EUROPEAN COMMISSION

ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Resources Based, Manufacturing and Consumer Goods Industries
Chemicals Industry

DRAFT OF THE FIRST CHAPTERS OF THE IMPACT ASSESSMENT REPORT[1]

1. INTRODUCTION

1.1. Introduction to nanomaterials

According to the Commission recommendation on the definition of nanomaterial[2], a nanomaterial is "a natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm". Some of those materials have been the subject of intensive research and development with a view to creating breakthrough innovation, e.g. in medicine, information technology, batteries, water treatment etc. Nevertheless, it should be highlighted that a large part of the nanomaterials on the market are commodity materials, some of them in widespread use for decades, without any major known incidents.

Toxicological knowledge about nanomaterials is improving continuously and a wide range of studies has been undertaken in recent times.[3] In its report on the risk assessment of nanotechnologies, the Scientific Committee on New and Emerging Health Risks (SCENIHR)[4] stated that "nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not, yet specific nanomaterials and specific uses of these nanomaterials may carry specific health and environmental risks." As the nano form of a substance may have different properties than the bulk ('non-nano') form, these risks may be different as well.

There are concerns that currently available information about nanomaterials is insufficient to guarantee their safe use. Part of these concerns is related to risk assessment and risk management. As this is addressed in a number of pieces of legislation and in a separate impact assessment on a revision of the Annexes to the REACH Regulation, this is not further developed here.

Another part of these concerns is related to the absence of sufficient information concerning the presence of nanomaterials on the market and their uses.

Existing knowledge was summarised in 2012 in the Commission Communication on the Second Regulatory Review as follows:

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[1] Please note that this is a draft version of the first chapters of the impact assessment report. This document will be further developed over the course of the impact assessment process. An updated version including a final version of the problem definition, objectives and policy options will be published by the end of May. A final version of the full document will be available at the end of the impact assessment process in the fourth quarter of 2014.

[2] Commission Recommendation of 18 October 2011 on the definition of nanomaterial, 2011/696/EU

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

[4] Scientific Committee on Emerging and Newly Identified Health Risks, 'Risk Assessment of Products of Nanotechnologies', 19 January 2009

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"The total annual quantity of nanomaterials on the market at the global level is estimated at around 11 million tonnes, with a market value of roughly 20bn €. Carbon black and amorphous silica represent by far the largest volume of nanomaterials currently on the market[8]. Together with a few other nanomaterials, they have been on the market for decades and are used in a wide variety of applications.

The group of materials currently attracting most attention are nano-titanium dioxide, nanozinc oxide, fullerenes, carbon nanotubes and nanosilver. Those materials are marketed in clearly smaller quantities than the traditional nanomaterials, but the use of some of these materials is increasing fast.

Other new nanomaterials and new uses are being developed rapidly. Many are used in innovative applications such as catalysts, electronics, solar panels, batteries and biomedical applications including diagnostics and tumour therapies."

More details and an overview of knowledge per substance are presented in Annex II to the Commission Staff Working Paper on Types and Uses of Nanomaterials[5]. Further information sources are referred to in the The JRC Web Platform on Nanomaterials[6] (hereafter referred to as the "JRC web platform").

Nevertheless, this information is perceived by many stakeholders as insufficient and an instrument to generate more complete, regularly updated and detailed information on nanomaterials and their uses is called for by these stakeholders.

1.2. Introduction to the impact assessment

Based on the above-mentioned concerns, this impact assessment will examine different policy options that are aimed at gathering available information or generating new information on the presence of nanomaterials and products containing nanomaterials on the market. This impact assessment will also generate data that will help address the more basic questions of whether, why and to what extent there is an information gap, whether and on what scale this poses a problem, what benefits additional information could bring and at what costs.

There is a range of available information sources on nanomaterials and products containing nanomaterials. These include the aforementioned Staff Working Paper, the results of the French notification scheme on nanomaterials[7], the Cosmetics notification portal and other sources, many of which are mentioned in the JRC web platform. Nevertheless, this information is incomplete, and additional information could provide a more complete picture.

It is important to regard the collection or generation of information in the context of its use. The benefits of additional knowledge for information purpose alone (i.e. dissociated from potential health and environmental benefits or better informed consumers resulting from this information) will be limited and difficult to quantify. The additional information itself may have effects in terms of public perception, either positive by creating trust through transparency, or negative by unjustified stigmatisation as the public may not understand that

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

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

[7] Anses (2010) 'Éléments issus des déclarations des substances à l'état nanoparticulaire, Rapport d'étude', November 2013, http://www.developpement-durable.gouv.fr/IMG/pdf/Rapport_public_format_final_20131125.pdf

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nanomaterials are not necessarily hazardous or cause risks. These effects are, however, rather speculative and can only be evaluated qualitatively. Therefore, the main focus of the impact assessment will be on how the additional information may be *used* to address health and environmental risks or inform consumers.

Importantly, this impact assessment does not address the overall question on how health and environmental risks can be best addressed, as there is a wide range of policy measures already in place or currently under separate assessments. These measures are described in the Commission Communication on the Second Regulatory Review on Nanomaterials[8].

In particular, this impact assessment will not directly address the question whether and how risk assessment and risk management of nanomaterials can be improved, as this is part of the ongoing revision of the REACH Annexes. Measures to increase knowledge on nanomaterials on the market will not generate new information on potential hazards of nanomaterials. Nevertheless, information on the presence of nanomaterials on the market may generate information on possible sources of exposure to nanomaterials. This may allow for a better assessment of where exposure and risks potentially occur in the workplace, during distribution and consumption, and at the end of life stage. Furthermore, such information may be used for setting enforcement priorities or for enhancing risk assessment. Moreover, information that would make nanomaterials traceable on the market could be used in case of acute incidents requiring the withdrawal of products containing those nanomaterials.

Labelling is generally considered as an important and perhaps the most straightforward way to inform consumers about the presence of nanomaterials in consumer products. Nevertheless, this impact assessment will not address labelling of nanomaterials, as the Commission has taken a final position on this question in the Commission Communication on the Second Regulatory Review on Nanomaterials. Ingredient labelling is in principle supported for all consumer products where ingredient lists exists but there are no indications that nanomaterials pose high levels of hazards or exposure in other products that would justify the introduction of labelling for products where no ingredient lists exist. Labelling should be risk-independent and be done by a mention of the term "nano" in brackets after the ingredient in question. Furthermore, hazard labelling for substances and mixtures is already done in accordance with the Regulation on the classification, labelling and packaging of substances and mixtures (CLP)[9]. Since hazards for nanomaterials follow the same categories as for any other chemical substances, there is no reason to introduce specific labelling on this.

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

2.1. Identification

Lead DG: Enterprise and Industry
Other involved DGs: Environment, Research and Innovation, Joint Research Centre, Health and Consumers, Employment, Social Affairs and Inclusion
Agenda Planning/WP Reference: t.b.d.

[8] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, 'Second Regulatory Review on Nanomaterials', COM(2012) 572 final

[9] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

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2.2. Organisation and timing

The initial plans for the impact assessment have been discussed with Member States Competent Authorities at the CARACAL meetings in 2013. In support of the impact assessment, DG Enterprise and Industry has launched an external study in December 2013 to gather available data with relevance to the impact assessment, in particular the experiences from existing nanomaterials notification schemes and relevant data regarding the policy options that will be assessed. An Impact Assessment Steering Group has been set up and will convene at least three times. The tentative timelines are as follows:

Date	Activity
16 Jan 2014	First Study Steering Group meeting
25 Feb 2014	First IA Steering Group meeting
6 Mar 2014	First evaluation report First building blocks report
20 Mar 2014	Discussion with MS at CASG Nano
3 Apr 2014	Discussion with MS at CARACAL
13 May 2014	Start of public consultation
13 Jun 2014	Final evaluation report Second building blocks report First options assessment report
30 Jun 2014	Validation workshop
5 Aug 2014	Close of public consultation
15 Aug 2014	Final building blocks report Second options assessment report
3 Oct 2014	Third options assessment report
15 Oct 2014	Circulate draft IA report to IASG
5 Nov 2014	Submission of draft IA report to IAB
3 Dec 2014	IAB meeting
10 Dec 2014	Final IAB opinion

When preparing the impact assessment, the European Commission will take into account the results of a study which was launched in December 2013, including a public consultation and the input from Competent Authorities for REACH and CLP (CARACAL) and its sub-group on nanomaterials (CASG Nano). The study is entitled "Study to assess the impact of possible legislation to increase transparency on nanomaterials on the market" and will provide a review of existing notification and registration schemes and data for the assessment of different policy options. The deliverables of the study include three reports: (1) the evaluation report, which comprises the results of the review of existing notification and registration systems, (2) the building blocks report, which provides the background information for the better definition and refinement of the policy options and (3) the options assessment report, which provides the results of the full analysis the policy building blocks. Please find further details about the study and the three aforementioned reports in the Annex.

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3. CONTEXT

3.1. Regulatory context

The impact assessment shall cover nanomaterials as defined in Recommendation 2011/696/EU (for possible restrictions as regards the scope of possible measures see below).

Most manufactured nanomaterials are substances in the sense of Regulations 1907/2006 ('REACH Regulation') and 1272/2008 ('CLP Regulation'). Therefore, the requirements of these Regulations apply to those nanomaterials. Most notably, these requirements include the following:

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

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. These are some of the most relevant requirements:

- The Cosmetics Regulation (No. 1223/2009) requires the notification of cosmetic products containing nanomaterials, including the submission of toxicological and safety data, six months prior to marketing (in addition to general notification for cosmetic products). Based on this information, a catalogue of all nanomaterials used in

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cosmetic products will be made available by the Commission by January 2014 (currently pending).

- The Biocidal Product Regulation (No. 528/2012) requires a dedicated risk assessment for the nanomaterial form of the substance and excludes biocidal products with nanomaterials from the simplified authorisation procedure.
- The Food Additives Regulation (No. 1333/2008) stipulates that a change in particle size of a substance requires a new entry in the list of authorised substances or a change in specifications.
- Without explicitly mentioning nanomaterials, a wide range of other product-specific legislation also applies to products containing nanomaterials. In addition, the General Product Safety Directive 2001/95/EC is intended to ensure a high level of product safety for consumer products that are not covered by specific sectorial legislation.
- Certain product-specific legislation requires the risk-independent labelling of ingredients with nanomaterials in consumer products with ingredient lists (e.g. cosmetic products, foodstuff and biocidal products). However, as described above in section 1.2, the labelling of nanomaterials is outside the scope of this impact assessment.

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

3.2. Political context

The European Parliament called on the Commission to compile "an inventory of the different types and uses of nanomaterials on the European market, while respecting justified commercial secrets such as recipes, and to make this inventory publicly available". In addition, it called on the Commission to evaluate the need to review REACH concerning inter alia "notification requirements for all nanomaterials placed on the market on their own, in preparations or in articles" (2008/2208(INI)).

Indeed, the absence of full knowledge on nanomaterials on the markets has already been the subject of initiatives to request information from companies. Initially, efforts focused on voluntary notification schemes, such as those developed in the United Kingdom[10] and Germany. However, the number of notifications received remained very low, leading to the general conclusion that voluntary initiatives do not produce satisfactory results.

Consequently, there have been calls for mandatory registration schemes. In September 2010, following a high-level event on the regulatory framework for nanomaterials, the Belgian Presidency of the Council of the European Union recommended that action should be taken "to develop harmonized compulsory databases of nanomaterials and products containing nanomaterials" and that "such databases must be the base for traceability, market surveillance,

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

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gaining knowledge for better risk prevention and for the improvement of the legislative framework".[11]

Some Member States have launched initiatives for national registries for nanomaterials, as described above. The French decree establishing a registry for nanomaterials, including substances, mixtures containing nanomaterials and articles containing nanomaterials, entered into force in January 2013.[12] The Belgian proposal for a decree on a notification scheme for nanomaterials was notified to the European Commission in July 2013 and was signed into law on 7 February 2014. The Danish proposal for a similar system was notified to the European Commission in November 2013.

Austria, Belgium, the Czech Republic, Denmark, France, Italy, Luxemburg, the Netherlands, Spain, Sweden and Croatia have asked the Commission to "propose legislation on registration or market surveillance of nanomaterials or products containing nanomaterials". Various stakeholders and non-governmental organisations have also called for a registry for nanomaterials.

4. PROBLEM DEFINITION

4.1. Introductory remarks

This impact assessment will start with the working thesis that the current level of information on nanomaterials on the market is insufficient for the protection of health and the environment and consumer protection. This could particularly be a problem in cases where nanomaterials are not covered by other registration schemes, exposures are unknown, or demand-side distrust develops among consumers due to a lack of transparency.

However, it should be noted that the aforementioned working thesis is not accepted by all involved actors. Although an increase of knowledge is generally desirable, much information is already available and it is not self-evident how more market information would create the value-added to improve the response to potential risks of nanomaterials. Part of this assessment will therefore focus on whether the information that can be realistically collected indeed fulfils the sought purpose of improving management of health and environmental risks or enhancing consumer information. Similarly, the assumption that there is market fragmentation due to national system still needs to be confirmed as part of the further analysis.

Moreover, it is important to understand that this impact assessment is on additional transparency measures on top of other policy measures which already have been decided (labelling of consumer products) or which are being assessed in a parallel impact assessment (improved hazard assessment, risk assessment and management of nanomaterials through revised REACH Annexes). Although these measures may provide better results in terms of informing consumers or in terms of improving risk management of nanomaterials, they are not part of this assessment.

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

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

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4.2. Problem definition

The main problem that this initiative aims to address is that the current level of available information on the presence of nanomaterials and products containing nanomaterials on the market is insufficient for an adequate response to health and environmental risks and for informed consumer choice.

In addition to the main problem described above, the establishment and proposals for national registration and notification systems for nanomaterials or products containing nanomaterials have caused concerns about market fragmentation and a divergence of requirements for the marketing of nanomaterials in different Member States. In particular, there are different obligations for downstream users and differences in exemptions for certain nanomaterials obligations between the established system in France and the proposed systems in Belgium and Denmark, in particular. This may hamper trade within the internal market.

4.3. Who is affected, in what ways and to what extent?

This initiative may affect manufacturers and importers, as well as distributors and downstream users of nanomaterials or products containing nanomaterials, by possibly imposing a notification duty. This may have a broader impact on sectors in which nanomaterials are produced and used, such as chemicals, engineering, pharmaceuticals, food and agricultural products.

The information that may be collected could be used by public authorities and policy makers (who might take decisions on the risk management of certain substances to prevent health and environmental damage), downstream user industries and workers (who might improve risk management measures in the working environment), consumer and environmental associations (who might raise concerns on particular substances and applications) as well as consumers (who might make choices on whether or not to buy products containing nanomaterials). Potential beneficiaries of decisions made on the basis of the additional information will be consumers, workers, and the environment.

4.4. EU right to act

Article 26 (1) of the Treaty on the Functioning of the European Union (TFEU) foresees that "the Union shall adopt measures with the aim of establishing or ensuring the functioning of the internal market". Moreover, Article 114 requires that in the proposals for these measures the Commission ensures a high level of health, safety, environmental protection and consumer protection, "taking account in particular of any new development based on scientific facts".

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

Nanomaterials and products containing nanomaterials are traded throughout the EU and the global market. The REACH and CLP Regulations on chemicals have already introduced harmonised requirements for chemicals, including nanomaterials. Potential measures regarding the collection of information on the presence of nanomaterials on the market may apply to the same harmonised area.

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National notification and registration schemes for nanomaterials may impose divergent requirements, thereby potentially hampering the functioning of the internal market for nanomaterials or products containing nanomaterials. This has also been recognised by those Member States who already have taken national initiatives, and who expressed their preference for a European rather than national approach.

It should also be noted that the impact assessment itself will assess the option of leaving action to the national level, i.e. a subsidiarity assessment is part of the impact assessment.

5. OBJECTIVES

The general, specific and operational policy objectives are captured in the following table:

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

6. POLICY OPTIONS

The following policy options will be considered in the assessment:

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

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

0. Baseline scenario

The baseline option would consist of the existing EU legislative framework for nanomaterials, including the registration and notification duties under the REACH and CLP Regulations and the obligations under the product-specific legislation. It would not involve any additional measures on an EU level.

The baseline scenario comprises the status quo. Given the recent establishment and proposals for national registries for nanomaterials in a number of Member States, a baseline analysis would not be complete without considering the current French registry and the proposed Belgian and Danish systems. Sensitivity calculations of the impacts of the existing registries will be held up against a theoretical scenario where no systems exist to allow for a comparative analysis of a registry as such (or other transparency measures).

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

This option would involve recommendations on how to implement a particular registry model at national level. Following analysis and discussion on the various models below, the Commission could identify an existing or planned model, possibly with a number of modifications, as good practice model, and recommend it for implementation at national level. Multiple registrations in different Member States could be avoided by using aligned IT systems and by inter-linking databases. This option would promote the establishment of national notification systems with harmonised requirements across Member States. At the same time, it would leave Member States the leeway to opt out and/or take their own national approaches.

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

This option would involve the establishment of a Nanomaterials Observatory collecting relevant information on nanomaterials on the market and presenting it in a clear and user-friendly way to the public online. The existing JRC web platform[13] could be used as a basis for this initiative.

The Observatory could contain both existing data, collected from existing databases and registries, and new information gathered in further studies. Data is already gathered through various systems: REACH registration dossiers (for nanomaterials that are subject to the registration duties of the REACH Regulation), notifications of nanomaterials in cosmetic products (through the Cosmetics Regulation), authorisations of biocides containing nanomaterials (under the Biocidal Product Regulation) and national registration or notification systems. The Nanomaterials Observatory should systematically extract information on nanomaterials, their markets and available safety information in a structured and consistent manner, in particular by linking releasable data from the systems mentioned earlier. This could build upon examples such as the nanomaterial registry by RTI

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

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International[14] and the Wissensplattform Nanomaterialien.[15] Collaboration (sharing data or interlinking) with other international initiatives may also be sought.

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

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

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

Manufacturers and importers would be responsible for submitting a dossier with substance identity information, as well as the quantity and use of the nanomaterial substance. Downstream users, including re-formulators or article manufacturers, and distributers of the substance would not be required to submit substance identity information (unless they modify the substance identity) and, instead, may refer to a registration number they receive from their supplier.

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

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

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

[14] https://www.nanomaterialregistry.org/
[15] http://nanopartikel.info/cms

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

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

This policy option would also comprise a minimum model (requiring a declaration for specific substances, mixtures and articles), building blocks and a maximum model (requiring a declaration for all substances, mixtures and articles) in parallel with policy option 4.

Combination of policy options

Options 1 and 2 (Recommendation and Nanomaterial Observatory) may be combined.

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ANNEX: OVERVIEW OF THE STUDY IN SUPPORT OF THE IMPACT ASSESSMENT

As part of the study in support of this impact assessment, three reports will be drafted: (1) the evaluation report, (2) the building blocks report, and (3) the options assessment report.

The **evaluation report** will in particular assess the following:

– Which information has been collected and is available to policy makers?

– Which information is publicly available?

– What use can be made of this information by policy makers and consumers?

– How much information has been collected, in particular which substances have been notified, how many notifications were made? What information is available on the notifiers (e.g. how many small companies have notified, how many notifications come from research bodies)?

– Which information is available on compliance and enforcement issues?

– What is the cost of notifications and what is the burden to gather the relevant information?

– Despite the early implementation stage, is there any initial information on impacts (e.g. identification of specific risks identified due to the notifications, effects on research and innovation)?

Some of the above points have already, at least partly, been addressed by the French implementation report[16] and will also to an extent be addressed in the Cosmetics report. Therefore, with respect to the French notification scheme, the consultant was asked to focus work on the following parameters:

a) notifiers – distribution between small and large companies;

b) manufacturers (M), importers (I) and downstream users (DUs) – how many notifiers by different role in the supply chain and by origin (France, EU, extra-EU);

c) physicochemical data – what information has to be notified;

d) terminology – clarity of information requirements and measurement techniques for notifiers;

e) enforcement/compliance – analysis of gaps, in so far as possible;

f) what are the direct costs, including on Authorities;

g) differentiation by actor – costs for M/Is versus DUs;

[16] Anses (2010) 'Éléments issus des déclarations des substances à l'état nanoparticulaire, Rapport d'étude', November 2013, http://www.developpement-durable.gouv.fr/IMG/pdf/Rapport_public_format_final_20131125.pdf

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h) what is the value added by the information?

i) innovation and competitiveness – in so far as possible gather information;

j) types of substances notified and their uses – e.g. pigments, food, cosmetics etc.;

k) status under REACH? Are the non-nano forms registered? Are they classified substances?

l) any information on substances in articles?

m) are the notified nanomaterials novel or have they been on the market for a long time? – Cross check against EINECS (differentiate nano vs. non-nanoform as far as possible)?

The **building blocks report** will elaborate a number of parameters which will be important in the options assessment. Further to the tasks identified in the terms of reference, the consultant was asked to elaborate on the following points, taking into account the experience of the French and the European cosmetics notification schemes:

• Profiling risks and hazards: What do we know on the notified substances? What are the DNELs/PNECs/OELs and what is the likelihood that there are exposures above those values? Are there any known incidents with those substances? What are the uncertainties, taking into account available studies, new forms, time they have been on the market? etc.

• Where is the biggest need for information with a view to defining the scope of possible measures?

• Value chain: Which actors are concerned, in terms of their different positions in the supply chain and business sectors? What is the value added of extending the notification obligation to the downstream users; how many SMEs have had to notify; what does the obligation mean in terms of costs?

• Effect on growth and innovation: Can the notified NMs be considered as innovative? How critical is the additional cost/transparency for localisation decisions?

• Fit for purpose: e.g. how much do data allow traceability, do they help in identifying possible exposure? What exactly do they change in terms of health and environmental protection? Would it be possible to identify any issues on the basis of the data that was unavailable so far? It should be underlined that the current notification schemes have only been in operation for a short period of time and may only give us very limited answers to these questions.

Following the finalisation of the problem definition, objectives and policy options, the options assessment will start. The **options assessment** will address in particular the following questions:

– The utility of generated, gathered or provided information to the specific target audiences (be it consumers or regulators) in the view of the described problem and its nature;

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– Potential impacts on health and environment (resulting from specific risk management measures taken by regulators and from different consumer choices)

– Administrative and any other costs associated with generating the information on the sides on institutions running the scheme and companies that are subject to any related requirements.

Particular aspects and sensitivity analysis will include a number of specific questions:

– Competitiveness proofing for key sectors with significant external trade exposure

– Possible impact on jobs and growth

– Possible impacts on SMEs and micro-enterprises

– Possible impacts on imported mixtures and articles

– Impact on innovation: IP rights and other CBI, impacts on time to market

– Assessment of effects from possible changes in the behaviour of the target audiences (e.g. consumer / company choices to avoid or chose nanomaterials / researchers changing orientations; increase/decrease in public confidence; changes of market availability of nanomaterials or products containing nanomaterials)

– Verification of impacts on borderline cases just below or above the threshold value of the nanomaterial definition (e.g. pigments, food powders, food additives, substances used for research in laboratories)

– Effects on the internal market, in particular comparing a European Union scheme to a number of possible national schemes (including impacts on SMEs, possible effects on internal trade, from internet trade etc.)

– Enforceability

– Effort needed to keep information up-to-date.

The planning for the external study, including the three aforementioned reports, is shown in the table below:

Month	Dec	J an	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan
Contract Signature	☑													
Inception Paper		☑												
Evaluation Report				❶			☑							
Building Blocks Report				❶			❷		☑					
Options Assessment Report							❶		❷		❸		☑	
Public Consultation						●	—	—	●					
Validation Workshop							◆							

Draft