KEMI
Swedish Chemicals Agency

Impact Assessment of Further Regulation of Nanomaterials at a European Level

PM 1/15

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KEMI
Swedish Chemicals Agency

The Swedish Chemicals Agency is supervisory authority under the Government. We work in Sweden, the EU and internationally to develop legislation and other incentives to promote good health and improved environment. We monitor compliance of applicable rules on chemical products, pesticides and substances in articles and carry out inspections. We review and authorise pesticides before they can be used. Our environmental quality objective is A Non-toxic Environment.

Article number: 511 144.

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Preface

The Swedish Chemicals Agency has been assigned by the Swedish Government to produce a national action plan for a toxic-free everyday environment: Action plan for a toxic-free everyday environment 2011 – 2014 – protect the children better. The work on the action plan has been extended until 2020.

Efforts are now going on in several areas, both in Sweden, within the EU and internationally and often in cooperation with other authorities. Reducing chemical risks in the everyday environment is one step towards attaining the Swedish Parliament´s environment quality objective A Non-Toxic Environment, which is the objective that we are responsible for.

Within the framework of the action plan, the Swedish Chemicals Agency compiles knowledge in our report and PM series elaborated by experienced colleagues, researchers or consultants. In this way, we present new and essential knowledge in publications which can be downloaded from the website www.kemikalieinspektionen.se

This report/PM has been produced within the framework of the government assignment to carry out the strategy on a non-toxic everyday environment and reaching the environmental quality objective A Non-Toxic Environment 2015–2017.

The main objective of the present report was to conduct an impact assessment of the cost and benefits of new regulation for nanomaterials in the EU. The report is intend as a basis for further informed discussion and work towards better regulation of nanomaterials. The Swedish Chemicals Agency is of the opinion that adequate information on nanomaterial needs to be made available through legislative action. Either via REACH or an additional regulation, this is motivated as a cost effective measure for EU over time. The continued growth of the nanomaterials industry must be met by a regulatory instrument providing legal clarity for the market, and achieving the protection of health and the environment as set out in the Treaty on European Union.

Because of the potential risks of nanomaterials and the need to ensure the functioning of downstream legislation and to provide workers with necessary information on nanomaterials, legislative action needs to be taken. Pertaining to that the EU-Commission has continuously delayed adaption of relevant legislation on nanomaterials, a harmonised definition of nanomaterials, and that the REACH registration procedure nears finalisation in 2018, we consider it timely to reconsider the development of a legislative tool which adequately considers nanomaterials below 1 tonne per year and incorporates a working definition for nanomaterials.

The Swedish Chemicals Agency have continued to explore the development of a new legal proposal, which was first explored in 2013. The options in the report are intended to act as examples to illustrate what measures could be the most cost efficient and what information elements for regulation need to be considered. This study has, based on our original proposal, conducted an impact assessment for two options for regulatory action. This is considered essential, as the present standard working practice requires an impact assessment before acceptance of new legislation.

The aim of the impact assessment was to facilitate an informed discussion on how to concretely move forward on regulating nanomaterials. The intentions was to:

- Answer the question “Has an impact study been conducted?” which is routinely asked when submitting proposals attempting to develop EU regulations.

- Move on from our policy option and consider how to build on other national agencies proposals.
- Move forward to the second step. Following a Copenhagen workshop in 2013 the Swedish Chemicals Agency and other Competent Authorities agreed that the first step should be to amend REACH annexes in order to include information requirements for nanomaterials in registrations of substances and then in a second stage develop a legislation.
- Timely start the second stage, by e.g. altering tonnage levels, and aiming for completion in advance of 2018.
- Promote action on an EU-level on the basic adaption of relevant legislation to nanomaterials.

The policy options were not intended to necessarily be included in REACH but the general ideas are connected to registration (in REACH) i.e. they are formulated with REACH in mind. However, our intention is not to exclude other options e.g. horizontal legislation but to establish an approximate estimate of the cost and benefits of legislation for nanomaterials and then based on the findings continue a discussion on the best type and form of such legislation.

The impact assessment showed that the number of cancer cases needed to be avoided to finance the option was 285. By comparison, cancer is predicted to kill about 1 359 100 Europeans only in 2015[1]. If our options only succeeds in reducing 285 cases over time it is economically beneficial. Our estimation is that the costs of the options therefore are relatively small and the benefits can be recovered quickly if implementation and regulation are not delayed.

This consideration makes a strong case for the implementation of our options which will, amongst other effects, enable risk management of potentially carcinogenic nanomaterials.

Our conclusion is that even the relatively high cost of the measure estimated in the study seems to be justified based on the socio-economic gain for society over time. We believe that the knowledge gained in this impact assessment is a good starting point to further develop effective legislation in the EU. Thus we invite interested parties to a constructive dialogue on how this may be achieved.

The report was written by Risk & Policy Analysts Limited (RPA). Project leader and contact at the Swedish Chemicals Agency was Elin Simonsson. Gregory Moore, Lena Hellmér and Yvonne Andersson also provided valuable comments to the report. Responsible for the project was Lisa Anfält, Head of Unit, EU Co-ordination.

[1] http://www.oxfordjournals.org/our_journals/annonc/prpaper.pdf.

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List of Abbreviations

AC Article Category

BIA Business Impact Assessment

CAD Chemical Agents Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

CAS Chemical Abstracts Service

CASG Nano Competent Authorities Sub-Group on nanomaterials

Cefic European Chemical Industry Council

CLP Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures

CMR Carcinogenic, Mutagenic and Reprotoxic substance

CPNP Cosmetic Products Notification Portal

CSA Chemical Safety Assessment

CSR Chemical Safety Report

CLP Regulation on Classification, Labelling and Packaging (of Chemicals)

DG SANCO Directorate-General Health and Consumers

DNEL Derived No-Effect Level

DPD Dangerous Preparations Directive 1999/45/EC

DSD Dangerous Substances Directive 67/548/EEC

EC European Community

ECHA European Chemicals Agency

ESIS European chemical Substances Information System

EU European Union

FAQ Frequently Asked Question

FNS French Notification System

GHS Global Harmonised System

GLP Good Laboratory Practice

IA Impact assessment

IARC International Agency for Research on Cancer

ID Identity

IUCLID International Uniform Chemical Information Database

JRC European Commission's Joint Research Centre

KemI Swedish Chemicals Agency

Kgpa Kilogrammes per annum

MEDDE	Ministère de l'Écologie, du Développement durable et de l'Énergie
NGO	Non-Governmental Organisation
nm	Nanometre
NM	Nanomaterial, as defined by the Recommendation 2011/696/EU
OECD	Organisation for Economic Co-operation and Development
OSHD	Occupational Safety and Health Framework Directive 89/391/EEC
PBT	Persistent, Bioaccumulative and Toxic substance
PC	Chemical Product Category
PNEC	Predicted No-Effect Concentration
QSAR	Quantitative Structure-Activity Relationship
REACH	Regulation (EC) No. 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measure
SAS	Synthetic Amorphous Silica
SCENHIR	Scientific Committee on Emerging and Newly Identified Health Risks
SDS	Safety Data Sheet
SME	Small or Medium Enterprise
SU	Sector of Use
TK	Toxicokinetics
tpa	Tonnes per annum
UFP	Ultrafine particles
UVCB	Substances of Unknown, of Variable Composition or of Biological origin
vPvB	Very Persistent and very Bioaccumulative substance
WPMN	OECD Working Party on Manufactured Nanomaterials
WTO	World Trade Organisation
WTP	Willingness to Pay

Summary

This study has been commissioned by the Swedish Chemicals Agency in order to analyse the consequences of the further regulation of nanomaterials at a European level.

At the present time, although not explicitly mentioned, nanomaterials are covered by the REACH and CLP Regulations. However, the quantity and quality of information on nanomaterials provided in REACH registration dossiers is lacking. Possible amendments to the REACH annexes in order to improve the process of identifying the potential hazards of nanomaterials are currently (December 2014) being discussed by the European Commission with the Member State Competent Authorities. Nevertheless, the tonnage thresholds defined in the Regulation will not be changed. Due to their properties (a low bulk density and high specific surface area), nanomaterials do not need to be applied in high mass (volume) per application/use to deliver the desired functions. For this reason, the Swedish Chemicals Agency believes that (eco)toxicological information should be required at lower tonnage bands than currently used for bulk substances so that REACH successfully ensures the safe use of nanomaterials.

The Swedish Chemicals Agency has therefore defined two policy options:

Policy option 1:

- Nanomaterials should be regarded as substances on their own and therefore have to be registered individually;
- A definition of the term ‘nanomaterial’ based on the EC-recommended definition should be made legally binding;
- Nanomaterials, either on its own or in one or more mixture(s), above ten kilograms should be registered as a prerequisite for manufacturing or placing on the market;
- Exposure information should be included in the technical dossier for nanomaterials in quantities of 10 to 100 kilograms;
- An obligation to perform a chemical safety assessment and a complete chemical safety report should be on registrants registering nanomaterials in quantities of 100 kilograms or more per year;
- The information requirements for a registrant should be those that are stated in the REACH Annexes;

Policy option 2:

- Bulk and nanoforms are registered together;
- All nanoforms manufactured or imported in quantities of more than 10 kg per annum must be identified in the registration;
- A Chemical Safety Assessment should be carried out and a Chemical Safety Report developed for every nanoform (≥10 kgpa) separately;
- The information requirements should be based on the total sum of all the nanoforms, and should follow article 12 of the REACH Regulation.

In order to define the baseline and to assess these policy options, information has been gathered through a review of the most recent studies looking at the potential effects of legislative initiatives in the nanotechnology field. The actual assessment of the costs and benefits has been carried out following the EC Impact Assessment guidelines. Potential economic, social and environmental impacts have been identified and qualitatively described. Subsequently, the potential administrative burden for companies manufacturing/importing

nanomaterials on the EU market has been quantified. For the assessment of the benefits, since the information that would be required for the quantification would be generated by the policy options, a "reverse" approach has been used to present some illustrative examples in terms of the number of health cases that would have to be avoided or environmental resource base that would have to be protected from future damage by the policy options in order to make worthy their implementation.

The analysis highlights that the introduction of information requirements for substances manufactured/imported in quantities of more than 10 kilogrammes per year causes a significant increase in the total marginal costs. In particular, requiring (eco)toxicological information up to Annex IX for substances at the nanoscale manufactured/imported in quantities over 1 tonne per year contributes significantly to the increased costs of the policy options.

A side effect of the extension of the information requirements is that, since in vitro tests, QSARs and read-across for nanomaterials are still being developed, it might lead to an increase in animal testing.

Total marginal costs between €790 million and €960 million for policy option 1 and between €750 million and €900 million for policy option 2 have been estimated, with the testing costs being the most important parameter (respectively, 88% for policy option 1 and 92% for policy option 2) to the final estimates.

In the first instance, the policy options ensure that the principle "no data, no market" is respected also in the commercialisation of nanomaterials. Further economic impacts will stem primarily from businesses choosing to withdraw some nanomaterials from the market (or not to invest in research and development of nanomaterials) in order to minimise registration costs. These effects are expected especially for pigments and dyes, which do not realise the same high prices of "newly engineered" nanomaterials and are not on the market in as high volumes as some commodity nanomaterials (e.g. carbon black, calcium carbonate, silicon dioxide). The withdrawal of pigments and dyes from the market might have knock-on effects for downstream sectors (e.g. textiles).

As the main objective of the policy options is to ensure the better protection of human health and the environment, workers would surely benefit from better information on nanomaterials and, consequently, from better risk management measures when handling nanomaterials in the workplace. Moreover, the options ensure that workers' rights are respected with regard to information and training, and would ensure that employers have the information required to ensure the protection of their workers.

The benefits would not be confined to only occupational health and safety, but also to the improved safety of consumer products and, more generally, contribute to reductions in health risks to the general population and the natural environment associated with emissions of nanomaterials to the environment. The generation of toxicological and ecotoxicological data on nanomaterials might lead to the establishment of better DNELs and PNECs, improving human health and the quality of environmental media (air, soil and water) over the longer term.

When comparing the costs and the benefits of the policy options it should be noted that, while the costs would be incurred by the companies over a specified number of years (the REACH Regulation provides different deadlines for different tonnage bands over an elapsed period of 11 years), the benefits (and thus the health cases to be avoided) would accumulate over a longer time horizon.

When considering the significance of the assumptions made to the final results, the cost-benefit estimates presented here should be taken as illustrative of their magnitude rather than as reflecting accurate figures.

It should also be noted that, at the present time, some challenges remain in the risk assessment of nanomaterials, more precisely in the characterisation of physicochemical parameters, in the metrology and dose metrics to be used for the hazard and exposure assessment, and for the determination of the environmental fate, persistence and bioaccumulation throughout their life cycles. Due to the lack of a clear consensus over the most suitable methods and standards, companies may struggle to comply with new regulatory measures until clear guidance is available.

Sammanfattning

Denna studie har beställts av Kemikalieinspektionen för att analysera konsekvenserna av ytterligare reglering av nanomaterial på europeisk nivå.

För närvarande omfattas nanomaterial av Reach och CLP-förordningarna, även om nanomaterial inte uttryckligen nämns. Omfattningen och kvaliteten på informationen om nanomaterial som finns i Reach-registreringarna är emellertid dålig. Ändringar av Reach-bilagorna för att förbättra processen med att identifiera potentiella risker med nanomaterial diskuteras för närvarande (december 2014) inom Europeiska kommissionen med medlemsstaternas behöriga myndigheter. De trösklar för tonnage som anges i förordningen kommer dock inte att ändras. Tack vare nanomaterialensegenskaper (låg densitet och stor yta), behöver de inte användas i stora volymer för att ge önskad funktion Därför anser Kemikalieinspektionen att (eko)toxikologiska uppgifter bör krävas för nanomaterial vid lägre volym än vad som nu gäller för ämnen i Reach för att garantera säker användning.

Kemikalieinspektionen har därför definierat två alternativ:

Alternativ 1:

- Nanomaterial ska betraktas som egna ämnen och därför registreras individuellt.
- En definition av termen nanomaterial baserad på kommissionens rekommenderade definition görs rättsligt bindande.
- Nanomaterial, ensamt eller i en eller flera blandning (ar), över tio kilo ska registreras som en förutsättning för tillverkning eller utsläppande på marknaden.
- Exponeringsinformation ska ingå i den tekniska dokumentationen för nanomaterial i volymer på 10 till 100 kg.
- En skyldighet att utföra en kemikaliesäkerhetsbedömning och en fullständig kemikaliesäkerhetsrapport ska gälla för nanomaterial registrerade i mängder på 100 kg eller mer per år.
- De informationskrav som ska gälla är de som anges i Reach-bilagorna.

Alternativ 2:

- Bulk och nanoformer ska registreras tillsammans.
- Alla nanoformer som tillverkas eller importeras i volymer på mer än 10 kg per år måste anges i registreringen.
- För varje nanoform (≥10 kg per år) ska en separat kemikaliesäkerhetsbedömning och kemikaliesäkerhetsrapport göras.
- Informationskraven för varje nanoform ska baseras på den totala volymen av alla nanoformer av ett ämne och följer artikel 12 i Reach-förordningen.

För att definiera ett nollalternativ och bedöma alternativen har information inhämtats genom att se över de senaste studierna som tagit upp de potentiella effekterna av lagstiftningsinitiativ på nanoområdet. Själva bedömningen av kostnader och fördelar har utförts enligt Europeiska kommissionen riktlinjer för konsekvensbedömningar. Potentiella ekonomiska, sociala och miljömässiga konsekvenser har identifierats och är kvalitativt beskrivna. Därefter har den potentiella administrativa bördan för företag som tillverkar/importerar nanomaterial på EU-marknaden kvantifierats. Ett ”omvänt” tillvägagångssätt har använts för att bedöma fördelarna med alternativen där illustrativa exempel i form av antal sjukdomsfall som skulle behöva undvikas eller naturresurser som skulle behöva skyddas från framtida skador har beskrivits för att ekonomiskt motivera alternativen. Detta tillvägagångssätt har valts eftersom datan som

behövs för en kvantitativ bedömning av fördelarna skulle genereras genom att införa alternativen.

Analysen visar att en betydande ökning av marginalkostnaderna beror på införandet av informationskrav på ämnen som tillverkas/ importeras i mängder på mer än 10 kg per år. I synnerhet bidrar kravet på (eko) toxikologiska uppgifter till bilaga IX för ämnen i nanoskala som tillverkas/importeras i mängder över 1 ton per år till de ökade kostnaderna för alternativen.

En bieffekt av utvidgningen av informationskraven är att de kan leda till en ökning av djurförsök eftersom in vitro tester, QSAR och read-across för nanomaterial fortfarande är under utveckling.

Totala marginalkostnader har beräknats på mellan 790 miljoner € och 960 miljoner € för alternativ 1 och mellan 750 miljoner € och 900 miljoner € för alternativ 2, där testkostnaderna är den viktigaste parametern (88 % för alternativ 1 och 92 % för alternativ 2) för kostnaden.

I första hand säkerställer alternativen att principen "inga data, ingen marknad" respekteras även i kommersialiseringen av nanomaterial. Ytterligare ekonomiska konsekvenser kommer främst gälla företag som väljer att ta bort vissa nanomaterial från marknaden (eller att inte investera i forskning och utveckling av nanomaterial) för att minimera registreringskostnaderna. Dessa effekter förväntas speciellt för tillverkare och importörer av pigment och färgämnen, som inte kan ta ut samma höga priser som för avancerade nanoematerial och inte säljer i så stora volymer som vissa råvaru-nanomaterial (t.ex. kimrök, kalciumkarbonat, kiseldioxid). Tillbakadragandet av vissa pigment och färgämnen från marknaden kan få dominoeffekter för nedströmssektorer (t.ex. textilier).

Eftersom det huvudsakliga syftet med alternativen är att säkerställa bättre skydd för hälsa och miljö, skulle arbetare säkert gynnas av bättre information om nanomaterial och därmed bättre riskhanteringsåtgärder när de hanterar nanomaterial på arbetsplatsen Dessutom säkerställer alternativen att arbetstagarnas rättigheter respekteras när det gäller information och utbildning, och skulle se till att arbetsgivarna har den information som krävs för att säkerställa skyddet för sina anställda.

Fördelarna skulle inte begränsas till hälsa och säkerhet utan också ge förbättrad säkerhet för konsumentprodukter och mer allmänt minskade hälsorisker för allmänheten och naturen i samband med utsläpp av nanomaterial i miljön. Den toxikologiska och ekotoxikologiska data som tas fram kan leda till att bättre DNEL och PNEC upprättas, förbättra människors hälsa och förbättra kvaliteten på miljön (luft, mark och vatten) på längre sikt.

När man jämför kostnaderna och fördelarna bör det noteras att kostnaderna uppstår under ett begränsat antal år för företagen (Reach-förordningen ger olika tidsfrister för registreringar av olika volymer under en period av 11 år) medan fördelarna (och därmed sjukdomsfall som skulle kunna undvikas) skulle samlas över en längre tidshorisont.

När man överväger betydelsen av de resultat som presenteras i den här studien, bör resultaten ses som vägledande uppskattningar snarare än exakta siffror.

Det bör också noteras att det för närvarande kvarstår en del utmaningar för riskbedömning av nanomaterial, närmare bestämt i karakterisering av fysikalisk-kemiska parametrar och metrologi och dosering som ska användas för att bedöma fara och exponering, och för bestämning av persistens och bioackumulerbarhet i miljön i nanomaterialens livscykel. På grund av avsaknaden av en tydlig enighet kring lämpliga metoder och standarder, kan företag ha svårt att följa nya regleringsåtgärder tills tydliga riktlinjer finns.

1 Introduction

1.1 Overview of the Study

Nanotechnology is the branch of technology that makes deliberate use of materials (known as "nanomaterials") with dimensions in the order of nanometres. One nanometre (1 nm) is 1 x 10^{-9} metre or one billionth of a metre, which equates to 10,000 times smaller than the diameter of a human hair. At such a scale (i.e. at a molecular scale), nanomaterials may show novel physicochemical properties compared to their bulk form, and industry is increasingly using these properties to enhance the performance of materials across several different fields and in a wide range of applications. The same special properties that occur at the nanoscale and can enhance the performance of materials could, however, result in hazard profiles that may also be different from those of the bulk form. The nature and extent of these hazards are currently difficult to predict given our level of understanding of properties at this scale. They therefore need to be assessed on a case-by-case basis. As stated in the Nanotechnology Communication of the European Commission: "*Nanotechnology must be developed in a safe and responsible manner. Ethical principles must be adhered to and potential health, safety or environmental risks scientifically studied... "*.[2]

In response to the call from the European Parliament for tighter controls on nanotechnologies (April 2009)[3], the European Commission has introduced nano-specific provisions in various legislative instruments, including in relation to cosmetic products, biocides and food information provision to consumers; the Commission has also brought forward the Recommendation for a definition of nanomaterials.[4]

However, a Commission study looking at the registration under REACH of NMs up to 1 December 2012 found the identification of dossiers that included NMs to be very challenging (JRC, 2012[5]). Since the publication of this document, limitations in the version of the REACH registration software available at the time of the initial registration phase have been addressed, and the recommended definition of NMs has been published. ECHA has also updated its guidance on substance identification, information requirements and chemical safety assessment for REACH registration, in order for this guidance to adequately address substances in the nano-form. Nevertheless, ECHA has received so far around six joint submissions and two individual submissions of dossiers for which registrants had ticked the "nano" box in the IUCLID dossier (section 2.1 & 4.1) referring to 13 substances only[6].

Possible amendments to the REACH Annexes in order to improve the process of identifying the potential hazards of nanomaterials are currently being discussed by the European Commission with the Member States Competent Authorities (CASG Nano).

In parallel, some Member States (Belgium, Denmark, France and Norway) already implemented mandatory notification schemes for manufactured nanomaterials (on their own,

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[2] EC (2004): Towards a European Strategy for Nanotechnology, Communication from the Commission, DG Research, Luxembourg.

[3] European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials (2008/2208(INI)). Available at: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2009-0328+0+DOC+XML+V0//EN

[4] Recommendation 2011/696/EU on the definition of nanomaterials.

[5] JRC (2012): NANO SUPPORT Project - Scientific technical support on assessment of nanomaterials in REACH registration dossiers and adequacy of available information, Final Report dated March 2012.

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

in mixtures or contained in articles) in light of the gaps in information in relation to market penetration and the potential risks associated with nanomaterials. The European Commission is also preparing an impact assessment to identify and develop the most appropriate way to increase transparency and ensure regulatory oversight for nanomaterials.

The aim of this study, carried out for the Swedish Chemicals Agency, is to determine the qualitative and, where possible, quantitative impacts of two potential legislative options that would establish separate requirements for nanomaterials (as opposed to the bulk form of the substance where applicable).

In accordance with KemI's proposed work plan, three main tasks have been undertaken:

- Task 1: Inception and information gathering - review of the relevant literature with the aim of gathering the information necessary for the definition of the baseline and the assessment of the policy options;
- Task 2: Option Assessment – the assessment follows the Commission's Impact Assessment guidelines;
- Task 3: Conclusions - upon completion of Task 2, drafting of three deliverables:
    - An executive summary of the report;
    - The final impact assessment report;
    - A stand-alone page summarising the conclusions of the study.

1.2 Structure of Report

This report has been structured to reflect the approach recommended by the European Commission in its *Impact Assessment Guidelines*[7]. The Guidelines specify the following steps for an impact assessment:

Identification of existing problems and objectives of policy intervention;

Defining the policy options;

Identification of impacts that are relevant and key stakeholders that might be affected;

Initial assessment of the importance of these impacts based on their expected magnitude and on the likelihood of them occurring;

In-depth analysis of the most significant impacts;

Comparison of the policy options; and

Identification of the preferred policy option.

Section 2 provides the review of the relevant reports and articles, in order to gather necessary information and data for the impact assessment. Section 3 of this report covers the definition of the problem (*why policy action is required?*) and the definition of the baseline (the basis for comparing policy options). Section 4 provides the definition of the policy options and the key data and assumptions, while Section 5 provides the initial screening and the qualitative description of the potential impacts and, where possible, the quantitative assessment of the costs and benefits of the policy options.

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

2 Literature Review

2.1 Introduction

Despite the fervent discussions that have been held over the regulation of nanomaterials, few studies have attempted a full assessment of the impacts of policy action in the field.

This Section presents a review of the studies that provide valuable information for this assessment.

2.2 Matrix (2014): Impact Assessment of Relevant Regulatory Options for Nanomaterials in the Framework of REACH

2.2.1 Introduction

This study was undertaken to support the proposed forthcoming Impact Assessment on the REACH Regulation as it relates to Nanomaterials, where the objective of the policy initiative is "*to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers*". The objective of the study is "*to provide technical assistance and support to the Commission with regard to certain elements of the impact assessment accompanying a potential policy proposal*".

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

2.2.2 Methodology

The study was undertaken using the following research methods:

- 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 findings from a Public Consultation Exercise were used to inform the study.

To complement the industry focus within the stakeholder interview programme, a small number of evidence reviews based upon selected nanomaterials was undertaken. The purpose of undertaking such studies was to focus more closely on understanding the potential impact of suggested measures in the regulatory system brought about by each of the options considered. The materials subject to assessment were selected on the basis of which would provide the broadest and most representative sample of materials and also follow on from recent research studies undertaken by BiPRO for the European Commission Joint Research Centre and RPA for CEFIC. The materials assessed were therefore:

- Titanium dioxide;
- Carbon black;
- Carbon nanotubes; and
- Synthetic amorphous silica (SAS).

2.2.3 Problem definition

Table 2-1 provides an overview of the problems associated with the current situation (in relation to how nanomaterials are considered within REACH). This was developed through reference to the Commission's Draft Road Map alongside primary evidence from stakeholder interviews with industry, environmental, trades union and scientific bodies, outputs from the Public Consultation Exercise and the secondary evidence review.

Table 2-1: Problem Definition Overview – a Summary

Aspect	Problem Definition
Nature and scale of problem	Principal problem is that 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 information 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, 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	Producers of NM are immediately affected, which in turn will impact a range of stakeholders across the supply chain. Stakeholders suggest that there may be a disproportionate impact for SMEs, which may be more likely than larger enterprises to respond to current regulatory uncertainty by withdrawing from the market or being dissuaded from entering the market.
Drivers/underlying causes	Immediate drivers of the problem relate to the absence of sufficient specific provisions for NM within the REACH annexes. The Public Consultation Exercise indicates that 68% and 18% of respondents consider the current registration provisions and information requirements for the registration of NM to be unclear or very unclear respectively
Problem development and 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 REACH annexes in relation to NM. There are risks relating to balancing potential regulatory benefits with increased costs for business and other stakeholders. Uncertainties relate to the evolving evidence base on NM safety testing.

2.2.4 Options Development and Refinement

The European Commission provided the options to be considered in the Matrix study. These options are outlined in Table 2-2.

Table 2-2: Study Options	
Option	**Description**
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	This option 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	This option is based on "soft law" and would include one or more of the following: 1) communication, 2) resolution and 3) other measures.
Option 4	This option 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	This option 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.
Option 6	This option 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 NM-specific properties on risk.

2.2.5 Cost Analysis

A key element of the Stakeholder Engagement Programme carried out by Matrix was to obtain up-to-date estimates of the prospective costs of testing (where tests were 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.

This cost assessment process involved determining what tests would be undertaken, designing a Data Capture Tool, sourcing of cost estimates from laboratories and collating data that had been returned from these laboratories. In relation to this, Matrix examined what type of testing approach was likely to be used for nanomaterials under REACH. Matrix note that the OECD and its member countries have come to the conclusion that the approaches for the testing and assessment of traditional chemicals are, in general, appropriate for assessing the safety of nanomaterials, but may also have to be adapted to the specificities of nanomaterials. As with other chemicals, it is clear that each nanomaterial may pose specific challenges but, in most instances, they can be addressed with existing test methods and assessment approaches. In some cases, it might be necessary to adapt methods of sample preparation and dosimetry for safety testing. Similarly, adaptations may be needed for certain Test Guidelines, but it should not be necessary to develop completely new approaches for nanomaterials. The OECD continues to review all existing methodologies to identify and implement the necessary changes needed for their application to nanomaterials.

The study indicates that at present it is not clear to testing laboratories what the exact nature of the "adaptations" to test guidelines would comprise per assay, and this represents a significant unknown for laboratories currently offering commercial services for nanomaterials testing, and in defining the exact costs of testing a nanomaterial per assay; such adaptations to methods are still being discussed at OECD level in various working groups for different areas

of testing; and some areas, like inhalation, are further along with their discussions than others. The most recent document from the OECD (2012), titled "Guidance on sample preparation and dosimetry for the safety testing of manufactured nanomaterials", and which is cited as being relevant to water insoluble manufactured nanomaterials (as soluble forms would not need special attention), provides further discussions but does not offer definitive guidance to practitioners as to what should be done on a case by case basis. As the OECD notes, it is a living document, and is evolving as the science of NM characterisation for the purpose of safety assessment develops. The 2012 document states that "due to the wide variety of nanomaterials, it is difficult to develop advice applicable to all nanomaterials; accordingly, the performer of a study will have to exert some judgment on a case-by-case basis on the applicability of the recommendations given in this guidance to their particular material".

For the purposes of the Matrix assessment, it was assumed that all standard physicochemical tests, mammalian toxicology and ecotoxicology guideline tests and risk assessment methods as used for "traditional chemicals" provide a relevant starting point in order to test and assess nanomaterials for REACH, as a minimum. It is noted that these methods will need adapting case-by-case; Matrix also argue that, in some instances, significant costs over and above the standard protocols can be expected with respect to, for example, additional characterisation, additional and specific histopathology/tissue sampling, specific expertise in designing and interpreting study data, etc. It is further noted that there is likely to be variability in the tests required for different nanomaterials.

Test Cost Data

Chemical characterisation laboratories were contacted to provide cost estimates for undertaking substance characterisation. Data obtained from two laboratories offering commercial services for nanomaterials indicated very different results. One of these laboratories indicated that it was difficult to provide generic costs per assay, as each nanoform they had experience with presented its own unique challenges when being characterised, and different methods were needed to obtain different parameters and measures to characterise size, shape, and a range of other properties thatcould be relevant to the toxicological properties of the material. However, the laboratory advised that, in its experience, costs had ranged from **€40,000 to €500,000 for a "characterisation" package**. The lower estimate relates to a technically straightforward analysis of simple particulates while the higher estimate relates to more complex characterisation of nanoforms (e.g. nanoforms with unusual size and shape properties) that require more sophisticated analytical techniques, such as specialist imaging techniques.

Discussions with the laboratories that took part in this study indicate that, in general, the requirement for chemical characterisation is an area where significant cost variations can occur. Therefore, in order to capture the possibilities for nanomaterials in general and to simplify the ensuing complexity, Matrix assumed that the generic range of **€40,000 to €500,000** is representative of a pragmatic minimum to outside maximum range. This range was adopted as a fit-for-purpose range that would cover the additional nature of characterisation according to the OECD WPMN parameters for nanomaterials and the JRC list of characterisation methods that could be determined for nanomaterials according to EU No 696 (2011). It is assumed that the process of obtaining the "standard" basic physicochemical properties (as per a REACH dossier list for any chemical e.g. melting point, boiling point, basic granulometry, etc.) would be the same for nanomaterials as any other substance. Full, detailed characterisation of the nanomaterial would require specific additional analyses including some or all of the OECD WPMN parameters and JRC characterisation

methods (estimated to cost between €40,000 and €500,000), as necessary, to describe the nanoform as manufactured, as dosed and ideally as taken up by the organism in a test, and as exposed for the purposes of risk characterisation in the exposure scenario being assessed.

Further test cost estimates provided by testing laboratories are provided in Annex 5 of the Matrix (2014) report.

Test Costs per Option

The cost data was divided for presentation purposes into two main elements. The first provides an overview of potential costs on a per form/dossier basis, providing a maximum and minimum scenario for the additional characterisation costs that might arise. Table 2-3 provides a summary of the total costs per option (in addition to the baseline), per REACH Annex and per nanoform by using the estimated cost range of undertaking a "characterisation" package of €40,000 to €500,000.

Option 6 results in a new testing programme and extensive characterisation, toxicokinetics and fate and behaviour analysis for each nanoform, and includes long-term tests via inhalation as the main routes, but all routes are covered, and this accounts for the high costs. Matrix assumes that option 6 measures would be adopted after Option 2 and 4 measures have been implemented. However, in order not to double count in costing Option 6, costs have not been added to Option 2 and 4; instead option 6 is a stand-alone worst case estimate for a full set of testing.

Table 2-3: Summary of the Total Cost per Option, per Annex and per Nanoform						
Annex	Totals Summary for Options 2, 4, 5 and 6 (€m)[1]					
	Baseline	Option 2 (Additional Total)	Option 4 (Additional Total)	Option 2 & 4 (Additional Total)	Option 5 (Additional Total)	Option 6 (Additional Total)[2]
Realistic average cost						
Annex X characterisation (€40,000)	3.16	0.06	0.02	0.08	-2.8	3.54
Annex IX characterisation (€40,000)	1.57	0.06	0.21	0.27	-1.18	1.93
Annex VIII characterisation (€40,000)	0.49	0.14	0.49	0.63	-0.3	0.83
Annex VII characterisation (€40,000)	0.05	0.15	0.59	0.74	0.01	0.38
Maximal average costs						
Annex X characterisation (€500,000)	3.16	0.65	0.02	0.67	-2.8	4.06
Annex IX characterisation (€500,000)	1.57	0.65	0.27	0.92	-1.18	2.45
Annex VIII characterisation (€500,000)	0.49	0.74	0.66	1.39	-0.3	1.35
Annex VII characterisation (€500,000)	0.05	0.74	0.79	1.53	0.01	0.9
[1] These costs are for testing and preparing/amending a dossier for one additional nanoform within one substance dossier. *[2] Costs for an additional set of baseline tests, new dossier, plus additional nanomaterials-specific characterisation, TK and Fate & behaviour work. Assumes 2 and 4 have been implemented, but costs for 2 and 4 have not been added to Option 6 total, as this would double account for some tests*						

Overview of Registration Costs of Nanomaterials Requiring Registration

For the purposes of the Matrix study, it was assumed that 500 to 2,000 nanomaterials are/will be manufactured or imported in quantities greater than 1 tonne per annum per legal entity and therefore subject to the REACH registration. For consistency with previous studies, notably RPA (2012) and BiPRO *et al* (2013)[8], and in the absence of more reliable information, it was assumed that additional testing requirements would be required for 100 to 400 nanomaterials, and that this would cover the registration of 400 to 1,600 nanoforms which would be adequately addressed through a grouping or read-across approach.

Matrix note that there is extensive uncertainty relating to the detailed strategy for registration and structure of a registration dossier for each of these substances. They therefore assumed that nanomaterials would be included within the registration dossier for the bulk substance. The extent to which read-across and grouping could be applied in terms of relating the

[8] BiPRO *et al* (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.

nanomaterial to the bulk form of the substance or between nanoforms of the same material would then be determined on a case by case basis.

Table 2-4 provides an overview of the number of nanomaterials/forms requiring registration, as taken from BiPRO *et al* (2013).

Table 2-4: BiPRO (2013) Overview on the Number of Nanomaterials/Forms requiring Registration				
Tonnage Band	**1-10 t/y**	**10-100 t/y**	**100-1,000 t/y**	**>1,000 t/y**
% distribution (untreated)	10%	20%	50%	20%
No. of nanomaterials/forms (untreated)	5-20	10-40	25-100	10-40
% distribution (treated)[1]	0%	20%	50%	30%
No. of nanomaterials/forms (treated)[1]	0	10-40	25-100	15-60
Total no. of nanomaterials/forms to be registered	5-20	20-80	50-200	25-100
[1] *Assuming grouping/read-across is possible.*				

Using the information in Tables 2-3 and 2-4, the total range of expected costs by Option as estimated by Matrix is provided in Table 2-5.

The second element of the costs data calculations uses the above estimates to develop an updated set of aggregate estimates of costs developed utilising the assumptions that underpinned the BiPRO study on the regulation of NM under REACH. Table 2-6 provides the extrapolated cost estimates produced by Matrix for each of the substantive options considered (with the costs for each option being additional to the baseline option).

Matrix note that these costs could increase or decrease depending on the actual number of nanomaterial forms and the degree/level of read across that may be applicable.

Table 2-5: Overview of Registration Costs of Nanomaterials requiring Registration under each Option						
Annex	Totals Summary for Options 2, 4, 5 and 6 (€m)					
	Baseline	Option 2 (Additional Total)	Option 4 (Additional Total)	Option 2 & 4 (Additional Total)	Option 5 (Additional Total)	Option 6 (Additional Total)
Realistic average cost						
Annex X characterisation (€40,000)	15.8-63.2	0.3-1.2	0.1-0.4	0.4-1.6	(-14)-(-56)	17.7-70.8
Annex IX characterisation (€40,000)	31.4-125.6	1.2-4.8	4.2-16.8	5.4-21.6	(-23.6)-(-94.4)	38.6-154.4
Annex VIII characterisation (€40,000)	24.5-98.0	7.0-28.0	24.5-98.0	31.5-126.0	(-15)-(-60)	41.5-166.0
Annex VII characterisation (€40,000)	1.25-5.0	3.75-15.0	14.75-59.0	18.5-74.0	(0.05)-(-0.2)	9.5-38.0
Maximal average costs						
Annex X characterisation (€500,000)	15.8-63.2	3.25-13.0	0.1-0.4	3.35-13.4	(-14)-(-56.0)	20.3-81.2
Annex IX characterisation (€500,000)	31.4-125.6	13.0-52.0	5.4-21.6	18.4-73.6	(-23.6)-(-94.4)	49.0-196.0
Annex VIII characterisation (€500,000)	24.5-98.0	37.0-148.0	33.0-132.0	69.5-278.0	(-15)-(-60.0)	67.5-270.0
Annex VII characterisation (€500,000)	1.25-5.0	18.5-74.0	19.75-79.0	38.25-153.0	(0.05)-(-0.2)	22.5-90.0

Table 2-6: Aggregate Cost Summaries under each Option (based on BiPRO assumptions)		
Option	Additional Testing Costs (€m)	Additional Administrative Costs (€m)
Baseline	(183)[1]	N/A
Option 2	30.75	15,200
Option 3	N/A	N/A
Option 4	104.4	22,100
Option 5	-136.4	2,800
Option 6	270.25	240,000
[1] *Baseline costs (i.e. 'additional testing costs' to be added to this baseline aggregate cost). Negative figures represent a cost saving.*		

2.2.6 Impact Analysis

Assessment of Options

Assessment of the potential impacts of the various options (outlined in Table 2-2) within the health and social, economic and environmental domains was principally qualitative. It was based upon secondary review and expert input from toxicologists with health and environmental expertise. A summary of the qualitative impacts as reported by Matrix under each of the options is outlined below:

- **Option 2**: potentially positive impact on human health and environmental safety, with a broadly neutral impact on economic or environmental issues.
- **Option 3**: as this option is not linked to any substantive clarification or extension of requirements, the same impact limitations as identified for the baseline are considered to apply (i.e. no change).
- **Option 4**: extends the scope of REACH and provides additional requirements, with the potential to identify and mitigate health and environmental risk.
- **Option 5**: could have positive impacts on employment, but increased risk of failing to identify and mitigate health and environmental risk.
- **Option 6**: involves 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.

Options Comparison

The final part of this study involved the comparison of each of the six options by assessing their effectiveness, efficiency and coherence (these being assessment criteria set out in the European Commission's Impact Assessment Guidelines). Comparison of the options was undertaken using a scoring method, which involved scoring each aspect from minus 5 (least positive) to plus 5 (most positive), with zero being a neutral (no impact) rating. The scores presented in Table 2-7 represent the total for a range of measures used to assess each summary measure.

Table 2-7: Summary of Option Assessment

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

The multi criteria assessment indicates that Option 2 scores significantly higher than the other options. This stands in contrast to the summary response of stakeholders in the Public Consultation Exercise[9] 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 (baseline) and soft law (Option 3) options received negative scores, which is in part a reflection of stakeholder evidence of negative 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.

Impacts on SMEs

Improved clarity of nanomaterials within the regulatory context was considered to be advantageous to SMEs, micro enterprises and start-ups. However, there was significant concern that an increase in the regulatory cost burden (in particular Option 6 and to a lesser

[9] The public consultation exercise received around 116 responses: 61% from industry stakeholders, 15% from public authorities, 12% from "Other" category (i.e. individuals), 9% from NGOs, 3% from research/academic institutions and 1% from consumer associations (Matrix, 2014, Appendix 10, page 167).

extent Option 4) could negatively impact the ability of European SMEs to compete in the nanomaterial market.

2.2.7 Conclusions

The core findings of the study are that:

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

2.3 RPA *et al* (2014): Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials in the Market – Evaluation Report

2.3.1 Introduction

In December 2013, the Commission commissioned a study to support the preparation of an impact assessment to identify and develop the most adequate way to increase transparency and ensure regulatory oversight for nanomaterials. The study is still ongoing[10] but some interim reports have been made available online[11] by the Commission in order to ensure transparency and to receive comments from stakeholders.

In particular, the evaluation report is relevant for this assessment, as it analyses the experience of the first year of implementation of the French Notification System (FNS), providing some data on the number of nanomaterials notified and costs incurred by the companies for notification purposes.

2.3.2 Methodology

The overview of the different policy initiatives implemented or proposed by European countries in order to increase the level of information on the nanomaterials on the markets is based on the review of the relevant legislative acts and initiatives implementing and proposing nanomaterials register-like schemes across Europe.

The analysis of the FNS is based on the report published by the French authorities in November 2013[12]. RPA compared the list of substances notified to the FNS and published in the French public report (Table 7 and 8, pages 27-80 and 81-108) with the ECHA registered

[10] October 2014.
[11] http://ec.europa.eu/enterprise/newsroom/cf/itemdetail.cfm?item_id=7523&lang=en&title=Validation-workshop-on-transparency-measures-for-nanomaterials
[12] http://www.developpement-durable.gouv.fr/IMG/Rapport_public_format_final_20131125.pdf

substances database, the European chemical Substances Information System (ESIS) and the Classification and Labelling Inventory. The exercise was carried out in order to determine the level of information available on the substances notified to the FNS and if any of the information refers specifically to the nanoforms of the substances, as opposed to the substances in general.

In parallel with the analysis of the available information, RPA launched an online survey addressed to companies with relevant experience of the FNS and/or the Cosmetic Products Notification Portal (CPNP). The survey aimed to gather information on the costs and administrative burden that the notification obligations may put on the enterprises. Moreover, two separate and brief questionnaires were sent by the authors to the French authorities and DG SANCO in order to gather information on the costs to set up and run the FNS and the CPNP for the public authorities.

The report also presents an analysis of the past and current debate in France over the notification system, in order to model any potential impacts of the availability of the information, such as long term health and environmental benefits for consumers and workers stemming from changes in the public perception of nanomaterials and, ultimately, resulting in behavioural changes when dealing with nanomaterials of both workers (e.g. increased awareness over health and safety issues of nanomaterials) and consumers (e.g. aversion to products containing nanomaterials).

2.3.3 Results

As France has been the first country to establish a mandatory reporting scheme, the FNS has been analysed in-detail. Manufactured nanomaterials produced, imported or distributed in France in quantities above 100 grams per year (as such or as part of a mixture without being bound, or in articles where the substance is intended to be released under normal or reasonably foreseeable conditions of use) need to be notified to the authorities. By and large, the definition of a nanomaterial as adopted by the French legislation coincides with the EC recommended definition 2011/696/EU[13], although the scope is restricted to intentionally manufactured nanomaterials only. The notification duty is on the manufacturers, importers and/or distributors to professional users of nanomaterials. The duty-holders are required to submit a variety of information, including substance identity (e.g. chemical name, formula, CAS, mean particle size, number size distribution for particles with an indication of the determination method used), quantity, use information and the identity of their professional customers. In turn, they receive a unique number for each notification, which needs to be passed on with all transfers of ownership to professional users and distributors so that they can make their own notifications referring to their suppliers' notification.

The deadline for the first year was set to the 30th June 2013. At the 1st July, the authorities received 3,409 notifications from 933 notifiers. For the purpose of the publication of the results of the first year of the FNS, of the 3,409 notifications finalised and validated, only 80% (2,776) were selected and analysed, excluding those notifications reported as erroneous by notifiers, those concerning actors outside the French territory and those covered by confidentiality rules. Around 1.5% (50 over 3,409) were simplified notifications submitted by public research organisations.

[13] Commission Recommendation of 18 October 2011 on the definition of nanomaterial (2011/969/EU).

Number of nanomaterials

In terms of the number of nanomaterials notified, the authors noted that, at November 2013, the French authorities were not in the position to provide an in-depth analysis of the database. As a matter of fact, only 59% of the notifications (1,632) reported a CAS number, while in the remaining 41% the nanomaterials were identified by a chemical name only. In first instance, the French authorities estimated that between 243 and 422 different substances have been notified as nanomaterials on the French market. It has to be noted that for each different CAS number (around 243) and different chemical name (around 179), there might be several distinct nanomaterials, depending on the basis of physicochemical parameters. Through the analysis of the 399 entries listed in the French public report, RPA identified around 258 different substances. However, RPA noted that during the 2014 notification process the French authorities have received almost three times (over 10,000) the number of notifications received in 2013; as a result, 258 substances "*… is not the definitive number of substances at nanoscale notified to the FNS and should be intended just as an indication*".

Table 2-8 reproduces Table 6-1 of the Evaluation report, presenting the number and percentage of substances at the nanoscale per notified quantities. Around one fifth of the different substances identified on the French public report list did not have assigned any tonnage band.

Table 2-8: Number and percentage of substances at the nanoscale per notified quantities

Notified quantities	Number of substances	% on the total number of substances	% over the 206 substances with reported quantities
Not reported	52	20.2%	-
0.1 - 1 kg	8	3.1%	3.9%
1-10 kg	9	3.5%	4.4%
10-100 kg	20	7.8%	9.7%
100 kg-1 t	51	19.8%	24.8%
1-10 t	47	18.2%	22.8%
10-100 t	45	17.4%	21.8%
100-1000 t	15	5.8%	7.3%
>1000 t	11	4.3%	5.3%
tot	**258**	**100 %**	

Source: RPA et al (2014), Table 6-1.

In terms of quantities, between June 2012 and June 2013, the data submitted to the French authorities indicates that around 282,000 tonnes of nanomaterials were manufactured in and 222,100 tonnes imported into France, for an aggregated amount of 504,100 tonnes. Around 50% of the substances notified are manufactured and/or imported in France in less than 1 tonne per year.

Notably, 50% of the number of notifications received in 2013 refer to only four substances: silicon dioxide (over 30%), titanium dioxide (over 8%), carbon black (over 6%) and cerium dioxide (over 5%). In terms of quantities, the market is dominated by four nanomaterials:

- Carbon black (over 50% of the market);
- Silicon dioxide (over 30%);
- Calcium carbonate (7%); and
- Titanium dioxide (3%).

RPA noted that the remaining five percent of the nanomaterials' tonnage on the French market is made up of the other 254 substances, of which over 150 have been identified as pigments and dyes.

Table 2-9 reproduces the results of the cross-analysis carried out by RPA between the list of notified substances and the ECHA registered substances database. RPA *et al* (2014) adds a disclaimer to the reported results: "*it is important to note that this analysis refers to the chemical substances as defined by the REACH Regulation and that the information in the REACH registration dossiers of the substances that were found in the ECHA database are unspecific and do not refer to the nanoforms. Aim of the analysis is to identify the number of substances with forms at the nanoscale which bulk forms have been registered or will be registered by the 2018 deadline. It is expected that following the development of better guidelines for the registration of nanomaterials by ECHA and the future implementation of the amendments to the REACH Annexes, more and better information will be submitted on the nanoforms. However, it is currently not possible to determine the extent of the increase in the level of information and of its quality*".

RPA found that around 62% of the **substances** that have been notified to the French Notification System as manufactured, imported or distributed in France at the nanoscale had a full registration dossier in the ECHA database. Around one hundred substances (38%) could not be found among the list of the registered substances: 16 substances were identified as polymers (outside the scope of the REACH Regulation) while, for the remaining 83 substances, RPA proposed as a possible reason for the lack of any information on the ECHA registered database the potential that the substances (at the nanoscale and macroscale) are currently manufactured/imported in quantities below 100 tonnes per annum and will be registered under the next Registration deadline.

Table 2-9: Results of the cross-analysis between the list of notified substances at the nanoscale and the ECHA registered substances database

Number of notified substances **found** on the ECHA registered substances database	**159**
Per tonnage band	**No.**
1 - 10 tonnes per annum	9
10 - 100 tonnes per annum	29
100+ tonnes per annum	1
100 – 1,000 tonnes per annum	46
1,000 – 10,000 tonnes per annum	33
10,000 – 100,000 tonnes per annum	17
100,000+ tonnes per annum	1
100,000 – 1,000,000 tonnes per annum	12
1,000,000+ tonnes per annum	2
1,000,000 – 10,000,000 tonnes per annum	5
100,000,000+ tonnes per annum	1
Tonnage data confidential	3
Number of notified substances that were **not found** on the ECHA registered substances database	**99**
Reason	**No.**
Polymer or polymer group (outside the scope of REACH)	16
Other (possible reason: tonnage lower than 100 tonnes per annum)	83
Total	**258**
Information not sufficient to carry out the research	12
Source: RPA et al (2014)	

Moreover, two substances might be covered by the exemption granted by the REACH Regulation to naturally occurring substances:

- Vitreous silica (also known as “fused silica”, EC number: 262-373-8, CAS number: 60676-86-0, number 82 in Table A3-1) is not covered by the Registration dossier for amorphous silica and it has not been registered because considered to fulfil the condition of the exemption granted to minerals which occur in nature, if not chemically modified (Article 2(7)(b));[14] and
- Palladium (EC number: 231-115-6, CAS number: 7440-05-3, number 78 in Table A3-1), that is a mineral which occurs in nature and thus exempted according to Article 2(7)(b).

Two hundred and eleven substances are listed with an EC number starting with 2 or 3, meaning that they were commercially available in the European Union between 1971 and 1981 and thus considered phase-in substances under the REACH Regulation. Eleven substances have an EC number starting with 4, meaning that they became commercially available in the European Union after 1981. One substance (Styrene, oligomers, EC number: 500-008-9, CAS number: 9003-53-6) has an EC number starting with 5 and thus is a “no longer polymer” substance, namely a substance that was considered to be a polymer as defined by Directive 67/548/EEC but was no longer considered to be a polymer after the definition of polymer was changed in the 7th amendment (92/32/EEC) to the Directive. Four substances had an EC number automatically assigned and starting with 6 because they were identified only with a CAS number. One substance (Reaction mass of cerium dioxide and zirconium dioxide, EC number: 909-709-8) had an EC number automatically assigned and starting with 9 because it did not have a CAS number or any other numerical identifier.

From the above, RPA concluded that around 80% of the substances that were notified to the FNS were already on the market before 1981. RPA note, however, that is possible neither to establish if the nanoforms of those substances were commercialised before that date nor to establish whether the nanoforms of the registered substances were on the EU market before 1 December 2008 (information relevant to establish whether the nanoforms are covered by the amendment of Annex III under Option 0B (see Section 4.2.3)).

The above analysis is relevant for the current assessment and discussions on the amendments of the REACH Annexes and discrimination between phase-in and non-phase in substances and, subsequently, in the definition of the added value of any national or EU-wide nanomaterials register.

In summary, around 160 substances (60%) have already a REACH Registration dossier, with another 80 substances likely to be registered before the 2018 REACH deadline. This implies that between 60% - 90%[15] of the substances notified to the FNS would be covered by the REACH Regulation, with the high end being the most probable.

Ten to forty per cent of the substances notified to the FNS are thus outside the scope of REACH: when considering the low end, 10% of the substances notified to the FNS are polymers, naturally occurring substances, substances exclusively used in medicinal products for human or veterinary use and in food or feeding stuffs (Article 2(5)(a)(b)), or substances exclusively used for research and development purposes; when considering the high end, the additional 30% of the substances notified to the FNS and not found in the ECHA database might be manufactured/imported in quantities below 1 tonne per year and, thus, not subject to the registration requirement.

[14] http://www.ima-reach-hub.eu/index.php?option=com_docman&task=doc_download&gid=138
[15] 160 + 80 = 240 on 260 substances

For the current assessment, it is important to note that, when extrapolating the results of the FNS to the European level, the French authorities reported that during the second year of the implementation of the system, they received over 10,000 notifications. Although it is likely that most of them come from duty-holders that became aware of their notification obligations only recently, some of these notifications might refer to nanomaterials that have not been previously notified.

Costs

RPA reported that, among the companies that had to characterise the nanomaterials, four of them (among the companies that notified the highest number of nanomaterials) estimated costs ranged from €3,000 to €10,000 per substance.

Another 5 companies provided figures ranging between €3,000 and €5,000: these companies had to generate only part of the information for the purposes of the notification. These are formulators having to submit, for example, information on the agglomeration/aggregation state or information on the modification of the surface coating.

For the current assessment, it is important to note that the FNS requires the mandatory submission of information only on a limited number of parameters, namely:

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

Applications and uses

RPA analysed also the descriptors of the Sectors of Use notified by the companies. Most of the notifications reported the Sector of Use (SU) 0 "Other" as one of the descriptors. In a REACH registration dossier, the descriptor "other" should be accompanied by an appropriate description of the "other" uses[16]. It is not known however if such a description was provided also under the FNS and, if it was, it has not been made available in the French public report. Around 132 substances were notified in SU10 "Formulation (mixing) of preparations and/or re-packaging (excluding alloys)": most of them have been identified by RPA as pigments and dyes. The other main Sectors of Use are the manufacturing of plastic products (SU12) and Agriculture, forestry and fishery (SU1). Table 2-10 reproduces Table 6-8 of RPA *et al* (2014) on the number of substances per notified sectors of use.

[16] ECHA (2010): Guidance on Information Requirements and Chemical Safety Assessment – Chapter R.12: Use Descriptor System, Version: 2. Available at: http://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

Table 2-9: Number of substances per notified sectors of use (SU)			
Code	**Supplementary descriptor: Sectors of end-use**	**NACE codes[17]**	**NMs**
SU1	Agriculture, forestry, fishery	A	60
SU2a	Mining, (without offshore industries)	B	3
SU2b	Offshore industries	B 6	1
SU4	Manufacture of food products	C 10,11	8
SU5	Manufacture of textiles, leather, fur	C 13-15	7
SU6a	Manufacture of wood and wood products	C 16	3
SU6b	Manufacture of pulp, paper and paper products	C 17	18
SU7	Printing and reproduction of recorded media	C 18	5
SU8	Manufacture of bulk, large scale chemicals (including petroleum products)	C 19.2+20.1	9
SU9	Manufacture of fine chemicals	C 20.2-20.6	27
SU10	Formulation [mixing] of preparations and/or re-packaging (excluding alloys)	C 20.3-20.5	132
SU11	Manufacture of rubber products	C 22.1	24
SU12	Manufacture of plastics products, including compounding and conversion	C 22.2	70
SU13	Manufacture of other non-metallic mineral products, e.g. plasters, cement	C 23	10
SU14	Manufacture of basic metals, including alloys	C 24	2
SU15	Manufacture of fabricated metal products, except machinery and equipment	C 25	7
SU16	Manufacture of computer, electronic and optical products, electrical equipment	C 26-27	6
SU17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	C 28-30,33	21
SU18	Manufacture of furniture	C 31	3
SU19	Building and construction work	F	28
SU20	Health services	Q 86	7
SU23	Electricity, steam, gas water supply and sewage treatment	C 35-37	2
SU24	Scientific research and development	C72	32
SU0	Other		147
Not reported			1
Source: reproduced from RPA et al (2014), Table 6-8.			

In terms of Chemical Product Category (PC) and Article Category (AC), fewer notifications provided information against these descriptors: most of the nanomaterials have been notified as used in coatings and paints, thinners, paint removers (PC9a), ink and toners (PC 18) and in polymer preparations and compounds (PC12). The article categories (describing the type of article in which the nanomaterials are contained during service life and waste life) most notified were AC2 “Machinery, mechanical appliances, electrical/electronic articles”, AC1 “Vehicles” and AC4 “Stone, plaster, cement, glass and ceramic articles”.

2.3.4 Limitations of the study

The analysis carried out by RPA *et al* (2014) is based on the first year of implementation of the French Notification System: already during the second year, the French authorities have received three times the number of notifications received in 2013. Although it is likely that most of these new notifications came from duty-holders that became aware of the notification

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

obligation at a later stage only, some of these might refer to new substances at the nanoscale that were not previously notified.

With regard to the cost assessment, the costs linked with the characterisation of the nanomaterials to be notified (estimated between €3,000 and €10,000) are based on the responses received from four companies only, although these ranked among the companies that more nanomaterials had to notify. Another five companies provided ranges between €3,000 and €5,000, but had to notify only some of the parameters. These cost ranges refer only to a partial characterisation of the nanomaterials (five parameters, of which shape and coating requiring a qualitative description), where a full characterisation would imply the consideration of more than 15 physicochemical parameters (as reported by Matrix, 2014).

2.4 BiPRO *et al* (2013): Examination and Assessment of Consequences for Industry, Consumers, Human Health and the Environment of Possible Options for Changing the REACH Requirements for Nanomaterials

2.4.1 Introduction

The objective of this study was to carry out the assessment of the consequences for industry, consumers, human health and the environment if the options to modify REACH as proposed by the NANO SUPPORT project would have been implemented. The NANO SUPPORT project "Scientific technical support on assessment of nanomaterials in REACH registration dossiers and adequacy of available information"[18] had the aim to analyse the information provided in a selected number of REACH registration dossiers addressing nanomaterials and, following this analysis, to propose some options for the modification of the REACH annexes in order to address the need for information requirements and Chemical Safety Assessment of nanomaterials.

2.4.2 Methodology

Due to the limited information available at the time of the study, especially on the Nanotechnology markets and on the characteristics of the nanomaterials, the quantification of indirect effects (i.e. impacts on innovation or on SMEs) was not possible and just a qualitative description was provided. The authors tried to estimate the number and the company size of the manufacturers and importers of nanomaterials on the EU market, mainly through the review of past studies and some selected interviews with experts. Moreover, in order to give an illustration of the magnitude of the potential health benefits, the authors looked at past assessments of REACH and, using a top-down approach, estimated the health benefits to be expected as a result of the amendment of the REACH annexes.

For the estimate of the direct effects on industry, a case study approach was used, with the selection of three nanomaterials (Titanium dioxide, Zinc oxide and Nano diamond): the results were then used for extrapolation to the whole nanomaterials' market. The criteria for the selection of the case study were the availability of the data, the expected tonnage bands and number of registrants, the possible hazardous properties.

[18] Available at: http://ec.europa.eu/environment/chemicals/nanotech/pdf/jrc_report.pdf

In order to define the baseline against which to assess the proposed options, the authors called on the expert opinion of the European Chemicals Agency, especially with regard to numbers of phase-in substances by different tonnage bands. A time horizon of 10 years was adopted.

Twenty-on options were put forward as a result of the first part of the NANO SUPPORT project. Some of these options were considered to be implicitly part of the current REACH requirements and thus considered in the baseline. The 21 options were classified by topic area:

- Substance identification and physicochemical parameters;
- General options for human health hazards, environmental fate, environmental hazards;
- Human health hazards;
- Environmental fate & hazards; and
- Exposure assessment and risk characterisation.

Within these topic areas, twelve options were considered to be part of the baseline and to be addressed by amendment of the ECHA guidance on the provision of information on the nanoforms of the substances within the registration dossiers; nine options were further considered for the assessment.

For the quantification of the costs, the so-called "Fleischer list"[19] on testing costs across the European labs were used, although it was not possible to determine the changes in costs for the nanomaterials, due to the fact that labs did not offer routine analysis for the nanoforms of the substances and the OECD was still developing the testing guidelines for most of the endpoints and their characterisation. With regard to the number of nanomaterials present on the EU market, the authors draw on the RPA report that was commissioned by Cefic and carried out in parallel (a review is provided below). The authors extrapolated the cost figures on the basis of the case studies' results.

2.4.3 Results

In the event that the new registration requirements would have been applied just to the untreated nanomaterials, the additional costs for industry were estimated at between €5.5 million and €35 million. The testing of each nanomaterial (that is the separate testing of each nanoform, treated and untreated, of the substances to be registered) would have resulted in additional costs for industry estimated at between €50 million and €315 million.

In the event that the registrants would have the possibility to present dossiers including information on both the bulk form and surface treated nanoforms of a substance, the costs were estimated at between €6 million and €38 million. In case read-across between nanoforms would not be allowed/possible, the costs were estimated to be nine times higher, between €54 million and €340 million.

In the event that treated nanoforms would have to be registered in separate dossiers but allowing for read-across, the costs were estimated at between €4 million and €27 million. Without grouping/read-across, costs were estimated to be ten times higher.

If all nine options would be implemented, but allowing for grouping of nanomaterials and read-across, the costs were estimated to be between €11 million and €73 million.

[19] http://www.businesschemistry.org/downloads/articles/Issue09-2007_52.pdf

It must be noted that all these figures refer to a ten years period (2012 – 2022). However, the authors noted that the actual costs were not quantifiable due to the broad estimate of number of nanomaterials affected by the options.

The estimated costs for complying with the registration requirements under the baseline for untreated nanomaterials (50 to 200) were between €4.5 million and €40 million. Extending the registration requirements to all the other nanoforms would lead to additional costs estimated at between €33 million and €270 million. Allowing for grouping of nanomaterials would result in costs estimated between €17 million and €120 million.

The authors attempted also an estimate of the potential revenues linked to the manufacture of nanomaterials at the European level for the ten year period, providing a figure of €40 billion.

With regard to the benefits stemming from the implementation of the options, the authors first presented some estimates of the human health and environmental benefits of REACH as a whole from other assessments. Then, underlining the importance of such options for the generation of new information regarding nanomaterials and their properties and assuming new toxicological knowledge on 500 nanomaterials, provided a "guesstimate" of €165 million, based on the key assumption that new information would lead to 20% additional health benefits.

Finally, the authors provide a qualitative description of wider costs and benefits stemming from the options, in terms of:

- Safeguarding and improving the corporate image of companies;
- Positive effects on public acceptance;
- Potential impacts on innovation;
- Potential impacts on downstream users;
- Potential impacts on consumers;
- Effects on small and medium-sized enterprises.

2.4.4 Limitations of the study

All of the cost estimates provided within the study are associated with a high degree of uncertainty. The main factors of uncertainty are:

- Number of nanomaterials on the EU market;
- Use of size as identifier;
- Number of surface treated substances and their characterisation;
- Definition of nanomaterial;
- Registration strategies (grouping and read-across);
- Testing costs across the EU labs.

With regard to the estimate of the benefits, the main factors of uncertainty are:

- Number of workers exposed to each nanomaterial and general population exposed to nanomaterials;
- Quantitative empirical dose-response functions linking exposure to nanomaterials to human health and environmental endpoints.

In addition, we would note that, if most of the nanomaterials are already on the market, then the benefits of having additional information on them under REACH may already be captured under the estimates of human health and environmental benefits of REACH as a whole. In addition, assuming a 20 % level of additional benefits could be considered disproportionate to

the number of nano substances for which new information would be provided, given that the more general REACH benefit estimates relate to the production of new information for roughly 70% of the 30,000 substances placed on the EU market. The 20% figure implicitly assumes that nanomaterials are by their nature around four times more hazardous than their bulk counterparts.

2.5 RPA (2012): Impact Assessment of the REACH Implementation Project on Substance ID for Nanomaterials

2.5.1 Introduction

The aim of this study was to undertake an impact assessment of the REACH Implementation Project on substance ID for Nanomaterials. The European Commission initiated three REACH Implementation Projects on Nanomaterials, with the first of these - RIP-oN1 - covering substance identification and examining different approaches to this.

The European Commission has since published a definition for nanomaterials[20] that it intends to use as a reference for any EU communication on legislation addressing nanomaterials. Risk & Policy Analysts Ltd (RPA) was commissioned by the European Chemical Industry Council (Cefic) to undertake an impact assessment of the introduction of a definition which may result in a change in substance identity.

The impact assessment was based on the currently available scientific and industry information, the RIP-oN1 report, the REACH legislation and its associated guidance documents. It aimed at providing information on:

- the number and cost of **separate registration dossiers**, in terms of fees, in particular for SMEs compared to the current legal requirements;
- the cost of **additional testing requirements** of identifying several distinct/new substances with the same CAS No.;
- the increase in the **number of animal tests needed** to comply with a distinct/new substance;
- the consequences for example in relation to the provision of **information to workers via (extended) SDS**, and the added value of such new information for workplace safety; and
- the consequences for **implementation of downstream regulations** due to the identification of several distinct/new substances with the same CAS No.

The focus of the study was on the first three points, with the latter two only addressed at a high level.

In order to prepare the impact assessment, two main tasks were undertaken. The first task focussed on specific case studies to assess the impact of size and surface treatment as

[20] Commission Recommendation of 18 October 2011 on the definition of nanomaterial, 2011/696/EU. The definition of a nanomaterial is as follows:
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 derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

identifiers for two substances (SAS and titanium dioxide). In the second task, the case study findings were used together with other assumptions to develop estimates of the costs of considering nanomaterials as separate substances under REACH for the EU chemicals industry as a whole.

Note that as this work was carried out prior to publication of the EC Recommendation for the definition of a nanomaterial, it considered two potential determinants of substance identity based on the discussions provided in RIP-oN1: **size** and **surface treatment**.

2.5.2 Methodology

As previously discussed, the main focus of this study was to identify the potential impact of using different substance identifiers for distinguishing nanomaterials. Therefore the main identifiers considered in the RIP-oN1 document formed the basis for this assessment. These are:

- Particle size (with the EC recommendation used as the basis for this); and
- Surface treatment.

In the study, it was decided to examine the implications of both particle size and surface treatment due to the level of attention these had been given as identifiers in the RIP-oN1 report. This was also in part due to the belief that a large percentage of the nanomaterials produced within the EU are surface treated to impart certain desirable properties onto the substance itself (e.g. a stabiliser) or for specific applications. Although no data exist to indicate what percentage of nanomaterials may be surface treated, the companies involved in this study indicated that it is an important aspect of the market for such substances. There are two main types of surface treatment: physical and chemical surface treatment. In the case of physical surface treatment, the base substance and the surface treating agent are considered separate substances and, hence, each would need to be registered separately under REACH.

Chemically surface treated substances are currently covered by REACH FAQ 6.3.8 and are therefore exempted from registration as separate substances under REACH. The rationale behind this exemption is that the surface is a minor part of the substance. However, REACH FAQ 6.3.8 does not specifically refer to nanomaterials and there is an on-going debate regarding whether the surface of a nanomaterial is a minor part of the substance. It was assumed for this impact assessment that chemical surface treatment of a nanomaterial does result in a separate substance (identified under REACH), which will therefore need to be registered. In addition, the study found that, in some cases, a nanomaterial may be surface treated using many different types of chemical surface treating agents. It was assumed therefore that either all chemical surface treatments can be grouped and registered together or that each of these types or categories would need to be registered separately under REACH.

2.5.3 Impact Scenarios

Based on the conclusions of RIP-oN1 and the above analysis, a series of scenarios were developed to reflect the implications of a new substance identity being triggered for the registration of nanomaterials under REACH. Separate, but consistent, scenarios were developed for substances already registered and those yet to be registered (under REACH). The scenarios and assumptions underlying them were as follows:

- For already registered nanomaterials two scenarios were assumed:

  1a) No conventional form exists and the substance is only manufactured as a particle falling within the Commission Recommendation for a nanomaterial. The existing EC

number will not change and no change in the REACH registration is required other than potentially to up-date it by indicating that the substance is a nanomaterial.

2a) The nanoform of the substance is already registered together with the macroform as part of a mono constituent substance; in this case, the CSR would require up-dating based on the use of new substance ID parameters. The nanoform will be a distinct substance which may require its own test or other data, e.g. read across, to fulfil information requirements and to demonstrate safe use, unless read across can be justified.

- For nanomaterials not yet registered three scenarios were assumed:

  1b) No conventional form exists and the substance is only manufactured as a particle falling within the Commission Recommendation for a nanomaterial. The existing EC number will not change and registration under REACH proceeds according to the timeframes set out in the Regulation, with there being no further implications.

  2b) The nanoform is given its own substance ID but is registered (under its own EC number) together with the macroform as part of a mono constituent substance. The nanoform will have its own data to fulfil information requirements and to demonstrate safe use, unless read across can be justified to enable data sharing.

  3) The nanomaterial does not have its own EC number but would have been registered under phase-in provisions together with the macroform. It now must be registered under its own substance ID, separately from the macroform.

It is important to note that the assumption that nanomaterials are mono constituent substances is a simplifying one. RPA did not examine issues regarding some nanomaterials possibly being classed as UVCBs (substances of Unknown or Variable Composition or of Biological origin).

Cost impacts – Direct costs

The costs to manufacturers and importers of a change in substance identity were considered dependent on which of the above scenarios applies to them. These costs would include administrative costs and then any additional costs of complying with the other requirements of REACH. At a general level, the following potential direct cost impacts were identified:

- The costs associated with assessing nanomaterial parameters for substance identification purposes (such as particle size, size distributions, surface area, etc.);
- the administrative costs and associated registration fees of either preparing a new registration dossier or of up-dating an existing dossier to take into account the new substance identification;
- The costs of fulfilling any further testing requirements (including substance ID testing for regulatory purposes, testing to fill data gaps, further animal testing) associated with preparation of separate registration dossier or to update an existing dossier; note that the costs of filling test gaps will vary depending on whether or not read across between substances, and hence dossiers, can or cannot be justified; and
- The cost of preparing safety data sheets for each substance registered using a separate REACH dossier.

In order to set a baseline for such costs, RPA reviewed the assumptions made in previous impact assessments; in particular, those regarding the availability of test data for a statistical substance and the costs of testing a statistical substance within each of the tonnage bands (as used in the first Business Impact Assessment (BIA) prepared by RPA and Statistics Sweden,

2003). These provided the starting point for the questions to be put to industry stakeholders consulted as part of the two case studies on synthetic amorphous silica (SAS) and titanium dioxide.

Note that for the case studies (SAS and titanium dioxide); data on their actual test costs were used, where it may be necessary to fill test gaps for nanoforms of the substance. For the extrapolation exercise, we used estimates of the costs for individual tests provided by Cefic, as these were more up-to-date than the figures developed for earlier REACH impact assessments (e.g. the BIA). The testing (study) costs provided by Cefic were based on price quotations that were collected from various (up to five) European toxicology labs. Depending on the end point, more price quotations were included in the average. These figures are updated when new quotes are received from labs, rather than being part of some automatic yearly updating process. With respect to Registration Fees, these were taken from the Regulation (EC) No 340/2008.

Cost Impacts – Indirect costs
The study found that the formal definition of nanomaterials as 'new' substances under REACH could have implications with respect to downstream legislation and hence lead to indirect costs.

Case study assessment
As noted above, Cefic selected two substances (synthetic amorphous silica - SAS and titanium dioxide) to be used as case studies as part of this impact assessment. A structured questionnaire was sent to a group of SAS industry manufacturers and titanium dioxide industry manufacturers to help with the impact assessment component of the study. The aim was to obtain quantitative and qualitative information from the SAS and titanium dioxide manufacturing industry to identify the potential direct and indirect impacts of introducing new parameters for substance ID under REACH apart from those in Annex VI.

In both cases, size and surface treatment were considered to be the main relevant substance identifiers and provided the basis for the case study assessment. For both of these case studies, the direct and indirect costs of identifying the nanomaterial separately from the macro form (should this exist) were considered.

Extrapolation exercise
The aim of the extrapolation exercise was to develop figures to illustrate the potential impacts of adopting a nanomaterial definition that would result in a change in substance ID. The exercise was based on the definition set out in the EC Recommendation. As the starting point for the analysis, estimates were developed on the numbers of nanomaterials currently placed on the EU market, the tonnages at which they are likely to be produced per manufacturer, and the extent to which they may need further testing should read across not be justified. Both size and surface treatment as identifiers were examined.

Results – Case study assessment
The impact scenarios and direct cost impacts outlined above were applied to determine the potential impact of using size and surface treatment as substance identifiers under REACH with regards to SAS and titanium dioxide.

The main difference in costs between scenarios for each of the identifiers was the number of tests that would potentially be required. If read-across could not be justified then testing would be required for each separately registered substance, which would result in a significant

number of test gaps and, hence, total costs for filling these. If read-across could be justified then testing information could be transferred between the separately registered substances, significantly reducing the number of tests required (and therefore the overall testing costs).

The cost estimates were based on two categories of surface treated SAS and two or 10 categories of surface treated titanium dioxide requiring new, separate registration under REACH. It may be the case, however, that surface treated SAS and titanium dioxide would be divided into more surface treatment sub-categories, which would multiply the registration costs significantly. The exact figures cannot be provided here, as the results are confidential and belong to Cefic. Nevertheless, the results of this study have been widely quoted (e.g. in the assessment by the JRC, as summarised above).

The main indirect costs considered as part of the assessment are the potential implications for the implementation of other downstream legislation due to the 'newly identified' substances falling into different categories for regulatory purposes.

As part of the extrapolation exercise, it was necessary to estimate the number of nanomaterials currently placed on the EU market, assuming that both size and surface treatment are identifiers. Information obtained from industry was used to estimate the proportion of nanomaterials that would be considered conventional substances (i.e. those that have been produced and used as a nanoform for a long period of time) and more newly engineered substances, as well as the proportion of these that have already been registered and those that are yet to be registered under REACH by tonnage band.

The study concluded that, if size is an identifier, then there are implications with respect to dossier preparation, registration fees, and testing, which can be fairly high. If surface treatment is an identifier, then the costs are multiplicative of those for size. The main difference in costs between scenarios for each of the identifiers is the number of tests that are required; if read across between the macro and nanoform, or between different surface treated materials, cannot be demonstrated then testing is required for each registered substance. This results in a significant number of test gaps and, hence, the total costs for filling these. In particular, for surface treated products, fewer tests have been undertaken and adopting this as an identifier will give rise to significant costs due to the number of variations in surface treatment that take place.

Thus, when looking across the analysis, there are a number of aspects that impact on the total costs that may arise from a change in substance identity:

- Whether the conventional substance has always been a nanomaterial under the recommended definition;
- The availability of test data for both the nanoform and the macroform where both forms exist;
- The extent to which read across of REACH testing information can be carried out across separate dossiers for the nano and macro forms, as this has a significant impact on the number of tests needed and thus on total costs;
- The inclusion of other identifiers in addition to size, as these will have a multiplicative effect on costs, due to the need to fill increasing numbers of test gaps should read across not be considered justified;
- The extent to which the nanomaterial can continue to be registered as part of a mono constituent substance alongside the macroform, i.e. through an update of the existing registration dossier rather than requiring a separate registration dossier; and
- The number of manufacturers / importers registering the substance and thus able to share testing and dossier preparation costs.

Another specific issue considered as part of the analysis is the degree to which a change in substance identity would give rise to particular impacts on Small and Medium-sized Enterprises (SMEs). For size as an identifier, the most significant element of the predicted costs relate to the filling of test gaps for substances registered at >100 tpa. It is likely that a higher number of SMEs will be registering substances in this tonnage band compared to the >1000 tpa, however, one might still expect a significant portion of these costs to fall on larger companies.

For surface treatment as an identifier, the picture is more complex. It was understood from the Cefic steering group (and in particular the manufacturers of SAS and titanium dioxide) that a large number of companies undertaking surface treatment will be SMEs. As a result, including surface treatment as an identifier was considered by the steering group as being likely to result in a significant proportion of the predicted costs falling on SME manufacturers and importers, as well as companies which currently consider themselves formulators.

Assumptions

Various assumptions were applied when calculating the costs of using size and surface treatment as identifiers for nanomaterials under REACH (particularly in relation to the extrapolation exercise). The main assumptions used in the extrapolation exercise are outlined below:

- Size as identifier and number of nanomaterials on the EU market;
- Number of conventional nanomaterials against number of newly engineered nanomaterials by REACH tonnage bands;
- Surface treatment as identifier and number of nanomaterials on the EU market;
- Additional costs of updating or submitting a new registration dossier by cost type (administration, preparation of robust summary studies, developing testing proposals, preparation of safety data sheets, characterisation of nanomaterials, testing for health and environmental endpoints.

3 Development of Options

3.1 Identification of Existing Problems

3.1.1 Introduction

Since its entry into force in 2007, there has been a lot of debate about the effectiveness of REACH in identifying the potential hazard properties of nanomaterials. 2012 was the first review year for the Regulation: several thematic studies were launched by the Commission to inform the process, among which one project led by the European Commission Joint Research Centre aimed to identify REACH dossiers with nanomaterials and to assess the quality of the information provided[21]. The conclusion of the assessment was that the information provided was either inadequate or insufficient and that the lack of agreed testing methods is invalidating the effectiveness of REACH in covering nanomaterials, leading to a call for further action.

Three major European NGOs[22] have drafted a document, known as "nano patch"[23], summarising the main points of criticism.

- Lack of a definition of nanomaterial within the Regulation and lack of a requirement to assess the relevant substances in their nanoforms;
- Possibility for nanomaterials introduced on the market after the entry into force of REACH to benefit from the phase-in status of the parental substances, with the possibility of a delayed registration and the possibility to submit just the physicochemical data for the substance if the latter is not classified as CMR, PBT or is a substance with dispersive and diffuse uses with a CLP classification;
- The tonnage bands defined by the Regulation are inadequate to trigger specific focus on nanoforms, given the actual quantities of most manufactured or imported nanomaterials;
- Lack of requirements to register or notify the use of nanomaterials; and
- Lack of recognised testing guidelines.

As a final issue, the document points to the inadequacy of workers' protection due to the lack of information on nanomaterials.

In the Second Regulatory Review on Nanomaterials[24], the Commission, although restating that REACH applies to all the substances and thus, in principle, to nanomaterials, recognises that REACH annexes could need amendment to ensure clarity on how nanomaterials should be addressed. In the document, the Commission also calls for ECHA to develop guidance on treating nanomaterials as forms of a bulk substance and acknowledges also that the Agency has already set up a Nanomaterials Working Group to give advice on scientific and technical issues on nanomaterials under REACH. On the 28 of February 2013, ECHA reported that the

[21] http://ec.europa.eu/environment/chemicals/reach/study12_review_2012.htm
[22] ClientEarth, Ciel and BUND Friends of the Earth Germany.
[23] Azoulay *et al* (2012): High time to act on nanomaterials – A proposal for a "nano patch" for EU regulation, commissioned by BUND Friends of the Earth Germany.
[24] Available at : http://eur-lex.europa.eu/legal-content/EN/ALL/;ELX_SESSIONID=RLn2JLRKLnjSgp1vSG29SqsgC168GsXvryvMGcKnBj1mwLyL2pFv!-1755307420?uri=CELEX:52012DC0572

IUCLID User Manual for nanomaterials has been updated in order to help registrants to prepare or update registration dossiers for substances that are nanomaterials or include nanoforms, and provided instructions on how they can explicitly report when a nanoform has been used in individual (experimental) studies[25]. Moreover, the ECHA guidance on information requirements and chemical safety assessment[26] has been updated with recommendations for nanomaterials relating to different endpoints and characterisation of dose. However, the Second Regulatory Review does not recognise the need for a change to the current tonnage bands for which a Chemical Safety Assessment is required for a substance.

The "nano patch" document proposed the implementation of a new Regulation, extending the definition of a nanomaterial from Recommendation 2011/696/EU to all other pieces of legislation. Furthermore, it proposes an obligation to register all the nanomaterials manufactured or imported above 10 kg per year, including provision of a separate dossier from their parental substances, and to extend the requirement for a Chemical Safety Assessment to all registered nanomaterials. Under this proposal, all of the suppliers of nanomaterials or mixtures containing nanomaterials would have to provide a Safety Data Sheet in accordance with Annex II of the REACH Regulation and would have to notify ECHA in order for the MNM to be included in the Classification and Labelling Inventory. It was also proposed that the Agency should perform a compliance check on all the nanomaterials dossiers submitted and that all nanomaterials shall be included in the list of substances for Evaluation within two years from Registration. Moreover, it was suggested that all the nanomaterials contained in consumer products should be labelled as "nano" in the list of ingredients and Member States should set up health monitoring programmes for workers potentially exposed to nanomaterials. As a final provision, it was proposed that in order to overcome the lack of agreed testing methods, some provisional measures should be implemented and each dossier should contain an explanation of the scientific appropriateness of the tests used.

In response to this document and to a letter sent by several NGOs and Consumer Organisations, Commissioner Janez Potočnik drafted a formal answer on behalf of the Commission, reassuring the NGOs that the REACH Regulation Annexes will envisage amendments in order to take into account the specific properties of nanomaterials.[27]

In the General Report on REACH[28], the Commission commits itself to *"…make an impact assessment of relevant regulatory options to ensure further clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers*" (EC, 2013, p.12). In the Commission Staff Working Document accompanying the General Report on REACH, it is explained that the definition provided in Recommendation 2011/696/EU *"…should be understood to apply in the context of REACH practical application*" (EC, 2013b, p.21) although consideration of its inclusion in Article 3 of REACH has been recommended (EC, 2013b).

[25] ECHA/NA/13/08. Available at Internet site: http://echa.europa.eu/view-article/-/journal_content/title/the-iuclid-user-manual-for-nanomaterials-has-been-updated
[26] http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment
[27] Letter signed by Janez Potočnik – Ref. Ares(2012)1448567 – sent on 05/12/2012.
[28] http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52013DC0049

The German Competent Authorities have also published their views on nanomaterials and REACH[29]; although recognising that REACH "*provides the suitable framework of the safe handling of substances in nanoform*", the Regulation should be amended to allow a specific treatment of nanomaterials, especially regarding:

- Specific testing requirements for substances in the nanoform (for their physicochemical characterisation and the generation of toxicological and ecotoxicological data);
- Tonnage thresholds to be applied for nanomaterials (advising to apply reduced registration requirements to nanomaterials manufactured or imported in quantities of more than 100 kg per annum and providing the possibility for the waiving of some tests when certain conditions are met); and
- Specific provisions for surface-treated nanomaterials.

3.1.2 Drivers/causes of the problem identified

According to KemI's description, the problem is that "*REACH does not successfully ensure the safe use of nanomaterials*". Moreover, because of their properties ("*a low bulk density and high specific surface area*"), nanomaterials do not need to be applied in high mass (volume) per application/use to deliver the desired functions. For this reason, "*environmental fate and exposure information requirements should be required at lower tonnage bands than currently used for bulk substances*". For the registration of manufactured or imported chemicals, REACH requires different levels of information according to the tonnage in which they are put on the market; the most widely used nanomaterials will pass the threshold of 10 tonnes per year for which a Chemical Safety Assessment needs to be prepared in order to comply with the legislation. However, many "novel" nanomaterials will not be manufactured or imported in quantities over that threshold, thus resulting in a lack of regulatory impetus for information to be provided within the REACH Regulation.

Table 3-1 presents the problem and its drivers.

Table 3-1: Regulatory failure and its drivers

Problem	Drivers
Manufacturers/importers of nanomaterials do not provide adequate/sufficient information on the nanoforms of the substances	- Lack of definition of what is a nanomaterial within the Regulation; - Nanomaterials have different physicochemical characteristics (and properties) from the bulk form of the substances that need different parameters for their proper characterisation; - Some nanomaterials might be manufactured/imported in quantities less than 1 tonne per year per manufacturer/importer; - Toxicological and ecotoxicological tests for nanomaterials need a proper preparation of the samples and new methods and standards are currently being developed.

[29] UBA *et al* (2013): Nanomaterials and REACH, Background Paper on the Position of German Competent Authorities, *UmweltBundesAmt (UBA), Bundesinstitut fur Risikobewertung (BfR) and Bundesanstalt fur Arbeitsschutz und Arbeitsmedizin (baua).*

3.2 Defining the Baseline

3.2.1 Overview

The baseline scenario (Option 0) represents the 'status quo'. According to the Commission "*although REACH and CLP do not contain explicit requirements for nanomaterials, nanomaterials are considered as substances in the meaning of the regulations and therefore the legislations apply*".

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

For the purposes of undertaking a more detailed analysis and in order to highlight the positive and/or negative impacts of the amendment of the main text of the REACH Regulation on top of the foreseen amendment of the REACH Annexes, consideration will be given to two sub-options:

- Option 0A - "Status quo"; and
- Option 0B – "Amendment of the REACH Annexes".

3.2.2 Option 0A "Status quo"

Nanomaterials are currently regulated at EU level by the legislative framework formed by:

- Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);
- Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).

These two Regulations are the mechanisms designed for the generation and the provision of the physicochemical, toxicological and ecotoxicological information that should ensure the achievement of the sound management of chemicals throughout their life cycle. For example, REACH and CLP allow the best functioning of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (known as "Chemical Agents Directive" or CAD), ensuring that the information generated for the registration of the substances is passed down through the supply chain via safety data sheets, which allow employers to carry out the risk assessment required under the CAD.

However, due to the specific properties of nanomaterials, the uncertainties regarding their hazard profiles and the lack of standardised methodologies for their testing, different stakeholders (e.g. national public authorities, NGOs, academics) have raised concerns over the suitability of the current chemicals regulatory framework in dealing with nanomaterials, identifying shortcomings and calling for additional policy initiatives.

Regulation (EC) No. 1907/2006

REACH is based on the principle that it is for industry to ensure that the substances that are manufactured, placed on the market or used in the EU do not adversely affect human health or the environment. As indicated above, Registration is the main focus of this impact assessment, although any newly introduced nanomaterial specific provisions may also have implications in relation to the provisions regarding Evaluation, Authorisation and Restriction.

Under Registration, companies are required to provide information on the risks posed by the use of the chemicals that they supply, throughout the life cycle of that chemical. This information must be communicated down through the supply chain via Safety Data Sheets (SDS) as required under Article 31 and Annex II. A SDS needs to be supplied for all substances that are:

- Classified as dangerous under Dangerous Substances Directive 67/548/EEC (DSD) or Dangerous Preparations Directive 1999/45/EC (DPD) or classified as hazardous under Regulation (EC) No 1272/2008 (CLP) (applies for SDS for mixtures);
- A substance that is persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB); or
- Included in the Candidate List of substances of very high concern (SVHCs);

A SDS is requested for a mixture that is not classified under DPD or CLP, but contains either:

- A substance posing human health or environmental hazards in an individual concentration of ≥ 1 % by weight for mixtures that are solid or liquids (i.e., non-gaseous mixtures) or ≥ 0.2 % by volume for gaseous mixtures;
- A substance that is PBT or vPvB in an individual concentration of ≥ 0.1 % by weight for mixtures that are solid or liquids (i.e., non-gaseous mixtures);
- A substance on the 'Candidate List' of substances of very high concern (for reasons other than those listed above), in an individual concentration of ≥ 0.1 % by weight for non-gaseous mixtures; or
- A substance for which there are EU-wide workplace exposure limits.

A SDS is not required where:

- Substances or mixtures are not classified as hazardous or considered PBT, vPvB, or of equivalent concern (e.g. endocrine disruptors);
- Substances and mixtures are supplied for uses exempt from REACH, e.g. medicinal products or cosmetics;
- Substances or mixtures are supplied to the general public accompanied by sufficient information on the safety and the protection of human health and the environment to allow safe use.

A SDS is required to include information for the following sections:

- Identification of the substance/mixture and of the company undertaking hazard identification;
- Composition and information on ingredients;
- First-aid measures;
- Fire-fighting measures;
- Accidental release measures;
- Handling and storage;
- Exposure controls and personal protection recommended;
- Physical and chemical properties;

- Stability and reactivity;
- Toxicological information;
- Ecological information;
- Disposal information;
- Transport information;
- Regulatory information; and
- Other information.

Where a substance has been registered as being manufactured/imported by a company in quantities of ten tonnes or more per year, the SDS will include exposure scenarios covered by the chemical safety assessment under REACH (extended or eSDS).

Manufacturers and importers are required to provide hazard, exposure and risk management information to their customers, primarily via (extended) Safety Data Sheets ((e)SDS), including Exposure Scenarios (ESs) where required (Article 31). The ESs communicated should not include those for uses where adequate control cannot be demonstrated. Where such uses are identified they should be explicitly advised against. Downstream users may not use a substance for an application that falls outside of the ESs supplied to them unless they produce their own Chemical Safety Report (CSR) to demonstrate their safe use of that substance (Article 37).

Where the downstream user does not use a substance in quantities greater than 1 tonne per year, it does not need to produce a CSR but it does need to inform the European Chemicals Agency (ECHA) of its use of a substance that falls outside of that covered by its suppliers SDS before continuing to use that substance; a downstream user must also inform ECHA if its hazard classification of a substance differs from that of its supplier (Article 38).

Further REACH provisions requiring companies to communicate information up and down the supply chain are listed below:

- (e)SDS should be communicated down the supply chain, together with a relevant ES, where required (Article 31);
- Where SDS are not required, companies are still required to communicate hazard information down the supply chain for substances subject to restriction, authorisation or which require specific risk management (Article 32);
- New hazard information or information questioning the validity of risk management measures must be communicated up the supply chain (Article 34);
- Suppliers of articles that contain substances identified as Substances of Very High Concern (SVHCs) and that are included on the candidate list for authorisation must, on request, provide the information available to them down the supply chain including to consumers, to enable safe use of those articles (at a minimum this should be the name of the SVHC) (Article 33);
- Downstream users have to identify, apply and recommend risk management measures for the known risks associated with their use of the chemicals supplied to them (Article 37); and
- Employers must provide workers and their representatives with access to information received in relation to substances or mixtures which they may use or be exposed to in the course of their work (Article 35).

With respect to the communication of information in the supply chain, the (e)SDS is the core instrument for communicating information down the supply chain from the manufacturer, importer and formulator. The requirement to implement recommended conditions of use is

expected to lead to the actual changes in risk management, but (e)SDS development and handling has been problematic for companies. The following issues in particular have been identified[30]:

- No consistent/common format for the (e)SDSs (even though this is set out in Annex II to REACH);
- ESs are long documents that are difficult to handle, leading to the loss or obscuring of relevant information; and
- Varying familiarity exists among companies regarding the processes/ mechanisms involved.

Enforcement authorities have found that 9% of companies did not have SDS available for inspection and the SDS provided by 16% of companies did not meet the requirements prescribed for SDS under REACH[31]. Furthermore, the provision of extensive ES information has been identified as having the potential to seriously interfere with the effective communication of safety information down the supply chain via eSDS. It is, however, noted that ECHA has since produced additional guidance on the preparation of (e)SDS which may serve to improve the quality of SDS generally.

As mentioned in Section 2, currently the information provided on nanomaterials is either inadequate or insufficient. ECHA has updated the IUCLID User Manual for nanomaterials to help registrants to prepare or update registration dossiers for substances that are nanomaterials or include nanoforms, and provided instructions on how they can explicitly report when a nanoform has been used in individual (experimental) studies (ECHA, 2013). Moreover, the ECHA guidance on information requirements and chemical safety assessment (ECHA, 2012) has been updated with recommendations for nanomaterials relating to different endpoints and characterisation of dose.

JRC (2012) identified and assessed information from only 10 dossiers. ECHA has reportedly received around 80 dossiers referring to four substances at the nanoscale for the 2013 REACH deadline.[32]

CLP Regulation (EC) No 1272/2008

The Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (known as "CLP") aims to "*ensure a high level of protection of human health and the environment*" (Art. 1(1)) and "*the free movement of substances, mixtures and articles*" by "*harmonising the criteria for classification of substances and mixtures, and the rules on labelling and packaging for hazardous substances and mixtures*" (Art. 1(1(a))), requiring "*manufacturers, importers and downstream users to classify substances and mixtures placed on the market*" (Art. 1(1(b))).

Article 2 of the Regulation provides the relevant definitions. In particular, "substance" is defined as "*a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any*

[30] RPA *et al* (2012): Assessment of health and environmental benefits of REACH, prepared for the European Commission DG Environment.

[31] FEIE (2011): Co-ordinated Forum REACH enforcement project on registration, pre-registration and safety data sheets (REF-1 project): Facts Report, Prolongation phase, May 2010 to April 2011, Forum for Exchange of Information on Enforcement (adopted 21 November 2011), unpublished.

[32] http://www.nanotechia.org/news/news-articles/early-results-indicate-total-4-nanomaterials-registered-2013-reach-deadline

impurity deriving from the process used…" and "article" is defined as "*an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition*".

Article 3 defines as hazardous substance or hazardous mixture "*a substance or a mixture fulfilling the criteria relating to physical hazards, health hazards or environmental hazards, laid down in Parts 2 to 5 of Annex I*".

Article 4 sets the general obligations of manufacturers, importers and downstream users: substances or mixtures shall not be placed on the market without a classification in accordance with Title II of the Regulation or Title V for those hazard classes or differentiations covered by harmonised classification and labelling. General obligation of distributors is to ensure that when a substance or a mixture is classified as hazardous, they are labelled and packaged in accordance with Titles III to IV (Art. 4(4)).

Title II of the Regulation sets out the process to identify the relevant information (Chapter I), to evaluate it and decide on classification (Chapter II). Article 5 clarifies that, although there is a direct mention of the REACH Regulation, information believed to be adequate, reliable and scientifically valid (Art. 5(2)) for the purposes of determining whether a substance entails a hazard can be compiled from other sources, with the provision under Art. 5(d) "*any new scientific information*" being the more general. It is to be noted that the second paragraph of article 5(1) specifies that "the information shall relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used". This provision is repeated in other articles (namely article 6(1) regarding the identification and examination of available information on mixtures, article 8(6) regarding the testing of the substances and mixtures and article 9(5) about the evaluation of the information) and is of relevance for nanomaterials placed on the market. The problem is with the availability of specific information on nanomaterials.

As already identified in the joint document produced by DG Environment and DG Enterprise and Industry[33], "*the classification and labelling of nanomaterials has to be done on a case-by-case basis (…) following the rules set out in CLP*"; moreover, "*taking into account the current knowledge on the properties of nanomaterials, a proper substance identification is essential and it is advisable that registrants would consider the following approaches in the classification and labelling of nanomaterials:*

1. The data sharing, should cover all relevant information including (but not limited to) sizes, forms and morphologies of the nanomaterial;

2. It is vital to evaluate whether changes in e.g. size, form or physical state influence considerably on the hazardous properties of the nanomaterial;

3. All available information of nanomaterials should be evaluated in the hazard assessment of the nanomaterial (REACH Article 1(3));

4. Special attention needs to be devoted to the appropriateness of the sample preparation and dosimetry used in the testing of nanomaterials;

5. The classification of nanomaterials should be done on a case-by-case basis giving due consideration to the relevant data on e.g. the bulk form and read-across to other nanomaterials;

[33] EC (2009b): Annex II: Final Version of Classification, labelling and packaging of nanomaterials in REACH and CLP, Doc.CA/90/2009 Rev2, available at Internet site (last access 19/06/2013): http://ec.europa.eu/environment/chemicals/reach/pdf/classif_nano.pdf

6. On the basis of the classification in accordance with CLP, the nanomaterial should also be labelled and packaged in accordance to CLP".

Currently, of the 258 different substances at the nanoscale identified and notified to the FNS, only 23 have a notification to the Classification and Labelling Inventory[34] specific to the nanoform.[35]

3.2.3 Option 0B "Amendment of the REACH Annexes"

The Commission is currently discussing with the CASG Nano members how to better amend the annexes of the REACH Regulation to ensure that manufacturers and importers provide sufficient and adequate information on the nanoforms of the substances put on the EU market.

Table 3-2 presents the expected amendments by REACH annex.

Table 3-2: Expected amendments to the REACH annexes
Annex I General provisions for assessing substances and preparing Chemical Safety Reports *"The purpose of this Annex is to set out how manufacturers and importers are to assess and document that the risks arising from the substance they manufacture or import are adequately controlled during manufacture and their own use(s) and that others further down the supply chain can adequately control the risks."* The amendments to annex I would require the inclusion of relevant information on the nanoforms of substances manufactured and imported in the chemical safety reports. When the nanoforms are covered by the registration, the chemical safety assessment should include relevant justifications and conclusions specific to the nanoforms. Moreover, scientific justifications should be provided whenever information relevant to a different (nano)form are used for one or more nanoforms of the substance (grouping and read-across). Scientific justifications should also be provided whenever exposure scenarios and risk management measures cover different (nano)forms of the substance. More precisely, the different steps of a chemical safety assessment (human health hazard assessment, human health hazard assessment of physicochemical properties, environmental hazard assessment, PBT and vPvB assessment and, when relevant, exposure assessment and risk characterisation) should address the nanoforms of the substance when they are covered by the registration.
Annex II Requirements for the compilation of safety data sheets No amendments are expected to this annex.
Annex III Criteria for substances registered in quantities between 1 and 10 tonnes The registration dossiers of substances manufactured/imported in quantities above one tonne per year and with one or more nanoforms, where these were not put on the market before 1 December 2008, will have to provide all the information specified in Annex VII for those nanoforms. All the information specified in Annex VII will have to be provided also for those nanoforms that were put on the market before 1 December 2008 and that are likely to meet the classification criteria for any human health or environmental effects. In the case the nanoforms were put on the market before 1 December 2008 and they are likely not to meet any classification criteria, only the information on physicochemical properties as specified in Annex VII Section 7 will have to be provided.
Annex IV Exemptions from the obligation to register in accordance with Article 2(7)(a) No amendments are expected to this annex.
Annex V Exemptions from the obligation to register in accordance with Article 2(7)(b) No amendments are expected to this annex.

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

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

Table 3-2: Expected amendments to the REACH annexes
Annex VI Information requirements referred to in Article 10 Annex VI would present the EC recommended definition of nanomaterials, clarifying that when a substance is manufactured or imported in nanoform, certain specific information should be provided. Registrants should gather information on the nanoforms of the substances too, identifying if there are data gaps on these and generating/proposing testing strategies to fill in the gaps. When a registration dossier of a substance covers one or more nanoforms, registrants should provide some additional parameters for the characterisation of those nanoforms (Section 2): - Any other identifiers of the nanoforms of the substances; - Particle number size distribution (there is the opportunity for grouping different nanoforms of the same substance deemed to have the same toxicological or ecotoxicological information); - Description of surface functionalization or treatment (opportunity for grouping); - Shape, aspect ratio and other morphological characterisation (opportunity for grouping); - Surface area (opportunity for grouping); - Description of the analytical methods. The information on manufacture and uses (Section 3) should be specific to the nanoforms of the substance, as well as the information on exposure (Section 6).
Annex VII Standard information requirements for substances manufactured or imported in quantities of one tonne or more The same testing waivers (with adaptations for some parameter) apply to the nanoforms of the substance provided the same classification applies. Any relevant physicochemical, toxicological and ecotoxicological information on the nanoforms should include the characterisation of the nanoforms and the test conditions. The same specific rules for adaptation of the standard information required apply to the nanoforms of the substance, with some adaptations (in order to make them relevant for the nanoforms).
Annex VIII Standard information requirements for substances manufactured or imported in quantities of ten tonnes or more The same testing waivers (with adaptations for some parameter) apply to the nanoforms of the substance provided the same classification applies. Any relevant physicochemical, toxicological and ecotoxicological information on the nanoforms should include the characterisation of the nanoforms and the test conditions. The same specific rules for adaptation of the standard information required apply to the nanoforms of the substance, with some adaptations (in order to make them relevant for the nanoforms).
Annex IX Standard information requirements for substances manufactured or imported in quantities of one hundred tonnes or more The same testing waivers (with adaptations for some parameter) apply to the nanoforms of the substance provided the same classification applies. Any relevant physicochemical, toxicological and ecotoxicological information on the nanoforms should include the characterisation of the nanoforms and the test conditions. The same specific rules for adaptation of the standard information required apply to the nanoforms of the substance, with some adaptations (in order to make them relevant for the nanoforms). Moreover, further testing for the physicochemical properties shall be considered whenever some specific property of the nanoforms are suspected to influence significantly hazard of or exposure to the nanoforms.

Table 3-2: Expected amendments to the REACH annexes
Annex X Standard information requirements for substances manufactured or imported in quantities of one thousand tonnes or more The same testing waivers (with adaptations for some parameter) apply to the nanoforms of the substance provided the same classification applies. Any relevant physicochemical, toxicological and ecotoxicological information on the nanoforms should include the characterisation of the nanoforms and the test conditions. The same specific rules for adaptation of the standard information required apply to the nanoforms of the substance, with some adaptations (in order to make them relevant for the nanoforms).
Annex XI General Rules for adaptation of the standard testing regime set out in Annexes VII to X When justifying that testing does not appear scientifically necessary, the following procedures have to be carried out on information specific to the nanoforms: - Assessment of historical human data; - Weight of evidence; - (Q)SARs; - in vitro methods; - grouping of substances and read-across approach.
Annex XII General provisions for downstream users to assess substances and prepare chemical safety reports Chemical safety assessments compiled by downstream users have to address the nanoforms of the substance when these are covered by the registration and any justification and conclusion need to be relevant to the nanoforms. Downstream users should keep record of information about the physical state, concentration, concentration range or quantities of the nanoforms in mixtures and articles that they use.
Annex XIII Criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substances No amendments are expected to this annex.
Annex XIV List of substances to Authorisation No amendments are expected to this annex.
Annex XV Dossiers No amendments are expected to this annex.
Annex XVI Socio-Economic Analysis No amendments are expected to this annex.
Annex XVII Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles No amendments are expected to this annex.

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

It should be noted that registration dossiers will provide information on the nanoform(s) of the substances only when the nanoform(s) are manufactured in quantities above one tonne per year. The Chemical Safety Reports of substances manufactured/imported in quantities of more than 10 tonnes per year will clarify where and when information related to the bulk form are used to cover the nanoforms, providing scientific justifications. However, the information to be provided will be based on the tonnages of the nanoforms. For example, Annex VIII information specific to the nanoforms (when necessary) will be required only if the nanoforms are manufactured/ imported in quantities of more than 100 tonnes per year.

Nevertheless, a nanomaterial manufactured/imported in quantities of less than 1 tonne per year that is put on the market and meets the criteria for classification as hazardous[36] needs to be notified to the Classification and Labelling Inventory.

3.3 Objectives of Policy Intervention

On the basis of the above problem analysis, the objectives of the policy intervention being proposed by KemI have to be defined at general, specific and operational levels. More precisely, the aim of the policy intervention is to ensure that the objectives of the REACH Regulation are fully achieved and that its requirements apply to nanomaterials. It is worth remembering that the REACH Regulation "*is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle*" (Article 1(3)).

Table 3-3 presents the objectives of the policy intervention proposed by KemI at the three different levels.

Table 3-3: Objectives of the Policy Intervention

General policy objectives	Specific policy objectives	Operational policy objectives
Ensure a high level of protection of human health and the environment from any risks related to nanomaterials.	Provide decision makers, regulatory authorities and professional users with information that allows for an appropriate response to the health or environmental risks of nanomaterials.	Ensure the availability of information on the (eco)toxicological profiles of nanomaterials.
Ensure a proper functioning of the internal market and a level playing field for businesses marketing nanomaterials.	Maintain the competitiveness and innovation of businesses bringing nanomaterials or products containing nanomaterials to the market (including SMEs).	Ensure the proportionality of the information requirements and the associated costs and administrative burden. Protect confidential business information.

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

4 Defining the Policy Options

4.1 Introduction

As agreed with KemI, two policy options are considered as part of this impact assessment:

- Option 1 – "Nanomaterials as substances on their own"; and
- Option 2 – "Separate risk assessments within the same registration dossier".

These are outlined in a little more detail below.

4.2 Option 1: Nanomaterials as Substances on Their Own

For Option 1, KemI has proposed the following:

- *"Nanomaterials should be regarded as substances on their own and therefore have to be registered individually;*
- *A definition of the term 'nanomaterial' based on the EC-recommended definition should be made legally binding;*
- *Nanomaterials, either on its own or in one or more mixture(s), above ten kilograms should be registered as a prerequisite for manufacturing or placing on the market;*
- *Exposure information should be included in the technical dossier for nanomaterials in quantities of 10 to 100 kilograms;*
- *An obligation to perform a chemical safety assessment and a complete chemical safety report should be on registrants registering nanomaterials in quantities of 100 kilograms or more per year;*
- *The information requirements for a registrant should be those that are stated in the REACH Annexes"*.

On this basis, the information on the nanoform(s) of a substance would be provided in a separate registration dossier. Moreover, the EC-recommended definition would be included under Article 3 of the REACH Regulation. In order to estimate the number of nanomaterials that would have to provide exposure information or a CSA/CSR, the results from the analysis of the French Notification System (RPA *et al*, 2014) provide a good basis for making assumptions.

4.3 Option 2: Separate Risk Assessments within the Same Registration Dossier

For Option 2, KemI has proposed the following:

> "*The same as option 1 but instead nanomaterials are not considered substances on their own, this would include not lowering the tonnage levels. However separate risk assessment should be conducted for each separate form of the substance while the tonnage is still calculated for all forms together. This approach views size as a characteriser instead of as an identifier. In practice this will give more information on nanoforms that are produced or put on the market in lower tonnages since the information requirement-level for each form will be based on the total tonnage of the registered bulk substance. However, this option will not require individual registrations or lowered tonnage levels*".

After further discussion, Option 2 has been refined, specifying that the tonnage triggering the information requirements should be based on the total quantities of the nanoforms (not the total of the bulk forms and nanoforms together).

In other words:

- Bulk and nanoforms are registered together;
- All nanoforms manufactured or imported in quantities of more than 10 kg per annum must be identified in the registration;
- A Chemical Safety Assessment should be carried out and a Chemical Safety Report developed for every nanoform (≥10 kgpa) separately;
- The information requirements should be based on the total sum of all the nanoforms, and should follow article 12 of the REACH Regulation.

4.3.1 Summary of the Options

Table 4-1 provides illustrative examples of the different information requirements expected under each baseline and option for different manufactured/imported quantities of nanomaterials and manufactured/imported quantities of the substances in the bulk form.

Table 4-1: Illustrative examples of the information requested under each option				
Example	**Option 0A**	**Option 0B**	**Option 1**	**Option 2**
Nanoform of the high production volume substance *XYZ* (>1,000 tonnes per year) manufactured in quantities of more than 10 kg per year (total tonnage of the nanoforms is >1,000 tpa)	No information.	No information.	Separate registration dossier with other nanoforms of the same substance, providing: - Physicochemical information; - Exposure information.	- Physicochemical information; - Chemical Safety Assessment/Chemical Safety Report; - Annex X information.
Substance *XXX* manufactured only in the nanoform in quantities of more than 100 kg per year	No information.	No information.	Separate registration dossier providing: - Physicochemical information; - Chemical Safety Assessment/Chemical Safety Report.	No information.
Nanoforms of the substance *YYY* (imported in quantities of more than 100 tonnes per year) imported in quantities of more than 10 tonnes per year (total tonnage of the nanoforms <100 tpa)	Maybe notification to the Classification and Labelling Inventory (depending on hazardousness).	- Chemical Safety Report addressing the nanoforms of the substance, providing a justification when the information for the bulk form cover also the nanoforms. - All Annex VII information.	Separate registration dossier for the nanoforms, providing: - Physicochemical information; - Chemical Safety Assessment/Chemical Safety Report; - Annex VII information.	- Physicochemical information; - Chemical Safety Assessment/Chemical Safety Report; - Annex VIII information.
Nanoform of the substance *ZZZ* (manufactured in quantities of more than 100 tonnes per year) manufactured in quantities between 1 tonne and 10 tonnes per year	Maybe notification to the Classification and Labelling Inventory (depending on hazardousness).	- Annex VII Section 7 information if the nanoform was on the market before 1 December 2008. - All Annex VII information and a CSA/CSR if the nanoform was not on the market before 1 December 2008 or it meets the criteria for classification.	Separate registration dossier for the nanoform, providing: - Physicochemical information; - Chemical Safety Assessment/Chemical Safety Report; - Annex VII Section 7 information if the nanoform was on the market before 1 December 2008. - All Annex VII information and a CSA/CSR if the nanoform was not on the market before 1 December 2008 or it meets the criteria for classification.	- Physicochemical information; - Chemical Safety Assessment/Chemical Safety Report; - Annex IX information.

5 Impact Assessment

5.1 Introduction

The first stage of analysing the potential impacts of a policy intervention is to identify the types of impact that might be relevant across the broad areas of economic, social and environmental impacts, using the categories set out in the Commission's *Impact Assessment Guidelines*. More specifically, it is important to identify:

- Direct and indirect environmental , economic and social impacts and how they occur;
- Who is affected by these impacts and in what way; and
- Whether there are specific impacts that should be examined (fundamental rights, SMEs, consumers, competition, international, national, regional).

The impacts need to be described qualitatively, quantified and translated into monetary terms wherever possible (and appropriate). In addition, particular consideration should be given to risks and uncertainties, for example, in relation to patterns of compliance and levels of enforcement. In addition, impacts should be expressed as net (or marginal) changes compared to the baseline(s).

The remainder of this Section is organised following the three steps set out in the Commission's *Impact Assessment Guidelines*:

- Step 1 - Identification of economic, social and environmental impacts (Section 5.2);
- Step 2 - Qualitative assessment of the more significant impacts (Section 5.3); and
- Step 3 - In-depth qualitative and quantitative analysis of the most significant impacts (Section 5.4).

5.2 Identification of Economic, Social and Environmental Impacts

5.2.1 Introduction

Within the Commission's *Impact Assessment Guidelines*, there is a set of questions to be considered for each of the possible impact categories. These questions provide the framework to differentiate the scale of the impacts of each option with respect to the baseline.

5.2.2 Identification of economic impacts

For each possible economic impact category listed in the Commission's *Impact Assessment Guidelines*, Table 5-1 presents the key questions and an initial qualitative assessment.

Table 5-1: Economic impact		
	Option	
Question	1	2
Functioning of the internal market and competition		
What impact (positive or negative) does the option have on the free movement of goods, services, capital and workers?	-	-
Qualitative Assessment: Options 1 and 2 extend the information requirements on the nanoforms of the chemical substances. As such there should not be any net change in terms of the free movement of goods. Both policy options might ensure that member states do not implement different legislative initiatives to cover nanomaterials manufactured/imported in quantities of less than one tonne per year.		
Will it lead to a reduction (or increase) in consumer choice, higher prices due to less competition, the creation of barriers for new suppliers and service providers, the facilitation of anti-competitive behaviour or emergence of monopolies, market segmentation, etc.?	Likely impact	Likely impact
Qualitative Assessment: In terms of consumer choice, Option 1 might increase it: if nanomaterials have to be regarded as substances on their own, SDSs distinct from the ones of the "parental" substances should be developed. Customers would then know when they are dealing with NMs and would be able to choose. In particular, this would improve the position of a customer when choosing between a substance in bulk form for which data have been generated and a nanomaterial for which data are still lacking. On the other hand, the extension of information requirements to NMs might decrease consumer choice because companies might decrease the number of products on the market (this impact is to be expected especially in the pigments and dyes sector). Both options, and in particular Option 1, are likely to lead to increases in the price of lower volume nanomaterials placed on the market, due to the inability of manufacturers to spread costs over a significant volume. These costs would likely have to be passed on to consumers raising questions over the ability of all current players to remain in the market if they are unable to pass such costs on and cannot readily absorb the additional costs of registration and testing. In this respect, the options may lead to the markets being increasingly dominated by larger companies rather than by SMEs, who may find it difficult to raise the finance required, particularly for the very low volume nanomaterials currently within their portfolios. This could lead not only to higher prices but also a reduction in the level of competition within the market. Moreover, the policy options might create a barrier to entry in the nanomaterials market for new companies, especially SMEs, by increasing the financial capital needed to invest in the generation of the physicochemical, toxicological and ecotoxicological information.		
Competitiveness, trade and investment flows		
What impact does the option have on the global competitive position of EU firms? Does it impact productivity?	Possible impact	Possible impact
Qualitative Assessment: The effects that the REACH Regulation has had on the global competitiveness of EU companies are still being debated, with some stakeholders arguing that the Regulation has strengthened the position of the EU chemical industry and others claiming that it has had negative effects on competitiveness. The extension of the information requirements on NMs would extend the debate to the nanotechnology field and add to concerns. There may be a net change in comparison with the baseline; however, the direction of this change is unclear. If the EU is the only jurisdiction placing increased information requirements on manufacturers of nanomaterials, then any increases in prices may result in EU NM products being more expensive compared to their global counterparts. This could impact on trade by reducing exports of certain NM products (see also below).		
What impact does the option have on trade barriers?	Possible impact	Possible impact
Qualitative Assessment: The same can be said on trade barriers, with some WTO members claiming that REACH violates WTO rules: in this specific case, the key is assessing the proportionality of extending the information requirements to NMs.		
Does it provoke cross-border investment flows (including relocation of economic activity)?	Possible impact	Possible impact
Qualitative Assessment: Both manufacturers and importers would be covered by the extension of the information requirements to NMs. Concern has already been expressed by certain industry sectors that		

Table 5-1: Economic impact		
	Option	
Question	1	2
REACH requirements on low volume substances may lead to the relocation of economic activity[37]; for example, it has been argued that the costs of registering pigments and dyes produced in low volumes may lead to significant levels of product withdrawal within the EU and the relocation of textile dying activities. As this is a key sector associated with NMs, such problems could be exacerbated by also requiring additional NM specific requirements.		
Operating costs and conduct of business/Small and Medium Enterprises		
Will it impose additional adjustment, compliance or transaction costs on businesses?	Yes	Yes
Qualitative Assessment: Manufacturers and importers would have to characterise and test their NMs according to the tonnage bands defined.		
How does the option affect the cost or availability of essential inputs (raw materials, machinery, labour, energy, etc.)?	Possible impact	Possible impact
Qualitative Assessment: As noted above, concern has already been expressed by certain industry sectors that the existing REACH requirements for low volume substances may lead to significant levels of product withdrawal for pigments and dyes. This in turn may lead to the relocation of textile dying activities outside the EU.		
Does it affect access to finance?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it impact on the investment cycle?	Not relevant	Not relevant
Qualitative Assessment: -		
Will it entail the withdrawal of certain products from the market? Is the marketing of products limited or prohibited?	Possible impact	Possible impact
Qualitative Assessment: Manufacturers/importers may not be able to bear the compliance costs associated with the registration and testing of NMs, particularly those that are produced in only lower volumes. This may lead to the withdrawal of certain products from the market.		
Will it entail stricter regulation of the conduct of a particular business?	Yes	Yes
Qualitative Assessment: The policy options will entail a stricter regulation of the conduct of manufacturers and importers of NMs. It will affect particularly businesses specialised in nanotechnology		
Will it lead to new or the closing down of businesses?	Possible impact	Possible impact
Qualitative Assessment: The information requirements do not cover nanomaterials in the research and development stage. High compliance costs might lead to the withdrawal of some NMs. Companies specialised in NMs with high characterisation and testing costs might be threatened.		
Are some products or businesses treated differently from others in a comparable situation?	No	No
Qualitative Assessment: The Options extend the principle "no data, no market" to NMs.		
Administrative burdens on businesses		
Does it affect the nature of information obligations placed on businesses (for example, the type of data required, reporting frequency, the complexity of submission process)?	Yes	Yes
Qualitative Assessment: The policy options entail significant administrative burdens on businesses		
What is the impact of these burdens on SMEs in particular?	Significant	Significant
Qualitative Assessment: The REACH Regulation has been indicated as the most burdensome EU regulation on European SMEs. The extension of the information requirements to NMs might entail significant burdens and in particular for SMEs.		

[37] http://chemicalwatch.com/21630/the-reach-data-market-an-sme-view

Table 5-1: Economic impact		
	Option	
Question	1	2
Public authorities		
Does the option have budgetary consequences for public authorities at different levels of government (national, regional, local), both immediately and in the long run?	Likely impact	Likely impact
Qualitative Assessment: At the EU level, ECHA would likely need a higher budget to deal with the stream of data. At national level, enforcement bodies would likely require higher budgets to enable appropriate levels of enforcement of the new provisions.		
Does it bring additional governmental administrative burden?	Yes	Yes
Qualitative Assessment: ECHA would have a higher workload administering the registration processes under REACH.		
Does the option require the creation of new or restructuring of existing public authorities?	No	No
Qualitative Assessment: ECHA could deal with the new requirements without a restructuring.		
Property rights		
Are property rights affected (land, movable property, tangible/intangible assets)? Is acquisition, sale or use of property rights limited?	Not relevant	Not relevant
Qualitative Assessment: -		
Or will there be a complete loss of property?	Not relevant	Not relevant
Qualitative Assessment: -		
Innovation and research		
Does the option stimulate or hinder research and development?	Likely Impact	Likely impact
Qualitative Assessment: The increased information requirements on NMs might divert R&D resources towards compliance activities, thus hindering the rate of R&D and innovation within the EU.		
Does it facilitate the introduction and dissemination of new production methods, technologies and products?	No	No
Qualitative Assessment: -		
Does it affect intellectual property rights (patents, trademarks, copyright, other know-how rights)?	No	No
Qualitative Assessment: The information on NMs would be handled by ECHA with the same confidentiality rules as for bulk chemical substances		
Does it promote or limit academic or industrial research?	Likely impact	Likely impact
Qualitative Assessment: The increased regulatory pressure would boost research on hazard and risk assessment methodologies for nanomaterials. It is unclear whether it would more generally affect academic or industrial research. However, it must be noted that the requirements would not apply to product and process orientated research and development involving NMs.		
Does it promote greater productivity/resource efficiency?	No	No
Qualitative Assessment: -		
Consumers and households		
Does the option affect the prices consumers pay?	Unlikely	Unlikely
Qualitative Assessment: -		
Does it impact on consumers' ability to benefit from the internal market?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it have an impact on the quality and availability of the goods/services they buy, on consumer choice and confidence?	Yes	Yes

Table 5-1: Economic impact		
	Option	
Question	1	2
Qualitative Assessment: The extension of information requirements to NMs might increase the consumers' confidence on nanotechnology. Impacts on the quality and availability of goods and services are likely to be limited, although in the extreme it cannot be ruled out if some NMs are removed from the market.		
Does it affect consumer information and protection?	Yes	Yes
Qualitative Assessment: The policy options would increase the level of information available to consumers. Assuming that there are currently unknown risks associated with NMs in consumer products being placed on the EU market, then the options would also increase the level of consumer protection.		
Does it have significant consequences for the financial situation of individuals / households, both immediately and in the long run?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect the economic protection of the family and of children?	Not relevant	Not relevant
Qualitative Assessment: -		
Specific regions or sectors		
Does the option have significant effects on certain sectors?	Yes	Yes
Qualitative Assessment: It might have a significant impact on the manufacturing of pigments and dyes and downstream industries.		
Will it have a specific impact on certain regions, for instance in terms of jobs created or lost?	No	No
Qualitative Assessment: EU-wide initiative		
Is there a single Member State, region or sector which is disproportionately affected (so-called "outlier" impact)?	Yes	Yes
Qualitative Assessment: Manufacturers and importers of pigments and dyes might be disproportionately affected (where "disproportionately" is not a judgment on the fairness of the requirements but a mere indication that the sector will be affected significantly more than other sectors, since the pigments and dyes sector is characterised by a high number of nanomaterials). In terms of potential regional issues, Italian manufacturers of pigments and dyes have already raised concerned over the current REACH requirements.		
Third countries and international relations		
How does the option affect trade or investment flows between the EU and third countries? How does it affect EU trade policy and its international obligations, including in the WTO?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option affect specific groups (foreign and domestic businesses and consumers) and if so in what way?	Not relevant	Not relevant
Qualitative Assessment: Any such issues are covered above.		
Does the option concern an area in which international standards, common regulatory approaches or international regulatory dialogues exist?	Yes	Yes
Qualitative Assessment: The OECD is greatly involved in setting the methodologies for the characterisation and testing of nanomaterials. Moreover, the International Standard Organisation has developed terminology and technical standards regarding nanomaterials.		
Does it affect EU foreign policy and EU/EC development policy?	Not relevant	Not relevant
Qualitative Assessment: -		
What are the impacts on third countries with which the EU has preferential trade arrangements?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect developing countries at different stages of development (least developed and other low-income and middle income countries) in a different manner?	Not relevant	Not relevant

Table 5-1: Economic impact		
	Option	
Question	1	2
Qualitative Assessment: -		
Does the option impose adjustment costs on developing countries?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option affect goods or services that are produced or consumed by developing countries?	Not relevant	Not relevant
Qualitative Assessment: -		
Macroeconomic environment		
Does it have overall consequences of the option for economic growth and employment?	Unlikely	Unlikely
Qualitative Assessment: -		
How does the option contribute to improving the conditions for investment and the proper functioning of markets?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option have direct impacts on macro-economic stabilisation?	Not relevant	Not relevant
Qualitative Assessment: -		

5.2.3 Social Impacts

For each possible social impact category listed in the Commission's Impact Assessment Guidelines, Table 5-2 presents the key questions and a first qualitative assessment.

Table 5-2: Social impact		
	Option	
Question	1	2
Employment and labour markets		
Does the option facilitate new job creation?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it lead directly or indirectly to a loss of jobs?	Possible impact	Possible impact
Qualitative Assessment: There may be some small impacts in Member States due to increases or decreases in the production of NMs, particularly by SMEs. Overall, the net effect is most likely very small.		
Does it have specific negative consequences for particular professions, groups of workers, or self-employed persons?	Possible impact	Possible impact
Qualitative Assessment: In light of the potential economic impacts described above, the policy options might threaten employment in the pigments and dyes sector and hence in the textile sector.		
Does it affect particular age groups?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect the demand for labour?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it have an impact on the functioning of the labour market?	Not relevant	Not relevant

Table 5-2: Social impact		
	Option	
Question	1	2
Qualitative Assessment: -		
Does it have an impact on the reconciliation between private, family and professional life?	Not relevant	Not relevant
Qualitative Assessment: -		
Standards and rights related to job quality		
Does the option impact on job quality?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option affect the access of workers or job-seekers to vocational or continuous training?	Not relevant	Not relevant
Qualitative Assessment:		
Will it affect workers' health, safety and dignity?	Yes	Yes
Qualitative Assessment: The extension of the information requirements to NMs would lead to better risk management measures in handling nanomaterials in the workplace.		
Does the option directly or indirectly affect workers' existing rights and obligations, in particular as regards information and consultation within their undertaking and protection against dismissal?	Yes	Yes
Qualitative Assessment: Both policy options ensure that workers receive adequate information on the health and safety profile of NMs		
Does it affect the protection of young people at work?	Not relevant	Not relevant
Qualitative Assessment:		
Does it directly or indirectly affect employers' existing rights and obligations?	Yes	Yes
Qualitative Assessment: Employers have the obligation to carry out hazard and risk assessments and to inform their employees (Chemical Agents Directive) of any risks in the workplace. The policy options ensure that employers can better comply with the requirements of the EU Occupational Health and Safety legislation.		
Does it bring about minimum employment standards across the EU?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option facilitate or restrict restructuring, adaptation to change and the use of technological innovations in the workplace?	Not relevant	Not relevant
Qualitative Assessment: -		
Social inclusion and protection of particular groups		
Does the option affect access to the labour market or transitions into/out of the labour market?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it lead directly or indirectly to greater equality or inequality?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect equal access to services and goods?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect access to placement services or to services of general economic interest?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option make the public better informed about a particular issue?	Yes	Yes

Table 5-2: Social impact		
	Option	
Question	1	2
Qualitative Assessment: Both policy options aim to increase the level of information on the health and safety of nanomaterials		
Does the option affect specific groups of individuals (for example the most vulnerable or the most at risk of poverty, children, women, elderly, the disabled, unemployed or ethnic, linguistic and religious minorities, asylum seekers), firms or other organisations (for example churches) or localities more than others? , firms, localities more than others?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option significantly affect third country nationals?	Not relevant	Not relevant
Qualitative Assessment: -		
Gender equality, equality treatment and opportunities, non-discrimination		
Does the option affect the principle of non-discrimination, equal treatment and equal opportunities for all?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option have a different impact on women and men?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option promote equality between women and men?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option entail any different treatment of groups or individuals directly on grounds of sex, racial or ethnic origin, religion or belief, disability, age, and sexual orientation? Or could it lead to indirect discrimination?	Not relevant	Not relevant
Qualitative Assessment: -		
Individuals, private and family life, personal data		
Does the option impose additional administrative requirements on individuals or increase administrative complexity?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option affect the privacy, of individuals (including their home and communications)?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect the right to liberty of individuals?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect their right to move freely within the EU?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect family life or the legal, economic or social protection of the family?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect the rights of the child?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option involve the processing of personal data or the concerned individual's right of access to personal data?	Not relevant	Not relevant
Qualitative Assessment: -		
Governance, participation, good administration, access to justice, media and ethics		

Table 5-2: Social impact		
	Option	
Question	1	2
Does the option affect the involvement of stakeholders in issues of governance as provided for in the Treaty and the new governance approach?	Not relevant	Not relevant
Qualitative Assessment: -		
Are all actors and stakeholders treated on an equal footing, with due respect for their diversity? Does the option impact on cultural and linguistic diversity?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect the autonomy of the social partners in the areas for which they are competent? Does it, for example, affect the right of collective bargaining at any level or the right to take collective action?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the implementation of the proposed measures affect public institutions and administrations, for example in regard to their responsibilities?	Yes	Yes
Qualitative Assessment: Both policy options promote the role of public institutions in ensuring the health and safety of products		
Will the option affect the individual's rights and relations with the public administration?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect the individual's access to justice?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it foresee the right to an effective remedy before a tribunal?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option make the public better informed about a particular issue? Does it affect the public's access to information?	Yes	Yes
Qualitative Assessment: Both policy options increase the level of information on nanomaterials		
Does the option affect political parties or civic organisations?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option affect the media, media pluralism and freedom of expression?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option raise (bio) ethical issues (cloning, use of human body or its parts for financial gain, genetic research/testing, use of genetic information)?	Yes	Yes
Qualitative Assessment: Both policy options raise a question over the ethics of allowing the manufacturing and importing of NMs without a proper characterisation of their health and safety profiles.		
Public health and safety		
Does the option affect the health and safety of individuals/populations, including life expectancy, mortality and morbidity, through impacts on the socio-economic environment (working environment, income, education, occupation, nutrition)?	Yes	Yes
Qualitative Assessment: Both policy options, increase the level of information on the toxicological and ecotoxicological aspects of NMs, and could therefore have a significant impact on public health and safety.		

Table 5-2: Social impact		
	Option	
Question	1	2
Does the option increase or decrease the likelihood of health risks due to substances harmful to the natural environment?	Possible impact	Possible impact
Qualitative Assessment: Generating information on ecotoxicological aspects of NMs, both policy options can contribute in decreasing the likelihood of health risks due to NMs found harmful to the natural environment.		
Does it affect health due to changes in the amount of noise, air, water or soil quality?	Likely impact	Likely impact
Qualitative Assessment: Both policy options could contribute in improving the quality of air, soil and water, through, for example, more stringent PNECs for NMs.		
Will it affect health due to changes in energy use and/or waste disposal?	Possible impact	Possible impact
Qualitative Assessment: The generation of new and better information on NMs might lead to different waste disposal strategies.		
Does the option affect lifestyle-related determinants of health such as diet, physical activity or use of tobacco, alcohol, or drugs?	Not relevant	Not relevant
Qualitative Assessment: -		
Are there specific effects on particular risk groups (determined by age, gender, disability, social group, mobility, region, etc.)?	Not relevant	Not relevant
Qualitative Assessment: -		
Crime, Terrorism and Security		
Does the option improve or hinder security, crime or terrorism?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option affect the criminal's chances of detection or his/her potential gain from the crime?	Not relevant	Not relevant
Qualitative Assessment: -		
Is the option likely to increase the number of criminal acts?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect law enforcement capacity?	Not relevant	Not relevant
Qualitative Assessment:		
Will it have an impact on security interests?	Not relevant	Not relevant
Qualitative Assessment: -		
Will it have an impact on the right to liberty and security, right to fair trial and the right of defence?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect the rights of victims of crime and witnesses?	Not relevant	Not relevant
Qualitative Assessment: -		
Access to and effects on social protection, health and educational systems		
Does the option have an impact on services in terms of quality/access for all?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it have an effect on the education and mobility of workers (health, education, etc.)?	Not relevant	Not relevant
Qualitative Assessment: -		

Table 5-2: Social impact		
	Option	
Question	1	2
Does the option affect the access of individuals to public/private education or vocational and continuing training?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect the cross-border provision of services, referrals across borders and co-operation in border regions?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option affect the financing / organisation / access to social, health and care services?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect universities and academic freedom / self-governance?	Not relevant	Not relevant
Qualitative Assessment: -		
Culture		
Does the proposal have an impact on the preservation of cultural heritage?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the proposal have an impact on cultural diversity?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the proposal have an impact on citizens' participation in cultural manifestations, or their access to cultural resources?	Not relevant	Not relevant
Qualitative Assessment:		
Social impacts in third countries		
Does the option have a social impact on third countries that would be relevant for overarching EU policies, such as development policy?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect international obligations and commitments of the EU arising from e.g. the ACP-EC Partnership Agreement or the Millennium Development Goals?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it increase poverty in developing countries or have an impact on income of the poorest populations?	Not relevant	Not relevant
Qualitative Assessment: -		

5.2.4 Environmental Impacts

For each possible environmental impact category listed in the Commission's Impact Assessment Guidelines, Table 5-3 presents the key questions and a first qualitative assessment.

Table 5-3: Environmental impact		
Question	Option 1	Option 2
The climate		
Does the option affect the emission of greenhouse gases (e.g. carbon dioxide, methane etc.) into the atmosphere?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option affect the emission of ozone-depleting substances (CFCs, HCFCs etc.)?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option affect our ability to adapt to climate change?	Not relevant	Not relevant
Qualitative Assessment: -		
Transport and the use of energy		
Does the option affect the energy intensity of the economy?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option affect the fuel mix (between coal, gas, nuclear, renewables etc.) used in energy production?	Not relevant	Not relevant
Qualitative Assessment:		
Will it increase or decrease the demand for transport (passenger or freight), or influence its modal split?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it increase or decrease vehicle emissions?	Not relevant	Not relevant
Qualitative Assessment: -		
Will the option increase/decrease energy and fuel needs/consumption?	Not relevant	Not relevant
Qualitative Assessment: -		
Air quality		
Does the option have an effect on emissions of acidifying, eutrophying, photochemical or harmful air pollutants that might affect human health, damage crops or buildings or lead to deterioration in the environment (soil or rivers etc.)?	Possible impact	Possible impact
Qualitative Assessment: Through the generation of new and better information on NMs, both policy options might contribute to the setting of lower emission levels		
Biodiversity, flora, fauna and landscapes		
Does the option reduce the number of species/varieties/races in any area (i.e. reduce biological diversity) or increase the range of species (e.g. by promoting conservation)?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect protected or endangered species or their habitats or ecologically sensitive areas?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it split the landscape into smaller areas or in other ways affect migration routes, ecological corridors or buffer zones?	Not relevant	Not relevant
Qualitative Assessment: -		

Table 5-3: Environmental impact		
Question	Option 1	Option 2
Does the option affect the scenic value of protected landscape?	Not relevant	Not relevant
Qualitative Assessment: -		
Water quality and resources		
Does the option decrease or increase the quality or quantity of freshwater and groundwater?	Possible impact	Possible impact
Qualitative Assessment: Through the generation of new and better information on NMs, both policy options might contribute to the setting of more stringent emission levels for hazardous NMs and to the implementation of better RMMs		
Does it raise or lower the quality of waters in coastal and marine areas (e.g. through discharges of sewage, nutrients, oil, heavy metals, and other pollutants)?	Possible impact	Possible impact
Qualitative Assessment: Through the generation of new and better information on NMs, both policy options might contribute to the setting of more stringent emission levels for hazardous NMs and to the implementation of better RMMs.		
Does it affect drinking water resources?	Possible impact	Possible impact
Qualitative Assessment: Through the generation of new and better information on NMs, both policy options might contribute to the setting up of more stringent emission level for hazardous NMs and to the implementation of better RMMs that might lead to an improvement in the quality of drinking water resources or reduce the risk of contamination.		
Soil quality or resources		
Does the option affect the acidification, contamination or salinity of soil, and soil erosion rates?	Possible impact	Possible impact
Qualitative Assessment: Through the generation of new and better information on NMs, both policy options might contribute to the setting of more stringent emission levels for hazardous NMs and to the implementation of better RMMs.		
Does it lead to loss of available soil (e.g. through building or construction works) or increase the amount of usable soil (e.g. through land decontamination)?	Not relevant	Not relevant
Qualitative Assessment: -		
Land use		
Does the option have the effect of bringing new areas of land ('green fields') into use for the first time?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it affect land designated as sensitive for ecological reasons? Does it lead to a change in land use (for example, the divide between rural and urban, or change in type of agriculture)?	Not relevant	Not relevant
Qualitative Assessment: -		
Renewable or non-renewable resources		
Does the option affect the use of renewable resources (fish etc.) and lead to their use being faster than they can regenerate?	Not relevant	Not relevant
Qualitative Assessment: -		
Does it reduce or increase use of non-renewable resources (groundwater, minerals etc.)?	Not relevant	Not relevant
Qualitative Assessment: -		
The environmental consequences of firms and consumers		
Does the option lead to more sustainable production and consumption?	Yes	Yes
Qualitative Assessment: Both policy options contribute to the promotion of "green chemistry".		

Table 5-3: Environmental impact		
Question	Option 1	Option 2
Does the option change the relative prices of environmental friendly and unfriendly products?	Not relevant	Not relevant
Qualitative Assessment: -		
Does the option promote or restrict environmentally un/friendly goods and services through changes in the rules on capital investments, loans, insurance services etc.?	Not relevant	Not relevant
Qualitative Assessment: -		
Will it lead to businesses becoming more or less polluting through changes in the way in which they operate?	Possible impact	Possible impact
Qualitative Assessment: Through the generation of new and better information on NMs, both policy options might contribute to the setting of more stringent emission levels for hazardous NMs and to the implementation of better RMMs.		
Waste production / generation / recycling		
Does the option affect waste production (solid, urban, agricultural, industrial, mining, radioactive or toxic waste) or how waste is treated, disposed of or recycled?	Possible impact	Possible impact
Qualitative Assessment: Both policy options might lead to changes in the disposal of waste containing NMs.		
The likelihood or scale of environmental risks		
Does the option affect the likelihood or prevention of fire, explosions, breakdowns, accidents and accidental emissions?	Possible impact	Possible impact
Qualitative Assessment: The better characterisation of NMs might lead to improved RMMs.		
Does it affect the risk of unauthorised or unintentional dissemination of environmentally alien or genetically modified organisms?	Not relevant	Not relevant
Qualitative Assessment: -		
Animal welfare		
Does the option have an impact on health of animals?	Possible impact	Possible impact
Qualitative Assessment: To the extent to which the policy options may impact on human health, they may also impact on the health of animals.		
Does the option affect animal welfare (i.e. human treatment of animals)?	Yes	Yes
Qualitative Assessment: The extension of the information requirements to NMs might lead to an increase in animal testing, as the validity of *in vitro* tests, QSARs and read-across for NMs is still under discussion.		
Does the option affect the safety of food and feed?	Possible impact	Possible impact
Qualitative Assessment: Better information on hazardous NMs might lead to the avoidance of their use in, for example, food contact materials.		
International environmental impacts		
Does the option have an impact on the environment in third countries that would be relevant for overarching EU policies, such as development policy?	Not relevant	Not relevant
Qualitative Assessment: -		

5.3 Qualitative Assessment of the More Significant Impacts

5.3.1 Introduction

Table 5-4 presents a summary of the impacts that will be further considered. The table provides also estimates on the likelihood and the magnitude of the expected impacts. These are further discussed in the following subsections.

Table 5-4: Summary of impact for further consideration					
Impact type	**Relevance**	**Positive/ Negative/ Uncertain**	**Likelihood**	**Magnitude**	**Importance**
Economic Impacts					
Functioning of the internal market and competition	**Potentially relevant**	**Uncertain**	**Medium**	**Uncertain**	**Medium**
Competitiveness, trade and investment flows	**Potentially relevant**	**Negative**	**Medium-high**	**Uncertain**	**High**
Operating costs and conduct of business/SMEs	**Relevant**	**Negative**	**High**	**High**	**High**
Administrative burdens on businesses	**Relevant**	**Negative**	**High**	**High**	**High**
Public authorities	**Potentially relevant**	**Negative**	**High**	**Medium**	**Medium-high**
Property rights	Not relevant	-	-	-	-
Innovation and research	**Potentially relevant**	**Negative**	**Medium**	**Uncertain**	**Medium**
Consumers and households	**Potentially relevant**	**Positive**	**Medium**	**Medium**	**Medium**
Specific regions and sectors	**Potentially relevant**	**Negative**	**High**	**High**	**High**
Third countries and international relations	**Potentially relevant**	**Uncertain**	**Medium**	**Low**	**Medium-low**
Macroeconomic environment	Not relevant	-	-	-	-
Social Impacts					
Employment and labour markets	**Potentially relevant**	**Uncertain**	**Medium**	**Low**	**Medium-low**
Standards and rights related to job quality	**Relevant**	**Positive**	**High**	**High**	**High**
Social inclusion and protection of particular groups	**Relevant**	**Positive**	**High**	**Medium**	**Medium-high**
Gender equality, equality treatment and opportunities, non-discrimination	Not relevant	-	-	-	-
Individuals, private and family life, personal data	Not relevant	-	-	-	-
Governance, participation, good administration, access to justice, media and ethics	**Potentially relevant**	**Positive**	**High**	**Medium**	**Medium-high**

Table 5-4: Summary of impact for further consideration					
Impact type	**Relevance**	**Positive/ Negative/ Uncertain**	**Likelihood**	**Magnitude**	**Importance**
Public health and safety	**Relevant**	**Positive**	**Uncertain**	**Uncertain**	**High**
Crime, terrorism and security	Not relevant	-	-	-	-
Access to and effects on social protection, health and educational systems	Not relevant	-	-	-	-
Culture	Not relevant	-	-	-	-
Social impacts in third countries	Not relevant	-	-	-	-
Environmental Impacts					
The climate	Not relevant	-	-	-	-
Transport and the use of energy	Not relevant	-	-	-	-
Air quality	**Potentially relevant**	**Positive**	**Uncertain**	**Uncertain**	**Medium**
Biodiversity, flora, fauna and landscapes	Not relevant	-	-	-	-
Water quality and resources	**Potentially relevant**	**Positive**	**Uncertain**	**Uncertain**	**Medium**
Soil quality or resources	**Potentially relevant**	**Positive**	**Uncertain**	**Uncertain**	**Medium**
Land use	Not relevant	-	-	-	-
Renewable or non-renewable resources	Not relevant	-	-	-	-
The environmental consequences of firms and consumers	**Relevant**	**Positive**	**High**	**High**	**High**
Waste production/generation/recycling	**Potentially relevant**	**Positive**	**High**	**Uncertain**	**Medium**
The likelihood or scale of environmental risks	**Relevant**	**Positive**	**High**	**High**	**High**
Animal welfare	**Relevant**	**Negative**	**High**	**High**	**High**
International environmental impacts	Not relevant	-	-	-	-

5.3.2 Economic impacts

The policy options are likely to impact on the choice available to professional end users: if nanomaterials have to be regarded as substances on their own, SDSs distinct from the ones of the "parental" substances should be developed. Professional end users would then know when they are dealing with NMs and would be able to choose between their use and the use of a substance in the bulk form. **This increase in information should be regarded as a positive effect on the functioning of the internal market.**

On the other hand, the extension of information requirements to NMs might impact negatively on the choices open to professional end users and consumers because manufacturers and importers might decrease the number of nanomaterials available on the market. This impact is to be expected especially in the pigments and dyes sector: pigments and dyes manufacturers/ importers might choose not to register the full range of pigments and dyes in order to minimise registration costs; similarly, downstream users might opt for "no nano" products in order to avoid any REACH duty[38]. Both of these actions may ultimately impact in a negative way on the competitiveness of other important economic compartments, such as the textiles and furniture manufacturing sectors.

The policy options may also create a barrier to entry in the nanomaterials market for new companies, especially SMEs, due to increases in the capital needed to cover the costs for generating of the physicochemical, toxicological and ecotoxicological information. However, this is unlikely to be a determining factor, as research on nanomaterials and the scaling up from the laboratory stage to the mass production requires significant investments: acquisition of know-how (e.g., research, research team, patents and licenses, etc.), research infrastructure and production equipment.

With regard to the impact on trade barriers, some WTO members raised concerns over the compliance of REACH with WTO rules[39]: the requirement for more information on the nanoforms of the substances would be regarded as a strengthening of technical barriers to trade already posed by REACH and a violation of proportionality. The WTO Technical Barriers to Trade Agreement states that "*no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal, and plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate*". However, Article 2.2 specifies that technical regulations should not be "*prepared, adopted or applied with a view to, or with the effect of, creating unnecessary obstacles to trade*". Unnecessary obstacles to trade can result when a regulation is more restrictive than necessary to achieve a given policy objective. Although no complaints resulting in disputes over the REACH Regulation have been filed to the WTO so far, it can be expected that the extension of the information requirements to nanomaterials manufactured/imported in low tonnages will raise more concerns among WTO members.

Economic impacts will stem primarily from businesses choosing to withdraw some nanomaterials from the market (or not to invest on research and development of nanomaterials) in order to minimise registration costs, in particular identification, characterisation and (eco)toxicological testing costs. Cost estimates are provided in the following Section.

The policy options entail of course a stricter regulation of the conduct of businesses operating in the nanotechnology field. The focus on nanomaterials would affect in particular companies specialised in the manufacturing or importing of nanomaterials or companies operating in sectors characterised by the common use of nanomaterials, such as the pigments and dyes sectors.

5.3.3 Social impacts

In the first instance, the policy options ensure that the principle "no data, no market" is respected also in the commercialisation of nanomaterials.

[38] RPA *et al* (2014) reports that some manufacturers of nanomaterials, responding to the survey launched for the purpose of the study, claimed that some downstream users are asking for "no nano" products in order to avoid any obligation under the French Notification System.
[39] http://www.wto.org/english/news_e/news08_e/tbt_20march08_e.htm

With regard to potential impacts of the policy options on the jobs market, the net effect is most likely to be very small: the withdrawal of some nanomaterials from the market in order to minimise compliance costs might lead to the loss of jobs. On the other hand, the policy options might create jobs in nanotoxicology, as laboratories and companies in the European Union would need expert in these fields.

As the main objective of the policy options is to ensure the better protection of human health and the environment, workers would surely benefit from better information on nanomaterials and, consequently, on better risk management measures when handling nanomaterials in the workplace. Moreover, the options ensure that workers' right are respected with regard to information and training as required by Article 8 of the Chemical Agents Directive[40] and Articles 6, 7 and 10 of Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work (known as "Occupational Safety and Health Framework Directive").

The Chemical Agents Directive (Art. 4) requires employers to carry out a risk assessment and to take all necessary preventive measures whenever "*hazardous chemical agents are present or may be present at the workplace*" (Art. 1(2)). Article 2(b) defines a "hazardous chemical agent" as:

a) A chemical agent which meets the criteria for classification as a dangerous substance according to Annex VI to the Dangerous Substance Directive (DSD); or

b) A dangerous preparation according to the Dangerous Preparation Directive (DPD)[41] or

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

Although nanomaterials are not explicitly included or excluded within the scope of the Directive, the "safeguard" subparagraph (Art. 2(b)(iii)) makes it clear that the general objective covers them in principle and the CAD applies provided the hazard is known, where "hazard" means "*the intrinsic property of a chemical agent with the potential to cause harm*" (Art. 2(g)) and "risk" means "*the likelihood that the potential for harm will be attained under the condition of use and/or exposure*". The key aspect is indeed the identification of the hazard. While it is true that "hazard identification" is the first step of a risk assessment, nevertheless the identification of a "chemical hazard" (where the identification of a hazard potentially posed by nanomaterials requires a similar level of knowledge) partially relies on information passed by the supplier of the substances or mixtures through the safety data sheets accompanying them. Thus, the applicability of the OSHD and the CAD to nanomaterials is partially dependent[42] on other legislation, particularly the CLP Regulation,

[40] 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).

[41] The DSD and the DPD were replaced by Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures (known as CLP). Although the CAD has not been amended yet, a parallel can be easily drawn between the Risk-phrases used by the DSD and the Global Harmonised System's (GHS) Hazard Statements introduced into the European Legislation by the CLP Regulation. Moreover, some R-phrases which do not have direct equivalents in the GHS or were intended for use in very specific circumstances have been incorporated specifically within the CLP Regulation.

[42] The dependence of the CAD to the CLP and REACH Regulations is only partial thanks to the "catch all" provision which was designed to bring within the scope of the Directive all those chemicals for which the hazardousness relies on properties other than toxicological or physicochemical as, for example, "*the temperature or pressure of the agent, its capacity to displace oxygen or the physical manner in which they are used or*

requiring the classification and labelling of a substance based on all available and reliable scientific information about potential hazards, and subsequently on the REACH Regulation, as the instrument that generates new information on physical, health and environmental hazards of chemical substances. The policy options would then ensure that employers can better comply with the requirements of Occupational Health and Safety legislation.

The implementation of either of the policy options would surely feed the public debate on nanomaterials, increasing the level of information on the risks and opportunities.

In terms of how the policy measures would affect the responsibilities of public institutions and administrations, according to Article 10 of the CAD, Member States have the obligation to "*introduce arrangements for carrying out appropriate health surveillance of workers for whom the results of [the risk assessment] reveal a risk to health*". Moreover, Article 3 of the CAD requires the Commission to "*evaluate the relationship between the health effects of hazardous chemical agents and the level of occupational exposure by means of an independent scientific assessment of the latest available scientific data*": the policy options may therefore provide new information on the hazard profiles of nanomaterials that might lead to the establishment of occupational exposure limit values.

It should be noted that the benefits of the policy options would not be confined just on occupational health and safety, but would ensure the safety of consumer products and, more generally, may contribute to reducing health risks to the general population and the natural environment associated with emissions of nanomaterials to the environment. The generation of toxicological and ecotoxicological data on nanomaterials might lead to the establishment of better DNELs[43] and PNECs[44], improving the human health and the quality of environmental media (air, soil and water).

5.3.4 Environmental impacts

Nanomaterials can reach the different compartments of the environment (water, soil, air and biota), finding their way into solid waste and wastewater effluents from disposed products containing nanomaterials, through direct discharge or accidental spillage from industrial sources, or by being transported to aquatic systems by wind or rainwater run-off. They can also be released from coatings materials and plastic composites via weathering processes, such as abrasion and sunlight-induced degradation.

Some nanomaterials may indeed present a risk to the environment. In a study published by the Swiss Centre for Technology Assessment[45], it is reported that nano-titanium dioxide (as used in some sun-screens) and nanosilver (as an anti-microbial agent) are hazardous to the aquatic environment. In the recent SCENIHR review on nanosilver[46], the authors concluded that

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handled", as explained in the Practical Guidelines developed by the European Commission to comply with Art. 12(2) of the CAD. The same Guidelines provide a more concrete example that can be extended to nanomaterials*: "chemical agents in the workplace may pose risks to the health or safety of workers on account of: (…) the manner in which they are present in the workplace (e.g.: inert solid in the form of a breathable powder)".* Guidelines available at:
https://osha.europa.eu/fop/netherlands/nl/fop/netherlands/nl/legislation/PDFdownloads/2261-EN.pdf

[43] Derived No-Effect Level

[44] Predicted No-Effect Concentration

[45] TA-SWISS (2013); Nanomaterialien: Auswirkungen auf Umwelt und Gesundheit, Zurich. Available at: https://www.ta-swiss.ch/en/projects/nanotechnologies/nano-and-environment/

[46] SCENIHR (2014): Opinion on nanosilver: safety, health and environmental effects and role in antimicrobial resistance, Scientific Committee on Emerging and Newly Identified Health Risks, Opinion approved at the 6th plenary of 10-11 June 2014.

silver nanoparticles, due to their capacity for distribution in the environmental compartments, can be a particularly effective delivery system of ionic silver to biota over extended periods of time and, thus, additional effects cannot be ruled out.

With regard to emissions to air that might affect human health, RPA *et al* (2014b) reports that "*according to the Health Effects Institute*[47]*, a growing number of epidemiological studies have been conducted over the last ten – fifteen years on the human health effects of ultrafine particles (UFP)*[48]*. However, the evidence of adverse effects from short-term exposure to ambient UFPs on acute mortality and morbidity from respiratory and cardiovascular diseases is suggestive rather than conclusive. Due to underlying deficiencies in exposure data, it is not possible to conclude (or exclude) that UFPs alone account substantially for the adverse effects associated with other ambient pollutants such as* $PM_{2.5}$*. No epidemiological studies of long-term exposures to UFPs have been conducted so far*".

With regard to intentionally manufactured nanomaterials, epidemiological studies have been conducted mainly on carbon black. These have led to the International Agency for Research on Cancer (IARC) to evaluate carbon black as *possibly carcinogenic to humans* (Group 2B), as there is sufficient evidence in experimental animals but inadequate evidence in human epidemiological studies[49].

As noted in the European Environment Agency report "Late lessons from early warnings: science, precaution, innovation"[50], the discussions over the potential risks of nanotechnology and the need for regulatory reform have been carried out in parallel with its development unlike preceding technologies where the discussions of associated risks have generally been carried out after their widespread use. However, the EEA (2013) argues that co-ordination across the actions from government and regulatory bodies is missing: the policy options under consideration might contribute in ensuring this co-ordination and in fostering further and better research on the potential effects on the environment of the manufacturing and use of nanomaterials. Considerable knowledge gaps on methods to measure and assess environmental pathways and resultant effects on the environment remain. The policy options might increase the pressure in filling these gaps; however, due to the lack of a clear consensus over the most suitable methods and standards, companies may struggle to comply with new regulatory measures. Moreover, since the validity of in vitro tests, QSARs and read-across for nanomaterials is still under discussion, the extension of the information requirements might lead to an increase in animal testing[51].

Undoubtedly, increasing regulatory pressure on nanomaterials would encourage the inclusion of environmental impact as a design parameter of nanotechnology.

[47] HEI (2013): Understanding the Health Effects of Ambient Ultrafine Particles, HEI Review Panel on Ultrafine Particles, HEI Perspective 3, Health Effects Institute, Boston, Massachusetts.
[48] The report focuses on ambient UFPs, mostly related to combustion processes. Key source of UFPs in urban areas are exhaust (result of combustion) and non-exhaust emissions (tire and break wear) from motor vehicles.
[49] http://monographs.iarc.fr/ENG/Monographs/PDFs/93-carbonblack.pdf
[50] EEA (2013): Late lessons from early warnings: science, precaution, innovation, EEA Report No 1/2013, available at http://www.eea.europa.eu/publications/late-lessons-2
[51] For an overview of the development of alternative testing strategies for nanomaterials, visit: http://www.nanowerk.com/spotlight/spotid=36452.php (last access: 10/11/2014)

5.4 Data Needs and Assumptions for In-depth Analysis

5.4.1 Introduction

This section outlines the key data that will be required in order to assist in the monetisation of the impacts associated with Option 1 and Option 2. Details of the information that is currently available (along with the data sources from which this information has been obtained) is provided. However, it is important to note that a number of assumptions need to be made where there is a lack of available information; these are highlighted. To ensure transparency, any assumptions that are required for the purposes of monetisation have been clearly outlined.

The key information required to undertake the assessment of Option 1 is as follows:

- Number of nanomaterials manufactured/imported in different tonnage bands;
- Cost of creating a new registration dossier for each newly registered nanomaterial, including administrative costs;
- Cost of information requirements for each nanomaterial (based on quantities manufactured/imported in the EU and hence, linked to the requirements outlined in REACH Annexes VII to X). This will include substance testing costs (e.g. physicochemical and toxicological data);
- Costs of undertaking nanomaterial characterisation (i.e. determining whether a substance is a nanomaterial in accordance with the EC recommendation, which is assumed to be made legally binding under this option). This is likely to include particle size, size distributions, surface area, etc. for substance identification purposes;
- Cost of performing a chemical safety assessment and completing a chemical safety report for each newly registered nanomaterial (for registrants manufacturing/importing in quantities of 100 kg/y or more);
- Cost of creating a SDS for each of the newly registered nanomaterial;
- Cost of obtaining exposure information/developing exposure scenarios for each of the newly registered nanomaterial (those that are manufactured/imported in quantities of 10 kg/y to 100 kg/y under Option 1).

The key information required to undertake the assessment of Option 2 is as follows:

- Number of nanomaterials manufacturer/imported in different tonnage bands;
- Cost of updating an existing dossier with information on the various nanoforms (of the bulk substance), including administrative costs;
- Cost of information requirements for all nanoforms of the bulk substance (based on total quantities manufactured/imported in the EU across all nanoforms of the bulk substance and hence, linked to the requirements outlined in REACH Annexes VII to X). This will include substance testing costs (e.g. physicochemical and toxicological data), but assumes read-across is allowed and accepted between nanoforms;
- Costs of undertaking nanomaterial characterisation (i.e. determining whether a substance is a nanomaterial in accordance with the EC recommendation, which is assumed to be made legally binding under this option). This is likely to include particle size, size distributions, surface area, etc. for substance identification purposes;
- Cost of performing a chemical safety assessment and completing a chemical safety report for the nanoforms of a bulk substance (for registrants manufacturing/importing in quantities of 10 t/y or more. This considers the combined total quantity of nanoforms of the bulk substance);

- Cost of updating the SDS with information on the nanoforms of the bulk substance; and
- Cost of obtaining exposure information/updating exposure scenarios with information on the nanoforms of the bulk substance (in relation to the total quantity of nanomaterials (of a bulk substance) that are manufactured/imported in quantities greater than 10 t/y under REACH).

The following paragraphs outline the data that are currently available and readily accessible with regards to the above information requirements. Where applicable, assumptions made to either fill data gaps or extrapolate information to a higher level is also highlighted.

5.4.2 Number of nanomaterials manufactured/imported in different tonnage bands

In terms of the current number of nanomaterials on the EU market, the industry steering group for the Cefic study (RPA, 2012) estimated that there are between **500 and 2,000 nanomaterials placed on the EU market**. Both the Matrix and the BiPRO studies used this range.

This estimate is based on a preliminary survey conducted by VCI in 2012 amongst German companies and further discussions with relevant industry associations (e.g. covering dyes and pigments). This wide range in numbers is due to the level of uncertainty and ambiguity surrounding existing measurement techniques to determine whether or not a material will fall within a nanomaterial definition based on the metrics of percentage of the particle number distribution for some of the most common classes of materials, e.g. pigments.

The steering group and key consultees suggested that around 50% of nanomaterials currently placed on the market are pigments, with a further 10% of the materials being fillers, catalysts and other high volume substances. These assumptions have been confirmed by the findings of the analysis carried out by RPA on the substances at the nanoscale notified to the FNS (RPA *et al*, 2014). Furthermore, the Cefic steering group believed that 90 - 95% (or more) of nanomaterials currently on the market are what would be considered conventional substances, with only 5% - 10% being the more newly engineered substances; as a result, the study carried out for Cefic adopted a split of 95% to 5% between conventional to newly engineered as representing a best estimate.

These assumptions are set out in Table 5-5. From these two sets of figures the following was carried forward:

- Low estimates: 90% conventional, 10% newly engineered; and
- High estimates: 95% conventional, 5% newly engineered.

Table 5-5: Numbers of Nanomaterials

Estimates	Total	High % of Newly Engineered		Best estimate of % Newly Engineered	
		Conventional	New	Conventional	New
		90%	10%	95%	5%
Low	500	450	50	475	25
High	2,000	1,800	200	1,900	100

The next step in the analysis carried out for Cefic was to identify the number of nanomaterials already registered and the number of nanomaterials yet to be registered under REACH. Two

approaches were considered for this purpose. The first was to assume that nanomaterials currently placed on the market follow the same tonnage distribution as other existing substances (given the high percentage assumed here to be existing, conventional substances). For these purposes, the tonnage distribution assumed in the original Business Impact Assessment (RPA and Statistics Sweden, 2002) was adopted.

As can be seen from Table 5-6, however, this results in a very high percentage of the conventional nanomaterials being categorised as low volume substances; industry sources indicated that this is at odds with the view that 50% of these materials will be used in pigments and thus be marketed at higher volumes. On this basis, an alternative distribution was developed by RPA (2012), with this distinguishing between conventional nanomaterials versus the more newly engineered materials. These figures which were developed based on discussions with industry experts at a small workshop in Brussels are also presented in Table 5-6.

Table 5-6: Number of Nanomaterials by Tonnage Band for all Scenarios

Tonnage Band	% of Nanomaterials by Tonnage	Low Estimate of Number of Nanomaterials – High % Newly Eng.		High Estimate of Number of Nanomaterials – Low % Newly Eng.	
		Conventional	Newly	Conventional	Newly
Estimates based on distribution of existing substances*					
>1000 tpa	9%	40.5	4.5	171	9
>100 tpa	8%	36	4	152	8
>10 tpa	15%	67.5	7.5	285	15
>1 tpa	68%	306	34	1,292	68
Totals	**100%**	**450**	**50**	**1,900**	**100**
Adjusted estimates based on industry assumptions*					
	Conv.	**New**	**Conventional**	**New**	**Conventional**	**New**
>1000 tpa	50%	1%	225	0.5	950	1
>100 tpa	20%	9%	90	4.5	380	9
>10 tpa	10%	20%	45	10	190	20
>1 tpa	20%	70%	90	35	380	70
Totals	**100%**	**100%**	**450**	**50**	**1,900**	**100**

** Distribution is based on that assumed in the REACH Business Impact Assessment*

*** Distributions for conventional nanomaterials and more newly engineered nanomaterials developed through discussions with industry for the purposes of this assessment*

RPA *et al* (2014) found that around 260 different substances[52] at the nanoscale were notified to the FNS. It should be noted however that this number refers to the first year of implementation of the system and that in the second year the French authorities received three times (over 10,000) the number of notifications received in 2013. This sharp increase in the number of notification is due, mostly, to the increased awareness of duty-holders (especially distributors) about their notifications duties and, only partially, to new substances at the nanoscale being notified[53]. MEDDE (2014) estimates that around 320 substances at the

[52] RPA analysis identified 259 different substances reported in MEDDE (2013).

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

nanoscale[54] have been notified in 2014 by French notifiers (the analysis does not cover the notifications received from countries other than France; however, 99.5% of the notifications have been received from French entities). The number and percentage of substances at the nanoscale notified by tonnage bands declared in 2013 and 2014 are presented in Table 5-7.

Table 5-7: Number and percentage of substances in nanoforms per notified quantities to the FNS in 2013 and 2014

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

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

Table 5-8 reproduces the results of the cross-analysis carried out by RPA between the list of notified substances at the nanoscale and the ECHA registered substances database. It is important to note that the analysis refers to the chemical substances as defined by the REACH Regulation and that the information in the REACH registration dossiers of the substances that were found in the ECHA database are unspecific and do not refer to the nanoforms.

RPA found that around 62% of the **substances** that have been notified to the French Notification System as manufactured, imported or distributed in France at the nanoscale had a full registration dossier in the ECHA database. Around one hundred substances (38%) could not be found among the list of registered substances: 16 substances were identified as polymers (outside the scope of the REACH Regulation) while, for the remaining 83 substances, RPA *et al* (2014) proposed as a possible reason for the lack of any information on the ECHA registered database the potential that the substances (at the nanoscale and macroscale) are currently manufactured/imported in quantities below 100 tonnes per annum and will be registered under the next Registration deadline. Within the new list of substances at the nanoscale published in MEDDE (2014), 80 substances that were not notified to the FNS in 2013 have been notified[55]. Most of these additional substances are pigments and dyes, pharmaceuticals, pesticides and some polymers. Consequently, the percentage of substances

[54] MEDDE (2014) identified 319 different substances/substance categories.
[55] According to the number of NMs notified in 2013 (258) and 2014 (319), only 61 new substances should have been identified. This difference might be due to some NMs notified in 2013 not being notified in 2014, to differences in reporting the substances by the French authorities or to errors in the cross-analysis.

at the nanoscale notified to the FNS without a REACH registration dossier is going to increase. However, most of them are not in the scope of the REACH Regulation.

Table 5-8: Results of the cross-analysis between the list of notified substances at the nanoscale and the ECHA registered substances database	
Number of notified substances **found** on the ECHA registered substances database	**159**
Per tonnage band	**No.**
1 - 10 tonnes per annum	9
10 - 100 tonnes per annum	29
100+ tonnes per annum	1
100 – 1,000 tonnes per annum	46
1,000 – 10,000 tonnes per annum	33
10,000 – 100,000 tonnes per annum	17
100,000+ tonnes per annum	1
100,000 – 1,000,000 tonnes per annum	12
1,000,000+ tonnes per annum	2
1,000,000 – 10,000,000 tonnes per annum	5
100,000,000+ tonnes per annum	1
Tonnage data confidential	3
Number of notified substances that were **not found** on the ECHA registered substances database	**99**
Reason	**No.**
Polymer or polymer group (outside the scope of REACH)	16
Other (possible reason: tonnage lower than 100 tonnes per annum)	83
Total	**258**
Information not sufficient to carry out the research	12
Source: RPA et al (2014)	

Another useful assumption was made in the Matrix study, where it was assumed that additional testing requirements are required for 100 to 400 nanomaterials, and that this will cover the registration of 400 to 1,600 nanoforms that can be adequately addressed through a grouping or read-across approach. Matrix note that there is extensive uncertainty regarding the detailed strategy for registration and the structure of a registration dossier for each of these substances. It is assumed that nanomaterials will be included within the registration dossier for the bulk substance. The extent to which read-across and grouping can be applied in terms of relating the nanomaterial to the bulk form of the substance or between nanoforms of the same material can only be determined on a case by case basis.

Table 5-9 provides an overview of the number of nanomaterials/forms requiring registration, in this case taken from BiPRO *et al* (2013).

Table 5-9: BiPRO (2013) Overview on the Number of Nanomaterials/Forms requiring Registration				
Tonnage Band	**1-10 t/y**	**10-100 t/y**	**100-1,000 t/y**	**>1,000 t/y**
% distribution (untreated)	10%	20%	50%	20%
No. of nanomaterials/forms (untreated)	5-20	10-40	25-100	10-40
% distribution (treated)[1]	0%	20%	50%	30%
No. of nanomaterials/forms (treated)[1]	0	10-40	25-100	15-60
Total no. of nanomaterials/forms to be registered	5-20	20-80	50-200	25-100
[1] *Assuming grouping/read-across is possible*				

Another source of information on the number of nanomaterials on the market is the ECHA newsletter of October 2014 Issue 5[56] reporting on the Austrian initiative: "*As one element of the Austrian Nanotechnology Action Plan adopted by the Austrian Federal Government in March 2010, Austria is now carrying out a nanomaterial inspection project. One of its goals is to find out if today's REACH requirements are being fulfilled. It also aims to clarify how inspectors can be helped to identify nanomaterials on the market and what kind of training they need. Spot checks are performed to gain insight into nanomaterials and nanomaterial products on the Austrian market (…) An initial list of 415 substances with potential nanoforms was compiled. This list was cross checked with individual substance entries in the ECHA database on registered substances. A few relevant substances with nanoforms that are currently without a REACH registration, for example fullerenes, were added, and the final list now contains* ***432 substances***".

Consideration may also need to be given to surface treated nanomaterials and whether these are to be considered as separate substances to the original (non-treated) nanomaterial (these would be considered separate substances that would require registration). As noted earlier in this report, there are two main types of surface treatment, physical and chemical surface treatment. In the case of physical surface treatment, the base substance and the surface treating agent are considered separate substances and, hence, each would need to be registered separately under REACH.

Chemically surface treated substances are currently covered by REACH FAQ 6.3.8 and are therefore exempted from registration as separate substances under REACH with the rationale behind this exemption being that the surface is a minor part of the substance. However, REACH FAQ 6.3.8 does not specifically refer to nanomaterials and there is an on-going debate regarding whether the surface of a nanomaterial is a minor part of the substance.

In the study undertaken by RPA for Cefic it was assumed that chemical surface treatment of a nanomaterial does result in a separate substance (identified under REACH) which will therefore need to be registered. In some cases, a nanomaterial may be surface treated using many different types of chemical surface treating agents. In RPA (2012) it was assumed that either all chemical surface treatments can be grouped and registered together or that each of these types or categories would need to be registered separately under REACH.

From the above discussion and for the purpose of the present assessment, the following assumptions are made:

- Five hundred different substances in total at the nanoscale are present on the EU market. This is consistent with the estimate used in the RPA, Matrix and BiPRO studies, with the information provided by the Austrians and with the findings of RPA *et al* (2014), of which 300 (around 60%) have already a registration dossier referring to the bulk form;
- There are two thousand different nanoforms (meaning an average of four nanoforms per substance);
- Four hundred and fifty nanomaterials manufactured/imported in quantities of more than 10 kilogrammes would have to be registered under option 1;
- Fifty substances at the nanoscale are manufactured/imported in quantities between 10 and 100 kilogrammes (in accordance with the tonnage bands distribution presented in Table 5-7) for which exposure information should be included in the technical dossier under option 1;

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

- Four hundred nanomaterials are manufactured/imported in quantities of more than 100 kilogrammes for which a chemical assessment will have to be performed and documented in a chemical safety report;

One thousand and eight hundred different nanoforms[57] will have to be identified in the registration dossiers of the bulk forms and for which a chemical safety assessment will have to be carried out.

Table 5-10: Assumptions for the assessment	
Number of substances at the nanoscale present on the EU market	**500**
Number of substances (with nanoforms) already registered	**300 (60%)**
Number of substances (with nanoforms) not registered	**200 (40%)**
Number of different nanoforms	**2,000**
Number of substances at the nanoscale manufactured/imported in quantities between 0.1 kg and 1 kg	25 (5%)
Number of substances at the nanoscale manufactured/imported in quantities between 1 kg and 10 kg	25 (5%)
Number of substances at the nanoscale manufactured/imported in quantities between 10 kg and 100 kg	50 (10%)
Number of substances at the nanoscale manufactured/imported in quantities between 100 kg and 1 tonne	125 (25%)
Number of substances at the nanoscale manufactured/imported in quantities between 1 tonne and 10 tonnes	100 (20%)
Number of substances at the nanoscale manufactured/imported in quantities between 10 tonnes and 100 tonnes	100 (20%)
Number of substances at the nanoscale manufactured/imported in quantities between 100 tonnes and 1,000 tonnes	50 (10%)
Number of substances at the nanoscale manufactured/imported in quantities of more than 1,000 tonnes	25 (5%)
Number of substances at the nanoscale manufactured/imported in quantities of more than 10 kg	**450**
Number of substances at the nanoscale manufactured/imported in quantities of more than 100 kg	**400**
Number of substances at the nanoscale manufactured/imported in quantities of more than 1 tpa	**275**

5.4.3 Cost of creating a new registration dossier for each newly registered nanomaterial

The costs outlined in Table 5-11 provide a summary of the administration cost, registration fees and SDS preparation costs associated with preparing/updating a REACH registration dossier as used in the study for Cefic undertaken by RPA in 2012.

The figures set out in Table 5-11 have been developed to reflect administration costs per new dossier and registration fees per registrant. The total registration fees will be significantly higher, as they will be incurred by each applicant. At 24 September 2014, the ECHA registered substances database contains 12,735 unique substances and contains information

[57] 1,800 = 450 (number of nanomaterials manufactured/imported in quantities of more than 10 kg per year) x 4 (average number of nanoforms per substance).

from 49,100 dossiers, a ratio of 3.85 dossiers per substance. The same ratio will be used for the purpose of this current assessment.

For the assessment of option 1, some assumptions need to be done on the registration fees that registrants should paid to ECHA for substances manufactured/imported in quantities of less than 1 tonne per year. In light of the recent reduction of the registration fees[58], the consultants assume zero registration fees for very low production volume nanomaterials.

Table 5-11: Administration and Fees per New Dossier	
Cost Item	**Fee/Cost**
Administration	€30,000 (per new dossier) €10,000 (update existing dossier)
Registration fees	Around €25,000 (per large company registrant)
	Fee assumptions per tonnage band*: · €30,000 for >1000 tpa; · €20,000 for >100 tpa; · €7,000 for > 10 tpa; and · €1,700 for >1 tpa
	€0 (update existing dossier)
Preparation of new SDS	€350
Note: It should be noted that the costs presented in this table reflect the marginal costs of preparing/updating a REACH dossier only. ** these refer to the average 'statistical' fees based on those calculated for the titanium dioxide case study but also taking into account likely numbers of registrants for substances at different tonnage bands and their likely sizes.*	

5.4.4 Cost of information requirements

Where additional testing for a nanomaterial is required, a robust study summary will need to be prepared for each new test in order to fulfil REACH information requirements. Where testing proposals need to be prepared (e.g. if vertebrate testing is required), then the costs associated with this work should also be taken into account. The assumptions on the costs per unit for this element as used in the Cefic study are given in Table 5-12.

Table 5-12: Cost Assumptions for Up-date of Preparation of New Dossiers	
Cost Item	**Cost (€)**
Robust study summary	Non-vertebrate testing = 150 Vertebrate testing = 450 (150 x 3 hrs)
Testing proposals	500

The Cefic study also estimated the potential cost of filling test gaps per statistical substance. The costs of filling gaps in the test data required under REACH Annexes VII to X will depend on the current availability of data for the nanoforms of the substances and whether read-across from the macro to the nanoform and vice versa can be justified. Even though there currently may be some test data for a nanomaterial, it is unlikely that a full data set will be available; furthermore, at present there is reliance on read-across from one form to the other to fill the data requirements of the REACH annexes.

Two sets of estimates were therefore prepared for the potential costs of meeting test data requirements. The first of these assumes some level of read-across is feasible (can be demonstrated between substance forms) in order to reduce the number and costs of additional

[58] http://www.ycf.org.uk/wp-content/uploads/2012/06/REACH-FeesFeb13-Comparative-Table.pdf.pdf

testing requirements, while the second assumes that read-across cannot be justified and therefore represents a high cost scenario. It should be noted that read-across is allowed and accepted when its application can be scientifically justified.

The resulting assumptions as to the number of tests that need to be undertaken are given in Table 5-13 for a 'statistical substance' where read-across cannot be justified as well as the numbers where read-across is possible; this includes the percentage of test end-points assumed to relate to vertebrate tests and thus that would incur higher robust study summary costs as well as the need for preparation of a test proposal. Both sets of assumptions assume some data already exist. The costs of filling test gaps per statistical substance are also given based on the business impact assessment assumptions and a set of higher cost assumptions.

Table 5-13: Annex VII to X Testing Requirements – Test Costs per Statistical Substance					
		<10 tpa	<100 tpa	<1,000 tpa	>1,000 tpa
Costs of filling test gaps per statistical substance	BIA estimates of data availability	€ 12,200	€ 77,200	€ 629,600	€ 861,700
	Higher cost assumptions reflecting low data availability	€ 40,000	€ 206,300	€ 737,700	€ 1,020,200
Assumed number of test gaps - no read across		4	17	31	45
Assumed number of test gaps - read across possible	Size as the identifier	0	4	10	10
	Surface treatment and size	4	7	20	30
% Vertebrate tests		0%	20%	30%	30%
Assumed number of vertebrate tests	Size as the identifier	0	1	3	3
	Surface treatment and size	0	1.4	6	9

The number of tests required to obtain physicochemical and toxicological data for each nanomaterial will depend on the extent to which read-across between nanomaterials can be scientifically justified (i.e. is allowed and accepted). If read-across can be justified then the number of testing gaps that require filling is likely to be significantly reduced, given that testing for every appropriate parameter will not be required for each nanomaterial.

5.4.5 Cost of nanomaterial characterisation

As part of the Matrix study chemical characterisation laboratories were contacted to provide cost estimates for undertaking substance characterisation. These discussions indicated that, in general, the requirement for chemical characterisation is an area where significant cost variations can occur. Therefore, in order to capture the possibilities for nanomaterials in general and to simplify the ensuing complexity, it was assumed that the generic range of **€40,000 to €500,000 for a "characterisation" package** is representative of a pragmatic minimum to outside maximum range.

The cost of nanomaterial characterisation as assessed for this study should be those that are in addition to the costs associated with any characterisation/commercial testing that is already

undertaken by industry. It is important to differentiate between existing costs (that will occur under the baseline options) and the additional costs that occur under the policy options.

As a result, the low end is adopted here as being relevant to "conventional nanomaterials", while the high end of the range as estimated by Matrix 2014 is only applied to "new nanomaterials".

5.4.6 Cost of performing a CSA/CSR (and developing exposure scenarios)

RPA *et al* (2012)[59] estimated costs for carrying out a CSA and drafting a CSR at around €1,500 for non-dispersive use substances and at around €4,200 for dispersive use substances.

5.5 In-depth Analysis of the Most Significant Impacts

5.5.1 Introduction

As already mentioned in the description of baseline 0A (Section 3.2.1) and as specified in numerous occasions by the Commission and ECHA, the EU regulatory framework covers nanomaterials which can either be:

- Registered as substances in their own right;
- Registered as forms of a substance and included in the dossier of the corresponding bulk or other forms of the substance.

The screening of registration dossiers for nano-specific information showed that limited information has been provided so far on nano-specific properties, studies and risk characterisation aspects; as a result, ECHA concluded that there is considerable room for improvement[60]. Table 5-14 provides more details on the extent to which nanomaterials are identified in REACH registrations.

Table 5-14: Nanomaterials in REACH registrations*

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

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

[59] RPA *et al* (2012b): Review of REACH Registration Requirements for Substances Manufactured or Imported between 1 and 10 Tonnes, prepared for DG Environment. Available at: http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/review2012/registr-req-final-report-part-b_en.pdf
[60] http://echa.europa.eu/chemicals-in-our-life/nanomaterials

ECHA recognises that companies are struggling to comply with the legislation and is following two different approaches to ensure the appropriate risk management of nanomaterials:

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

As of March 2013, ECHA had already sent around 170 "Article 36" letters urging companies to submit as much information on nanomaterials as possible in order to demonstrate safe use[61]. The dossier evaluations carried out in 2013 resulted in the general recommendation to registrants of clearly identifying the substances, of demonstrating the relevance of the testing undertaken, of providing clear information on use and exposure and of making good use of available information and alternative approaches. These initiatives, however, seem to have increased neither the quantity nor the quality of the dossiers with information specific to nanomaterials; moreover, industry is challenging the legitimacy and proportionality of requiring more information on the nanoforms of the substances: on 16 September 2014, ECHA's Board of Appeal received an appeal regarding ECHA decision, following the evaluation of the registration dossier of titanium dioxide, asking the registrants to submit more information on phases of the substance, the nanoforms and the surface treatment of the nanoforms[62]. The registrants claim that the Agency breached the principle of proportionality requesting additional information that is not required by legislation (referring to Section 2 of Annex VI of the REACH Regulation) and is not necessary.

For the purposes of the assessment and for comparison with the second baseline and the policy options considered here, it is assumed that under baseline 0A the quality and quantity of the dossiers referring to nanomaterials will not increase. Baseline 0B considers the implementation of the amendments to the REACH Annexes, which are intended to ensure that manufacturers and importers provide sufficient and adequate information on the nanoforms of the substances placed on the EU market. **For the purposes of this assessment, it is assumed that baseline 0B will result in full compliance with the Commission's and ECHA's positions on REACH requirements for nanomaterials. Full compliance is also assumed under policy option 1 and 2.**

Table 5-13 summarises the relevant parameters and the cost estimates under the baselines and the options. Figure 5-1 presents the results in stacked columns chart.

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

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

Table 5-13: Relevant parameters and costs under baselines and policy options				
	Baseline 0A	**Baseline 0B**	**Option 1**	**Option 2**
No. of nanomaterials to be registered	13 NMs registered so far	275 NMs manufactured/imported in quantities of more than 1 tpa	450 NMs manufactured/imported in quantities of more than 10 kgpa	275 NMs manufactured/imported at more than 1 tpa (but 450 nanoforms will have to be identified in the registration dossiers)
Expected no. of dossiers to be submitted/updated	13 between individual and joint submissions	Around 1,000 dossiers to be submitted (of which 600 to be updated and 400 to be submitted)	1,700 dossiers to be submitted	Around 1,100 dossiers (of which 400 to be prepared and submitted and 700 to be updated)
Registration administration costs	Around €0.15M (12 dossiers to be updated at a cost of €10,000, 1 dossiers to be prepared and submitted at a cost of €30,000)	Around €18M (€6M to update 600 dossiers and €12M to prepare and submit 400 new registration dossiers)	Around €51M	Around €33M (€12M to prepare and submit 400 new registration dossiers and €21M)
Registration fees €30,000 > 1,000 tpa €20,000 > 100 tpa €7,000 > 10 tpa €1,700 > 1 tpa €0 >100 kgpa €0 >10 kgpa	Around €0.03M (only one dossier, assuming it is submitted by a large company for a NM in quantities of more than 1,000 tpa)	Around €4.1M (€1.2M for 30 dossiers >1,000 tpa €1.6M for 70 dossiers >100 tpa €1.05M for 150 dossiers >10 tpa €0.25M for 150 dossiers >1 tpa)	Around €9.8M (€2.7M for 90 dossiers >1,000 tpa €3.8M for 190 dossiers >100 tpa €2.7M for 380 dossiers >10 tpa €0.6M for 380 dossiers >1 tpa €0 for 660 dossiers <1tpa)	Around €4.1M (€1.2M for 30 dossiers >1,000 tpa €1.6M for 70 dossiers >100 tpa €1.05M for 150 dossiers >10 tpa €0.25M for 150 dossiers >1 tpa)
Preparation of new SDS €350	€350 (1 SDS for Multi-walled Carbon Nanotubes)	If no amendment to Annex II €0 With amendment to Annex II around €0.35M	Around €0.65M	Around €0.4M
Nanomaterial characterisation costs €40,000 - €500,000 full characterisation costs	Between €0.7M and €1.4M (assuming 11 “conventional” NMs and 2 “new” NMs)	Between €30.5M and €61M (assuming 950 dossiers for “conventional” NMs and 50 dossiers for “new” NMs)	Between €54M and €107M (assuming 1,615 dossiers for “conventional” NMs and 85 dossiers for “new” NMs)	Between €34.65M and €69.3M (assuming 1,045 dossiers for “conventional” NMs and 55 dossiers for “new” NMs)

Table 5-13: Relevant parameters and costs under baselines and policy options				
	Baseline 0A	**Baseline 0B**	**Option 1**	**Option 2**
€20,000 - €250,000 assuming only partial characterisation is needed for compliance and decreasing costs over time and for "batches"				
Testing costs For policy option 1 and 2: €0.85M – €1M > 1,000 tpa €0.85M – €1M > 100 tpa €0.85M – €1M > 10 tpa €0.67M – €0.74M > 1 tpa €0.08M – €0.2M >100 kgpa €0.012M – €0.04M >10 kgpa	With testing carried out on the nanoforms the cost estimates would be of around €10.3M (9 NMs manufactured/imported in more than 1,000 tpa, 4 NMs manufactured imported in quantities between 100 tpa and 1,000 tpa)	Between €127.9M and €172M (€42.5M-€50 M for 50 dossiers >1,000 tpa €67M - €74M for 100 dossiers >100 tpa €16M - €40M for 200 dossiers >10 tpa €2.4M - €8M for 200 dossiers >1 tpa)	Between €856.3M and €1,044M (€76.5M-€90 M for 90 dossiers >1,000 tpa €161.5M - €190M for 190 dossiers >100 tpa €323M - €380M for 380 dossiers >10 tpa €254.6M - €281.2M for 380 dossiers >1 tpa €38.4M - €96M for 480 dossiers >100 kgpa €2.3M – €7.6M for 190 dossiers >10 kgpa)	Between €856.3M and €1,044M (€76.5M-€90 M for 90 dossiers >1,000 tpa €161.5M - €190M for 190 dossiers >100 tpa €323M - €380M for 380 dossiers >10 tpa €254.6M - €281.2M for 380 dossiers >1 tpa €38.4M - €96M for 480 dossiers >100 kgpa €2.3M – €7.6M for 190 dossiers >10 kgpa)
CSA/CSR costs €1,500 – €4,200	€0.0015M (1 CSA/CSR per Multi-walled Carbon Nanotubes)	Between €1.5M and €4.2M	Between €2.55M and €7.14M	Between €1.65M and €4.62M
Total	**Between €0.88M and €1.58M (plus €10.3M in case of testing on the nanoforms)**	**Between €182M and €260M**	**Between €974M and €1,220M**	**Between €930M and €1,155M**

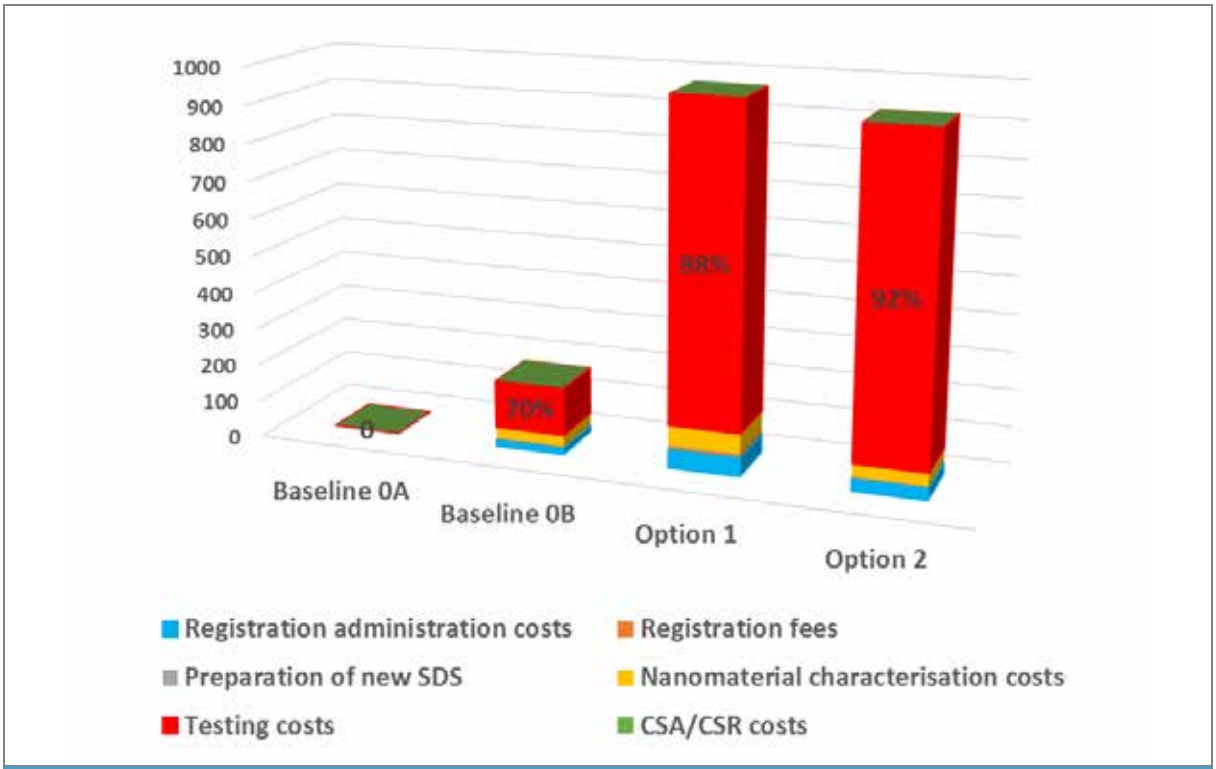

Figure 5-1: Cost estimates under baselines and policy options (low end estimates)

Two sets of estimates – a lower bound and an upper bound - have been developed and the results are mainly driven by the testing costs and the assumed level of read-across. For the lower bound scenario, some level of read-across has been assumed as feasible (can be demonstrated between substance forms) in order to reduce the number and costs of additional testing requirements; while the upper bound scenario assumes that read-across cannot be scientifically justified.

Table 5-14 presents the marginal costs of policy option 1 and 2 in comparison with baseline 0B (where for both the baseline and the policy options, full compliance is assumed).

Table 5-14: Marginal costs of the policy options in comparison with baseline 0B

	Policy option 1	Policy option 2
Registration administration costs	€33M	€15M
Registration fees	€5.7M	€0
Preparation of new SDS	€0.3M	€0.05M
Nanomaterial characterisation costs	€23.5M – €46M	€4.15M – €8.3M
Testing costs	€728.4M – €872M	€728.4M – €872M
CSA/CSR costs	€1.05M – €2.94M	€0.15M – €0.42M
Total	**€791.95M – €960M**	**€747.75M – €896M**

Even when some level of read-across is assumed as feasible, testing costs are extremely high and, as highlighted in Figure 5-1, correspond to 85% of the total costs for policy option 1 and 92% for policy option 2.

The level of read-across deemed to be scientifically justifiable was determined during the RPA study for Cefic and based on the analysis of two nanomaterials. Test gaps and end-points

for which read-across was deemed acceptable were identified by the Cefic expert group. The feasible level of read-across will vary from substance to substance. At the present time, it is impossible to determine in general what the possible level of read-across may be, although it is currently very low in terms of acceptance by ECHA. An increasing amount of funds are now dedicated to researching methodologies for read-across through different forms of the substances and grouping of nanomaterials.

Another important parameter determining the magnitude of the cost estimates is the number of registration dossiers submitted for each nanomaterial. This has been assumed equal to the current average number of dossiers for the substances already registered. Encouraging joint submissions from companies may result in significant cost savings. However, at present, it is unlikely that the registration of nanomaterials would result in an increase in joint submissions: companies, especially in the nanotechnology field, might prefer individual submissions in order not to disclose commercially sensitive information to their competitors.

It is clear from the analysis that the introduction of information requirements for substances manufactured/imported in quantities of more than 10 kilogrammes per year causes a significant increase in the marginal costs of both policy options, compared to the costs of these options for substances manufactured/imported in quantities of more than 1 tonne per year.

Policy option 2 results in slightly lower costs than policy option 1 due to the savings stemming from the lower costs of updating the registration dossiers (instead of developing new ones) and the savings on registration fees.

In consideration of the significance of the assumptions made to the final results, the cost estimates presented should be taken as illustrative of the magnitude of the costs rather than as reflecting accurate figures.

Some nanomaterials (e.g. carbon black, calcium carbonate, silicon dioxide) are commodity materials manufactured globally in hundreds or thousands of tonnes. As their prices are low, due to the production volumes involved, manufacturers and importers of these nanomaterials may well be able to sustain the costs of registration but may also face difficulties in passing these on given the commodity nature of the substance. On the other hand, "new" nanomaterials are manufactured in very low quantities, but their per unit prices are very high (ranging from one euro to one thousand euros per gram[63]). At such prices, manufacturers and importers of nanomaterials are likely to register the nanomaterials rather than consider any substance withdrawal.

Nevertheless, it is likely that some nanomaterials will fall between these two cases, especially pigments and dyes, that do not realise the same high prices and are not on the market in high volumes: it is much more likely that for these nanomaterials manufacturers and importers would consider the rationalisation of their product portfolios and may withdraw some pigments and dyes from the market. This would have knock-on effects for downstream sectors (e.g. textiles). One of the leading manufacturers of pigments and dyes and the largest chemicals manufacturer, BASF, has increased the prices for pigments and dyes worldwide due to "*the current market situation, significantly higher raw materials costs and rising cost of environment, health and safety as well as maintenance*"[64].

[63] Prices of nanomaterials researched at: http://www.sigmaaldrich.com/united-kingdom.html
[64] http://www.basf.com/group/pressrelease/P-14-316

5.6 Benefits of the Policy Options

5.6.1 Introduction

A rigorous benefits appraisal requires identifying exposure-response functions for each nanomaterial, both in terms of human health and environmental effects. It would then involve predicting the effects of the new information requirements in reducing exposure levels and translating those into reduced effects levels, to enable the change in effect to be valued in monetary terms using economic valuation procedures. To be strictly rigorous, the methodology should also involve careful selection of an appropriate discount rate and consideration of the distribution of the impacts over time. Detailed data on nanomaterials properties, dose-response relationships and exposures are needed to undertake such an ideal analysis. Such data do not currently exist, making such an assessment impossible. Indeed, it is the aim of the policy options to generate this type information in the future.

As a result, it is proposed that a "reverse" approach is adopted, estimating the number of health cases that would have to be avoided or environmental resource base that would have to be protected from future damage by the policy options in order to make worthy their implementation.

5.6.2 Human health

For the estimation of the number of health cases that would have to be avoided by the policy options in order to make their implementation worthy, a range of health end-points can be used as indicators. Three different examples are presented below, based on:

- The willingness to pay to avoid a lethal cancer (roughly equivalent to the Value of a Statistical Life);
- The willingness to pay to avoid a non-lethal cancer;
- The health care costs and lost productivity associated with skin diseases.

As mentioned before, the policy options might contribute in identifying new hazards, among them carcinogens and skin sensitizers. Clearly, nanomaterials can (or cannot) have different human health hazards. The numbers presented in Table 5-15 should be seen as illustrative examples only.

It is assumed that:

- The value of a statistical life in the EU28 is €3.371 million[65];
- The willingness to pay to avoid a non-lethal cancer is around €450,000[66];
- The health care cost for "rash or other non-specific skin eruption" is around €550[67] per case[68];
- The lost productivity per skin disease case is around €720 per year[69].

[65] http://heatwalkingcycling.org/index.php?pg=requirements&act=vsl
[66] ECHA (2008): Guidance on Socioeconomic Analysis – Restrictions, page 84 uses a WTP value of €400,000, resulting in a 2014 value of around €450,000 (using OECD inflation rates). ECHA (2008) available at: http://echa.europa.eu/documents/10162/13641/sea_restrictions_en.pdf
[67] NHS (2013): National Schedule of Reference Costs Year: 2012-13. Available at: https://www.gov.uk/government/publications/nhs-reference-costs-2012-to-2013
[68] This is the cost in the UK; it is assumed that the average cost in the EU28 is equivalent.
[69] Labour productivity per hour worked is €32.1 in the EU28 (http://epp.eurostat.ec.europa.eu/tgm/table.do?tab=table&init=1&plugin=1&language=en&pcode=tsdec310);

Table 5-15 presents the results.

Table 5-15: Number of lethal cancers to be avoided by the policy options in order to make worthy their implementation		
	Policy option 1	**Policy option 2**
Total marginal costs	**€791.95M – €960M**	**€747.75M – €896M**
Total number of lethal cancers to be avoided	235 - 285	222 – 266
Total number of non-lethal cancer to be avoided	1,760 – 2,133	1,662 – 1,991
Total number of skin disease cases to be avoided	622,602 - 754,717	587,854 – 704,403

Table 5-15 presents the total number of cases to be avoided for each one of the three health end-points used as examples in comparison with the total marginal costs of the policy options: **it must be noted that it is the combination of health cases and environmental damages (following sub-section) avoided that has to outweigh the costs of the policy options.** Moreover, while the costs would be incurred by the companies in a determined number of years (the REACH Regulation provides different deadlines for different tonnage bands in a lapse of 11 years), the benefits (and thus the health cases to be avoided) would accumulate over a longer time horizon.

5.6.3 Environment

For an indication of the level of environmental damages that would have to be prevented by the policy options in order to make their implementation economically justified, the willingness to pay of UK households for improving the quality of water bodies to different Water Framework Directive Status levels is used as an indicator[70]. Three different values, referring to willingness to pay to improve the quality of water bodies from "bad" to "poor", from "poor" to "moderate", and from "moderate" to "good" have been used as presented in Table 5-16.

Table 5-16: km^2 of water bodies to be improved by the policy options to make their implementation worthy			
	WTP per km^2	**Policy option 1**	**Policy option 2**
Total marginal costs		**€791.95M – €960M**	**€747.75M – €896M**
Improve from "bad" to "poor"	€22,000	36,000km^2 - 44,000km^2	34,000km^2-41,000km^2
Improve from "poor" to "moderate"	€25,200	31,000km^2 - 38,000km^2	30,000km^2 - 36,000km^2
Improve from "moderate" to "good"	€29,200	27,000km^2 - 33,000km^2	26,000km^2 - 31,000km^2

The numbers presented in Table 5-16 indicate the area in km^2 of rivers that would need to be protected from a degradation in their quality status, for example through the setting of stricter emission levels or the setting of better/more stringent risk management measures, in order for the benefits (as reflected in WTP values) to outweigh the costs. As can be seen from the table, the implied area of water bodies is 26,000 km^2 to 44,000 km^2 which would equate to the total area across several EU Member States.

assuming a work day of 7.5 hours and three days' sick leave per case per year (Pickvance *et al*, 2005) gives €722.

[70] Environment Agency (2013): Updating the National Water Environment Benefit Survey values: summary of the peer review. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/291464/LIT_8348_42b259.pdf

As mentioned in the previous sub-section, it is the combination of health cases and environmental damages avoided that needs to be compared with the costs of the implementation of the policy options.

5.7 Conclusions

The assessment of the implementation of the policy options highlighted that the introduction of information requirements for substances manufactured/imported in quantities of more than 10 kilogrammes per year causes a significant increase in the total marginal costs. In particular, requiring (eco)toxicological information up to Annex X for substances at the nanoscale manufactured/imported in quantities over 1 tonne per year contributes to drastically increase the costs of the policy options.

Total marginal costs between €790 million and €960 million for policy option 1 and between €750 million and €900 million for policy option 2 have been estimated, with the testing costs being indeed the most important parameter (respectively, 85% for policy option 1 and 92% for policy option 2) to the final estimates.

Policy option 2 results in slightly lower costs than policy option 1 due to the savings stemming from the lower costs of updating the registration dossiers (instead of developing new ones) and the savings on registration fees.

In consideration of the significance of the assumptions made to the final results, the cost estimates presented should be taken as illustrative of the magnitude of the costs rather than as reflecting accurate figures. Moreover, the costs estimated are marginal to a full compliance scenario (baseline 0B) were the reality is closer to the description of baseline 0A, with few REACH registration dossiers containing information on nanomaterials.

It should be noted that, at the present time, some challenges remain in the risk assessment of nanomaterials, more precisely in the characterisation of the physicochemical parameters, in the metrology and dose metrics to be used for the hazard and exposure assessment and for the determination of the environmental fate, persistence and bioaccumulation throughout their life cycles[71].

Two factors that could result in cost savings are read-across and grouping of nanomaterials and the encouragement of joint submissions of registration dossiers. With regard to read-across and grouping, although their acceptance and validity is still very low, an increasing amount of funds are now dedicated to researching methodologies for the improvement of these procedures. With regard to encouraging joint submissions, it would be very important to reinsure companies of the trustfulness of the process in not-disclosing commercially sensitive information to their competitors.

Further economic impacts will stem primarily from businesses choosing to withdraw some nanomaterials from the market (or not to invest on research and development of nanomaterials) in order to minimise registration costs. These effects are expected especially for pigments and dyes, which do not realise the same high prices of “newly engineered” nanomaterials and are not on the market in high volumes as some commodity nanomaterials

[71] For more details about the regulatory challenges in risk assessment of nanomaterials, see: http://echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/topical-scientific-workshop-regulatory-challenges-in-risk-assessment-of-nanomaterials

(e.g. carbon black, calcium carbonate, silicon dioxide). The withdrawal of pigments and dyes from the market might have knock-on effects for downstream sectors (e.g. textiles).

For the assessment of the benefits, information that is the objective of the policy options to generate is needed. Therefore, a "reverse" approach has been used to present some illustrative examples in terms of number of health cases that would have to be avoided or environmental resource base that would have to be protected from future damage by the policy options in order to make worthy their implementation.

In the first instance, the policy options ensure that the principle "no data, no market" is respected also in the commercialisation of nanomaterials.

As the main objective of the policy options is to ensure the better protection of human health and the environment, workers would surely benefit from better information on nanomaterials and, consequently, on better risk management measures when handling nanomaterials in the workplace. Moreover, the options ensure that workers' right are respected with regard to information and training and help employers in complying with health and safety legislation.

The benefits would not be confined on occupational health and safety only, but would ensure the safety of consumer products and, more generally, may contribute to reducing health risks to the general population and the natural environment associated with emissions of nanomaterials to the environment. The generation of toxicological and ecotoxicological data on nanomaterials might lead to the establishment of better DNELs and PNECs, improving the human health and the quality of environmental media (air, soil and water).

A side effect of the extension of the information requirements is that, since in vitro tests, QSARs and read-across for nanomaterials are still being developed, it might lead to an increase in animal testing.

When comparing the costs and the benefits of the policy options it should be noted that, while the costs would be incurred by the companies in a determined number of years (the REACH Regulation provides different deadlines for different tonnage bands in a lapse of 11 years), the benefits (and thus the health cases to be avoided) would accumulate over a longer time horizon.

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