

9.9 APPENDIX IX: Assessment of non-significant impacts

9.9.1 Functioning of internal market and competition

9.9.1.1 General comments

Given the nature of all the options i.e. committee changes to some technical provisions of an already established internal market based Regulation, neither of the measures as such lead to any principal changes of the functioning of the internal market. However, in light of the current regulatory uncertainty there is a risk that some Member States may introduce national based measures to counteract political pressures which may have significant negative internal market effects. This has not yet happened, but closely related to this area it is noteworthy that three EU Member States have enacted or at least notified their intentions to introduce specific reporting obligations for nanomaterials.

9.9.1.2 Option 2

Analysis. In principle, the clarification involved in this option may foster an increment in the circulation of goods, due to increased confidence across borders with regards to product characteristics and safety. There are no concrete data at the moment validating this hypothesis.

Competition could decrease if some firms are driven out of the market. However, if reduced uncertainty over the registration process leads to more registrations then it would increase. Overall, for an option aimed specifically at reducing uncertainty, the impacts should be marginally positive.

9.9.1.3 Option 3

Analysis. We do not anticipate significant impacts on the viability of SMEs and hence on market structure under option 3. On the other hand, there could be positive effects in terms of easier circulation of goods in presence of greater clarity, if the latter results from "soft law" measures.

9.9.1.4 Option 4

Analysis. The effect on consumer confidence and hence on the circulation of goods described above in reference to option 2 would be potentially stronger under option 4, especially due to its greater focus on a thorougher (data basis for) chemical safety assessment.

On the other hand, the possible effects on businesses and in particular on SMEs, in particular for substances with nanoforms subject to Annex VIII or VII as a result of increased upfront (registration) costs for using nanomaterials, could also change the competitive landscape in several sectors, leading to greater market concentration in the manufacturing and importing of nanomaterials. Higher market concentration could also entail higher prices downstream in the supply chain. -

9.9.1.5 Option 5

Analysis. Almost half of the respondents (large majority when industry is excluded) to the public consultation express the belief that safety in the use of nanomaterials could be undermined. Uncertainties could in turn undermine the circulation of goods due to possible higher uncertainties with regards to safety. Market concentration is unlikely to be affected; in fact, existing fragmentation in many EU sectors could even rise if lower costs boost market access.

9.9.1.6 Option 6

Analysis. The further increment in requirement established under option 6 could enhance the magnitude of the effects mentioned under option 4 in terms of market concentration (mainly due to possible exit of SMEs which are negatively affected by this option), and hence prices charged to downstream users.

9.9.2 Impacts on consumers

Analysis. The costs involved for the different options are fixed, meaning that, once a firm has to engage in costly activities determined under an option, increasing further its level of production using the same substances does not involve any additional cost. This implies that changes in the fixed cost are less likely to lead to changes in the profit-maximising sale price faced by consumers.

On the other hand, increases in market concentration that may arise under option 4, and especially under option 6 (because of the possible exit from the market of some firms), could lead to higher prices. Limitations in data and high variability in the markets affected prevent the drawing of clear-cut conclusions.

As well as prices, the other impacts on consumer relate to information and protection. At this stage we do not have enough information to establish *ex ante*, for each option, to which extent consumers are likely to receive and benefit from information specifically referred to nanomaterials. More, differentiated information leads to increased security and reassurance to immediate customers and to the public directly or indirectly in contact with the relevant types of nanoforms. This contributes to a better informed and more differentiated opinion, attitude and level of awareness of customers and consumer protection organisations, showing that not all nanomaterials *per se* are dangerous or problematic. Products with nanomaterials having been tested and proved to be non-problematic will gain a higher and sustainable degree of public acceptance. This also increases the trust in industry and authorities.

Finally, availability of different substances to buyers of intermediate goods could also be affected. We note that the previous KPMG impact assessment on REACH reports that case study analysis provides no indication of future significant impacts in terms of availability of substances. While we cannot provide further evidence in that respect, we argue that increased information on nanomaterials arising from options establishing stronger test requirements could increase knowledge base and future product development.

The effects of the options on health and safety are discussed in more detail among the social impacts.

9.9.3 Public authorities

The role of public authorities is to assess compliance and to pursue the objectives of the legislation. By doing so, public authorities incur costs. Since we do not have information related to these, we provide below a qualitative reasoning. However, as the options aim to create more clarity on what to be expected it is anticipated that the overall compliance and enforcement costs for public authorities will go down. It is even possible in cases of more vigorous testing that it will off-set needs for substance evaluation which further will significantly cut cost for the competent authorities.

9.9.4 Employment and labour markets

The development of nanotechnology is increasingly associated with job creation, as mentioned in the problem definition section. Modification in regulatory requirements

regarding nanomaterials may ease or hamper job creation, in firms specialised in nanotechnologies and in the other businesses operating with nanoforms. Data on the workforce involved in testing are very limited, and it is impossible to quantify likely effects. We provide here a qualitative evaluation of the mechanisms behind effects in labour market.

Among previous studies, the CSES interim evaluation reports a downward trend in employment in the chemical sectors that is not, in principle, associated to REACH, but rather to a long-term relocation trend of activities outside Europe, mainly into Asia, and increases in productivities leading to less need for workers. On the other hand, REACH also leads to the creation of specialised units within firms devoted to regulatory requirements. Specific requirements for substances with nanoforms are likely to show similar effects.

The assumption used here is that increases in the details regarding nanoforms would create demand for professional services related to registration and testing. This would be the most direct effect. The extent of the positive impacts of this increase in demand on employment and salaries depend on several factors, including the landscape in specific sectors and in the overall economy.

The magnitude of salary growth depends on whether there is a "reserve" of unemployed people with required professional characteristics, in which case salary rates would remain largely unaffected, or if on the contrary there is scarcity of available workers, in which case firms will need to compete to attract them. Situations in EU labour markets widely vary across countries and regions, and we anticipate that, in presence of high unemployment, effects will mainly involve increase in employment rather than in salaries; vice-versa in contexts with low unemployment.

Labour demand would increase even more if increases in buyers' confidence determine an expansion in the markets for goods produced using nanomaterials.

On the other hand, if some of SMEs involved in the supply of nanomaterials close down as a result of higher costs, this would shift downward the labour demand in the sectors affected, with negative impacts on employments and salary rates.

Given the context of all the measures that are technical changes to an existing Regulation is it not possible to extrapolate meaningful job figures at EU level. All the options will entail the characteristics described above but none of them stands out based on the information currently available. It is therefore assumed that the overall impact on employment and labour markets is negible for all the options.

9.9.5 Standards and rights related to job quality

9.9.5.1 Introduction

The job quality dimension mainly involves safety in relation to the manipulation of substances containing nanomaterials. The 2003 Commission Staff Working Paper presented the "Extended Impact Assessment" of REACH[128] mentions that "it is impossible to identify the benefits that will arise from REACH" (p.25). It is even harder to establish and quantify health benefits for workers from modifications accounting for the specificities of nanomaterials. A document by the European Trade Union Institute[129] underlines that nanoparticles pose

[128] COM (2003) 644 Final

[129] Ponce del Castillo, A.M. (2013): "Nanomaterials and workplace health & safety. What are the issues for the workers?" European Trade Union Institute.

potential dangers additional to the ones already recognised in current REACH regulation with regards to chemical substances. Inhalation is the main route to exposure to nanoparticles, which can deposit in the respiratory tract and also be transported to other organs, as they can easily enter the blood stream. Ingestion and absorption through skin are other potential entry routes, from which nanoparticles can enter the blood stream. Therefore nanomaterials could in principle exacerbate the occupational dangers inherent in the manipulation of chemical substances.

9.9.5.2 Option 2

Analysis. Increases in the details regarding nanoforms, defined under option 2, would create limited additional demand for professional services related to registration and testing. This would be the most direct effect. However, the number of jobs created would be fairly limited as there would be little or no additional expenditure compared to what is expected already now.

The potentially strongest effect would come from an increase in productions related to increased confidence in the properties of nanomaterials.

On the other hand, if some of SMEs involved in the supply of nanomaterials close down as a result of higher costs, this would reduce labour demand.

9.9.5.3 Option 3

Analysis. The soft-law approach could in principle entail some limited health impact. A full-fledged analysis cannot be developed without knowing ex ante which types of measures would be developed. However, as the requirements to be clarified equals those that are applicable in option 2 some of the same benefits may be seen but due to the non-binding nature the soft-law approach may not be as effective in delivering exactly because the core technical provisions will continue to be unspecific to nanoforms.

9.9.5.4 Option 4

Analysis. This option entails an increase in requirements with respect to the baseline. The measures requiring data on dustiness (measure 10), route of exposure (measure 11) and non-bacterial in vitro gene mutation study (measure 13) could potentially entail significant improvements on occupational safety, especially in terms of prevention of lung cancer, ameliorating the informational asymmetries suffered in this case by workers, who may ignore the extent of exposure to hazardous substances.[130] Those health impacts would affect workers in the chemical sector but also those in downstream sectors using nanomaterials. Benefits would also indirectly affect employers, as they are legally responsible for workplace safety, as specified by the European Framework Directive 89/391/EC.

Under this option, potential risks related to lung cancer and other serious conditions, especially in relation to respiratory diseases, would be ameliorated. As is the case with previous evaluation exercises conducted for nanomaterials, and also with regards to the evaluation of REACH in general, it is difficult to establish to what extent occupational risk of a given condition is reduced under a specific regulatory option.

[130] **Measure 10:** Inclusion of information on dustiness; **Measure 11:** Requirement of acute toxicity data for the most relevant route of exposure; **Measure 13:** Requirement of non-bacterial in vitro gene mutation study; for a further detail on the measures, refer to Appendix I

9.9.5.5 Option 5

Analysis. The reduced requirements for nanoforms under this option could potentially entail a higher risk of disease for workers. However, previous considerations in terms of reduction of risk, in particular in relation to lung cancer, are reversed. Exactly because there is no clarity with regards to actual risks in relation to nanoforms of substances, this option could allow potential dangers to materialise. For instance, the omission of mutagenicity and acute toxicity tests in lower tonnages could result in missing the identification of adverse health impacts (e.g. cancer) and (to a lesser extent) possibility of accidental death from acute exposure.

9.9.5.6 Option 6

Analysis. Option 6 further reinforces the prevention of disease established under option 4. Additional requirements in terms of physico-chemical characterisation (measure 44) and separate documentation for each nanoform (measure 45) can enhance the informational benefits of testing, and establishing inhalation as the appropriate route of exposure in repeated dose toxicity study unless such exposure can be excluded (measure 50) can help protecting from cancer and other respiratory diseases.[131]

[131] **Measure 44:** For nanoforms, require additional physic-chemical characterisation along the particle's fate when particle properties impacts on hazard; **Measure 45:** Phys-chem, (eco) tox and CSA documented separately for each nanoform; and **Measure 50:** Choose inhalation as the appropriate route of exposure in repeated dose toxicity study unless such exposure can be excluded; for a further detail on measure, refer to Appendix I

9.10 APPENDIX X: Summary of the Matrix Study

This Research Study has been undertaken to support the proposed forthcoming Impact Assessment on the REACH Regulation as it relates to Nanomaterials (NM), where the objective of the policy initiative is "to ensure further clarity on how NM are addressed and safety demonstrated in registration dossiers".

The Research Study includes an assessment of future options to address NM under REACH while taking into account, on the one hand, the competitiveness of the European chemicals and NM sector, innovation and employment, including SME-specific impacts, and on the other hand, human health and the environment and impacts from the use of NM.

9.10.1 Methodology

The Research Study was undertaken over a ten-month period starting from January 2013, with the following research methods being utilised:

- secondary evidence review;
- semi structured interview programme;
- testing cost capture and analysis;
- impact assessment; and
- options comparison informed by the assessment of multiple criteria.

In addition the Research Team worked closely with colleagues from the Commission on the development of the formal Public Consultation Exercise and have used the findings to inform the study. The Research Study additionally drew upon a number of prior studies, with the 'Bipro/JRC' 2012 Final Report, prepared for the European Commission, Joint Research Centre, Institute for Health and Consumer Protection providing comparative references and assumptions.

9.10.2 Problem Definition

The Problem Definition was developed primarily by reference to the Commission's Draft Road Map (Appendix One) alongside primary evidence from stakeholder interviews with industry, environmental, trades union and scientific bodies, the output from the Formal Public Consultation Exercise, as well as a secondary evidence review. Following Commission Impact Assessment Guidelines the Problem Definition has been outlined as follows:

> **The nature and scale of problem** – The principal problem is there is currently sub-optimal regulation of NM within REACH. This problem is considered by a broad range of stakeholders to be linked to the current perceived lack of clarity regarding informational requirements for NM within REACH. The consequence is that dossiers that are submitted for NM do not provide sufficient evidence to ensure protection of human health and the environment and the free movement of substances on the internal market while enhancing competitiveness and innovation, or alternatively/additionally that dossiers for NM are not being submitted to ECHA for assessment.
>
> **Stakeholders most affected by it** – Producers of NM are immediately impacted by current issues regarding clarity of requirements, which in turn will impact on a range of stakeholders across the supply chain from the production of NM into the product lifecycle for goods and products that contain NM, impacting as it does on consumers, workers and the wider environment. Stakeholders suggest that there may be

disproportional impact for SME, micro enterprises and start-ups, which maybe more likely than larger enterprises to respond to current regulatory imprecision by withdrawing from the market or being dissuaded from entering the market.

Drivers or underlying causes of the problem – The immediate drivers of the problem relate to the absence of sufficient specific provisions for NM within the annexes of REACH. Results for the Commission's Formal Public Consultation Exercise found that in relation to the overall view of the current registration provisions and information requirements for the registration of NM, 68% considered it to be "unclear" and a further 18% "very unclear".

Problem Development and the impact of existing policies at Community or Member State level – A functional starting point for the problem can be identified from the establishment of REACH, the setting of the definition of NM by the Commission and then the issuing of ECHA Guidance. One of the main responses at Member State level has been the introduction of national registers of NM, although this has limited connection to the issue of the requirements for NM within REACH or the associated guidance provided by ECHA.

Assumptions, Risks and Uncertainties – Key assumptions relate to estimating the potential impact of any changes to the annexes of REACH on NM. There are risks relating to balancing potential regulatory benefits with increased costs for business and other stakeholders. Uncertainties pertain to the evolving evidence base on NM safety testing.

Justification for Community level action – The principle of chemical regulation being a Community-level responsibility is well established. Although there is scope for MS to support the guidance process, there remains an evident need for central coordination.

9.10.3 Options Development and Refinement

The European Commission provided options for change to the Research Team.

Baseline – The baseline option incorporates the European Commission's definition of NM and is supported by the most recent ECHA guidance on the interpretation of REACH requirements for NM.

Option 2 – Would introduce "changes to certain Annex provisions clarifying what companies are expected to do in accordance with the registration obligations of REACH and the specific guidance which takes into account CA/59/2008 and the RIPoN 2 and 3 reports from 2011". The measures would require more precise descriptions of the scope of the dossier, clarification of requirements for nanoform-specific information in endpoint sections, and clarification of how data is to be reported.

Option 3 – Is based on "soft law" and would include one or more of the following:

- Communication;
- Resolution; and
- Other Measures.

Option 4 – is built upon the requirements specified in Option 2 with further requirements focussed on additional testing, clarifications and elaborations to further describe the potential impact of the NM.

Option 5 – is based upon tailored information requirements in a dossier for NM placed on the market, a reduction in certain testing requirements, clarification of regulatory provisions and the ability to maximise the use of non-testing methods and exposure categorisation, and in doing so maintain openness to flexible solutions.[132]

Option 6 – includes the full implementation of Option 2 and 4 and the inclusion of a number of additional requirements. Option 6 gives additional emphasis to the generation of targeted information with the objective of further reducing uncertainty in an area where knowledge is still under development regarding the influence of particle and nanomaterial-specific properties on risk.

In terms of the overall integrity of individual options, it is difficult on an a priori basis to find the grounds to exclude individual measures within any of the options or to include further measures. What is certain is that, having established the costs and potential benefits of individual measures, there will need to be a level of scrutiny as to whether particular tests within each option are cost beneficial. This could lead to further restructuring of options or the partial or full merging of one or more options.

9.10.4 Cost Analysis

The data capture element of the Stakeholder Engagement Programme constituted a core element within the broader Research Programme and provides up-to-date estimates of the prospective cost of testing (where tests and such information are available from GLP-compliant laboratories currently offering NM testing to private clients as a service) as relevant to each of the Options considered within the study.

The methodology for the cost assessment included determining relevant tests, designing a Data Capture Tool, sourcing of laboratories and finally collating data returned from laboratories into a form for use in the Cost Data Assessment.

The presentation of the cost data divides into two broad elements. The first provides an overview of potential costs on a per form/dossier basis, providing a maximum and minimum scenario for additional characterisation costs that might arise.

The second element draws on these estimates to develop an updated set of aggregate estimates of cost developed utilising the assumptions that underpinned the last commissioned JRC/Bipro study on the regulation of NM under REACH. In table 9.3 the costs have been extrapolated to provide estimates of the respective costs under each of the substantive options under consideration (costs for each option being additional to the Baseline position).

[132] European Commission Impact Assessment of the possible amendment of REACH Annexes for nanomaterials Preliminary options and measures

Table 9.10-1: Aggregate Cost Summaries based upon BIPRO assumptions

	Baseline	Option Two	Option Three	Option Four	Option Five	Option Six
Additional Testing Costs €M)	**(183)***	**30.75**	**n/a**	**104.4**	**-136.4**	**270.25**
Additional Administrative Costs (€)	**n/a**	**15,200**	**n/a**	**22,100**	**2,800**	**240,000**

(*baseline costs i.e. 'additional testing costs' to be added to this baseline aggregate cost.)

It is important to stress that these costs could increase or decrease depending on the actual number of forms as well as the degree/level of read across that may be applicable.

9.10.5 Impact Analysis

Assessment of impact has been the least developed area of research into the regulation of NM and the Research Team were only able to make limited progress in assessing how each of the options under consideration may impact within the health and social, economic, and environmental domains. Assessment was principally qualitative, being based upon secondary review and expert input from toxicologists with health and environmental expertise.

- **Option 2** was viewed to have a potentially positive impact on human health and environmental safety, with a broadly neutral impact on economic or environmental issues.
- **Option 3** not being linked to any substantive clarification or extension of requirements had the same limitations in terms of impact as the Baseline (no change).
- **Option 4** extends the scope of REACH as well as providing additional requirements, with the potential to identify the highest consequence health and environmental impacts.
- **Option 5** could have positive impacts on employment, but increased risk of failing to identify and mitigate health and environmental risk.
- **Option 6** involved a potential doubling of costs over the baseline position with only a limited number of measures that could be viewed to have the highest potential impact on improved human health and environmental safety.

9.10.6 Impact on SMEs

Whilst improved clarity was considered to be advantageous to SMEs, micro enterprises and start ups, there was significant concern that an increase in the regulatory cost burden, and most particularly Option 6 and to a lesser extent Option 4, could negatively impact on the ability of European small businesses to compete in the NM market.

9.10.7 Options Comparison

The final chapter of this study involves a comparison of each of the six options under consideration, bringing together assessments of effectiveness, efficiency and coherence, these being the assessment criteria set out in the European Commission's Impact Assessment Guidelines. Scoring for each aspect was ranked from minus 5 (least positive) to plus 5 (most positive), with a zero being a neutral (no impact) rating. Scores represent the total for a range of measures used to assess each summary measure.

The multi criteria assessment presents Option 2 to be significantly higher scoring than any other option. This stands in contrast to the summary response of stakeholders in the Public Consultation Exercise where Options 5 and 6 were the most popular, but is in line with stakeholder assessments of each Option when assessed on a measure-by-measure basis. The no change and soft law options received negative scores, which is likely to be in part a reflection of stakeholder evidence that was negatively impacted by perceptions as to the current application of REACH for NM as opposed to the ideal or complete application of all the measures that constitute each of these options.

Table 9.10-2: Summary Option Assessment

Summary Impact Measure	Option One	Option Two	Option Three	Option Four	Option Five	Option Six
Effectiveness	**-1.4**	**1.6**	**-1.0**	**1.75**	**0.55**	**1.65**
Efficiency	**-0.8**	**0.4**	**-0.8**	**-1.0**	**1.4**	**-2.6**
Coherence	-2.4	3.0	-2.4	2.2	0.2	2.0
Total Assessment Score	**-4.6**	**5.0**	**-4.2**	**2.95**	**2.15**	**1.05**
Ranking	**6th**	**1st**	**5th**	**2nd**	**3rd**	**4th**

9.10.8 Conclusions

This Research Study provides a range of new evidence and analysis to support the European Commission's Impact Assessment process. The core findings of the study are that:

- A significant majority of stakeholders believe REACH to be the appropriate means to regulate NM.
- Equally the majority of stakeholders believe that NM require particular provisions within REACH in order for the wider aims of REACH to be deliverable for NM.
- Stakeholders also agree that the current provisions within REACH require further development if the full benefits of REACH are to be obtained for NM.
- The multi criteria assessment presents Option 2 to be significantly higher scoring than any other option.
- There are a number of measures contained within each of the Options with high cost benefit, which suggests further review of the composition of existing options would be appropriate.

9.11 APPENDIX XI: Matrix report: impacts on competitiveness

9.11.1 Option 2

Cost and price competitiveness	Positive	Negative
Cost of compliance	Possible savings in the long term	Likely to increase slightly in the short term.
Cost of capital	May decrease in the long term due to reduced uncertainties	
Cost of production, distribution, after-sales services		Cost of production may increase slightly in the short term.
Price of outputs (directly not through the cost, e.g. price controls)	Exit of some SMEs could lead to increase in prices. Unlikely to have a major impact.	
International competitiveness	Positive	Negative
Market shares (single market)	Possible increase due to higher confidence in EU products containing NM. Possible replacement of dangerous NM, to the advantage of producers of substitute products.	Possible exit from the market of producers or users of NM found to be dangerous.
Market shares (external markets)	Possible increase due to higher confidence in EU products containing NM	Possible exit from the market of EU producers or users of NM found to be dangerous.
Revealed comparative advantages	Possible increase due to higher confidence in EU products containing NM	
Capacity to innovate	Positive	Negative
Capacity to produce and bring R&D to the market	Stimulated by generation of information base on NM	Slight increase in cost of compliance could reduce resources devoted to R&D.

Capacity for product innovation	Same as above	Same as above
Capacity for process innovation (including distribution, marketing and after-sales services)	Unlikely to be affected	
Access to risk capital	In the long run fewer uncertainties may increase access to capital	

9.11.2 Option 4

Cost and price competitiveness	Positive	Negative
Cost of compliance	Possible savings in the long term from improvement in risk management and enhanced knowledge of NM.	Likely to increase, especially in the short term.
Cost of capital	May decrease in the long term due to reduced uncertainties.	May increase if cost increases render the financial viability of SME uncertain.
Cost of production, distribution, after-sales services		Cost of production likely to increase, especially in the short term.
Price of outputs (directly not through the cost, e.g. price controls)		Exit of some SMEs could lead to increase in prices of NM (due to higher market concentration) that would be reflected in a price increase for downstream users.
International competitiveness	Positive	Negative
Market shares (single market)	Possible increase due to higher confidence in EU products containing NM. Possible replacement of dangerous NM, to the	Possible exit from the market due to higher costs. Possible exit if some NM are prohibited on safety grounds.

	advantage of producers of substitute products.	
Market shares (external markets)	Possible increase due to higher confidence in EU products containing NM	Possible exit of firms unable to cope with increase in fixed costs. Possible exit from the market of EU firms if some NM are found to be dangerous in the short term – in the long term, prohibitions are likely to align in other markets.
Revealed comparative advantages	Possible increase due to higher confidence in EU products containing NM.	Possible disadvantage, especially in the short term, due to higher costs for EU firms.
Capacity to innovate	Positive	Negative
Capacity to produce and bring R&D to the market	Stimulated by generation of information base on NM	Increase in cost of compliance could reduce resources devoted to R&D. Possible exit from the market of some SMEs operating in nanotechnologies.
Capacity for product innovation	Same as above	Same as above
Capacity for process innovation (including distribution, marketing and after-sales services)		Higher compliance costs could force SMEs to reduce investment in process innovation.
Access to risk capital	In the long run fewer uncertainties may actually increase access to capital	Uncertainty in financial viability could worsen the risk profile of SMEs.

9.11.3 Option 5

Cost and price competitiveness	Positive	Negative
Cost of compliance	Cost decrease in relation to NM.	Possible long-term savings due to increased knowledge

		of NM are limited if informational requirements are reduced.
Cost of capital	Enhanced viability may facilitate access to capital.	Limited effect. May increase in the long term if reductions in informational requirements preserve uncertainties.
Cost of production, distribution, after-sales services	Likely to decrease, especially in the short term.	
Price of outputs (directly not through the cost, e.g. price controls)	Entry of new SMEs could result in stronger competition and decrease in output prices, in relation to NM and to products for which NM are used as input down the supply chain.	
International competitiveness	Positive	Negative
Market shares (single market)	Possible increase in the combined output of NM producers or importers, and in the output of firms using NM as production input.	Possible decrease (in comparison with the counterfactual option 1) due to lower confidence in EU products containing NM.
Market shares (external markets)	Possible increase due to lower cost of production for EU NM producers and importers.	Possible decrease (in comparison with the counterfactual option 1) due to lower confidence in EU products containing NM.

Revealed comparative advantages	Cost decrease.	Possible decrease (in comparison with the counterfactual option 1) due to lower confidence in EU products containing NM.
Capacity to innovate	Positive	Negative
Capacity to produce and bring R&D to the market	Reduction in cost of compliance could enhance resources devoted to R&D. Prevention of possible exit from the market of some SMEs operating in nanotechnologies.	Reduction in information requirements would entail less creation of new information regarding NM, that would otherwise be useful for innovation activities.
Capacity for product innovation	Same as above	Same as above
Capacity for process innovation (including distribution, marketing and after-sales services)	Lower compliance costs would allow firms, and SMEs in particular, to invest more in process innovation.	
Access to risk capital	Improvement in the risk profile of SMEs due to lower costs of compliance.	In the long run, uncertainties in safety could increase the risk associated with activities entailing the use of NM, and hence worsen the risk profile, in particular for SMEs.

9.11.4 Option 6

Cost and price competitiveness	Positive	Negative
Cost of compliance	Possible savings in the long term from improvement in risk management and enhanced knowledge of NM.	Likely to increase .substantially, especially in the short term.

Cost of capital	May decrease in the long term due to reduced uncertainties.	May increase if cost increases render the financial viability of SME uncertain, thereby worsening the risk profile of those firms..
Cost of production, distribution, after-sales services		Cost of production involving NM as inputs likely to increase significantly, especially in the short term.
Price of outputs (directly not through the cost, e.g. price controls)		Exit of some SMEs as well as cost-shifting could lead to increase in prices of NM (due to higher market concentration) that would be reflected in a price increase for downstream users.
International competitiveness	Positive	Negative
Market shares (single market)	Possible increase due to higher confidence in EU products containing NM. Possible replacement of dangerous NM, to the advantage of producers of substitute products.	Higher possibility (with respect to option 4 and to all other options) of exit from the market due to higher costs. Possible exit if some NM are prohibited on safety grounds.
Market shares (external markets)	Possible increase due to higher confidence in EU products containing NM	Possible exit of firms unable to cope with increase in fixed costs. Possible exit from the market of EU firms if some NM are found to be dangerous in the short term – in the long term, prohibitions are likely to align in other markets.
Revealed comparative advantages	Possible increase due to higher confidence in EU products containing NM.	Likely disadvantage, especially in the short term, due to higher costs for EU firms.

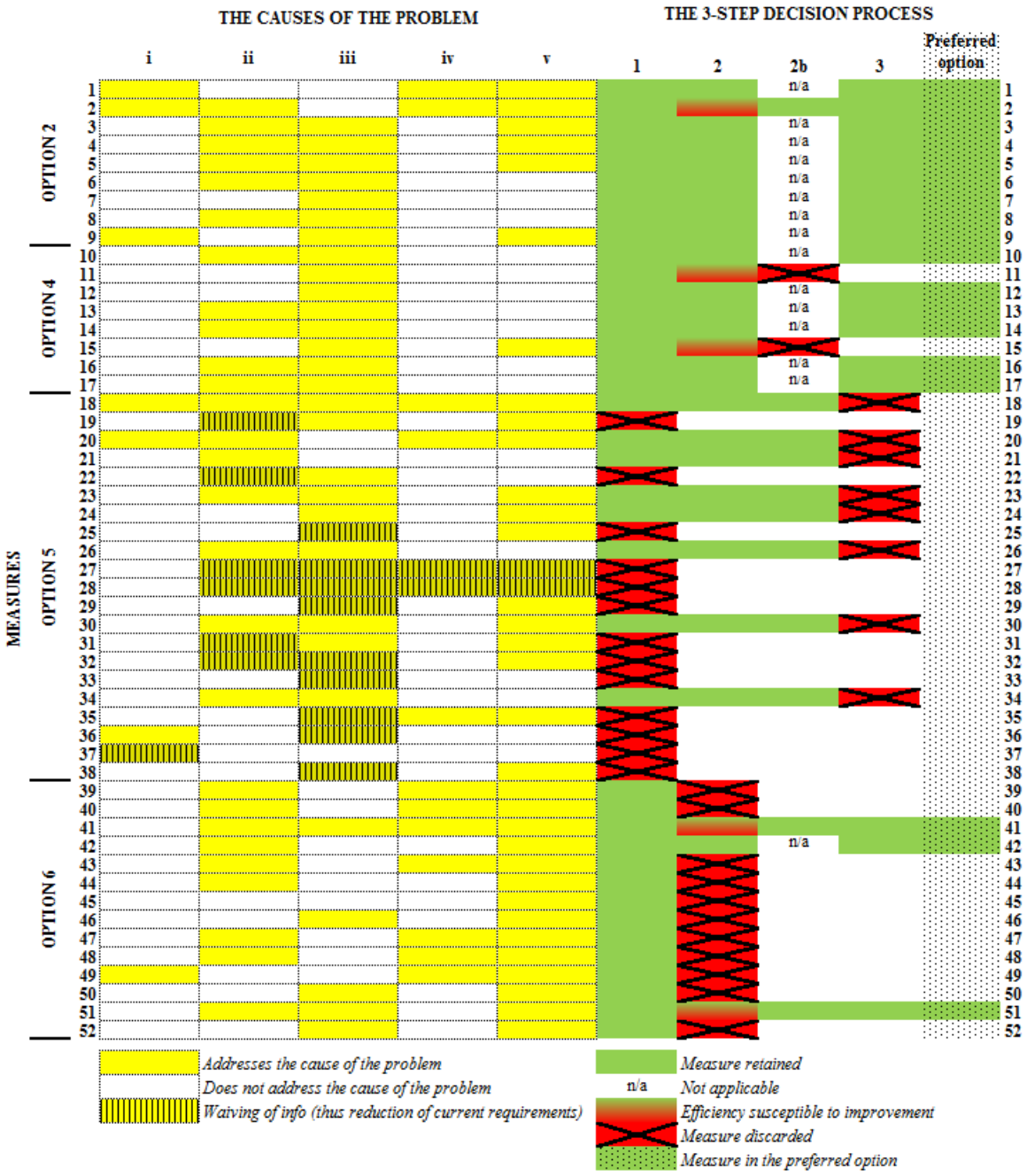
Capacity to innovate	Positive	Negative
Capacity to produce and bring R&D to the market	Stimulated by generation of information base on NM	Increase in cost of compliance could reduce resources devoted to R&D. Possible exit from the market of some SMEs operating in nanotechnologies.
Capacity for product innovation	Same as above	Same as above
Capacity for process innovation (including distribution, marketing and after-sales services)		Higher compliance costs could force SMEs to reduce investment in process innovation.
Access to risk capital	In the long run fewer uncertainties may actually increase access to capital	Uncertainty in financial viability could worsen the risk profile of SMEs.

9.12 APPENDIX XII: Measures included in the preferred option (initial Commission proposal)

9.12.1 The 3-step decision process towards the preferred option

The 3-step decision process follows on from an initial assessment of the effectiveness of the measures, thus considering how each of the measures addresses the causes of the problem, as indicated in 2.2.1 *The problem and its consequences*: (i) Nanomaterials definition, (ii) Physico-chemical properties, (iii) Applicability of tests methods, (iv) Substance identification and (v) Description of the CSA and multiplicity of forms. The subsequent 3-step process applies as follows:

1. **Effectiveness:** based on the criterion that the preferred option needs to ensure that nanomaterials are properly addressed and safety demonstrated, those measures which impose reduction of the current requirements have been discarded (this concerns thirteen out of the twenty-one measures of option 5).
2. **Efficiency:** eleven measures from option 6 and two measures from option 4 were considered as too costly compared to the information they would provide and were discarded; furthermore it was considered that one measure of option 2, two of option 4 and two of option 6 were too costly but could be adapted in order to render them less burdensome while keeping their effectiveness; the one option from option 2 and the two from option 6 have been modified accordingly, as explained in 9.12.2 *Detail of the measures*.
3. **Overlap:** the eight remaining measures from option 5 have been discarded as they were already covered by other retained measures; the resulting preferred option contains eighteen measures, some of them adapted as explained below.



9.12.2 Detail of the final measures within the preferred option

Option	Measure	Detail	Modification
2	1	Explicitly require registrants to describe the scope of the registration dossier	None
	2	Explicitly require registrants to provide more detailed characterisation of nanoforms	Further clarification is provided by explicitly including a number of nano-relevant physico-chemical properties under new endpoint 'Other information'

			only for high tonnage substances (Annexes IX and X), subject to testing proposal.
	3	Require that nanoforms are explicitly addressed in the endpoint sections. Forms should be clearly addressed in study summaries.	None
	4	Require detailed description of the test material/sample preparation	None
	5	Require scientific justifications for grouping / read-across / QSAR and other non-testing approaches for different forms	None
	6	Require considerations of most appropriate/relevant metric with preferable presentation in several metrics	None
	7	Require that bioaccumulation is addressed specifically for the nanoforms	Effectively taken by measure 3, also 1 and 5. No additional obligation at lower tonnages is considered.
	8	Specify that absorption/desorption behaviour of nanoforms should not be assessed based on Kd values derived from Koc and Kow	None
	9	Require identification of uses and exposure assessment of the nanoforms	None
4	10	Include information on dustiness	None
	12	Change ‘particles’ to ‘(nano)particles’ for repeated dose toxicity studies (inhalation)	None
	13	Require non-bacterial in vitro gene mutation study	None
	14	Consider water solubility in relation to test waiving	None
	16	Specify that algae testing should not	Wording is ‘solubility alone’; consequently, solubility can be

		be waived based on insolubility	used as an argument but in context
	17	Require that testing on soil and sediment organisms is prioritised	No modification of existing obligations (in relation to tonnage) is considered. Wording in waiver is however modified to ensure proper justification is provided.
6	41	Information requirements for substances covered by Annex III (b) must also apply to nanoforms	Instead of blanket application to all nanoforms, modified to apply only to priority/insoluble nanoforms
	42	For nanoforms, require all information on potential alterations of hazard due to operational conditions upstream the exposure situation is considered	Same
	51	Perform toxicokinetic screening	Instead of blanket requirement for the test, wording requires to address only the difference (some information may be available). The requirement is also subject to testing proposal so that ECHA and MSCA can review the need prior to actual testing, which involves animals.

9.13 APPENDIX XIII: Analytical models used in preparing the impact assessment – Costing methodology

9.13.1 Main assumptions

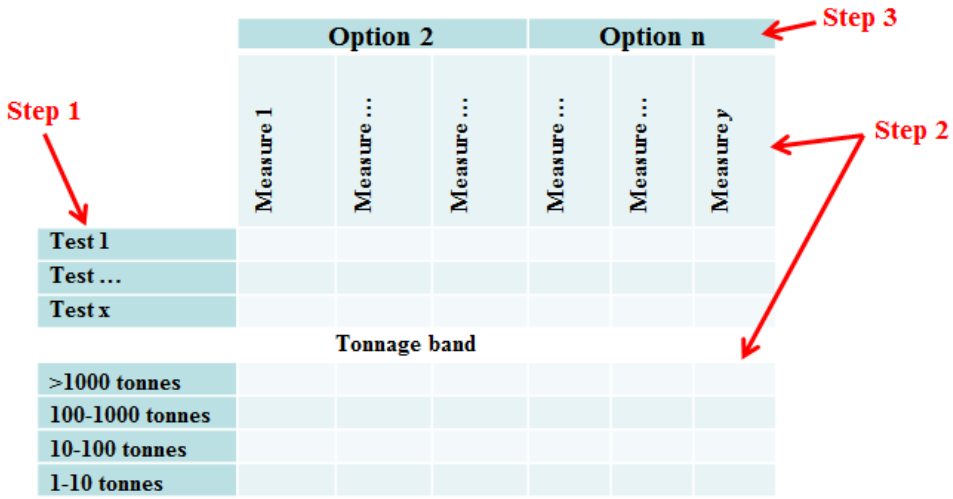
In summary:

- **Generation of information:** when a nanoform of a substance is placed on the market, the REACH registration dossier is expected to include relevant information.
- **Separate and single dossiers:** information on a nanoform may be provided in a separate dossier (in case the nanoform is considered a separate substance) or within one dossier together with other forms of the substance. The estimation of the cost in either approach is effectively the same, as substantial needs to characterise the material and generate relevant safety data, when not already available, do not depend on the administrative procedure chosen and it can be assumed that the same effort will be applied to justify the relevance of existing or specifically generated data.
- **Unit cost:** the **"nanoform or set[133] of nanoforms"** is the basic element of the model for which the 'unit cost' is calculated. It is assumed that data for this basic element, when covered by the registration, is either generated (via specific testing per information requirement) or filled by existing data for other substances or forms of the same substance for the specific nanoform or set of nanoforms and this is justified (e.g. read-across and grouping). Test costs were compiled via a survey, and assumptions were made regarding the possibilities for read-across for each individual test, leading to 'normalised testing cost' per information requirement.
- **Assumptions:** cost calculations require a number of assumptions, some of which are difficult to verify; for example, the ability to read-across between nanoforms of the same substance or between substances or to identify a 'worst case' (i.e. the form of a substance that is likely to have the most severe outcome in a given test) will always be case-specific.
- **Cost at nanoform or set of nanoforms level:** summation over all the relevant information requirements, accounting for the impact of measures taken under the individual option, leads to cost for the nanoform or set of nanoforms when registered for a specific tonnage band.
- **Cost at option level:** multiplying the cost at nanoform (or set of nanoform) level with the assumed number of nanoforms or sets of nanoforms registered within the tonnage bands enables calculation of the total cost per option and tonnage band.

The graph below schematically depicts the different steps in the calculation:

[133] A set would cover different nanoforms that are, however, sufficiently similar to be covered by the same toxicological and ecotoxicological information (see 9.8 Appendix VIII)).

Figure 9.13-1: The steps in the calculation:



Step 1: the cost per nanoform or set of nanoforms for each information requirement is calculated, taking into account possible read-across/grouping, and cost of fulfilling information requirements for each tonnage level;

Step 2: the costs for the individual measures at each tonnage level are calculated;

Step 3: the costs of information requirements as foreseen including impact of each of the measures under each option are summed together to obtain the total cost per nanoform, at each tonnage level and for each option.

All resulting costs are provided in the tables below in absolute terms. It has to be noted (as mentioned in section 2.2.3 *Initiatives undertaken*, also 4.8 *The Baseline* and 4.9 *Industry appeals to ECHA decisions on registration of substances with nanoforms*) that industry may not share ECHA's interpretation that measures listed in option 2 of this impact assessment are current obligations that are derived from the general REACH requirements. The relative costs of options 4, 5 and 6 may be calculated by subtracting the respective total cost of either option 1 or option 2 from these.

For option 3, it can be assumed that the costs would be eventually similar to option 2, supposing that option 2 is confirmed as the baseline and that the measures in option 3 would aim to come as close as possible to option 2 (see description of option 3 in section 4.3 *Option 3: Soft law measures* and discussion in section 2.2.3 *Initiatives undertaken*).

9.13.2 General methodology and discussion in detail

The very basic concept in understanding the model is the 'unit' to which all is related. As the main costing aspect are costs of tests and documentation, the basic element of the model for which the 'unit cost' is calculated, is a nanoform or set of nanoforms as explained in Appendix VIII. For such a unit it should be possible to identify (with justification) relevant datasets in the existing substance registration documentation, and if they cannot be identified, further tests (and therefore associated costs) are required. It is further assumed that for a single nanoform or set of nanoforms only one test per information requirements is sufficient.

The unit cost thus obtained can be used to directly compare impacts of the different options. The total cost can be calculated by the multiplication of unit cost with a number of nanoforms

or sets of nanoforms that are expected to be registered. This number is however associated with significant uncertainty as it is associated with the research and development as well as market uptake. All assumptions are listed and discussed in a subchapter below.

Calculation[134] is performed in several steps:

- Testing costs are mainly provided from the Matrix study. For many tests a minimum/maximum cost interval could be assigned but calculations apply an average cost. There is no information or experience to indicate the appropriateness of the assumption regarding the average cost. However, it is likely that at least for some if not many challenges in implementation of the test on a nanoform may increase costs rather than reduce them. In some specifc results an interval is used to discuss sensitivity of the calculation. Specific attention is given to characterisation of nanoforms as an expected main contributor to the cost: including also information provided by CEFIC, the cost of several applied methods was combined into an average cost of characterisation of nanoform or set of nanoforms and a default characterisation of the sample was added to any test cost.
- Basic unit costs are calculated for each tonnage interval, based on the respective REACH information requirements as applied to the individual unit (nanoform or set of nanoforms). Assumptions are made in terms of average applicability of waivers and the ability to use alternative ways to fil the information requirement instead of testing (read-across, weight of evidence etc.). The latter is throughout the model applied as the 'normalised testing cost', i.e. the full test cost is reduced in proportion[135] to the assumed availability of waivers or 'alternative means' for the particular information requirement, but in the same proportion a justification cost is added (as it is necessary to explain in the registration dossier e.g. why a waiver applies or an alternative method can be used).
- Assumptions related to such a proportion under 'normalised testing cost' is arguably the most critical aspect of the model. In the absence of more robust data, the model assumes that the statistics derived for chemicals in general regarding application of non-testing methods (e.g. read across between substances) for individual endpoints[136] can be applied also to the nanoforms, including in relation to the use of information from the bulk or another form (also nanoform) of the same substance. As such application remains to be justified on a case-by-case basis, these statistical factors are highly speculative in either direction: in the first instance, information to be potentially useful in the non-testing method should already exist as vast majority of nanoforms are

[134] Raw input data and equations are available in the attached XLS spreadsheet which was used to calculate all the results (including sensitivity analysis) presented in the impact assessment.

[135] With proportion 0%, the 'normalised testing cost' is the full testing cost, while with proportion 100%, this cost would include only cost caused by the justification why testing is not necessary. With 50%, this cost is half the testing cost plus half cost of justification.

[136] ECHA reporting under REACH Article 117(3) on the use of alternative methods. The proportion includes e.g. 48% for in vivo skin irritation or 64% for repeated dose toxicity testing, 13% for short term sudy on Daphnia. Where such information is not available default factors were used (e.g. 0% in phys-chem characterisation or 33% for other).

expected to belong to substances also containing non-nano forms, many registered already. On the one hand, as none of the methods are explicitly validated for nanomaterials[137], one may argue that such argument cannot even be made at this time (i.e. the proportion is 0%), while on the other hand, current application in the registration dossiers as well as demonstrations in the ECHA Nano Materials Working Group for selected substances with nanoforms have shown that very often "the worst case" can be argued[138] that alleviates the need to perform more than one tests for an information requirement for many if not all forms of the substance, even when there are a number of "nanoforms or sets of nanoforms" (i.e. proportion 95% in case of 10 nanoforms of the same substance and assuming that no information is available, otherwise 100%). Sensitivity to different assumptions is explored in Appendix XVI.

- Option 1 is a special case as a single test is considered adequate for the substance regardless of the forms covered by the registration. To calculate the cost per nanoform or set of nanoforms, the basic cost (i.e. cost for one form without any nano-consideration such as characterisation) is divided by an estimated average number of 'nanoforms' or 'sets of nanoforms' for a substance at a given tonnage band. This conservatively assumes that information for bulk substance is not yet available as otherwise the cost to register additional nanoforms under option 1 assumptions would be zero.
- For each measure under the different options (with the exception of option 5 where all measures are assessed jointly), the impact of the measure is calculated – sometimes the impact is expressed as administrative cost, sometimes as extra testing either due to explicit requirements (characterisation), and sometime implicitly through the expected reduced ability to apply an otherwise available waiver. Few specific measures under option 5 and option 6 also have the specific effect of increasing/reducing the ability to apply an alternative way to fill an information requirement.
- In option 6, some measures (addressing Annexes IV and V) do not change the cost but effectively increase the number of nanoforms. To enable direct comparison of the 'unit costs' while not disregarding this impact, the unit cost for the option was increased in proportion to the estimated increase in number of nanoforms.
- It is anticipated that any changes to the registering regime of nanoforms will have impact also on the registration of other (bulk) form of a substance. Impacts are expected to span from neutral (most bulk forms of substances with nanoforms are expected to be already registered) to reduced cost (testing strategies may optimize/reduce also testing on bulk via read across and application of worst case approach), but also in increased cost at least in the

[137] It should be noted, though, that validation of the test method is always restricted in scope: showing applicability for a specific chemical (or nanoform) may not prove that the applicability domain may be extended to all chemicals (or nanoforms of any substance), regardless of their chemistry or the specifics (coating, shape, size).

[138] This is a well established approach in the testing of chemicals. In case when within two or more forms, a single form can be identified in advance, due to shape, size etc., for which the most pronounced effect can be expected for s specific information requirement (e.g. most adverse toxic effect), such form may be chosen for testing as 'the worst case'. This information is then used to interpret the information requirement for all other forms.

cases where measure may have an impact on registration obligation. Positive impacts are not being quantified and the measures are by large strictly restricted in scope of their impact to nanoforms. Measure 41 (modification of conditions of Annex III of REACH, prioritising substances in low tonnage interval for full testing or phys-chem only) however cannot be fully restricted in scope, so the indirect impact to registering bulk form of the low-tonnage registration of substance with nanoforms is quantified and presented in addition, assuming that no (eco)tox information on the bulk for of the substance affected by the change is available and needs to be generated in full.

- For each of the options, the cost of fulfilling information requirements is compiled with the impact of different measures to get the total cost for a single nanoform or set of nanoforms registered in a specific tonnage interval. While the impact of the measures is assessed to the maximum extent as 'additional' to the situation without the measure being implemented, this is difficult in cases where the measure was set to clarify and not essentialy change the existing requirement or when the measures are partially overlapping. The impact of individual measures is therefore of more ilustrative nature, but great effort was invested in avoidance of any double counting to ensure that the total cost per option is as representative as possible.
- Based on further assumptions on the total number of nanoforms or sets of nanoforms and the average number of companies registering the individual set (note that the information under Annex VI should be supplied individually), two ‘totals’ are provided: the cost per company and the 'grand total' cost, again for each of the options and the tonnage interval. The number of nanoforms considered within a specific tonnage thresholds was set by the assumptions provided in different reports, the survey of existing dossiers under Nano support and discussion in the subgroup of CARACAL[139]. In addition, a ratio between all nanoforms in the 1-10 tonnes interval and those that would be affected by Annex III was also assumed on the basis of existing information on the classification of substances.

The calculation as presented above requires a few caveats for proper interpretation.

- The information under option 1 applies to 'average chemicals' as information was, as far as possible, pinned to the available data (mostly ECHA report under Article 117(3)). For nanoforms, some assumptions (e.g. likelihood of conclusion that inhalation is the most appropriate route of exposure, insolubility, complexity to perform test) probably systematically diverge from the average for all chemicals and to the extent reasonable, this was explicitly accounted for in the evaluation of the options. The most important impact is

[139] A number of nanoforms that would potentially be included in the registration dossiers e.g. by 2018, 2020 or 2030 is difficult to establish for a number of reasons. While the number of substances containing nanoforms has been identified in a range of ca 200 (2nd regulatory review) to 500-2000 nanomaterials (CEFIC), it has been stressed that the number of substances with nanoforms with significant market presence at the moment is probably less than 20. The high CEFIC estimate of 2000 is associated primarily with organic pigments with narrow specific use that are not expected to result in variety of forms as more general-purpose nanomaterials such as silica or carbon nanotubes. Associating an 'average' number of "nanoforms or sets" (4-10 dependent on tonnage) to individual substance in such an already divergent set therefore adds further uncertainty.

visible in option 2, where by far the highest cost is incurred by the requirement set under OECD test guidelines to characterise test samples. Similar requirements apply to all complex chemicals, not just nanomaterials, but such requirements are not included in the option 1 cost.

- Costs as presented cannot be directly translated to the cost of e.g. a grade or an individual material as still several materials may be described by a single 'nanoform' or 'set of nanoforms'.
- As already mentioned above: the total data to be generated for the specific information requirement is expected to be reduced via a 'worst-case argument', grouping/read-across and in particular read-across between forms of the same substance. The arguments are however always case/form specific and any statistical approach, as the one taken in this model, is speculative.
- Characterisation cost attempts to include in an informed manner all the costs that would be expected by the individual registrants under Annex VI, making assumptions on the average number of registrants as well as individual nanoforms so as to be able to normalise the cost back to the individual nanoforms/set. It is expected that each registrant would incur some basic characterisation costs to understand the scope of his dossier and accordingly develop appropriate sets (i.e. define ranges of required characterisers) and 'sort' its nanoforms accordingly within the sets. Only some representative measurement information for the set is eventually required – as now, documentation does not need to be provided for individual grades.

9.13.3 Input tables

Table 9.13-1: Estimated average number of nanoforms or sets of nanoforms per substance registered in the specific tonnage bands

Tonnage band	NF/sets per substance
> 1000	**10**
100 - 1000	**7**
10 – 100	**5**
1 - 10	**4***

** This estimate is used also when considering indirect impact of measure 41*

Table 9.13-2: Ratio between substances registered in different tonnage bands (based on ECHA's registration statistics and estimation for 2018 registration)

Tonnage band	Substances registered per tonnage band (ratio of total)
> 1000	**0,12**
100 – 1000	**0,21**
10 – 100	**0,13**
1 – 10	**0,53**

Table 9.13-3: Estimated number of nanoforms or sets of nanoforms to be registered per tonnage band (the ratio of substances with nanoforms is expected to follow the ratio between 'normal' substances in various tonnage bands)

	Number of NF/sets		
Tonnage band	**Typ**	**Min**	**Max**
> 1000	**460**	230	920
100 – 1000	**553**	277	1106
10 – 100	**250**	125	500
1 – 10 Full	**800**	400	1600
1 - 10 AIII applied*	**566**	283	1133
1 - 10 AIII not appl.	234	117	467
Total	**2063**	**1032**	**4126**
(# substances)	375	187,5	750

** Ratio based on assumption regarding phase-in chemicals that could not benefit from reduced information requirement due to conditions (ca. 73% hazard* 40% dispersive use = 29.2%)*

Table 9.13-4: Average number of companies in SIEF registering in specific tonnage band (assumed to apply to number of companies registering nanoforms in that specific tonnage band)

Tonnage band	**Companies per SIEF**
> 1000	**7**
100 - 1000	**3**
10 – 100	**1,8**
1 - 10	**1,8**

Table 9.13-5: Testing costs (based on Matrix Study and further internal communication with developers and applicants of the tests) and ratio of applied alternative information to derive normalised testing cost (based on Article 117(3) ECHA report and default internal assumptions where data not available)

REACH Information requirements as specified in Annex VI - X (IUCLID codes)	**Minimum Cost**	**Maximum Cost**	**Probability for alternative Opt 2-4***	**Toxico kinetic factor****
v 011 - Spectral data	150	6450	0%	100%
v 012 - Analytical characterization	Bespoke	Bespoke	0%	100%
v 014 - Development of analytical method	Bespoke	Bespoke	0%	100%
v 5.02 - Melting point	100	850	33%	100%
v 5.04 - Relative density	750	750	33%	100%
v 5.05 - Vapour pressure	3780	3780	33%	100%
v 5.06 - Surface tension	1900	1900	33%	100%
v 5.07 - Water solubility	4930	4930	33%	100%
v 5.08 - Partition coefficient	3890	5490	33%	100%
v 5.09 - Flash-point	950	950	33%	100%

v 5.10 - Flammability	1190	1190	33%	100%
v 5.11 - Explosive properties	750	3800	33%	100%
v 5.12 - Self-ignition temperature	1620	2840	33%	100%
v 5.13 - Oxidising properties	750	3800	33%	100%
v 5.14 - Granulometry	990	3480	0%	100%
vii 5.18 - Stability in organic solvents	4930	4930	33%	100%
vii 5.19 - Dissociation constant	1260	5630	33%	100%
vii 5.20 - Viscosity	1630	1630	33%	100%
v 6.1 - In vitro skin irritation/corrosion	3233	3233	30%	100%
vi 6.1.1 - In vivo skin irritation/corrosion	1575	1575	48%	100%
v 6.2 - In vitro eye irritation/corrosion	2320	2320	29%	100%
vi 6.2.1 - In vivo eye irritation/corrosion	1573	1573	45%	100%
v 6.3 - Skin sensitisation (LLNA)	4320	4320	54%	100%
v 6.4.1 - In vitro gene mutation study (Ames test)	3377	4775	56%	105%
vi 6.4.2 - In vitro cytogenicity study in mammalian cells (CA)	17517	21550	56%	110%
vi 6.4.2 - In vitro cytogenicity study in mammalian cells (MNT)	14742	20200	56%	105%
vi 6.4.3 - In vitro gene mut. study in mammal. cells (MLA)	16440	22400	56%	105%
vi 6.4.3 - In vitro gene mut. study in mammal. cells (HPRT)	19093	21400	56%	105%
vii 6.4 - Mouse micronucleus assay	16294	20400	59%	105%
viii 6.4.4 - Furtherin vivo mutagen. study: micronucleus or UDS test (16850-34500) ; worst case: Consider TGR as preferred and most expensive option for in vivo GT	120000	120000	59%	105%
COMET ASSAY	6500	34200	59%	105%
vi 6.5.1 - Acute toxicity, oral route (rats)	1680	1680	49%	105%
vi 6.5.2 - Acute toxicity, inhalation route (rats)	8000	8000	49%	105%
vi 6.5.3 - Acute toxicity, dermal route (rats)	2380	2380	49%	105%
vi 6.6.1a - Short-term repetead dose toxicity: 28 days, oral (rats)	48000	48000	64%	105%

vi 6.6.1b - Short-term repetead dose tox.: 28 days, inhalation (rats)	50000	50000	64%	105%
vii 6.6.1c - Further short-term repetead dose tox.: 28 days, dermal (rabbit)	49615	49615	64%	105%
vii 6.6.1d - Further short-term repetead dose tox.: 28 days, inhalation	50000	50000	64%	105%
vii 6.6.2a - Sub-chronic repetead dose tox. study: 90 days, oral (rats)	101075	101075	64%	105%
Sub-chronic repeatad dose tox. study: 90 days, inhalation (rats)	108000	108000	64%	105%
viii 6.6.3 - Long-term repetead dose tox. study (longer than 12 month)	331180	331180	64%	105%
vi 6.7.1 - Screening for reproduction/developmental tox. (rats)	69590	69590	67%	105%
vi 6.7.2 - Developmental toxicity study (rats), oral gavage	86735	86735	68%	105%
vi 6.7.2 - Developmental toxicity study (rabbits), oral gavage	146450	146450	68%	105%
vii 6.7.3 - Two-generation reproduction tox. study, oral gavage/ (371095 euro)replaced by EOGRTS (	750000	750000	67%	105%
vi 6.8.1 - Assessment of toxicokinetic behaviour (no data generation)	1300	1300	0%	100%
viii 6.8.2 - Further studies on toxicity of particular concern	800000	800000	33%	105%
viii 6.9 - Carcinogenicity study (rats)	815890	815890	62%	105%
v 7.1.1 - Short-term acute toxicity study on daphnia	4348	5421	13%	100%
v 7.1.2 - Growth inhibition study on algae	5057	5057	13%	100%
v 7.1.3 - Short-term acute toxicity study on fish	5339	6072	60%	100%
v 7.1.4 - Activated sludge repiration inhibition testing	3327	5978	13%	100%
vii 7.1.5 - Long-term toxicity study on daphnia, 21 days	22595	22595	13%	100%
vii 7.1.6 - Long-term toxicity study	17232	17232	78%	100%

on fish				
vii 7.1.6.1 - Fish early-life stage (FELS) toxicity test	31646	31646	60%	100%
vii 7.1.6.2 - Fish short-term tox. test on embryo & sac-fry stages	14853	14853	60%	100%
vii 7.1.6.3 - Fish, juvenile growth test	21309	24299	60%	100%
vi 7.2.1.1 - Ready biodegradability	5809	5809	0%	100%
vii 7.2.1.2 - Simul. test. on ultimate degrad. in surface water	6974	53731	33%	100%
vii 7.2.1.3 - Soil simulation testing (for subst. adsorbing to soil)Simul. test. on ultimate degrad. in surface water	70207	70207	33%	100%
vii 7.2.1.4 - Sediment simulat. test. (for subst. asorb. to sedim.)	77612	77612	33%	100%
viii 7.2.1.5 - Further studies on confirmatory biodegradation rates	72180	72180	33%	100%
vi 7.2.2.1 - Abiotic degradation: Hydrolysis as a function of pH	6381	24711	0%	100%
vii 7.2.3 - Identification of degradation products	4500	9500	66%	100%
vi 7.2.3 - Adsorption/desorption screening study (HPLC method)	4816	5328	0%	100%
vii 7.3.2 - Bioconcentration in (one) aquatic species, preferably fish	49800	76565	87%	100%
vii 7.3.3 - Further studies on adsorption/desorption	37844	42627	0%	100%
viii 7.3.4 - Further environmental fate and behaviour studies - Aerobic transformation in soil	43693	44807	33%	100%
Transformation in aquatic sediment	26860	68010	33%	100%
Mineralisation in surface water	19680	28400	33%	100%
vii 7.4.1 - Short-term toxicity testing on earthworms	6186	6186	33%	100%
vii 7.4.2 - Effects on soil micro-organisms	11459	11459	33%	100%
vii 7.4.3 - Short-term toxicity testing on plants	13934	13934	33%	100%
viii 7.4.4 - Long-term toxicity testing on earthworms	12273	12273	33%	100%

viii 7.4.4 - Long-term toxicity testing on soil invertebrates	10928	10928	33%	100%
viii 7.4.6 - Long-term toxicity testing on plants	18922	18922	33%	100%
viii 7.5 - Long-term toxicity testing on sediment organisms	22052	22052	33%	100%
viii 7.6 - Long-term or reproductive toxicity to birds:	120880	120880	74%	100%
- Metabolism study, OECD 417	**50000**	**50000**	20%	100%
Tox of particular concern (estimate)	**100000**	**200000**	33%	100%
Dustiness	**2000**	**3000**	0%	100%
Dissolution rate in water as well as in relevant biological and environmental media	**8000*****	**32000**	0%	100%
Dispersion stability	**10000*****	**20000**	0%	100%

** Probability to apply 'alternatives' instead of testing, expressed in percentage. Listed values are used under option 1, option 2, option 4 and the preferred option. For option 5 the value is assumed to be increased (by 1.4) due to measure 33 "default presumption of validity of non-testing methods in all endpoints" while decreased (multiplied by 0.6) for option 6 due to measure 46 "…limit the potential for use of non-testing approaches for hazard and exposure where science is not consolidated".*

*** For some information requirements the possibility to use alternative methods is expected to benefit from availability of toxicokinetic information (as required by measure 51 under option 6 and the preferred option). This has been translated into a 'boost' to application of alternatives under selected information requirements (by 5%).*

**** TG for dissolution rate is still in development, exact standardised media not yet defined. Cost is based on input by industry (internal communication with Eurometaux) on the TD 29 (Transformation dissolution test on metals and metal compounds) with cost per material/media range from 2000 for 24 h test-8500 for 28 day test). Cost for the recently adopted OECD TG 318 Dispersion stability of Nanomaterials in Simulated Environmental Media has been estimated at 10000 Euro (high end) by the developing OECD party (internal communication); the higher estimate links to the fact that further development currently ongoing in OECD may include additional biologically relevant media, leading to higher cost. A conservative estimate is made that no possibility of use of information between the different nanoforms is possible for these two endpoints.*

The cost of justification when alternative methods for providing information are used (read-across, grouping) has been estimated as 300 EUR. While such cost may be considered low in particular for more complex information requirements, it should be reflected that a similar argument (e.g. ion toxicity) would then normally be recycled in more than one information requirement while costed each time.

9.13.4 Characterisation costs

Upon the Matrix calculations and the discussions with CEFIC, the characterisation costs are based on the following:

- Principal methods

Table 9.13-6: Principal methods costs (minimum and maximum)

	Minimum Cost	**Maximum Cost**

Principal methods with costs where available		
Agglomeration/aggregation	100	100
Water Solubility/ Dispersibility	4930	4930
Crystalline phase	100	100
Crystallite size	200	200
Representative Electron Microscopy (TEM) picture(s)	200	200
Particle size distribution – dry and in relevant media	100	3480
Specific surface area	100	140
Zeta potential (surface charge)	100	100
Surface chemistry, where appropriate	200	200
Pour density	100	750
Porosity	100	100
Octanol-water partition coefficient	5490	5490

- Basics

Table 9.13-7: Basics based on the cost of identified methods and associated cost calculation

	Minimum Cost	**Maximum Cost**
Characterisation per test*	2000	24000
Characterisation cost Annex VI (per form) for each registrant	9000	15000

** For some (simple) tests a standard 3.000 EUR cost was used, while for the majority the assumption is that two sample characterisations are required, i.e. once as received in a test facility and once as tested. The wide interval between minimum and maximum (set as 2 x 12.000 EUR) costs is due to the fact that while it is possible that a full set of characterisation methods is always applied (twice), it is likely that a lot of characterisation data will be 'recycled' and that the tests are accompanied by a minimum set that validates continued representativeness of the characterisation performed before and as necessary its specific delivery in the test medium.*

Annex VI characterisation cost per nanoform or set of nanoforms depends on the tonnage band and number of companies and is calculated as:

CharC = CostPerForm* # of companies in SIEF– CostGranulometry

Granulometry cost (incurred jointly as presented for the nanoforms or set of nanoforms in the joint dossier) is deducted as it is reasonably expected that the generation of characterisation information by the registrants covered this information requirement.

- Spectral information

Requirement to document nanoforms or sets of nanoforms also leads to additional costs to obtain (simple) spectral information under Annex VI per registrant (estimated at 150-6450EUR) and is calculated in a similar way:

SIDC = CostPerForm* # of companies in SIEF

- Specifics of the preferred option

For the preferred option, it is explicitly considered that more precise characterisation (beyond basic size, shape, surface area and surface) may be required and is estimated to be in the range 2-8KEUR plus 3KEUR as basic phys-chem characterisation during such test.

- Measure 44

Measure 44 requires characterisation along the path; an estimation of range of additional 10-20K multiplied by the number of grades per tonnage band is employed.

9.13.5 Adaptations, tiered approaches and administrative costs

- Adaptation

Column 2 adaptation to standard information requirements offers the possibility of waiving of the test requirement or lead to performance of another test. The table below indicates how frequent the adaptation is implemented (0-test is waived; 1-test is performed)

Table 9.13-8: Adaptation

9.3.2 Cross membranes vs phys-chem (KoW and else) in bioaccum		1
9.2.2 Abiotic degradation (solub)		0,5
9.3.1,9.3.3 Low adorption potential vs physchem	0,8	0,5
9.1.1, 9.1.3 long term rater than short trigered	0,9	0,2
9.2.1.2 Water simulation – solubility	0,85	0,5
9.5.1 Sediment org	0,75	0,5
9.1.1,9.1.2,9.1.5 algae and daphnia -solubility	0,85	0,5
9.1.3, 9.1.6 Fish-solubility	1	0,94
9.1.4 Sludge-solubility	0,9	0,6
8.6.1,8.6.2 Inhallation subchronic tox	0,8	0,18
8.6.2 Subchronic waivers -Short term no tox 90d	1	0,75
8.6.3 Very long term testing	0,02	0,01
8.6.4 Tox of particular concern (triggered in Annex X)	0,02	0,01
8.9.1 Carcinogenicity^	0,0086	0,086
9.2.1.3-4 Simulation (unlikely exposure)	0,85	0,5
9.6.1 Birds^	0,0048	0,048
M50 - increased prob. inhallation testing	0,95	0,18
8.6.1 90d instead of 28d triggered		0,2
Toxicity of particular concern (triggered in 28d or 90d)	0,030	0,015
8.7.1,8.7.3 Reproductive toxicity		0,647
8.7.2 Developmental toxicity		0,841556
9.1.6 Long term fish		0,57

** Values were mostly derived from 2015 ECHA 117(3) report. Values for nanoforms are based on internal assumptions based on most general common features (e.g. insolubility).*

^ For carcinogenicity and toxicity to birds, the statistics derived from the (mainly old) testing registered high tonnage substance was not transferred directly to nanoforms as considered unrealistic, view supported by the very low number of such additional testing triggered by REACH. Lower percentage was used.

- Genotoxicity

Estimating genotoxicity testing costs is rather difficult due to the tiered nature of the information requirement. The 2014 RPA study shows that due to the small percentage of actual CMRs, testing is driven mainly by exclusion of 'false positives'. The calculation applies same assumptions as 2014 RPA study as for normal chemicals further in vitro testing is triggered in 28% of cases, while the results of Annex VIII in vitro test will on average trigger in vivo TGR testing (assumed as worst case- in many situations much cheaper Comet assay may be appropriate as seen also in current implementation under REACH) in 65% of the cases and MNT testing in 73%. Same statistical information on false positives was adapted to assess triggering of in vivo testing in absence of reliable AMES results (52% and 73% for TGR and MNT testing, respectively).

- Some other basics:

  - Assuming 100 EUR for an hour of work, extra documentation cost was associated with additional hours that could in turn be dependent on the comprehensiveness of the dossier i.e. proportional to the tonnage band

Table 9.13-9: Administrative costs

Measure	Administrative cost (hours)*
M01	4
M03	10 (for 1-10t, and multipliers)
M09^	2
M18	1 (per test in tonnage band)
M40	2
M42	8 (for each registration)
M43	16
M44^	2 (for each grade)
M45	8 (for 1-10t, and multipliers)
M47	3 (for each grade, and multipliers)
M48	5 (for 1-10t, and multipliers)

** Hours are multiplied based on the tonnage band (e.g. 0.8 for 1-10t unhazardous phase-in and 1.2 respectively for each higher tonnage band) and by number of registrants in SIEF or number of grades as appropriate.*

^ Indicates that further costs beyond working hours are considered.

  - Measure 6 (required consideration of metrics) was assumed to be linked to 5% increase of all tests

- Inclusion of nanoform specific consideration when performing inhalation testing (impact assigned in measures 11 and 12 and Option 5) was estimated to increase the cost of the test by the factor 1.6.
- Measure 9 (information on exposure and use), beyond admin cost also extra cost per nanoform or set of nanoforms was estimated at 2 K EUR multiplied by number of companies in SIEF
- Measure 39 (new data entry) estimated by 4250-5250 EUR for 1-10t (full) with weights 0.8 and 1.2 for 1-10t (phase in) and each jump to higher tonnage bands, respectively. The split is estimated in 10% of the cases.
- PBT assessment: assumptions were used from the 2014 RPA study, with 250EUR for screening and 1KEUR for PBT assessment, with further assessment triggered in 2% of the cases, while emission characterisation is triggered in 0.4%.
- Measure 41: Estimating indirect costs on registering bulk form for substances per nanoform is made by estimation of total cost of (eco)tox information requirements under Annex VII, divided by an average number of nanoforms in the tonnage band (i.e. 4). Total indirect cost is then calculate in the same manner as other impacts, by multiplying with the number of nanoforms 'affected', i.e. 566 nanoforms under the typical assumption. When estimating testing cost for bulk form, an additional assumption is made that read-across is always possible, at an estimated proportion derived principally from ECHA 117(3) report (see table 9-9 *Testing Costs* above). While Measure 41 is considered modified in the preferred option, triggering less full (eco)tox data generation (see Appendix XII above, ratio is 0.8 compared to all nanoforms captured by option 6) estimated impact is considered the same (conservative estimate – each of the 4 forms may trigger the requirement).

9.13.6 Additional costs scenarios

9.13.6.1 Costs per nanoform without alternative information available

The assumptions concerning the possibility to use alternative methods significantly impact the costs of the different options, as shown in the table below, which provides cost estimations when it is considered that no alternative information could be used and no worst case approach could be followed. As expected, the costs are substantially higher than with alternative information available.

Table 9.13-10: Costs of options per nanoform and per tonnage band (use of alternative information not considered possible, typical cost) (in thousand Euro):

	1[a]	**1[b]**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**
>1000 tonnes	1686	169	2312	2312	2490	1078	3277
100-1000 tonnes	1246	178	1720	1720	1935	898	2561
10-100 tonnes	348	70	640	640	830	73	1189

1-10 tonnes[c]	67	17	157	157	193	17	639[d]
Weighted Average	**778**	**100**	**1115**	**1115**	**1249**	**496**	**1809**

[a] *Costs per substance regardless of the number of forms – one test performed per substance per information requirement*

[b] *To calculate and present the cost per nanoform or set of nanoforms, the costs for conducting all tests according to the measures constituting option 1 are divided by an estimated average number of nanoforms or sets of nanoforms for a substance at a given tonnage band*

[c] *Weighted average: depending on applicable conditions of Annex III to REACH, the implications differ between registrants in the 1-10 tonnage band; see assumption details above*

[d] *Estimated indirect cost of Measure 41 through registration of bulk form, per nanoform: 10,000 Euro (1.5%); see assumption details above*

9.13.6.2 Costs per registration dossier

As explained already, in reality registration is not made per nanoform but per substance. The costs of each registration dossier are case-specific and are highly influenced, among other things, by the number of nanoforms to be addressed in the registration dossier[140].

The table 9-12 below presents the additional costs of a registration dossier (with one single registrant) for one bulk form and 4 nanoforms/sets, assuming that the information on bulk form is complete and already included in the dossier.

As the dossier is now expected to include not one but 5 forms that are assumed to require separate assessment, the costs of including the 4 nanoforms in the dossier lead to increased costs compared to 'bulk only' for all options, except option 1 (as it assumes by default that already existing information on bulk is adequate, so the additional cost is zero). For the 4 nanoforms, default assumptions regarding the possibility to use alternative methods for generating information are applied.

Table 9.13-11: Additional costs to bulk per option for a registration dossier of 4 nanoforms, assuming bulk information is already available in the dossier (in thousand Euro):

	1[a]	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**
>1000 tonnes	0	4350	4350	4746	1831	8745
100-1000 tonnes	0	3170	3170	3669	1499	6857
10-100 tonnes	0	1403	1403	1850	159	3444
1-10 tonnes (Full Annex VII)	0	714	714	962	78	1831
1-10 tonnes (Only Phys-chem)[b]	0	315	315	332	37	1831[c]

[a] *Costs per substance regardless of the number of forms – one test performed per substance per information requirement*

[140] Please refer to Appendix XIII (*9.13.7 Additional illustrative cases*) for examples on how the costs may develop depending on different scenarios.

[b] *For the 1-10 tonnage band tox/ecotox testing is required only for phase-in substances that fulfil the Annex III conditions; therefore, for most substances no information requirements beyond physico-chemical properties are requested, apart from option 6 (due to measure 41)*

[c] *Estimated additional indirect cost of Measure 41 through registration of bulk form: 41.000 Euro (+2%); see assumption details above*

Costs are extremely sensitive to the ability to identify relevant information prior to resort to additional testing. As in this prototype example it is already assumed that the full dataset on the bulk form of the same substance is already available, it is very likely/expected that the default assumptions are overly conservative. Assuming that for every endpoint 'the worst case' form can be identified (which is then the only one to be tested), and that in half of the situations the bulk form is the worst case so data is already available (see also note c in table below), the estimation for additional registration cost for the 4 extra nanoforms would be as set out in the table below.

Table 9.13-12: Additional costs to bulk per option for a registration dossier of 4 nanoforms, assuming bulk information is already available in the dossier and assuming that worst case approach can be fully applied and such data (i.e. from bulk) available in 50% of the cases (in thousand Euro).

	1[a]	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**
>1000 tonnes	0	1554	1554	1652	669	2238
100-1000 tonnes	0	1195	1195	1312	549	1747
10-100 tonnes	0	509	509	616	79	868
1-10 tonnes (Full Annex VII)	0	251	251	316	36	492
1-10 tonnes (Only Phys-chem)[b]	0	136	136	145	19	492[c]

[a] *Costs per substance regardless of the number of forms – one test performed per substance per information requirement*

[b] *For the 1-10 tonnage band tox/ecotox testing is required only for phase-in substances that fulfil the Annex III conditions; therefore, for most substances no information requirements beyond physico-chemical properties are requested, apart from option 6 (due to measure 41)*

[c] *Estimated additional indirect cost of measure 41 through registration of bulk form: 41.000 Euro (+8.3%); see assumption details above*

Costs include characterisation of 4 nanoforms, additional one test per information requirement in half of the cases and justifications documenting relevance of the existing or newly generated information to all 4 nanoforms.

9.13.7 Additional costs scenarios including the preferred option

9.13.7.1 Registration cost per company (registrant), per nanoform

Table 9.13-13: Costs per company, with the preferred option (per tonnage band, use of alternative information methods possible) (in thousand Euro):

	1[a]	**1**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**	**Preferred (Mix)**

>1000 tonnes	110	11	165	165	179	65	322	176
100-1000 tonnes	179	26	271	271	313	125	579	300
10-100 tonnes	102	20	199	199	262	22	483	229
1-10 tonnes	27	7	64	64	76	7	259[b]	89[c]
Weighted Average	**96**	**14**	**159**	**159**	**185**	**53**	**386**	**182**

[a] *The column represents the cost for a substance with one (bulk) form, which can be directly compared with the majority of REACH registration cost assessments for substances, as the usual assumption in those calculations is that one test is performed per substance per information requirement*

[b] *Estimated additional indirect cost of Measure 41 through registration of bulk form, per company with present obligation in phys-chem only: 6.000 Euro (+2.1%); see assumption details above*

[c] *Estimated additional indirect cost of Measure 41 through registration of bulk form, per company with present obligation in phys-chem only: 6.000 Euro (+6.7%); see assumption details above*

9.13.7.2 Preferred option - sensitivity to assumptions

As mentioned above, the costs are highly sensitive to assumptions concerning key cost elements and these uncertainties equally apply to the cost calculations for the preferred option. The two following tables provide some sensitivity analysis for the preferred option[141].

The table below illustrates different ranges of costs of registration per nanoform, depending on whether alternatives to testing exist or not and on different assumptions on the cost of testing.

Table 9.13-14: Costs per nanoform for the preferred option under different assumptions (in thousand Euro):

	No alternative, typical test cost	**Default alternatives, typical test cost**	**High alternative assumption, typical test cost**	**Default alternative assumption, low testing cost**	**Default alternative assumption, high testing cost**
>1000 tonnes	2515	1234	633	989	1479
100-1000 tonnes	1924	901	464	712	1090
10-100 tonnes	756	413	202	286	540
1-10 tonnes (Full Annex VII)	377	235	103	163	307
1-10 tonnes (Only Phys-chem)[b]	184	128	62	104	152
1-10 tonnes[a]	240	159	74	121	197
Weighted Average	**1261**	**628**	**319**	**493**	**764**

[a] *Weighted average*

[b] *Estimated additional indirect cost of Measure 41 through registration of bulk form, per nanoform: 10,000 Euro (+5.5%; +7.8%; +16.1%; +9.6%; +6.6% respectively); see assumption details above*

The table below shows how the figures for the Grand Total costs vary in function of assumptions on the existence of alternatives and on the number of nanoforms.

[141] Please refer to Annex XVI for sensitivity analysis addressing these uncertainties.

Table 9.13-15: Grand total registration costs for the preferred option under different assumptions (in million Euro):

	High alternative assumption, minimum number of nanoforms	Default alternative assumption, minimum number of nanoforms	Default alternative assumption, typical number of nanoforms	Default alternative assumption, maximum number of nanoforms	Default alternative assumption, inverted assumption on substances/ tonnages based on FR notification results[b]
>1000 tonnes	146	284	568	1135	1481
100-1000 tonnes	128	249	498	997	757
10-100 tonnes	25	52	103	206	165
1-10 tonnes (Full Annex VII)	12	27	55	110	53
1-10 tonnes (Only P-chem)[c]	18	36	73	145	12
1-10 tonnes[a]	30	64	127	255	51
Total[d]	**329**	**648**	**1297**	**2593**	**2468**

[a] *Weighted average*

[b] *See section 9.16.2 in Appendix XVI for details on the assumptions based on results from FR nanomaterial notification scheme*

[c] *Estimated additional indirect cost of Measure 41 through registration of bulk form, grand total: (2.92 M Euro, 5.83M Euro, 11.7 M Euro for minimum, typical and high number of nanoforms, respectively) and 2.34M Euro under FR registry assumption. In relative terms, the additional contribution is (+16.2%; +8.1%; +8%; +8%; +19.5% respectively); see assumption details above*

[d] *Estimated additional indirect cost of Measure 41 through registration of bulk form, per nanoform: 5.83M Euro and 2.34M Euro under FR registry assumption (+0.8%; +0.4%%; +0.4%; +0.4%; 0.1% respectively); see assumption details above*

9.13.8 Additional illustrative cases

The tables below illustrate different scenarios for calculating the cost of a registration dossier of a substance depending on the number of nanoforms / set of nanoforms that need to be addressed and whether or not alternative information is considered possible. For convenience, Table 5-1 presented already in section 5.2.1.2 *Costs calculations* of the main text and the table from section 9.13.6 *Additional costs scenarios* above are reproduced as starting information for the estimation of costs for a few illustrative cases later in the text.

*Table 9.13-16: **Registration costs of options per nanoform** and per tonnage band (use of alternative information considered possible, typical cost) (in thousand Euro):*

	1*	1**	2	3	4 (including 2)	5	6 (including 2 and 4)
>1000 tonnes	772	77	1157	1157	1256	458	2256
100-1000 tonnes	538	77	814	814	939	375	1736
10-100 tonnes	183	37	359	359	471	40	869

1-10 tonnes (full)	78	20	187	187	249	20	466
1-10 tonnes (Annex III)	37	9	87	87	91	9	466***
1-10 tonnes (w.av.)	49	12	116	116	137	12	466
Weighted Average	358	**47**	**565**	565	**642**	**212**	**1254**

** Costs per substance with one form (bulk) - one test performed per substance per information requirement. The column represents cost for bulk form, which can be directly compared with the majority of REACH cost assessments for substances, as the usual assumption in those calculations is that one test is performed per substance per information requirement*

***To calculate and present the cost per nanoform or set of similar nanoforms, the costs for conducting all tests according to the measures constituting Option 1 is divided by an estimated average number of nanoforms or sets of nanoforms for a substance at a given tonnage band*

**** Indirect impact of measure 41 on registration of bulk form may bring estimated additional cost of 10,000 Euro per nanoform of substance otherwise benefiting from Annex III exemption. Relative additional contribution: +2%; more details on assumptions above*

In case that no alternative information can be used when registering a substance with nanoform(s) and a full set of tests is required, the costs are substantially higher:

*Table 9.13-17: **Registration costs of options per nanoform** and per tonnage band (**use of alternative information not considered possible, typical cost**) (in thousand Euro):*

	1*	**1****	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**
>1000 tonnes	1686	169	2312	2312	2490	1078	3277
100-1000 tonnes	1246	178	1720	1720	1935	898	2561
10-100 tonnes	348	70	640	640	830	73	1189
1-10 tonnes (full)	120	30	280	280	391	30	639
1-10 tonnes (Annex III)	45	11	106	106	111	11	639*
1-10 tonnes (w.av.)	67	17	157	157	193	17	639
Weighted Average	778	**100**	**1115**	1115	**1249**	**496**	**1809**

*For * and **, see footnotes of table 9-17 above*

**** Indirect impact of measure 41 on registration of bulk form may bring estimated additional cost of 10,000 Euro per nanoform of substance otherwise benefiting from Annex III exemption. Relative additional contribution: +1.5%; more details on assumptions above*

The difference between option 1 and e.g. option 2 in the above tables comes primarily from the assumption that under option 1, the testing cost is divided between all forms of the substance registered (e.g. for tonnages >1000 tonnes it is assumed that there are 10 nanoforms or sets per substance, see 9.13.3 above). But as can be observed from the difference between 1* and 2, there are additional costs caused by some measures under option 2, the main drivers

being characterisation costs for identification of nanoforms and when testing nanoforms. The two tables below include additional rows that indicate the difference in cost and impact of individual options on low tonnage dossiers, depending on the applicability of conditions of Annex III of REACH. It is evident that the relative impacts are largest for options that include measures requiring generation of tox/ecotox data also for the substances that are generally required to document only physico-chemical hazards.

Several **illustrative cases** estimating cost of specific registration dossiers (registration fee not included) are presented below. For completeness, the proposed preferred option is also included. The tables are followed by comments that explain how the unit cost "per nanoform/set" from the first table can be used to estimate the cost for an individual case.

9.13.8.1 Registration of substance with bulk form and one nanoform/set (default assumptions), one registrant (in thousand Euros)

Table 9.13-18: Registration of bulk form and one nanoform (default assumptions).

	1	2	3	4 (including 2)	5	6 (including 2 and 4)	Preferred
>1000 tonnes	772	1860	1860	1959	1230	2959	**1937**
100-1000 tonnes	538	1331	1331	1456	913	2253	**1418**
10-100 tonnes	183	534	534	645	223	1044	**587**
1-10 tonnes (Full Annex VII)	78	257	257	319	98	536	**305**
1-10 tonnes (Only Phys-chem)	37	116	116	120	46	495[a]	**157[a]**

[a] *Indirect impact of measure 41 on registration of bulk form may bring estimated additional cost of 22,900 Euro per substance per company otherwise benefiting from Annex III exemption. Relative additional contribution in option 6 is +4.6% and for the preferred option 14.6%; more details on assumptions above*

If one disregards the costs for bulk (e.g. interested only in the additional cost for an existing dossier where bulk and 1 nanoform/set are registered but at present the dossier documented only bulk), the costs in options 2, 4, 6 and preferred are effectively the costs per nanoform under default assumptions (see above table), together with the impact of measure 41 when applied.

9.13.8.2 Registration of substance with bulk from and one nanoform/set (existing data can however not be applied, complete testing battery needed for the nanoform/set), one registrant (in thousand Euro)

Table 9.13-19: Registration of bulk form and one nanoform (existing data cannot be applied).

	1*	2	3	4 (including 2)	5	6 (including 2 and 4)	Preferred
>1000 tonnes	1686	3929	3929	4107	2765	4893	**4132**
100-1000 tonnes	1246	2944	2944	3159	2143	3785	**3147**
10-100 tonnes	348	980	980	1170	421	1529	**1095**
1-10 tonnes (Full Annex VII)	120	392	392	503	151	751	**488**
1-10 tonnes (Only Phys-chem)	45	142	142	147	56	675[a]	**220[a]**

**For illustration purposes, here the cost for the bulk is also presented without application of any adaptation; full test battery is assumed*

[a] *Indirect impact of measure 41 on registration of bulk form may bring estimated additional cost of 22,900 Euro per substance per company otherwise benefiting from Annex III exemption. Relative additional contribution in option 6 is +3.4% and for the preferred option 10.4%; more details on assumptions above*

As no existing information (either for this or another substance) can be justified as being relevant for the nanoform/set, the cost in addition to the cost for bulk is effectively the cost per nanoforms of the table above, together with the impact of measure 41 when applied.

An analogue approach is taken to estimate cost for a dossier with multiple nanoforms – such prototype dossier cost estimation is presented already in the main text under section 5.2.1.2:

9.13.8.3 Registration of substance with 4 nanoform/sets (default assumptions), one registrant (in thousand Euro)

Table 9.13-20: Registration of substance with 4 nanoforms (default assumptions, 1 registrant)

	1*	2	3	4 (including 2)	5	6 (including 2 and 4)	Preferred[b]
>1000 tonnes	1686	4350	4350	4746	1831	8745	**4659**
100-1000 tonnes	1246	3170	3170	3669	1499	6857	**3517**
10-100 tonnes	348	1403	1403	1850	159	3444	**1618**
1-10 tonnes (Full Annex VII)	120	714	714	962	78	1831	**908**
1-10 tonnes (Only Phys-chem)	45	315	315	332	37	1831[a]	**479[a]**

** For illustration purposes, the cost is presented without application of any adaptation; one full test battery is assumed*

[a] *Indirect impact of measure 41 on registration of bulk form may bring estimated additional cost of 22,900 Euro per substance per company otherwise benefiting from Annex III exemption. Relative additional contribution in option 6 is +1.2% and for the preferred option 4.8%; more details on assumptions above*

[b] *Estimation for initial Commission proposal, uncorrected.*

The cost is effectively 4 times the cost indicated in table above 'cost per nanoforms under default assumptions' – options 1 and partly 5 reflect the fact that nano-specificity is not required, and their costs reflect testing for 1 form only. Indirect impact of measure 41 should also be considered, with similar relative contributions.

9.13.8.4 Registration of substance with 4 nanoform/sets

Assumed that worst case approach is applicable (only 1 data set needed), and that in 50% of the cases bulk form, for which data is already available, represents worst case. One registrant (in thousand Euro)

Table 9.13-21: Registration of substance with 4 nanoforms (worst case approach)

	1*	2	3	4 (including 2)	5	6 (including 2 and 4)	Preferred[b]
>1000 tonnes	1686	1557	1557	1655	669	2242	**1763**

100-1000 tonnes	1246	1197	1197	1315	549	1750	**1392**
10-100 tonnes	348	511	511	618	79	870	**641**
1-10 tonnes (Full Annex VII)	120	253	253	317	36	494	**308**
1-10 tonnes (Only P-chem)	45	138	138	147	19	494[a]	**182[a]**

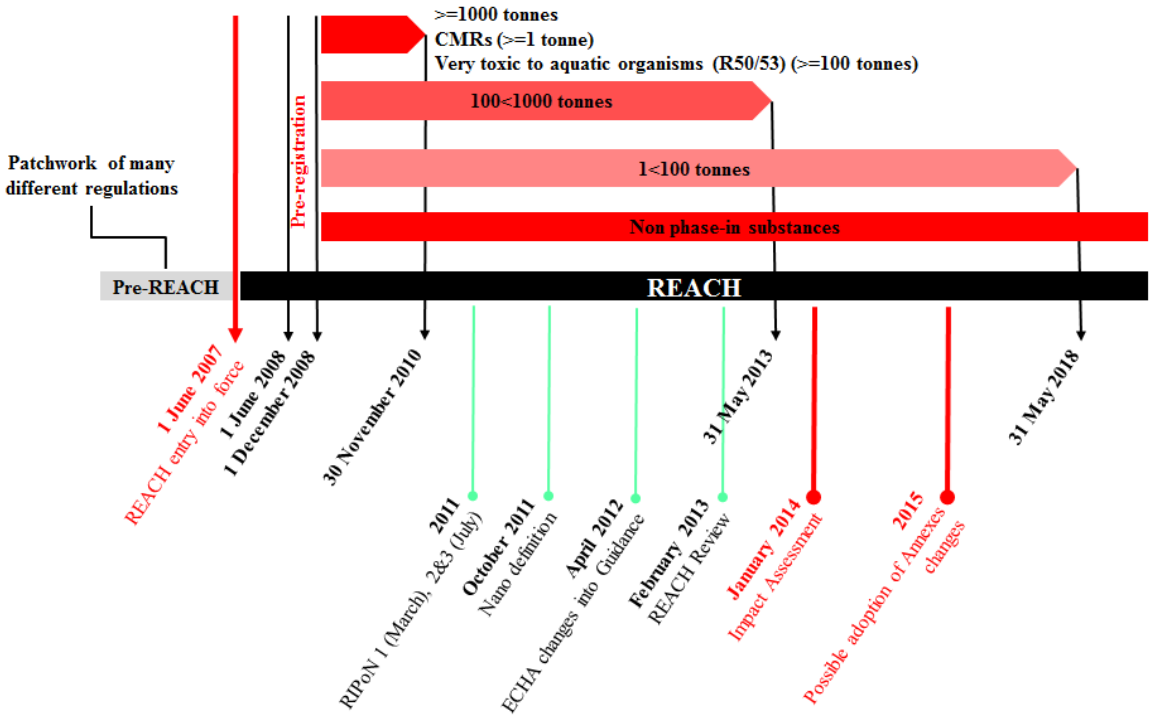
** See footnote at table above*

[a] *Indirect impact of measure 41 on registration of bulk form may bring estimated additional cost of 22,900 Euro per substance per company otherwise benefiting from Annex III exemption. Relative additional contribution in option 6 is +4.6% and for the preferred option 12.6%; more details on assumptions above*

[b] *Estimation for initial Commission proposal, uncorrected.*

While under option 1 the estimation of cost does not differ e.g. from the case c) above, as only 1 dataset is considered adequate, the cost of the other options include characterisation and justification costs, and in 50% of cases generation of data for one test material (worst case). This demonstrates how strongly the assumption on the availability of alternative to testing affects the result.

9.14 APPENDIX XIV: REACH in brief



9.14.1 REACH

REACH entered into force on 1 June 2007. The concepts of phase-in and non phase-in substances are introduced in order to distinguish between substances manufactured or placed on the market before and after REACH's entry into force[142].

REACH introduced a harmonised set of rules for the management of chemicals in the EU with the two key most striking changes to the past system being 1) the reversal of the burden of proof i.e. under REACH producers must demonstrate safety before producing or placing on the market and 2) identical requirements to new and old substances. The latter was introduced to tackle the huge volume of legacy substances, for which little knowledge was available, as well as to stimulate innovation due to much less stringent rules for new substances. Several instruments, e.g. exemptions for research and tiered information requirements, should further foster innovation.

REACH establishes procedures for collecting and assessing information on the properties and hazards of substances. Manufacturers and importers need to register their substances in order to access the EU market. The European Chemicals Agency (ECHA) is the responsible organization for the reception and evaluation of individual registrations for their compliance, whereas the EU Member States evaluate selected substances to clarify concerns for human health or for the environment. Authorities and ECHA's scientific committees assess whether the risks of hazardous substances can be adequatly managed. Authorities can ban hazardous substances if their risks are unmanageable. They can also propose to restrict a use or make it subject to a prior authorisation.

[142] For further details on *phase-in* and *non phase-in* substances, refer to the Glossary

9.14.2 The Registration process

This Impact Assessment exercice relates to the Registration process. Registration is one of the REACH Regulation's core mechanisms delivering on the reversed burden of proof. The registration obligation seeks to address the concerns pre-REACH[143] regarding the lack of information for 99% of the volume of chemicals on the market in the EU. In general, it requires companies to register all substances manufactured or imported in quantities of one tonne or more per year per manufacturer/importer. Failure to register would result in a manufacturer or importer being unable to legally manufacture or/and import or place their substance on the EU internal market.

REACH sets three distinct registration deadlines:

1. 30 November 2010: substances manufactured or imported at 1.000 tonnes or more per year[144], carcinogenic, mutagenic or toxic to reproduction substances above 1 tonne per year, and substances dangerous to aquatic organisms or the environment above 100 tonnes per year;
2. 31 May 2013: substances manufactured or imported at 100-1.000[145] tonnes per year;
3. 31 May 2018: substances manufactured or imported at 1-100[146] tonnes per year.

A registration dossier should demonstrate that the risks through the lifecycle of a substance are controlled. The amount of information required for registration is depending on tonnage and it increases along with the volume of the substance manufactured and/or imported. Manufacturers and importers are required to submit a technical dossier for substances registered in quantities of one tonne or more per year per legal entity. The technical dossier contains information on the physicochemical, toxicological and ecotoxicological properties, on the uses and on the classification of a substance as well as guidance on safe use. For substances registered at quantities of 10 tonnes or more per year, a chemical safety assessment (CSA) also needs to be conducted and documented in a chemical safety report (CSR) which accompanies the technical dossier.

Different forms of a substance can be considered within a single registration. **G**enerally the term 'form' can be understood to identify the state of a substance e.g. granular, lamellar, sheets, but is usually (and in this document) applied more widely to allow differentiation when one or more intrinsic physico-chemical properties (i.e. characterisers) differ. Form would therefore include bulk(solid) in different crystalline forms, different powders etc. Forms may differ based on the differences in the values of these characterisers. A form fulfiling the nano-definition is called nanoform. There is a defined minimum list of characterisers of a nanoform, included by the proposal as new information requirement in Section 2.4. of the Annex VI of REACH, that enable characterisation of (and differentiation between) nanoforms. The list includes: particle size distribution, description of surface functionalisation or treatment, particle shape, aspect ratio and other morphological characterisation, and surface area. Substance may be in many forms, include multiple

[143] White Paper for the Strategy for a future Chemicals Policy, Commission of the European Communities, 27 February 2001: http://eur-lex.europa.eu/LexUriServ/site/en/com/2001/com2001_0088en01.pdf

[144] Referred to in REACH Annex X: Standard information requirements for substances manufactured or imported in quantities of 1.000 tonnes or more

[145] Referred to in REACH Annex IX: Standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more

[146] Referred to in REACH Annexes VIII and VII: Standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more and 1 tonne or more, respectively

nanoforms. For example, depending on the difference in particle number size distribution or particle shape, the same substance may exist in several different nanoforms. A particular form may change during its life cycle; for nanoforms, the change in state of aggregation/agglomeration is most frequently encountered. As different nanoforms may exhibit very similar behaviour – a proposition that needs to be adequately justified – identified **sets of similar nanoforms** may be approached jointly using same documentation requirements.

9.15 APPENDIX XV: Procedural information

9.15.1 Procedural issues and consultation of interested parties

The IA has been undertaken by DG ENV in co-responsibility with DG GROW.

Preparatory work for the IA started immediately upon adoption of the Nano Communication in October 2012. An IASG was then established. Its inaugural meeting took place on 16 January 2013 with the participation of SG, MARKT (now part of GROW), JRC, RTD, SANTE and TRADE.

A public consultation was carried out for 12 weeks (from 21 June to 13 September 2013), which resulted in inputs from 142 respondents. The Commission's minimum standards for consultation have been met. The consultation focused on the options assessed in this report with a view to get feedback to the proposed detailed measures in each option. The inputs of the consultation are reflected in the analytical part of this Impact Assessment. The results highlighted the fact that currently there is a problem in the way REACH obligations address and safety is demonstrated for nanoforms of a substance in the registration dossiers[147]. The majority of industry and private companies preferred reduced information requirements and thus lower associated cost, while governments, academic/research institutions, NGOs and consumer organisations favoured more extended requirements. Please refer to Appendix V for a summary of the results of the public consultation.

In addition to the public internet consultation, three meetings with the Competent Authorities for the implementation of REACH as well as stakeholders have been held in 2013-14 (CASGNano on 15 April and 24 October 2013 and on 12 May 2014) with a view to discuss progress of the work and to gather data and information to improve the evidence base.

Additional information necessary to assess the policy options has been gathered through two studies prepared by external consultants - BiPRO[148] (covering certain measures in options 2 and 4 of this impact assessment) and Matrix (covering all measures included in this impact assessment).

9.15.2 Consultation of the Regulatory Scrutiny Board

The Impact Assessment Report was examined by the Regulatory Scrutiny Board on 3 February 2016. The Board gave a negative opinion to the report due to a number of shortcomings that required improvement.

The following table briefly explains how the Board's recommendations have led to changes compared to the earlier draft.

[147] 86% of the respondents answered that the requirements of REACH for nanomaterials within the registration process are unclear or very unclear.

[148] Examination and assessment of consequences for industry, consumers, human health and the environment of possible options for changing the REACH requirements for nanomaterials, BiPRO, 14 January 2013 http://ec.europa.eu/environment/chemicals/nanotech/pdf/Final_Report.pdf

Table 9.15-1: Response to Regulatory Scrutiny Board recommendations

Main recommendations for improvement from the Board	**Implementation of the recommendations into the revised IA Report**
Procedure and presentation	
a. The consistency between this initiative and the one on transparency of nanomaterials should be fully ensured in the presentation of the policy context, the overarching problems, the policy objectives and the baseline scenario. b. If merging the two IA reports into one is not possible, 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	Complete redrafting of section 1 with the insertion of a common chapeau in both reports Creation of a separate section 1.6 on the IA on transparency measures. 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
c. Avoid technical language to make the report more accessible to the non-expert reader	Technical language avoided as far as possible. Insertion of illustrative figures in several parts of the report to better convey the messages.
d. Presentation to be improved	The presentation has been modified in order to improve the readability.
e. Report to be shortened	Explanations on the calculations moved to Appendix XIII.
1. Clarify the broader context	
a. Outline upfront the global issues relating to nanomaterials	The explanation of the global issues is included in section 1, under the common chapeau which also applies for the report on transparency for nanomaterials.
b. Clarify what scientific evidence is available on characteristics of nanomaterials, including their potential health and environmental implications	General overview is provided in the common chapeau including chapter 1.3 that outlines some of the characteristics and related scientific evidence.
c. Systemic description of how information on nanomaterials is generated and acted upon and where the shortcomings are	Substances with nanoforms (i.e. nanomaterials) are chemicals as any other; information is generated according to REACH requirements, explained in more detail in Annex XIV. Shortcomings are addressed by further clarification in the problem definition section.
d. Existing policy framework and how it relates to the initiative on transparency measures	Creation of a new section 1.6 specific to the transparency measures report where the differences between the two initiatives are explained.
e. Clarify the sequencing and link with the revision of the definition of nanomaterials, the outcome of the ECHA Board of Appeal and the CLP	Clarification of the presumable impact of the revision of the nanomaterial definition on section 2.2.3. Impact of the Board of Appeal decision is addressed by further narrative in section 4.9. Relation of REACH and CLP is clarified in the chapeau, while

	more details on the impact of CLP have been included in subsection 5.6.
2. Improve the problem definition and develop a robust baseline scenario	
a. Specify the particular problem(s) this initiative aims to address	"Lack of clarity" replaced by "Nanoforms of substances not properly addressed and safety demonstrated by REACH" throughout the text. The problems this initiative aims to address are included in section 2; the explanations are underpinned by a graphical illustration.
b. Illustrate, with examples, why the nanoform has substantially different characteristics than other forms of the same chemical, and when or where it may pose a different risk for health and the environment	Under section 2.3 "underlying causes of the problem", several nanoform characterisers are listed with specific references showing how reviews (each comprising a large number of scientific articles with compiled scientific evidence) brought conclusions on (nano)material properties and related classification/risk management dependent on the characterisers.
c. Clarify what proportion of nanomaterials on the market would be covered by the amendment of REACH annexes given the one tonne threshold	Inclusion of a new section 2.2.2 on the size of the market.
d. As part of the baseline scenario, clarify what information can be obtained within the existing REACH requirements and how the outcome of the ECHA Board of Appeal will affect it	Insertion in section 4.1 of a figure illustrating the evolution in the no-change scenario. Creation of a specific section 4.8 explaining the baseline. Insertion of a figure and a narrative in section 5.7.7 illustrating how the no-change scenario would be affected by the Board of Appeal's opinions.
e. Explain how the situation would evolve in terms of market size for nanomaterials, as well as health and environmental implications, assuming a no-policy change scenario	Health and environment implications of no-change scenario are addressed in the text. The relation between the size of market and the problem is, to the extent possible, captured in section 2.2.2.
3. Clarify the policy options	
a. Clarify the content of policy options and simplify their presentation and explain the underlying logic in combining the different measures into policy options	Clarifications included in the description of the options of the purposes and content of each of them. Insertion of a figure illustrating the differences between the options and the current REACH requirements according to ECHA's interpretation (section 4.2). Insertion of a graphical illustration of the differences between the options in section 4.7.
b. Explain why the lowering of the threshold for nanomaterials (i.e. below one tonne) was discarded as an option	Clarification added in the introduction of section 4 explaining that modification of thresholds is not within the legal limitations of this exercise because it could not be achieved through modification of the REACH Annexes but would require modifying the

	enacting terms of the Regulation.
4. Improve the analysis of impacts	
a. Better demonstrate the cost-effectiveness of the different measures, in particular when comparing costs in relation to the total market value of the nanomaterials	The description of the effectiveness and the efficiency of each of the measures has been enhanced in section 6 and a table has been included in Appendix I showing how each of the measures addresses the underlying causes of the problem. Cost-effectiveness of different options can be compared between each other (see section 6). Large uncertainties in estimates of total size of the market impacted by proper functioning of REACH for nanomaterials, together with complex correlation with assumptions (e.g. number of nanoforms, in which tonnage bands, role of 'old nanomaterials' with already existing data in present market valuation etc.) would however make comparison in absolute terms highly speculative and potentially misleading, so it is not attempted. Proportionality in comparison to chemicals in general, and then relation to general cost-effectiveness of REACH is a better marker.
b. Better explain differences between options 2 and 3	Clarifications in the narrative and graphs have been provided to illustrate the differences between options 2 and 3.
c. Further elaborate on the impacts on SMEs and any mitigation measures envisaged	Creation of a specific section on SMEs in section 5.2 Economic impacts where all the comments on SMEs are gathered. Inclusion of a qualitative appreciation of how REACH addresses SMEs (6.1).
d. Better explain the choice of the preferred option	Further clarification how options are constructed from individual measures that were individually assessed for effectiveness and efficiency (incl. cost). Insertion of a graphical illustration of how the preferred option is built and how it compares to the other options in section 6.2.
5. Clarify monitoring and evaluation arrangements	
a. Present the key indicators that will be used to measure the success of the chosen policy-mix	Insertion of clarifications in section 7.

The revised Impact Assessment Report was resubmitted with the above mentioned modifications and, on 14 September 2016, the Regulatory Scrutiny Board provided its positive opinion, with a number of recommendations for improvement, which have been addressed on the following manner:

Main recommendations for improvement from the Board	**Implementation of the recommendations into the final IA Report**
	The description of the individual options has been further improved in chapter 4, with clarifications and

1. Further clarify the policy options. The report should better explain the underlying logic of the policy options. It should show on the basis of which criteria the various policy measures have been screened and selected to be included into the policy options. In this context, the relevance of option 3 needs to be clarified (option 3 is identical to option 2 if the Board of Appeal confirms ECHA's interpretation while option 3 is not viable in case of rejection of this interpretation, see page 24 of the report). Moreover, the choice of policy measures to be included in the preferred option needs to be better explained.	insertions along the text, fine tuning of the graphs and inclusion of an explanatory table in section 4.7. The particularities of option 3 have been better explained in the description of the option part (chapter 4) and on the assessment of the impacts, in terms of compliance costs, certainty, health impacts and environmental impacts (chapter 5). The choice of the policy measures has been elaborated by explaining a 3-step decision process leading to the preferred option, emphasising the importance of the effectiveness and the efficiency of each of the measures; explanations have been underpinned by illustrative tables and graphs in chapter 6 and Appendix XII.
2. Improve the analysis of impacts. The report should better demonstrate how the policy options compare with regard to their cost-effectiveness, i.e. explain how, in the absence of quantitative benefit estimates and the presence of uncertain cost estimates, the trade-off between benefits and costs was made in order to identify the most efficient policy option. Moreover, the baseline should be used in a consistent way throughout the report and its tables.	The report now explicitly explains how the policy options compare in terms of their cost-effectiveness (chapter 6). The inclusion of the explanations about the 3-step process allows strengthening the appropriateness of the measures within the preferred option. It has been ensured that the baseline is addressed in a consistent way throughout the report and that the uncertainties related to the decision of the Board of Appeal, which may have an effect on the baseline, are clearly underlined and highlighted.
3. Consistency with the impact assessment on 'transparency measures for nanomaterials on the market'	Consistency with the other impact assessment has been maintained by introducing the same changes to the common chapter (chapter 1).

9.15.3 Update of the information following the discussions and partial modification of the Commission proposal in the REACH Committee

The Impact Assessment Report has been finalized addressing the Recommendations of the Regulatory Scrutiny Board (see 9.15.2 above), passing the inter-service consultation along the Commission proposal in October 2017.

Based on the discussions with the Member states in the Committee under the Regulation 1907/2006 (the REACH Committee), the Commission modified several elements of its proposal that was eventually voted upon and unanimously approved in the REACH Committee on 26 April 2018. There were numerous changes to the legal text in several Annexes of the proposal. Most changes are improving the clarity of the text but do not affect the scope or content of the provisions, nor would they change the estimated impact. Nevertheless, some changes may increase the costs and the benefits. The impact of these changes, as well as some relevant legislative developments during that time, have been assessed and discussed with the Member States prior to the vote. The assessment is presented below together with reference to some relevant developments. This assessment supersedes the information provided in the main text and the sensitivity analysis in Annex XVI but doesn’t change the outcome of the performed assessment. The individual changes are presented in the

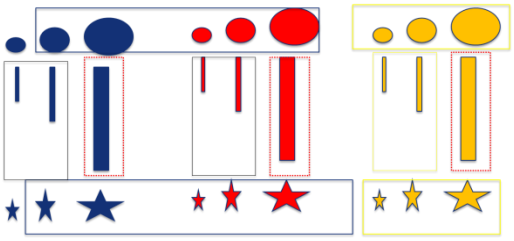
table below. The main changes and the estimated impacts on costs have also already been included in the main tables in Section 6. The changes include also the revisit of an assumption and eliminate minor calculation errors identified during the review[114].

The table with estimated animal use for all options as well as the initial and final Commission proposals is also attached for transparency. The sensitivity analysis, of which none of the outcomes is qualitatively altered by the changes, is not repeated.

Relevant complementary information	
Subject	**Content, reference in the main text**
Statistical information regarding REACH implementation	Number of registration dossiers explicitly indicating nanomaterials is a constantly moving target. In March 2018, the total number of registered substances with nanoforms was 21, compared to 13 in August 2015. (Chapter 2.2.1, p.14).
Initiatives undertaken (Chapter 2.2.3)	In addition to the 2013 ECHA Guidance updates mentioned in the text (p.17), ECHA in May 2017 updated the Appendices to Guidance on Information Requirements and Chemical Safety Assessment (IR & CSA), together with the further Appendix on Grouping and Read-across for nanoforms, and published the Practical guide "How to prepare registration dossiers that cover nanoforms: best practices". In February 2017, ECHA updated the mandate of NMWG, including also the implementation of Biocidal Product Regulation and renamed the working group into "Nanomaterials Expert Group (NMEG) (p.17) ECHA Board of Appeal Decisions on appeals against ECHA evaluation decisions addressing nanomaterials listed in footnote 50 (p.18) have been complemented by further two decisions on appeals A-014-2015 and A-0015-2015, addressing substance evaluation of silicon dioxide. BoA decisions partially annulled the substance evaluation decision, supporting some but not all of the requested testing, with the principal arguments that a) concern was not demonstrated for all types of

	silica; b) the request was in parts disproportionate and c) there was lack of clarity in the use of the term 'SAS form'. Unlike the BoA decision A-11-2014 already referred to in the main text, these decisions did not further influence the baseline applied as described in the Chapter 4.8. Further adjustments of the OECD Test Guidelines (TGs) are currently being discussed by the OECD Working Party on Manufactured Nanomaterials (WPMN). Three test guidelines that specifically address nanomaterials have been published by the OECD, two new TGs specifically addressing nanomaterials are under development in the OECD Test Guidelines Programme (TGP), and two have been proposed to the TGP for development[149]. Furthermore, several test guidelines are developed in the WPMN. Additionally, several OECD guidance documents have also been proposed as a way of addressing the regulatory testing of nanomaterials. The last state of development in March 2018, including information on costs where available, has been taken into account during the finalization of the Commission proposal in the REACH Committee.
Terminology: set of similar nanoforms	The concept of set of nanoforms has been extensively discussed in the REACH Committee and eventually kept in the proposal. While the concept (and associated impacts evaluated in this report) has remained as in the original proposal, the term 'set of similar nanoforms' is now consistently used instead. As part of the discussion, the following clarification has been presented to the REACH Committee on the nanoforms and

[149] Published: TG318 (Dispersion stability of nanomaterials in Simulated Environmental Media), TG412 and TG413 on subchronic inhalation toxicity. In preparation: TG on particle size and size distribution of Manufactured Nanomaterials, TG on the Determination of (Volume) Specific Surface Area (V)SSA of Manufactured Nanomaterials. See also programme of WPMN on http://www.oecd.org/science/nanosafety/.

	sets of nanoforms: *The symbols below represent a hypothetical substance that exists in a number of different nanoforms (potential bulk forms are not presented). Each symbol stands for an individual nanoform, and its colour, size and shape depict characterisation of the nanoform: size indicates different particle sizes (e.g. average particle size 10 nm, 50 nm and 95 nm), shape of the symbol indicates shape (e.g. spheres, rods, stars), while the colour indicates application of different surface coating (uncoated blue, and red and yellow depicting coating with chemical groups A and B). For simplicity let's assume all rods are long but only the thickest are rigid. Each nanoform can be represented by the characteriser troika in square brackets e.g. [50nm,rod,coating B].*  *27 different combinations are possible. Of these, there is no present interest in placing on the market uncoated little stars and spheres, so 25 have to be covered by registration.* *Based on the invented information available, stars and spheres are applied for the same uses while rods may differ. Modelling and tests indicate that size does not play a role, apart in the case of large (rigid) rods. While coating A does not seem to affect any hazard or fate properties, coating B seems to influence it strongly. Stars are expected to behave like spheres but this is to be further confirmed. One way to consider the sets would be [square brackets represent characterisation, which is provided in ranges]:*

	• *Set 1 : [5-100nm, spheres or stars, uncoated or coating A]* • *Set 2 : [5-100nm, spheres or stars, coating B]* • *Set 3 : [5-50nm, rods, uncoated or coating A]* • *Set 4 : [5-50nm, rods, coating B]* • *Set 5 : [5-100nm, rods, uncoated or coatings A or B]*
Changes to the proposal in Annexes VII-X (information requirements)	These assessed impacts relate to information provided in Chapter 6 and Annexes XII and XIII.
Changes regarding physico-chemical requirements (Modification of application of measures 2 and 3)	The Member States have received this information in a separate Explanatory note that accompanied the changed proposal for the discussion and vote in the meeting of the REACH committee in April 2018. The Commission proposal now includes explicit reference to two physico-chemical properties (dissolution rate and dispersion stability), to be considered as part of existing water solubility and octanol-water partition coefficient (K_{ow}) information requirements under Annex VII of REACH. **Dissolution rate** The dissolution rate with its recognised importance for the preparation of tests and for the interpretation of test results, plays a pivotal role in the safety assessment and the justification for read across between different forms. For nanoforms, the characterisation of the dissolution rate is in the proposal explicitly included under Point 5.2.3 of Annex I on Chemical Safety Assessment. Testing of the "*dissolution rate in water as well as in relevant biological and environmental media*" is for nanoforms becoming a mandatory consideration under the Point 7.7. on Water Solubility. A Test Guideline for the dissolution rate is still under development and the exact standardised media are not yet defined. The Commission estimate for the cost of the test

	per nanoform, considering all the listed media, is EUR 8-32K[150]. In a conservative approach (assuming there is no potential for read across between the nanoforms/sets), the total additional cost for all nanoforms is estimated in the order of EUR 16.5-66M. As this information is a key element of intelligent testing strategies and the chemical safety assessment, the registrants may have already generated such information to support these needs. These costs could also be offset by the increased efficiency of the employed testing strategies, in particular when it comes to higher tier testing. However, no robust quantitative assumption can be made on the net impact so full cost, for each nanoform, was used in the estimates. The additional burden is estimated at an average of EUR 20K for the set of tests. On average, this represents around 3% of the cost of registration of one nanoform[151], but a relative increase of 10.9% for the low volume registrants. **Dispersion stability (agglomeration behaviour)** Dispersion stability is included with the proposal as a mandatory consideration under Annex VII whenever octanol water partition coefficient (K_{ow}) is not applicable. This is assumed to be true in 90% of the cases. It is also recognised[152] as one of the crucial physico-chemical properties of the nanoform, influencing its bioavailability, kinetics, transformation and fate. As for the dissolution rate, the information is a key element of intelligent testing strategies and the chemical safety assessment and the same consideration would apply as for the net impact of the requirement but, again, no

[150] In the assessment of impact, the cost of the water solubility measurement, estimated at EUR 5.5K could be deducted because it is in principle expected to be provided by the same test. The cost is based on input by industry (internal communication with Eurometaux) on the OECD TD 29 "Transformation dissolution test on metals and metal compounds" with cost per material/media range from 2 000 for the 24h test to the 8 500 for 28-day test that already includes consideration of sample preparation and improved filtration techniques, but was complemented to consider multiple media covered.

[151] Respectively to the probable baseline as estimated in the impact assessment report.

[152] Agglomeration behaviour is part of the information that relates to the dispersion stability.

	robust quantitative assumption can be made on the net impact. The cost for the recently adopted OECD TG 318 (Dispersion stability of Nanomaterials in Simulated Environmental Media) has been estimated at EUR 10K (conservative estimate) by the competent authority leading the development of the OECD guideline[153]. Considering that in the future additional biologically relevant simulated media are expected to be included in the Guidance Document (assuming the similar cost of EUR 10K), the Commission estimates the additional cost per nanoform of including dispersion stability under the Point 7.8. Octanol water partition coefficient to be in the order of EUR 4.1K-13.1K[154] or 5.0% of the baseline cost in the Annex VII where the relative impact is highest, leading to an additional total cost of EUR 8.4-26.9 million. **Further information on physicochemical properties (Measure 44*)** The Commission modified its initial proposal regarding the need for consideration of additional physico-chemical properties of nanoforms, moving the information requirements from Annex IX to Annex VIII. Due to the other changes (inclusion of dissolution rate, dispersion stability), it is difficult to estimate what could cost of further information be while avoiding any double counting. Conservatively ignoring the possibility of double counting and keeping the initial estimate of the measure (average EUR 8K per nanoform), the change would increase in relative terms cost per nanoform under Annex VIII by 1.8%, and 1.2% compared to an average. The change contributes EUR 2M or 0.15% to the total cost.

[153] Internal communication.

[154] When applied, it is assumed that the testing of K_{ow} at the cost of EUR 5.49K, currently assumed in the impact assessment, would not be performed, and that K_{ow} is not applicable for 90% of nanoforms, triggering consideration of dispersion stability testing.

Changes regarding the testing of acute toxicity via the most appropriate route (Measure 11)	As above, summary is based on the explanatory note to the Member states: The proposal modifies the default route for acute toxicity testing of nanoforms in Annex VII from the oral route (standard requirement for substances) to the inhalation route, because this route has been considered to be more relevant for nanoforms. This change indirectly considers animal welfare concern: when necessary to use animals, maximum relevance of the test should be pursued. In the original Commission proposal, the text of the Annex was just encouraging such testing, so the measure was not explicitly recognized as implemented under the preferred option. The main text of this report is therefore not consistent anymore with the proposal in this regard. Performing the inhalation instead of the oral test under Annex VII is expected to bring additional costs and animal use: Firstly, the test costs are higher by approximately EUR 6.3K per nanoform. Secondly, as the requirement differs from standard requirements for substances, the possibilities for read across from bulk or other substances will be reduced. This factor is currently set at 49% i.e. roughly half of the information requirements are presently fulfilled using adaptation that avoids performing the test. Assuming the reduction of this percentage to 20% (e.g. 80% of all nanoforms registered would require the test), the additional cost per nanoform in the lowest tonnage range is roughly estimated at EUR 9.5K[155]. As generally more animals are used in the inhalation test than in the oral one (the assumption in the impact assessment report is 40 vs 15 for the respective tests), the increase in the additional use of animals per nanoform,

[155] Characterisation of the testing material is also included in the estimation whenever the test is triggered. Estimation includes the difference in triggering as well as the differences between the tests in use of animals.

	considering also that most but not all nanoforms will be tested, is estimated to be 24. For the registration at the higher tonnages, the change in provisions does not have any effect as the second route must always be considered. The total impact of the requirement therefore only relates to the lowest tonnage rate. When full Annex VII submission is required, the change is resulting in increase of EUR 6.5M (0,5% of average total cost or 3.8% of cost for full Annex VII registrants), with an additional use of 16500 animals. With a worst-case estimate that all Annex VII registrations would be subject to this provision, this would lead to EUR 7.6 million and an additional use of 19200 animals[156]. For consistency with data for the other options, tables below however include the former assumption.
Changes regarding the wording of Column 2 in the ecotoxicological information requirements, indicating adaptations to perform long term testing (Measures 14,16,17)	Triggers of long term testing on daphnia and fish (Points 9.1.1 and 9.1.3) now explicitly include the triggering for low-dissolution rate nanoforms. However, the current assessment for this information requirement already estimates that long term testing of nanoforms would be triggered in 90% of the cases based already on the existing trigger. It is hard to justify further increase in the assumption. While the change will contribute to triggering that is better informed and targeted, the initial estimates do not need to change.
Summary of the impact and assessment of the benefits of the changes to the proposal	As indicated individually above, each of the changes in the proposal aims at increasing the relevance of available information on nanoforms. It is however not possible to quantify the benefit of the significantly improved relevance of the basic toxicological

[156] Scenario that all low tonnage nanoforms (800) may be considered for the testing, rather than only the subset not benefiting from Annex III prioritisation as taken in the present IA estimations in the report. This is based on present statistics on very low number of dossiers including only physico-chemical information, and the ongoing discussion in the application of phase-in status. As the baseline animal use per nanoform for low volume registration is13; additional 24 represent 60% of the estimated use at this tonnage level. But in total, the additional 19200 animals represent roughly 1,3% increase in the estimated use of animals.

	information. As regards the cost, the average cost per nanoform is estimated to be increased by EUR 31K, with a total additional cost estimate EUR 63M, or 4.5% increase as compared to original proposal. Regarding the scenario of registration of bulk with 4 nanoforms, the cost of registration compared to baseline would increase by 27%. In terms of animal use, on average an additional 8 animals per nanoform are expected to be used, with total additional use of 16 thousand animals (+1.3% compared to original proposal). This estimate is still within estimates for animal use under baseline scenario, as additional animal testing is offset in the calculation by the increased ability to read-across, based on better and available non-animal supporting data.

Final tables on estimated animal use

Table 9.15-1: Animal use per option per nanoform (or set of nanoforms), use of alternative methods considered possible, with default assumptions (see Appendix XIII). Complements Table 5-3 and discussion under Chapter 6.4 in the main text:

Animal Use per form	Estimated baseline	2	3	4 (incl. 2)	5	6 (incl. 4)	Preferred-initial proposal (Oct 2017, corrected*)	P pr (2
>1000 tonnes	1178	1178	1178	1182	552	2395	1120	
100-1000 tonnes	1076	1076	1076	1081	548	2166	1024	
10-100 tonnes	485	485	485	496	97	817	488	
1-10 tonnes (w.av.)	9	9	9	16	2	128	16	
Weighed Average	613	613	613	619	283	1263	589	

Table 9.15-2: Total estimated animal use per option (in thousands). Complements Table 5-4 and discussion under Chapter 6.4 in the main text:

Animal Use Total (thousands)	Estimated baseline	2	3	4 (incl. 2)	5	6 (incl. 4)	Preferred (Oct 2017, corrected*)	P pr (2
>1000 tonnes	542	542	542	544	254	1102	515	

100-1000 tonnes	595	595	595	598	303	1198	566	
10-100 tonnes	121	121	121	124	24	204	122	
1-10 tonnes (w.av.)	7	7	7	12	2	102	13	
Total	**1266**	**1266**	**1266**	**1278**	**583**	**2606**	**1216**	

9.16 APPENDIX XVI: Sensitivity analysis

This appendix elaborates a sensitivity analysis that allows establishing high, low and realistic scenarios which put into context the cost figures presented in the main text. The sensitivity analysis has been calculated for the cost per nanoform, for the grand total and for the cost per company.

9.16.1 Cost per nanoform

In Appendix XIII, illustrative cases presented the importance of case-specific parameter, such as number of forms per substance, to the estimation of cost of a registration dossier. Appendix XIII also outlines the way to calculate dossier cost based on the unit cost table 9-9 and shows that the main driver of dossier costs is the availability of data that can be applied as alternative to testing of individual nanoforms/sets of nanoforms:

- High cost scenario: alternatives are not available, full testing cost applies. Presented e.g. in Table 9-18 of Appendix XIII.

  While such a situation can probably not be excluded for some individual nanoforms, it is in many cases unrealistic to expect that alternatives would not be available for any nanoform/set of nanoforms as this would contradict existing information on selected nanomaterials (see e.g. discussions of ECHA Nanomaterial Working Group)

- Default: the 'default assumptions' (e.g. Table 9-17 of Appendix XIII), based on the information on application of alternative methods for substances already registered, as this is the most robust data available.

- Low cost scenario: specific situations have been outlined in the illustrative cases in Appendix XIII: it is probable, due to economic as well as regulatory pressures (animal testing as a last resort) to assume that all existing data, in particular available data on the same substance (but another form) will be exploited to the maximum before commissioning any testing. For the vast majority of substances with nanoforms with known bulk form (i.e. excluding carbon nanotubes etc.), data on bulk form is already available. As identified also in the Impact assessment on the transparency measures, many nanomaterials (though presently not registered as substances with nanoforms) are commodity materials, often with limited number of nanoforms with already available toxicity data.

  In short, a significantly lower proportion of testing than under default assumption is also a realistic assumption. For simplicity, cost is approximated by assuming that testing (Annex VII-X only, for Annex VI full costs apply) is required in the same proportion as the number of substances with nanoforms vs number of nanoforms, i.e. 18%. In other cases, only justification is sufficient. For option 1, where a single dataset is applied to different nanoforms, the default assumption is applied also for the low cost scenario.

Table 9.16-1: Sensitivity analysis with regard to the proportion of available use of alternative information (high/default/no alternative). Cost per nanoform, in thousand Euro)

	1	2	3	4 (including 2)	5	6 (including 2 and 4)	Preferred (Mix)[c]
>1000 tonnes	77/77/169	575/1157/2312	575/1157/2312	609/1256/2490	225/458/1078	796/2256/3277	633/1234/2515
100-1000 tonnes	77/77/178	409/814/1720	409/814/1720	450/939/1935	185/375/898	591/1736/2561	464/901/1924
10-100 tonnes	37/37/70	168/359/640	168/359/640	205/471/830	23/40/73	286/869/1189	202/413/756
1-10 tonnes (Full Annex VII)	20/20/30	84/187/280	84/187/280	107/249/391	10/20/30	163/466/639	103/235/377
1-10 tonnes (Only Phys-chem)	9/9/11	47/87/106	47/87/106	49/91/111	5/9/11	163/466/639 [b]	62/128/184 [b]
1-10 tonnes[a]	12/12/17	58/116/157	58/116/157	66/137/193	7/12/17	163/466/639	74/159/240
Weighed Average	47/47/100	281/565/1115	281/565/1115	307/642/1249	105/212/496	434/1254/1809	319/628/1261

[a] *Weighted average*

[b] *Indirect impact of measure 41 on registration of bulk form per nanoform (10K EUR) is not included in the sensitivity analysis in the table; contributions are identified in the tables in Appendix XIII. Maximum relative additional contribution is 16.1% for the preferred option, when using assumption for high use of alternative information. Even maximum contribution is several times lower compared to the uncertainty regarding this single assumption.*

[c] *Estimation for initial Commission proposal, uncorrected.*

The other main drivers for the cost per nanoform are the assumptions on the cost of testing. To evaluate the maximum potential impact on individual registrations of the assumptions on test costs, the impact of applying a low and high cost estimate instead of an average one has been evaluated in the costing per nanoforms in a scenario when full testing is required. Ratios between the results were calculated. The impact shows a maximum increase of 34% for a new substance under 1-10t under option 2, with an average increase of 20% for all options 2, 4 and 6 under a high testing cost assumption, and a corresponding 20% decrease under low testing cost assumption (this result is as expected, as typical cost is set as an average between the two).

9.16.2 Grand total costs

The main driver of the grand total costs is the number of nanoforms or set of nanoforms which will need to be registered, as the total is directly proportionate to this number. The assumption on the number of forms (and the ratio of nanoforms registered in respective registration tonnages) is highly speculative, but has been compared against data or similar estimations developed under other studies or activities[157]:

Based on the general survey of available information (see summary of main studies below), it had to be concluded that no hard data is available. Assumptions have therefore been made that 0.5% / 1% / 2% of all substances (in individual tonnage bands) have nanoforms which are expected to be registered. The ratio of nanoforms per substances (10/7/5/4 for highest to lowest tonnage band, respectively) is then applied. Such choice leads in the default assumption to a total of 2063 nanoforms, a number that can be roughly associated with the limited data available. It also corresponds to the number of substances (375) known or expected to have nanoforms at present or in the near future. The sensitivity range presented above leads to 1032/2063/4126 nanoforms respectively, with corresponding number of substances 188/375/750.

As the grand total cost is directly proportionate to the number of nanoforms, applying the sensitivity range leads to costs **from one half to 2 times** the grand total costs presented in the main text.

9.16.2.1 Existing REACH registrations

REACH registrations, which allow the voluntary indication that nanoforms are covered by a registration since 2010, are not a reliable source: by March 2018, only 21 substance registrations had indicated nanoform as any of the forms of the substance registered. For the majority, no estimations of actual numbers of nanoforms can be made at present but it can be expected, based on the different compositions reported, to be well below the average number of 10 different nanoforms/sets of nanoforms assumed in this impact assessment for high tonnage substances.

9.16.2.2 French registry

The French nanoregistry report[158] identified in 2014 319 notified substances. Comparison with ECHA's REACH database indicates that 60% are already registered, with an additional

[157] Please refer to table 'Estimated number of nanoforms or sets of nanoforms' under *9.13.3 Input tables and summary of main assumptions* for a detail of the assumptions which have been used for this impact assessment.

[158] Rapport d'étude 2014 des élements issus des déclarations des substances à l'état nanoparticulaire, Ministère de l'Ecologie, du Développement durable et de l'Energie, p.23 https://www.ecologique-solidaire.gouv.fr/sites/default/files/2014-11%20-%20Rapport%20R-nano%202014.pdf

. Since 2015 further notifications have been provided that however do not qualitatively change the assessment based on 2014 data. See R-nano.fr.

5% expected by 2018 with certainty, while 35% are outside REACH's scope or notified at present below 1 tonne. Again there is no clear link to nanoforms, but ca. 210 substances (corresponding to the 65% mentioned above) is within the interval of the assumption made.

The French registry however indicates that the ratio between the number of substances with nanoforms in different tonnages might be rather inverted to the one observed from chemicals in general. The sensitivity analysis can address that by a new ratio proposed which would put ca. 60% of substances in higher tonnages, and 40% in lower. In the absence of other knowledge, these can be distributed equally (30% in >1.000t, 30% 100-1.000t, 20% 10-100t, 20% 1-10t). Using the same ratios forms/substance and aim at number of substances at minimum to be roughly the number of reported substances that are already or are expected to be registered by 2018, the following alternative table 9-25 results:

Table 9.16-2: Number of nanoforms/sets of nanoforms expected to be registered (based on FR registry):

	Number of NF/sets		
Tonnage band	**Typ**	**Min**	**Max**
> 1000	1200	600	2400
100 – 1000	840	420	1680
10 – 100	400	200	800
1 – 10 Full	320	160	640
1 - 10 Annex III applied	227	113	453
1 - 10 Annex III not appl.	93	47	187
Total	2760	1380	5520
(# substances)	400	200	800

The 210 substances reported from the French registry roughly fit with the the lower estimate.

Using the default assumptions for the cost per nanoforms, but applying the numbers from Table 9-25 the grand total e.g. increases by **90%** for the preferred option, with a 2.6 times increase in registrations >1000t.

9.16.2.3 Canadian nanomaterial survey 2015

Canada has identified 206 substances with anticipated nanoforms for mandatory reporting of substance identity/composition, volumes and uses of nanoforms. Considering that some substances are excluded due to the fact they have been included under new substances assessment, the number fits within the interval used.

9.16.2.4 US list of substances that could have nanoforms

The US EPA has solicited information on likely chemicals that could be nanoscale materials. The Nanoscale Materials Stewardship Program (NMSP) report[159] identified 2.328 chemicals with differing CAS numbers, based on 3 sources (Nanowerk, PEN and NMSP). Many of these overlap or could be considered as forms of same substances and the report (p.18) concludes: "Combining all three datasets, EPA identified over 200 existing chemicals that are produced at the nanoscale for commercial and R&D purposes, of which 91 are likely to be manufactured for commercial purposes". The numbers are difficult to compare to the number

[159] Chemical Substances When Manufactured or Processed as Nanoscale Materials: TSCA Reporting and Recordkeeping Requirements, US EPA, 2015, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/control-nanoscale-materials-under

of substances or nanoforms used in this IA and cannot be used directly but on the other hand do not undermine the assumptions made.

9.16.2.5 BiPRO/Oeko report

This report of 2012 under the Nano support project led by JRC used 500-2.000 as the actual number of forms to be assessed. This interval overlaps with the lower range of the interval used in this assessment.

9.16.2.6 RPA/CEFIC 2012

The most frequently quoted numbers regarding nanomaterials are 500-2.000 which originate from the 2012 RPA/CEFIC study. The objective of the study was to estimate impact of changes to Substance ID rules to the number of substances and is indirectly applicable as the number of 'new' substances can be related to the number of forms, elevated to substances in their own right due to modified rules. The study based the interval on estimation by several VCI experts. With a number of caveats (the main ones regarding the implementation of the nano-definition), the 500-2.000 in the study indeed determines the number of potential chemical substances with nanoforms to be registered under REACH, on top of which two assumptions were made regarding the number of nanoforms that could become substances under modified rules: a) 1 nanoform per substance (size as identifier) or b) 2-5 (coating as identifier, low/high estimate).

These assumptions lead to 500-2.000 substances with nanoforms and 1.000-16.000 nanoforms, respectively. The latter high-end estimate was used as part of the sensitivity analysis and in the analysis triggered significant implications to the ratio between tonnages registered (the study assessed the substance identity changes that would trigger separate registration). The numbers are difficult to compare with the 'nanoform/set of nanoforms' convention used in this impact assessment as that might include both size and coating as relevant characterizers, while on the other hand allows for ranges to be combined within a single set. Comparison may also put in question the average ratio of the number of form-per substance (10/7/5/4) applied, as they are at the high end of the CEFIC approach. This was further confirmed in the bilateral discussions with CEFIC – the higher end of the range of 2.000 was principally based on the high number of organic pigments with nanoforms; for which experts could not, in spite of high tonnage, identify high numbers of nanoforms per substance. Rather the opposite – it was indicated that many (48%, see RPA/CEFIC p.46) fall under the study's 'Scenario 1' that indicates little effort beside 'ticking the nano box', as the relevant form of this 'conventional substance' is already registered and presented in the dossiers. As regards the high end assessment with 5 coatings leading to 5 nanoforms, the association of the organic pigments industry consistently claimed that practically for all organic pigments with nanoforms, despite potential differences in chemical identity of coatings, a single dataset per substance will be adequate as coatings serve the same function and therefore bring very similar physico-chemical surface properties. Under the assumptions of the impact assessment, such an approach is well within a single set concept. In any case, these substances (one half of 2.000) are therefore very unlikely to correspond to the average 10 nanoforms per substance. It should also be noted that under RPA/CEFIC assumptions, only 10% of forms (high estimate, likely estimate 5%) are actually expected to come from new chemicals, while 95% are 'legacy materials'.

9.16.3 Cost for the registrant

A single company may produce and register 1 or many nanoforms (or substances).. Sensitivity analysis may however be applied to the number of companies registering the same nanoforms.

As indicated in the main text, the costs of addressing information requirements in Annexes VII-X of REACH are shared between them.

The situation is complex as registrants of the same nanoforms may register at different tonnage levels or opt out for individual information requirements, making their shares variable. To better address these variations in cost calculations, a Monte Carlo approach is required, as applied in some studies[160]. As such, a methodology is not applied in the model used in this impact assessment, the sensitivity analysis can only estimate difference in costs when the number of registrants of the substances with nanoforms varies within the tonnage band. The lower estimate is that a registrant is registering the nanoform of a substance alone, which leads to the highest cost per company. The higher estimate can be set by doubling the average number of registrants in a SIEF[161] as observed for already submitted registrations, used under default assumption – even more registrants is possible, but increasingly unlikely. The analysis confirms what can be deduced directly by observing the magnitudes of different contributions to the total cost: with increasing tonnage, the contribution of characterisation costs under Annex VI becomes less and less important in comparison to the testing costs under Annexes VII-X of REACH, making the total cost almost inversely proportionate to the number of companies in the SIEF. A single registrant in the highest tonnage band may incur 6 times the costs compared to the average situation (and correspondingly 3, 1.7 and 1.5 times in the respective lower tonnages), while doubling the numbers of registrants in a SIEF divides the cost in half.

9.16.4 Alternative Methodology for cost calculation

As explained in section 5.2.1.2 the main text and in more detail in Appendix XIII, the core methodological approach is the attribution of unit cost per nanoform. Another way is to calculate costs and use of animals for one registration dossier of a substance with nanoforms in each tonnage band. The calculation of the costs and use of animals for one registration dossier of a substance with nanoforms takes place in a following manner:

1. The costs and use of animals for the testing of the conventional form of a substance with nanoforms is presented in Option 1, while the absolute costs and use of animals after additional nanoform specific measures requested Options 2-6 and in the Preferred Option (in line with the draft legal proposal) are presented under Options 2-6 and the Preferred Option. As the endpoint specific testing costs from the Matrix study used in the impact assessment relate to minimum and maximum costs for conventional substances and are expected to be lower than for nanomaterials on average, the highest prices instead of the average ones are used for endpoint specific testing costs (see Appendix XIII).
2. The decision from the Board of Appeal of 2 March 2017 provided clarity about the current requirements in REACH. Consequently, neither Option 1 nor Option 2 are the baseline, but it is situated in between Options 1 and 2. Accordingly, the soft law measures in Option 3 of a non-legally-binding nature related to the REACH provisions for nanoforms of substances are at the same level as in the baseline in this alternative methodology. Where requested in measures related to Annex VI in Options 2, 4, 6 and in the Preferred Option each registrant in a SIEF is requested to report characterisation data on its different nanoforms to ECHA and the average cost of characterisation (12 000 €/nanoform) is multiplied in each tonnage band by the number of registrants in a SIEF and by the number of different nanoforms;

[160] See for example recent RPA study on impact of modification of information requirements for 1-10t, http://ec.europa.eu/environment/chemicals/reach/pdf/1-10t%20P2%201-10t.pdf

[161] Reminder from Appendix XIII: >1000: 7; 100-1000: 3; 10-100: 1,8; 1-10: 1.8

3. The measure 41 in Option 6 and in the Preferred Option requires a full Annex VII dossier with (eco)toxicological information for 100% (Option 6) and 80% (Preferred Option) instead of 29,2% (Option 1). So additional costs and animal uses of the testing of both substance and nanoform at 1-10 tpa tonnage on top physicochemical information have been included under Option 6 and Preferred Option; and
4. Otherwise, the lead registrant of a SIEF of a substance with nanoforms is reporting in the Joint Submission any relevant nanoform specific information requested in measures related to Annex VII-X in line with practices in REACH e.g. for positive triggers for additional testing and applying the worst case approach also in testing of nanoforms. The costs and animal uses are calculated for Scenario 1 and Scenario 2: The former represents a situation without alternative methods for nanoforms and the latter one where alternative methods will be available for nanoforms as for conventional substances today.

The costs and use of animals in one registration dossier of a substance with nanoforms is multiplied by the total number of substances with nanoforms to be registered (CEFIC 2012) to obtain a Grand Total Costs and Grand Total Use of Animals. The division of the costs and use of animals by the average number of companies in SIEF in each tonnage band provides the company specific costs.

It should be noted that the final "Preferred mix" results of the alternative methodology do not include reassessment due to the changes made in the Commission proposal in the REACH committee and are thus not directly comparable to the estimates for the final Commission proposal.

The results in different scenarios are as follows:

Table 9.16-3: Total costs of one registration dossier of substances with nanoforms

Scenario 1 No alternative methods for Nanoforms (1000 €, high price)	**1**	**Baseline**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**	**Preferred Mix**
>1000 tonnes	756	872	3740	872	4080	1210	5099	**4267**
100-1000 tonnes	654	732	2808	732	3160	1064	3940	**3293**
10-100 tonnes	268	302	1081	302	1308	274	1744	**1298**
1-10 tonnes, Full Annex VII	124	127	538	127	655	124	967	**667**
1-10 tonnes, Annex VII PC	36	37	212	37	216	36	737	**449**
1-10 tonnes (w.av.)	*62*	*64*	*307*	*64*	*344*	*62*	*804*	*513*
Weighted average	**299**	**299**	**1.358**	**335**	**1.524**	**442**	**2.117**	**1.664**
Scenario 2 Alternative methods for Nanoforms (1000 €, high price)	**1**	**Baseline**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**	**Preferred Mix**
>1000 tonnes	756	854	2673	854	2838	1210	3517	**2913**
100-1000 tonnes	654	715	1800	715	1967	1064	2441	**2003**
10-100 tonnes	268	297	771	297	893	274	1196	**863**
1-10 tonnes, Full Annex VII	124	127	418	127	476	124	660	**470**
1-10 tonnes, Annex VII PC	36	37	186	37	191	36	594	**334**
1-10 tonnes (w.av.)	*62*	*64*	*254*	*64*	*274*	*62*	*613*	*374*
Weighted average	**299**	**299**	**945**	**329**	**1.028**	**442**	**1.432**	**1.094**

Table 9.16-4: Grand total costs of registration dossiers of 500 substances with nanoforms

Scenario 1 No alternative methods for Nanoforms (MEURs high price)	**1**	**Baseline**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**	**Preferred Mix**
>1000 tonnes	46	53	229	53	250	74	313	**262**
100-1000 tonnes	69	77	296	77	333	112	415	**347**
10-100 tonnes	18	20	72	20	87	18	116	**87**
1-10 tonnes, Full Annex VII	10	10	42	10	51	10	75	**52**
1-10 tonnes, Annex VII PC	7	7	40	7	41	7	139	**85**
1-10 tonnes (w.av.)	*8*	*8*	*41*	*8*	*44*	*8*	*120*	*75*
TOTAL	**150**	**168**	**679**	**168**	**762**	**221**	**1058**	**832**
Scenario 2 Alternative methods for Nanoforms (MEURs, high price)	**1**	**Baseline**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**	**Preferred Mix**
>1000 tonnes	46	52	164	52	174	74	216	**179**
100-1000 tonnes	69	75	190	75	207	112	257	**211**
10-100 tonnes	18	20	51	20	60	18	80	**58**
1-10 tonnes, Full Annex VII	10	10	33	10	37	10	51	**37**
1-10 tonnes, Annex VII PC	7	7	35	7	36	7	112	**63**
1-10 tonnes (w.av.)	*8*	*8*	*34*	*8*	*36*	*8*	*94*	*55*
TOTAL	**150**	**164**	**473**	**164**	**514**	**221**	**716**	**547**

Table 9.16-5: Total costs of one registration dossier of substances with nanoforms per company

Scenario 1 No alternative methods for Nanoforms (1000 €, high price)	**1**	**Baseline**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**	**Preferred Mix**
>1000 tonnes	108	125	534	125	583	173	728	**610**
100-1000 tonnes	218	244	936	244	1.053	355	1.313	**1.098**
10-100 tonnes	149	168	601	168	727	152	969	**721**
1-10 tonnes, Full Annex VII	69	71	299	71	364	69	537	**370**
1-10 tonnes, Annex VII PC	20	21	118	21	120	20	409	**249**
1-10 tonnes (w.av.)	*34*	*35*	*170*	*35*	*191*	*34*	*447*	*285*
Weighted average	**97**	**108**	**434**	**108**	**492**	**135**	**733**	**554**
Scenario 2 Alternative methods for Nanoforms (1000 €, high price)	**1**	**Baseline**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**	**Preferred Mix**
>1000 tonnes	108	122	382	122	405	173	502	**416**
100-1000 tonnes	218	238	600	238	656	355	814	**668**
10-100 tonnes	149	165	428	165	496	152	664	**480**
1-10 tonnes, Full Annex VII	69	71	232	71	265	69	367	**261**
1-10 tonnes, Annex VII PC	20	21	103	21	106	20	330	**186**
1-10 tonnes (w.av.)	*34*	*35*	*141*	*35*	*152*	*34*	*341*	*208*
Weighted average	**97**	**106**	**305**	**106**	**335**	**135**	**503**	**366**

With the estimated number of animal use:

Table 9.16-6: Total use of animals per one registration dossier of substances with nanoforms

Scenario 1 No alternative methods for Nanoforms	**1**	**Baseline**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**	**Preferred Mix**
>1000 tonnes	940	940	3656	1072	4116	1446	5066	**4239**
100-1000 tonnes	938	938	3655	1070	4113	1444	5062	**4001**
10-100 tonnes	269	269	979	269	1261	269	1774	**1217**
1-10 tonnes, Full Annex VII	51	51	108	51	227	51	548	**188**
1-10 tonnes, Annex VII PC	0	0	0	0	0	0	171	**102**
1-10 tonnes (w.av.)	*15*	*15*	*31*	*15*	*66*	*15*	*281*	*127*
Weighted average	**357**	**357**	**1.366**	**401**	**1.575**	**526**	**2.074**	**1.593**
Scenario 2 Alternative methods for Nanoforms	**1**	**Baseline**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**	**Preferred Mix**
>1000 tonnes	940	940	1923	958	2147	1446	2624	**1933**
100-1000 tonnes	938	938	1922	956	2144	1444	2621	**1853**
10-100 tonnes	269	269	557	269	692	269	1013	**566**
1-10 tonnes, Full Annex VII	51	51	85	51	161	51	393	**106**
1-10 tonnes, Annex VII PC	0	0	0	0	0	0	136	**57**
1-10 tonnes (w.av.)	*15*	*15*	*25*	*15*	*47*	*15*	*211*	*71*
Weighted average	**357**	**357**	**728**	**363**	**832**	**526**	**1.122**	**741**

Table 9.16-7: Grand total use of animals in registration dossiers of 500 substances with nanoforms

Scenario 1 No alt.methods for Nanoforms (1000)	**1**	**Baseline**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**	**Preferred Mix**
>1000 tonnes	58	58	224	66	252	89	311	**260**
100-1000 tonnes	99	99	385	113	433	152	533	**421**
10-100 tonnes	18	18	65	18	84	18	118	**81**
1-10 tonnes, Full Annex VII	4	4	8	4	18	4	43	**15**
1-10 tonnes, Annex VII PC	0	0	0	0	0	0	32	**19**
1-10 tonnes (w.av.)	*1*	*1*	*2*	*1*	*5*	*1*	*35*	*18*
TOTAL	**178**	**178**	**683**	**200**	**787**	**263**	**1037**	**797**
Scenario 2 Alt. methods for Nanoforms (1000)	**1**	**Baseline**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**	**Preferred Mix**
>1000 tonnes	58	58	118	59	132	89	161	**119**
100-1000 tonnes	99	99	202	101	226	152	276	**195**
10-100 tonnes	18	18	37	18	46	18	68	**38**
1-10 tonnes, Full Annex VII	4	4	7	4	13	4	31	**8**
1-10 tonnes, Annex VII PC	0	0	0	0	0	0	26	**11**
1-10 tonnes (w.av.)	*1*	*1*	*2*	*1*	*4*	*1*	*27*	*10*
TOTAL	**178**	**178**	**364**	**181**	**416**	**263**	**561**	**371**

Table 9.16-8: Total use of animals in one registration dossier of substances with nanoforms per company

Scenario 1 No alternative methods for Nanoforms	**1**	**Baseline**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**	**Preferred Mix**
>1000 tonnes	134	134	522	153	588	207	724	**606**
100-1000 tonnes	313	313	1.218	357	1.371	481	1.687	**1.334**
10-100 tonnes	150	150	544	150	700	150	986	**676**
1-10 tonnes, Full Annex VII	28	28	60	28	126	28	304	**105**
1-10 tonnes, Annex VII PC	-	-	-	-	-	-	95	**57**
1-10 tonnes (w.av.)	*8*	*8*	*17*	*8*	*37*	*8*	*156*	*71*
Weighted average	**107**	**107**	**403**	**118**	**474**	**151**	**659**	**483**
Scenario 2 Alternative methods for Nanoforms	**1**	**Baseline**	**2**	**3**	**4 (including 2)**	**5**	**6 (including 2 and 4)**	**Preferred Mix**
>1000 tonnes	134	134	275	137	307	207	375	**276**
100-1000 tonnes	313	313	641	319	715	481	874	**618**
10-100 tonnes	150	150	310	150	384	150	563	**315**
1-10 tonnes, Full Annex VII	28	28	47	28	89	28	219	**59**
1-10 tonnes, Annex VII PC	-	-	-	-	-	-	76	**32**
1-10 tonnes (w.av.)	*8*	*8*	*14*	*8*	*26*	*8*	*117*	*40*
Weighted average	**107**	**107**	**217**	**108**	**253**	**151**	**368**	**227**

9.16.5 Sensitivity analysis – summary

Due to the unknown distribution of the probabilities between the different assumptions, it is inappropriate to combine them in a way that would range from using always the lowest to always the highest assumptions, as this would result in a giant interval of cost figures. Some qualitative summary is however possible:

- It is shown that the estimates are very sensitive to the underlying assumptions; the uncertainties of the average cost is likely to be in the order of at least 50%, with the understanding that the differences in cost for specific substances with nanoforms are likely to vary within one order of magnitude.
- The impact of the application of different assumptions under the sensitivity analysis is visible in particular between the tonnages, as proportions of individual contributions to the cost differ (e.g. testing cost vs characterisation); on the other hand, the comparison between options is rather robust. The uncertainties are not by themselves reducing the ability to analyse the impacts of individual measures and thus making an informed choice between the options.
- The grand total cost is directly proportionate to the assumed number of nanoforms and numbers of substances with nanoforms. That number is however proportionate also to the presence of these nanomaterials in the market and therefore to the associated potential benefits (in terms of economic value as well as getting things right in relation to health and environmental protection).
- The results of the cost calculations from the methodology described in Appendix XIII and the alternative methodology used in section 9.16.4 of this Appendix can be compared for the Grand Total Costs, i.e. between Table 6-4 from the main text (section 6.3 *The costs of the preferred option*) and Table 9.16-4 in section 9.16.4. *Alternative Methodology for cost calculation* of this Appendix. Such a comparison

shows that the costs of registration in Table 6-4 are roughly 3.2 times higher than in 9.16-4. This is mainly due to the assumption of possibility to apply the worst case approach. When a similar assumption is applied in the main methodology[162], total costs for the preferred option are estimated at 736 million EURO, to be compared against the 547 million Euro in the Table 9.16-4.

[162] The assumption can be approximated in the main methodology as follows: a) the same number of nanoform per substance is assumed (Nf = 10/7/5/4 respectively, see Table 9.13-1). b) It is assumed that 1 full dataset is required (i.e. cost per nanoform with no alternative possible). c) For (Nf-1) nanoforms, a full read-across is assumed (i.e. effectively only characterisation costs of Annex VI + justification costs remain. Note that characterisation is calculated for all registrants of the nanoform). d) Costs under b) and c) are added. e) Such cost is multiplied by number of substances (500), assuming same ratios between the tonnage bands (Table 9.13-2), and summed across all tonnage bands.