

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

**First Draft - Evaluation Report**  
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**RPA**  
Risk & Policy Analysts

DRAFT

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

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## List of Abbreviations

<b>Anses</b>	<i>Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail</i>
<b>ANSM</b>	<i>Agence Nationale de Sécurité du Médicament et des Produits de Santé</i>
<b>BNR</b>	Belgian Nano Register
<b>CPNP</b>	Cosmetics Products Notification Portal
<b>DPR</b>	Danish Product Registry
<b>EC</b>	European Commission
<b>ECHA</b>	European Chemicals Agency
<b>EEA</b>	European Economic Area
<b>EFTA</b>	European Free Trade Association
<b>EU</b>	European Union
<b>ESIS</b>	European chemical Substances Information System
<b>FNS</b>	French Notification System
<b>FPS</b>	Belgian Federal Public Service on Health, Food Chain Safety and Environment
<b>GMO</b>	Genetically Modified Organisms
<b>Ineris</b>	<i>Institut National de l'Environnement Industriel et des Risques</i>
<b>INRS</b>	<i>Institut national de recherche et de sécurité pour la prévention des accidents du travail et des maladies professionnelles</i>
<b>InVS</b>	<i>Institut de Veille Sanitaire</i>
<b>MEDDE</b>	<i>Ministère de l'Écologie, du Développement durable et de l'Énergie</i>
<b>nm</b>	Nanometre
<b>NM</b>	Nanomaterial, as defined by the French authorities, unless otherwise stated
<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>PET</b>	Polyethylene Terephthalate
<b>SCCS</b>	Scientific Committee on Consumer Safety
<b>R&amp;D</b>	Research and Development
<b>VAT</b>	Value Added Tax
<b>XAN</b>	The XAN number is the name approved by a specific country (X) for a cosmetics product

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# 1 Introduction

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The overall aim of this study is to provide support to the European Commission in the preparation of an impact assessment to identify and develop the most adequate way to increase transparency and ensure regulatory oversight for nanomaterials. The contractor is expected to:

- Gather relevant information on the experience from other nanomaterials register-like schemes;
- Provide information on health and safety, markets and research trends of nanomaterials for the better definition of the policy options to be assessed; and
- Support the impact assessment of the policy options.

The technical specifications set out a detailed framework for the study and identified five different tasks, namely:

1. Lessons learned from other schemes;
2. Background information for building blocks of policy options;
3. Organise and carry out public consultations;
4. Support for the option assessment; and
5. Validation workshop.

This Evaluation Report documents the findings of task 1, namely the lessons that can be learned from the French Notification System (FNS) and the Cosmetic Products Notification Portal (CPNP).

## 1.1 Task Objectives

In other to gather relevant information on the experience from the FNS and the CPNP, different subtasks have been defined:

- **Task 1.1:** preparation of an inception paper, refining the methodology and the work programme (**final version submitted on 25 February 2014**);
- **Task 1.2:** kick-off meeting (**held on 23 January 2014**) with the steering group of the project, composed by representatives of:
  - DG Enterprise and Industry;
  - DG Environment;
  - DG Research and Innovation;
  - DG for Health and Consumers;
  - DG Joint Research Centre; and
  - French competent authorities on the FNS.

During the meeting, the project team presented the methodology proposed and the steering group clarified the key milestones of the project;

- **Task 1.3:** overview and comparative analysis of past, present and proposed NM transparency measures, in order to put the current regulatory situation concerning NMs in context and to evaluate the advantages and disadvantages of the respective transparency measures;
- **Task 1.4:** in-depth analysis of the FNS and the CPNP, aiming to gather relevant information on the experience from these NMs registries. This subtask has been organised in five interrelated parts:

- **Task 1.4a:** an industry stakeholders meeting is being organised in France in order to get accurate data and feedback from the stakeholders that have been involved in the preparation, implementation and operation of the FNS. It will also serve to maximise the response of participating companies to the targeted online surveys;
- **Task 1.4b:** qualitative and quantitative analysis of the FNS and CPNP, aiming to identify critical aspects of the schemes, including structures, data requirements, number of notifiers, number of notifications, etc.;
- **Task 1.4c:** analysis of the costs for both public authorities and industry due to the implementation of the schemes;
- **Task 1.4d:** assessment of long term health and environmental benefits, aiming to provide a qualitative description of the possible benefits of the notification schemes and, where possible, to estimate the cost savings potentially generated by a better knowledge of the sector (i.e. rapid exchange of information between MS on NMs discovered to pose a risk to the health and safety of consumers);
- **Task 1.4e:** assessment of competitiveness and innovation impacts, aiming to provide an overview on the issues (if any) arising from the implementation of the notification schemes regarding intellectual properties and confidential business information as well as any change in the public perception of nanomaterials and any diversion of resources from research and development.

## 1.2 Evaluation Methodology

This section presents the methodology that is being applied in undertaking the different subtasks.

The overview of the transparency measures (**Task 1.3**) is based on the review of the relevant legislative acts and initiatives implementing and proposing nanomaterials register-like schemes across Europe.

A stakeholder meeting (**Task 1.4a**) is being organised on 10 March 2014 in Paris in conjunction with the session of French working group on nanomaterials and it is hosted by the French *Ministère de l'Écologie, du Développement durable et de l'Énergie* (MEDDE).

The analysis of the FNS and the CPNP (**Task 1.4b**) is based on the information available at the time of writing (6 March 2014), namely the public report<sup>1</sup> published by the French authorities on November 2013 and the documents available on the CPNP website. The project team has prepared two lists of aggregated data that were not published but that are necessary for a thorough assessment of the two systems and is currently awaiting feedback from the French authorities and DG SANCO (the Directorate General managing the CPNP). Moreover, the French authorities should publish a second public report in the course of this year and DG SANCO is preparing a catalogue of all nanomaterials used in cosmetic products placed on the market (required by Article 16(10)(a) of Regulation (EC) No 1223/2009 on cosmetic products). These document will be carefully reviewed.

The list of substances notified to the FNS published in the French public report (Table 7 and 8, pages 27-80 and 81-108) is being analysed and compared to the ECHA registered substances database<sup>2</sup> and to the information reported in the Commission Staff Working Document on the types and uses of

<sup>1</sup> French public report (2013): Éléments issus des déclarations des substances à l'état nanoparticulaire, Rapport d'étude, November 2013. Available at: <http://www.developpement-durable.gouv.fr/Bilan-de-la-premiere-annee-de.html>

<sup>2</sup> <http://echa.europa.eu/information-on-chemicals/registered-substances>



nanomaterials.<sup>3</sup> The list reported in the French public report (2013) has not been refined prior publication and it is split between two tables: Table 7 reporting the substances notified to the FNS and identified by the notifiers through their CAS number; Table 8 reporting the substances notified to the FNS and identified by the notifiers through the chemical names. The list presents double entries and incongruences (for example, carbon black has been reported as “carbon black” but also as “noir de carbon”) and in order to proceed with the comparative analysis, as the list is provided in French, each substance has been translated to English and searched directly in the ECHA database or in other relevant databases (as the European chemical Substances Information System - ESIS<sup>4</sup>) in order to identify CAS numbers (not reported on the French public report) and EC numbers. The search in the ECHA database is carried out entering the CAS numbers and/or EC numbers identified (considered a more reliable search than using chemical names, as chemical substances have different chemical names and commercial names). For each substance, the information on the quantities and on the uses notified to the FNS and registered in the ECHA database (under the different registration dossiers publicly available on the website) are reported and compared. The ECHA database has also been consulted in order to identify any hazard endpoints classification reported in the registration dossier. It has to be noted of course that the information notified to the FNS should be related to the nanoforms of the substance reported while the information present on the ECHA website, unless differently specified, refer to the bulk form of the substances. Particular care has been taken in identifying any information reported on the ECHA website and specifically referred to the substances nanoforms. The substances notified to the FNS but that were not found in the ECHA database have been flagged out and checked on whether they are exempt from registration obligations under REACH. This comparative analysis, being a time and resource consuming task, is an ongoing exercise: it is however a valuable source of information.

In parallel to the analysis of the available information, an online survey<sup>5</sup> addressed to companies with relevant experience of the FNS and/or the CPNP has been launched on 27 February 2014. The survey aims to gather information on the costs and administrative burden that the notification obligations may put on the enterprises (**Task 1.4c**). Moreover, two separate and brief questionnaires have been sent to the French authorities and DG SANCO in order to gather information on the costs to set up and run the notification schemes for the public authorities. The Standard Cost Model will be the basis for all aspects of the cost analysis.

In order to model the impact of the availability of the information gathered to the authorities, consumers and workers on long term health and environmental benefits (**Task 1.4d**), an analysis of the past and current debate in France over the notification system has been carried out. This should allow to estimate any changes in the public perception of nanomaterials, resulting in behavioural changes in 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).

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<sup>3</sup> EC (2012): EC (2012): Commission Staff Working Paper “Types and uses of nanomaterials, including safety aspects” accompanying the Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee on the Second Regulatory Review on Nanomaterials, COM(2012) 572 final. Available at: [http://ec.europa.eu/nanotechnology/pdf/second\\_regulatory\\_review\\_on\\_nanomaterials\\_-\\_staff\\_working\\_paper\\_accompanying\\_com%282012%29\\_572.pdf](http://ec.europa.eu/nanotechnology/pdf/second_regulatory_review_on_nanomaterials_-_staff_working_paper_accompanying_com%282012%29_572.pdf)

<sup>4</sup> <http://esis.jrc.ec.europa.eu/>

<sup>5</sup> Available at: <http://www.rpaltd.co.uk/news-nanoregistry.shtml> and <http://www.bipro.de/sub/en/nano.html>

This part of the analysis is also very important for the initial assessment of impacts on competitiveness and innovation (**Task 1.4e**). The assessment is being complemented with information gathered through the survey submitted to industry stakeholders.

The results and findings of the tasks described above are being used to highlight the critical issues that need to be taken into account for extrapolation of the results of the FNS to the EU level (Task 1.5). Attention has been paid to the compliance aspect: both the FNS and the CPNP entered into force in 2013, meaning that many companies might not be aware of the notification obligations and subsequently might be non-compliant. This is particularly true for distributors that have to notify not only nanomaterials on their own but also nanomaterials contained in mixtures and/or articles. The communication issues across the supply chain have been highlighted as critical and one of the most problematic aspects also under the REACH Regulation.<sup>6</sup>

### 1.3 Structure of the Evaluation Report

The reminder of this report has been organised as follows:

- Section 2 provides the overview on the nanomaterials transparency measures planned and already implemented;
- Section 3 presents the analysis of the information available on the FNS and the CPNP;
- Section 4 provides some preliminary evidence over the discussion/reception on the notification schemes that should enable the modelling of any human health and environmental benefits;
- Section 5 presents the initial assessment of the impacts on competitiveness and innovation; and
- Section 6 highlights the critical issues to be considered in extrapolating the findings on the FNS to the EU level.

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<sup>6</sup> EC (2013): Commission Staff Working Document accompanying the document General Report on REACH, Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, in accordance with Article 117(4) REACH and Article 46(2) CLP. Available from <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2013:0025:FIN:EN:PDF>

## 2 Overview of the Nanomaterials Transparency Measures

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### 2.1 Introduction

In light of the gaps in information in relation to market penetration and the potential risks associated with nanomaterials, a number of countries in and outside of Europe have developed specific reporting initiatives, from mandatory registries to voluntary notification schemes. Other countries have carried out surveys in order to gather the information required to determine whether current legislation is adequate, and to inform debate concerning whether additional legislation is required. France is the first Member State to implement a mandatory reporting scheme; Belgium and Denmark recently approved the legislative proposals for mandatory registries. Norway announced that starting in January 2014 notifiers to the Norwegian Product Register have to update their entries to disclose whether their products contain nanomaterials. In addition, Germany released a position paper calling for an EU-wide initiative and Sweden is currently investigating the need to implement a national scheme. There have been several voluntary initiatives in different countries; however, it has been concluded that reporting on a voluntary basis has not achieved any satisfactory level of information gathering or participation by industry.<sup>7</sup>

The following sub-sections provide an overview of the initiatives in Belgium, Denmark, Germany and Norway, while the FNS and CPNP are analysed in Section

### 2.2 Belgium

Following the Belgian Presidency of the Council of the European Union (July - December 2010), the Belgian Federal Public Service on Health, Food Chain Safety and Environment (FPS) examined the appropriateness of, and the resources required for, setting up a register for the nanomaterials placed on the Belgian market.

In this context, FPS commissioned a study on the scope of a Belgian national register for nanomaterials and products containing nanomaterials which was published in June 2013.<sup>8</sup> The study reported that nanomaterials are present on the Belgian market in a large variety of products within many economic sectors and along the entire supply chain. The authors concluded that imposing notification requirements and obligations to allow the traceability of the nanomaterials along their lifecycle would result in significant costs for industry stakeholders. The analysis revealed that, in many sectors, it is very difficult to obtain accurate information on nanomaterials in products due to unavailability of data communication issues along the supply chain. This is particularly true for importers.

The study also considered the risks, costs and benefits of inaction. It noted that some of the costs of inaction for certain aspects are clearly identifiable from a financial perspective, e.g. the costs of establishing the register, the direct costs for industry and subsequently, the impact on the EU internal

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<sup>7</sup> Milieu & RPA (2010): Information from Industry on Applied Nanomaterials and their Safety: Proposal for an EU Reporting System for Nanomaterials, Final report prepared for DG Environment.

<sup>8</sup> BiPRO and Oko-Institut e.V. (2013): Study of the Scope of a Belgian National Register for Nanomaterials and Products containing Nanomaterials. Final report prepared for the Federal Public Service on Health, Food Chain Safety and Environment. Available at:  
<http://www.health.belgium.be/eportal/Environment/19086002?backNode=83&&fodnlang=fr#.UgovKW0xPuR>

market. However, the costs of inaction for other aspects are better assessed from a political perspective (in terms of the level of transparency) or from the perspective of a strategic risk analysis and communication as they relate to the potentially high costs of public distrust, which in itself presents a risk. The study translates the present information gaps into uncertainties, for example, with regard to large-scale exposure assessments. The study also mentions several other costs of inaction, such as potential confusion due to the presence of multiple databases and difficulties in enforcement, health and safety surveillance, and dealing with false claims.

In order to provide for a practicable, manageable register with a focus on "manufactured" nanomaterials, the authors compared different options with respect to the objectives of the Belgian Nanomaterial Register (BNR) and the direct costs for industry.

Based on these findings, the Belgian FPS developed a draft decree<sup>9</sup> to establish a notification scheme for nanomaterials. This decree was notified to the European Commission (EC) in July 2013: EU MS were invited to submit comments on the draft decree until October 2013. The decree was signed into law on 7 February 2014.<sup>10</sup>

Under the decree, substances manufactured at the nanoscale, as such or in a mixture, must be notified if more than 100 grams are placed on the market for professional users per year. The decree establishes also the notification obligations to articles and complex objects containing nanomaterials, if the possibility of release cannot be excluded and if the release rate exceeds 0.1 percent of the initial mass contained in the article. However, the application of the notification obligations for articles and complex objects has been postponed and the date will be decided after an evaluation of the articles.

The decree **exempts** a variety of products from notification obligations. These exemptions are contained in Article 2 and include products that are already subject to other regulatory provisions, namely

- 1) Cosmetic products which have been notified in accordance with the provisions of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products;
- 2) Biocides and treated articles falling within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocides and biocides which have been registered or authorised in accordance with the Royal Decree of 22 May 2003 concerning the placing on the market and use of biocides;
- 3) Medicines falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;
- 4) Medicines for human use and veterinary medicines falling within the scope of the Royal Decree of 14 December 2006 on medicinal products for human and veterinary use;

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<sup>9</sup> For details, see *Royal Decree on the market placement of substances manufactured at the nanoscale*, SPF Santé publique, Sécurité de la Chaîne alimentaire et Environnement. Available at : [http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?fuseaction=pisa\\_notif\\_overview&sNlang=EN&iyear=2013&inum=369&lang=EN&iBack=4](http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?fuseaction=pisa_notif_overview&sNlang=EN&iyear=2013&inum=369&lang=EN&iBack=4)

<sup>10</sup> <http://www.laurette-onkelinx.be/production/content.php?ArticleId=100&PressReleaseId=515>

- 5) The foodstuffs and materials and objects intended to come into contact with foodstuffs referred to in Article 1, 1° and 2°, b) of the Law of 24 January 1977 on the protection of consumer health in regard to foodstuffs and other products;
- 6) Animal feed, as defined in Article 3 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety;
- 7) Medicines and medicated animal feed falling within the scope of the Law of 21 June 1983 on medicated animal feed;
- 8) Processing aids and other products which may be used in processing organically produced agricultural ingredients, mentioned in Part B of Annex VIII to Commission Regulation (EC) No 889/2008 of 5 September 2008 laying down detailed rules for implementing Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and inspections;
- 9) Pigments, defined as substances which are insoluble in typical suspension media, used for their optical properties in a mixture or article.

Substances manufactured at the nanoscale included within the scope of the decree would encompass nanomaterials as **defined** in the EC's October 2011 recommendation on the definition of nanomaterials:

*“A substance containing unbound particles or particles in the form of an aggregate or agglomerate, of which a minimum proportion of at least fifty per cent of the size distribution, by number, have one or more external dimensions within the range of one nanometre and one hundred nanometres, excluding chemically unmodified natural substances, accidentally produced substances and substances whose fraction between one nanometre and one hundred nanometres is a by-product of human activity. Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below one nanometre shall be treated as substances manufactured at the nanoscale.”*

Annex 1 to the decree **lists the information to be notified for a substance** manufactured at the nanoscale and placed on the market as such. When one or more of the substances manufactured at nanoscale are placed on the market in a mixture, it is this mixture which shall be notified with data to be provided as set out in Annex 2 of the decree. The required data for a nanomaterial and/or a mixture containing nanomaterials are compiled in Table .

Table 2-1: Information requirement of the Belgian Notification Register		
No.	Information requirements	Comment
<b>Section 1: Identification of the notifier</b>		
1	Name of the person/company placing the substance on the market	-
2	Banque Carrefour des Entreprises (BCE) identification no.	-
3	Sector of activity	-
4	Address of their headquarters	-
5	In the case of companies headquartered outside the EEA: reference to the capacity of the extra-national legal body or authorised representative	-
6	Contact details of a natural person: surname, first name, address, telephone number, email address	-

Table 2-1: Information requirement of the Belgian Notification Register		
No.	Information requirements	Comment
<b>Section 2: Identification of the substance</b>		
1	Chemical identification of the substance(s), i.e. chemical name, chemical formula, CAS no., and, where applicable, the EC no (EINECS or ELINCS)	-
2	Average and median particle size, relative to a standard deviation	Additionally to indicate for points 2 to 5 in a traceable way (i.e. can be related to a reference through a documented unbroken chain of calibrations, each contributing to the measurement uncertainty): - method used to determine these variables, - explanation as to why this method is applicable to the substance concerned - description of the experimental conditions
3	Particle size distribution curve (by number)	
4	Average aggregate size and, if the substance is sold in the form of agglomerates, the average agglomerate size, these sizes being given relative to a standard deviation when available	
5	Qualitative description of the particle shape	
6	Where appropriate, a qualitative description of particle coverings (coating)	
Information to be communicated if available at the time of notification		
1	REACH registration number, if the substance has been registered under the REACH regulation	The part of the registration no. referring to the individual notifier may be omitted (last 4 numbers of the complete registration no.)
2	Where appropriate, the nature and quantity of each impurity with a mass concentration exceeding 0.1% in the substance manufactured at the nanoscale and, where the transmission of this information is compulsory for other regulations, the nature and quantity of each impurity with a mass concentration lower than 0.1% in the substance manufactured at the nanoscale	-
3	The nature of the crystallographic phases and, in the case of a mixture of phases, the proportion of each phase, including the amorphous phase if there is one	-
4	The average specific surface area, associated with a standard deviation	Additionally to indicate: - method used, - explanation why this method is applicable - description of experimental conditions
5	Zeta potential, indicating environmental, pH and ionic strength conditions	-
<b>Section 3: Quantity of the nanomaterial placed on the market during the reporting period</b>		
1	Estimation of the total quantity of notified substance, which will be placed on the market by the notifier between the time of the notification and the end of the calendar year, as such or contained in mixtures (expressed in kg)	-
2	If in a mixture, mass concentration of the nanomaterial(s)	-
3	State in which the nanomaterial(s) is present in the notified mixture	Solid, liquid, gaseous, powder, mesophase or other
<b>Section 4: Uses of the nanomaterial (and, if applicable, of the mixture containing nanomaterial(s))</b>		
1	All intended uses for the notified substance. If applicable, brief description of the use(s) of the nanomaterial(s) contained in the mixture and uses of the mixture	-
2	Trade name or registered trademark of the substance as placed on the market	-
3	Claimed properties for which the notified substance is used	Optional



Table 2-1: Information requirement of the Belgian Notification Register		
No.	Information requirements	Comment
Section 5: Identity of the professional users to whom the notifier will be transferring the nanomaterial/ mixture containing nanomaterial(s) between the date of the notification and the end of the calendar year (if known at the moment of notification)		
1	Name of the party acquiring the notified substance (or mixture)	Data have to be provided for each professional user.
2	<i>Banque Carrefour des Entreprises</i> (BCE) identification no.	
3	Address of headquarters	

Upon notification, the notifier receives a unique number which needs to be passed on along the value chain. Furthermore, the notifier should forward the chemical name, CAS number and, if available, the EINECS or ELINCS number of the nanomaterial(s) to the professional user. Where the notification relates to a mixture, this requirement pertains to the chemical formula of each nanomaterial contained in the mixture at a mass concentration greater than or equal to the minimum consideration threshold for classification purposes.

A simplified notification procedure is foreseen if the nanomaterial or the mixture containing such substance is exclusively used in the context of scientific research and development or in the context of product and process orientated research and development.

All notifications are to be made via electronic media to the FPS and need to be updated annually before 31 March according to Annex 3 (nanomaterial) and Annex 4 (mixture) of the decree. If the notification is incomplete or inaccurate, the FPS can request the notifier to provide additional necessary information (toxicological data, exposure data and any other information relevant to the assessment of risks to human health). In this case, the notifier has two month to provide the requested data (unless a different time frame is set out by the FPS).

It must be noted that the information with regard to the identity of the notifier, identification of nanomaterials (with the exception of the chemical name, the chemical formula, the CAS and the EINECS or ELINCS number of these substances), the concentration of nanomaterials in the mixture, the trade name of the product as well as the identity of the professional users is subject to confidentiality. Access to data may be granted to federal, regional and local authorities in Belgium but must be proportionate to the specific purposes. Infringements of the decree will be sought, identified, prosecuted and punished in accordance with Belgian Law (Law of 21 December 1998, Art. 15-18).

The notification must be made by or on behalf of the person/entity responsible for placing the substance or mixture on the market, prior to the actual placement.

The provisions of the legislative act have effect from 1 January 2016 for nanomaterials placed on the market, while the date of entry into force of the provisions applying to mixtures containing nanomaterials is 1 January 2017. With regard to articles containing nanomaterials, the decision has been postponed and will be taken after an evaluation of the registry.

## 2.3 Denmark

The Danish Environmental Protection Agency performed two impact assessments with regard to nanomaterials and the introduction of a nano-product register. The first was published in 2012 and investigated the extent of the exposure of consumers and the environment to nanomaterials as well

as the types of nanomaterials to which they were exposed.<sup>11</sup> Based on a screening process of products imported and manufactured in Denmark, the product categories 'paint and varnish', 'coatings', 'other building materials' (e.g. bricks, cement/concrete), 'sports', 'cleaning', 'textiles' as well as 'electric and electronic products' were identified as those product types which are most likely to contain nanomaterials. A 'miscellaneous'<sup>12</sup> category was added for products which do not fall into the aforementioned categories. Carbon black, titanium dioxide, pigments, silica and metals/metal compounds were identified as the most utilised nanomaterials within the different product categories.

The impact assessment evaluated the administrative burden for Danish manufacturers and importers in case of introducing a nano-product database<sup>13</sup>, where reporting requirements would be limited to products covered by the Danish Chemicals Act and exclude products already covered by other regulations.<sup>14</sup> At the time when the impact assessment was conducted, 949 companies had been registered as manufacturers or importers of products in the aforementioned categories on the basis of the related trade codes. More than 75% of these companies had less than 50 employees (full-time equivalents) and almost 60% had less than 20 employees (full-time equivalents). As a result of the evaluation, the following conclusions were made:

- The administrative burden would vary between the different economic sectors due to substantial differences in companies' knowledge of the content of nanomaterials in their products and the possibility of obtaining such information;
- The limited knowledge and the obtaining of information would apply especially to importers;
- The administrative burden with regard to subsequent annual reporting would vary between the different economic sectors depending on the number of products containing nanomaterials and the frequency of introduction of new products;
- Companies dealing with paints, coatings and plastics were identified to have the highest administrative burden as almost all products in these categories are considered as nano-products and therefore would have to be notified.

A quantitative overview of the results of the evaluation of the administrative burden is presented in Table 2-2 which is based on feedback from Danish companies working in the relevant sectors. However, it was only possible to identify companies manufacturing or importing electrical equipment containing nanomaterials sparsely. As such, a quantification of the administrative burden for them was not possible. This also applies to the category 'miscellaneous' due to the different kinds of products and their wide range of uses.

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<sup>11</sup> Danish Environmental Protection Agency, *Anvendelse af nanoprodukter på det danske marked - Vurdering af de administrative konsekvenser for virksomheder ved indberetning til en nanoproduktdatabase*, Miljøprojekt no. 1451, 2012.

<sup>12</sup> Included in the category 'miscellaneous': catalysts, lubricants, fuel additives, polymer nano-composites such as thermoplastic products, tires and other rubber products

<sup>13</sup> The Danish Budget for 2012 included an agreement on increased efforts in relation to nanomaterials from 2012-2015, inter alia the establishment of a nano-product database.

<sup>14</sup> cosmetics, foodstuff, foodstuff contact materials, medicine and medical equipment which are covered by other legislation



**Table 2-2: Results of the evaluation of administrative burden for companies having to notify to the Danish nano-product register**

Category	No of companies	Share with nano-products (%)	Administrative burden, implementation (hrs per company / yr)		Administrative burden, regular annual reporting (hrs per company / yr)		Total admin. burden (hrs/yr)	Implementation (hrs)
			Companies with nano-products	Companies without nano-products	Companies with nano-products	Companies without nano-products		
Paint, varnish, coatings	79	100	150	40	15-50	10	800-1000	> 3800
Building materials	369	5-10	100	10	20	0	500-600	> 5800
Sports	52	30-40	100	50	50	15	1300-1500	> 3300
Cleaning	63	15-20	30-100	50	10-20	10	600-800	> 2900
Textiles	200	0-20	50	20	30	10	2000-2500	> 4600
Electric & electronic products	19	No data						
Miscellaneous	No data							

Further challenges identified by companies and trade associations with regard to an implementation of a nano-product database were:

- Definition of a nano-product;
- Technical knowledge;
- Reporting parameters;
- Confidentiality;
- Impaired innovation potential leading to reduction of the application of nanomaterials in order to minimize the work related to reporting obligations; and
- Reduced competitiveness due to increased financial costs related to reporting.

The second impact assessment was published in 2013 and was related to possible ways of reducing the administrative burden identified by the previous study, and which would arise due to obligatory reporting to the nano-product register.<sup>15</sup> Table 3 summarises the possibilities for reduction of the administrative burden which were examined as well as the related results.

**Table 2-3: Overview of possibilities for reduction of the administrative burden and their related results**

No.	Possibility of reduction of administrative burden	Estimated results
1	<b><i>Moderate or substantial reduction of the amount of technical information to be reported for each nano-product</i></b> (3 different scenarios for reporting parameters investigated: list A, B and C, with list A being the most comprehensive, and also used in the first Impact Assessment ,requiring	<b><i>The administrative burden for companies could be reduced by 20-50% and 60-80% according to the reporting requirements of lists B and C, respectively.</i></b> It is estimated that information regarding concentration, amount and size distribution of the nanomaterial has a major influence in the size of the administrative burden. However, list C was determined to be less suitable for providing an overview of

<sup>15</sup> Danish Environmental Protection Agency, *Muligheder for reduktion af danske virksomheders administrative byrder ved indberetning til en nanoproduktdatabase*, Miljøprojekt no. 1462, 2013.

Table 2-3: Overview of possibilities for reduction of the administrative burden and their related results

No.	Possibility of reduction of administrative burden	Estimated results
	<p>notifiers to report on 39 parameters. List C contains minimum requirements with regard to reporting parameters, i.e. overview of which NMs are used in the defined product categories and number of products in which NMs are used. The requirements of list B fall between those of lists A and C.</p>	<p>the use of NMs in a subsequent environmental or health assessment.</p>
2	<p><b>Exemption from reporting with regard to products containing the carbon black and/or non-catalytically active titanium dioxide</b></p>	<p>Carbon black and titanium dioxide are NMs that have been long known and used in large amounts as regular chemicals for a wide range of applications. Therefore, they are subject to registration under the REACH regulation. <b>By exempting products containing carbon black and/or non-catalytically active titanium dioxide from the reporting obligation, it is estimated that the administrative burden in the product categories ‘Paint, varnish and coatings’ and ‘Miscellaneous’ can be reduced by up to 80%.</b> If one or both of the NMs are exempted from the reporting obligation, the database will not give a satisfactory overview of the application of these NMs in products. On the other hand, the database will focus more on NMs developed in recent years, and thus focus more on NMs where the uncertainty regarding the health and environmental impacts is higher.</p>
3	<p><b>Exemption from reporting with regard to certain product groups, i.e. only chemical mixtures containing NMs and no other products (i.e. articles, cf. REACH)</b></p>	<p>If other products (articles) containing NMs are exempted from reporting obligation, thus leaving only mixtures containing NMs to be included in the obligation, the major part of the products in the product categories ‘Sports’, ‘Textiles’ and ‘Electronics and electronic products’ will be exempted from the reporting obligation. <b>It is estimated that the total administrative burden in these product categories will be reduced by up to 90%.</b> This also includes companies not manufacturing or importing nano-products since it will be easier for them to determine whether their products have to be reported. However, this solution will reduce the relevance of the database considerably as many ordinary consumer products will no longer have to be reported.</p>
4	<p><b>Use of the information about mixtures already registered in the existing Danish Product Registry<sup>16</sup> (DPR), so that only additional information about the nanomaterial in the mixtures has to be reported to the nano- product database</b></p>	<p>The use of information about mixtures already registered in the DPR will reduce the administrative burdens for some companies since they would only have to report supplementary data about NMs in the mixtures to the nano-product database. However, the DPR only contains information about mixtures for professional use containing substances classified as dangerous. This means that the DPR</p>

<sup>16</sup> Substances and materials have to be notified to the Danish Product Registry, which provides an overview of chemicals in Denmark. The submitted data is used by the Danish Environmental Protection Agency and the Danish Working Environment Authority for risk prevention work. More information available at: <http://arbejdstilsynet.dk/en/engelsk/produktregistret/om-produktregistret.aspx>

**Table 2-3: Overview of possibilities for reduction of the administrative burden and their related results**

No.	Possibility of reduction of administrative burden	Estimated results
		does not cover all nano-products. Therefore, importers of consumer products, i.e. <b>the major part of the companies in the product categories 'Sports', 'Electronics and electronic products' and 'Textiles', will often not be able to refer to data in the DPR.</b> Therefore, it is estimated that the administrative burden of these product categories will not be reduced considerably. On the other hand, <b>the administrative burden of many manufacturers within the product categories 'Paint, varnish and coatings', 'Cleaning' and 'Miscellaneous' would be reduced to some degree by this initiative. However, it is estimated that the administrative burden reduction is less than 20%</b> when additional information about the NM in the mixtures still has to be reported to the nano-product database.

Table describes quantitatively the estimated potential reduction of the administrative burden according to the investigated possibilities (1 – 4) for the first reporting year. Possibilities 2, 3 and 4 were estimated based on the scenario that notifiers would have to submit data on all 39 parameters (i.e. scenario A of possibility 1) as also used in the first impact assessment. The administrative burden of the product categories 'Electronics and electronic products' and 'Miscellaneous' are not included in the estimates of the total administrative burden.

**Table 2-4: Estimates of the reduced administrative burden for implementation of the nano-product database in the first implementation year related to the different possibilities (1-4) investigated (values indicated in %)**

Category	No of companies	Share with nano-products (%)	1			2	3*	4
			A	B	C			
Paint, varnish, coatings	79	100	0	20-30	60-80	60-80	Limited	10-20
Building materials	369	5-10	0	20-30	60-80**	Limited	90	Limited
Sports	52	30-40	0	50	60-80	Limited	90	Limited
Cleaning	63	15-20	0	20-30	60-80	Limited	Limited	10-20
Textiles	200	0-20	0	20-30	60-80	Limited	90	Limited
Electric & electronic products	No data							
Miscellaneous	No data	No data	0	20-30	60-80	No data	No data	No data
<b>Total hours of administrative burden for companies with nano-products</b>			10.000 (100%)	8.000 (80%)	4.000 (40%)	7.500 (75%)	5.900 (59%)	9.200 (92%)
<b>Total hours of administrative burden for companies without nano-products</b>			11.000 (100%)	11.000 (100%)	11.000 (100%)	11.000 (100%)	3.700 (34%)	11.000 (100%)
<b>Total administrative costs (hours)</b>			21.000 (100%)	19.000 (90%)	15.000 (71%)	18.500 (88%)	9.600 (46%)	20.200 (96%)
* The initiative will have an impact on companies with and without nano-products.								
** The percentage reduction is not based on company interviews. It is assumed that the product category follows the same trend as the remaining product categories.								

It was estimated that the annual administrative burden in the second year would be significantly lower (approximately one-third to one-fifth) compared to the first year of implementation.

Taking the results of both impact assessments into account, a draft order<sup>17</sup> for a nano-product register was elaborated, covering mixtures and articles that contain nanomaterials and indicating the reporting requirements for producers and importers. The Danish Environmental Protection Agency launched a public consultation<sup>18</sup> related to the draft order on 4<sup>th</sup> July 2013. The public consultation notice was accompanied by a letter explaining the need for, and the intention of, the registry. It announced that a guide describing how the reporting should be made and providing concrete examples on which products are covered by the order would be released in autumn 2013.

The Danish Environmental Protection Agency notified the Commission of its intention to set up a nanomaterial product register on the 5<sup>th</sup> November 2013 by submitting the draft order proposal.<sup>19</sup>

As stipulated in the notified draft order, its purpose is to establish a register of mixtures and articles that contain nanomaterials and which are intended for sale to the general public as well as to require producers and importers of these mixtures and articles to report relevant information to the register.

The reporting requirement of the register includes mixtures and articles that are intended for sale to the general public and which contain nanomaterials, where the nanomaterial itself is released under normal or reasonably foreseeable use of the mixture or article or where the nanomaterial itself is not released, but substances in soluble form that are classified as CMRs (category 1A or 1B) or environmentally dangerous substances (acute category 1 or chronic category 1-4) under Regulation (EC) No 1272/2008 (CLP) are released from it .

The mixtures and articles exempted with regard to the notification include:

- a) Foodstuffs and food contact materials.
- b) Feed.
- c) Medicinal products.
- d) Medical devices.
- e) Cosmetic products.
- f) Pesticides.
- g) Waste.
- h) Mixtures and articles in which the nanomaterial includes nanoscale substances listed in Annex IV or V to Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH).
- i) Mixtures and articles for which the nanomaterial is not intentionally produced at the nanoscale.
- j) Articles in which the nanomaterial is part of a fixed matrix, unless wear and tear, washing, breaking, and similar normal use of the article leads to the release of free nanomaterials;

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<sup>17</sup> Draft order available at: <http://prodstoragehoeringspo.blob.core.windows.net/766544ef-cd98-4ca7-8f78-b482ae9e8005/Bekendtg%C3%B8relse%20udkast%20nanoproduktregister%20i%20h%C3%B8ring.pdf>

<sup>18</sup> Information on the public consultation available at: <http://hoeringsportalen.dk/Hearing/Details/16910>

<sup>19</sup> Notification Number: 2013/603/DK:  
[http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?fuseaction=pisa\\_notif\\_overview&sNlang=EN&iyear=2013&inum=603&lang=EN&iBack=3](http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?fuseaction=pisa_notif_overview&sNlang=EN&iyear=2013&inum=603&lang=EN&iBack=3)

- k) Articles or their labels on which the nanomaterial is used directly as ink, including newspapers, periodicals, magazines, packaging that is not coloured in the mass or dyed, etc.
- l) Textiles with nanomaterial used as ink or for dyeing.
- m) Paint, wood preservative, glue and filler that contains pigment on the nanoscale where the pigment is added solely for the purpose of colouring the mixture.
- n) Articles of rubber, or rubber parts of articles that contain the nanomaterials carbon black (EINECS No 215-609-9) or silicon dioxide (EINECS numbers 231-545-4, 262-373-8, 238-455-4, 238-878-4 and 239-487-1 or CAS numbers 13778-37-5, 13778-38-6, and 17679-64-0).

Furthermore, mixtures and articles produced or imported by individuals for their own, non-commercial use are not covered by the Order.

The definition of a nanomaterial follows the EC Recommendation 2011/696/EU on the definition of nanomaterial:

*A natural, incidental, or manufactured material that contains 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 (nanometres).*

Annex 1 to the executive order lists the information to be notified, namely:

A. Registrant's identity

- 1. CBR No
- 2. Registrant's name (entity name)
- 3. Address
- 4. Registrant's contact person(s)/email(s)
- 5. Type of entity
- 6. Size of the entity

B. Product information

- 7. Product name
- 8. Production volume (number of products/volume/mass) during the reporting period
- 9. Professional application (yes/no)
- 10. Description of application (free text)

C. Information on the nanomaterial

- 11. Name of nanomaterial
- 12. Is the nanomaterial, or substance with which the nanomaterial is made, registered in REACH? Yes/no
- 13. The nanomaterial's manner of inclusion in the product

D. Chemical information on the nanomaterial

- 14. Name of the chemical compound (IUPAC)
- 15. CAS No
- 16. EC number (EINECS/ELINCS/INCI)
- 17. Formula

Annex 2 lists information that notifiers could voluntarily submit to the register:

- E. Category
  - 18. Chemical product category/REACH (PC)
  - 19. Process category/REACH (PROC)
  - 20. Environmental release category/REACH (ERC)
  - 21. Article category/REACH (AC)
- F. Contents of the nanomaterial in the article or mixture
  - 22. Nano content/product (grams)
  - 23. Nano content/product (%)
- G. Physical information on the nanomaterial
  - 24. Particle size
  - 25. Numerical size distribution
  - 26. Aggregation
  - 27. Agglomeration
  - 28. Form
  - 29. Specific surface area
  - 30. Crystalline state
  - 31. Surface chemistry
  - 32. Surface charge

Chapter 3 of the draft order indicates the requirements for producers and importers to notify to the nano-product register. Manufacturers and importers who have already notified a mixture containing a nanomaterial to the Danish Product Register are exempted from full reporting obligations. The submission of information on the registration number of the mixture, the CAS numbers of nanomaterials as well as information on the nanomaterial in the mixture and production volume of the mixture, as required under Annex 1 to the nano-product register, will be sufficient (Art. 5 (3)). Reporting to the nano-product register may also be narrowed down to the reporting number for a mixture or article if it is contained in another mixture or article for which obligatory data has already been reported or if it is a processing of another mixture or article which has already been notified to the nano-product register and no further nanomaterials have been added (Art. 5 (4)). Some information in categories C and D of Annex 1 may be omitted from reporting if, in conjunction with the reporting, it is also concomitantly documented that it is not possible to obtain the information or that excessive costs would be incurred in doing so (Art. 5 (5)).

Chapter 4 sets up the rules for the protection of confidential information. The notifier can indicate whether specific information should be treated as confidential (trade secret), e.g. data on production methods, chemical information, substance identification, composition or purity. In this case, an appropriate justification must be delivered. It must be noted that information may be disclosed in accordance with applicable Danish legislation. Access to the register is restricted to employees of the Danish Environmental Protection Agency and the Danish Working Environment Authority; however, data can be obtained upon request and to the extent necessary, for example, by other authorities.

The Danish Environmental Protection Agency is responsible for creating and maintaining the nano-product register, performing duties related to it, and carrying out inspections and checks to ensure compliance. Failure to report information on sold mixtures and articles falling within the scope of the order is punishable by fines.

The executive order entered into force on 18<sup>th</sup> March 2014 (Art. 16) and the first reporting is due no later than 30<sup>st</sup> June 2015 for the period from 1<sup>st</sup> May 2014 to 1<sup>st</sup> May 2015. The Danish Environmental Protection Agency will publish an annual report on the previous reporting year. Reporting for producers and importers is obligatory on an annual basis and should be carried out digitally via the portal [virk.dk](http://virk.dk). Support for companies which have to notify will be provided in form of a guidance document as well as in form of a helpdesk by the Danish Environmental Protection Agency.

## 2.4 Germany

Following a review of the legal feasibility of a mandatory nano-product registry in 2010, the German Federal Environment Agency (UBA) published a “Concept for a European Register of Products Containing Nanomaterials”.<sup>20</sup> The proposed register aims at establishing regulatory oversight to set priorities in monitoring and enforcement, in enhancing transparency, in estimating exposure for humans and the environment, and in ensuring traceability.

A key point of the Concept is that regulatory overlaps and administrative efforts are minimised. To this end, it suggests that an umbrella regulation set out general provisions and that the register be established at European, rather than national, level. Subject to notification are substances and mixtures that comprise or contain nanomaterials (as defined in the EC-recommended definition). In addition, notification obligations also arise for articles that intentionally or unintentionally release nanomaterials (analogous to provisions under REACH). In this context, it is important to note that potential releases during the entire life-cycle (including the waste stage) need to be taken into consideration.

According to the Concept, notification requirements apply to manufacturers, distributors and importers. All relevant legal entities need to submit data on the quantity manufactured or imported; the concentration of nanomaterials in the respective product; the use, characterization and functionality of the nanomaterials used; product and trade name as well as the name and address of the registrant. For confidentiality reasons, the proposed register will contain both a publicly accessible and a secured part.

The concept paper served as a basis for a subsequent study to assess the impacts from the implementation of such a notification scheme, the results of which should be soon published.

## 2.5 Norway

On 9 January 2013, the Norwegian Climate and Pollution Agency (presently the Norwegian Environment Agency<sup>21</sup>) posted a notice<sup>22</sup> concerning the annual update of information and mandatory reporting of quantities for chemicals for 2012 to the Norwegian Product Register. The Product Register is the central register for chemical products in Norway and contains about 25,000 registered products. Nanomaterials need to be notified within the new update. According to the notice, the

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<sup>20</sup> UBA (2012): *Concept for a European Register of Products Containing Nanomaterials*, German Federal Environment Agency.

<sup>21</sup> <http://www.miljodirektoratet.no/english/>

<sup>22</sup> [http://www.miljodirektoratet.no/no/Nyheter/Nyheter/Old-klif/2013/Januar\\_2013/Innrapporering\\_av\\_arsmengder\\_for\\_2012\\_til\\_produktregisteret/](http://www.miljodirektoratet.no/no/Nyheter/Nyheter/Old-klif/2013/Januar_2013/Innrapporering_av_arsmengder_for_2012_til_produktregisteret/)



registration of nanomaterials will provide better knowledge about where and how nanomaterials are used.

Information to the Norwegian Product Register must be submitted on all chemical products (substances and mixtures) that are classified with respect to health, environmental or fire and explosion hazards under section 6 of the Norwegian Chemical Labelling Regulations<sup>23</sup> or article 3 of the EU's CLP Regulation if 100 kg or more of the product are imported or manufactured per year. Changes must be updated in the Register annually. In addition, microbiological and biocidal products must always be reported to the Norwegian Product Register regardless of quantity.

The registration of a product is done by means of submitting a notification form which must be completed for all chemicals being notified. Article 21 of the Norwegian Chemical Labelling Regulation sets out the scope of the chemical registry and contains, among others, content specification for substances and mixtures.

According to the notice, changes to the reporting format include a 'tick box' in the notification form which registrants should mark if the reported chemical contains nanomaterials. The notification form requires registrants to state the full chemical composition, listing all chemical substances as they exist in the product. When a constituent occurs at the nano-size, it should be identified in the same composition field with a note.

According to the Norwegian authorities,<sup>24</sup> the yearly update will cover quantities of the chemical products rather than the constituents of the products. This means that, on a yearly basis, newly-registered products will generally be subject to the nanomaterial evaluation in the form. The notification of possible nano-constituents of the already registered products will take longer and be notified over time. A possible speed-up of the registry of nanomaterials in the latter group of products may occur as a result of change from paper to digital notifications in the near future.

The developments in Norway indicate that no specific priority is given to a separate portal for a nanomaterial registry. Rather, the preferred option seems to be the integration of the nanomaterial notification in the already existing Norwegian Product Registry.

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<sup>23</sup> Forskrift om klassifisering, merking mv. av farlige kjemikalier, FOR-2002-07-16-1139. <http://lovdata.no/dokument/SF/forskrift/2002-07-16-1139>

<sup>24</sup> Based on personal communication with Norwegian authorities, February 2014.



## 3 Analysis of Existing Nanomaterials Transparency Measures

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### 3.1 France

Within the European Union, France has become the first country to establish a mandatory reporting scheme for 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 intended to release such substances under normal or reasonably foreseeable conditions of use).

The Interministerial decree No. 2012-232 was published following an extensive public consultation (within the National Agreement for the Environment, “*Grenelles de l’environnement*”) that led to the commitment<sup>25</sup> to anticipate any risks deriving from the exposure to nanomaterials. The commitment was supported by Anses<sup>26</sup>, which called for action due to the uncertainties over hazards and public exposure to nanomaterials. The decree was published in February 2012 and entered into force in January 2013, allowing registrants to submit their declarations until the 30<sup>th</sup> April 2013 (for the first year of implementation, an additional period of two months was granted postponing the deadline to the 30<sup>th</sup> June 2013).

The general aim was to improve the information available to the public, the consumers and the workers. The specific objectives were set in the *Grenelle II* Act, approved in July 2010, namely:

- To get a deeper knowledge on nanomaterials, their identities, the quantities handled and the different uses and applications;
- To obtain the traceability of the nanomaterials on the market: from the manufacturers or importers via the distributors to the final professional users; and
- To gather all the available information on hazard and exposure of nanomaterials with the view to evaluate the risks and to provide the information to the public (French public report, 2013).

On this basis, Articles L.523-1 and L.523-2 of the Environment Code (“*Code de l’Environnement*”) established the notification duty and, in order to make it executive, two subsequent decrees<sup>27</sup> defined the scope, the information to be notified and the terms for the notifications. More precisely, the 2012-232 decree defines:

- The dutyholders;
- The definition of nanomaterial (based on the European Commission Recommendation);
- The quantity threshold, that is established at 100 grams; and
- The possibility to ask for confidentiality on some of the information to be notified.

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<sup>25</sup> *Engagement n. 159.*

<sup>26</sup> Anses (“*Agence nationale de sécurité sanitaire de l’alimentation, de l’environnement et du travail*”) was born by the merge between Afssa and Afsset.

<sup>27</sup> *The “décret n. 2012-232 du 17 février 2012” and “l’arrêté du 6 août 2012.”*

The Ordinance of the 6<sup>th</sup> August 2012 clarifies the information to be notified and the terms for the notification:

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

An expert working group including Anses and Ineris has been formed to determine the physicochemical parameters necessary to characterise the nanomaterials. Anses has been appointed to develop and maintain the database and the website for the operation of the notification scheme. In this role, Anses is responsible for the provision of assistance and guidance to the notifiers, to check the completeness of the notifications, to gather the additional information on the hazards and exposures to nanomaterials that could be used for the assessment of the risk to the human health and the environment and to provide some of the information notified to other authorities (listed in the decree and namely: Ineris, InVS, INRS, ANSM).

With regard to the confidentiality of the information notified, the legislative framework established that the information about the identity and the uses of the nanomaterials have to be made available to the public. More precisely, however, the information about the identity of the nanomaterial, with the exception of the chemical name of the substance, are considered confidential, as well as the information about the quantities, the commercial name of the nanomaterial or mixture and the identity of the professional users.

Moreover, Article R.523-18 of the *Code de l'Environnement* provides the notifiers with the opportunity to list the information that they would like to be kept confidential because their public availability might lead to break industrial or commercial secrets or to the intellectual property of the research and innovation results. For this first year, all the confidentiality claims have been accepted (French public report, 2013).

Although it must be noted that the distributors to the public are not within the scope of the legislative framework and it is, thus, not possible to identify precisely the final products on the market that might contain nanomaterials, the French authorities expect that, in the long term, the data contained in the notifications should enable the traceability of the nanomaterials in the country. Moreover, the public authorities will be able to ask for additional information to the notifiers, notably those toxicological, ecotoxicological and exposure data needed for the risk assessment.

On the 1<sup>st</sup> January 2013, Anses uploaded online the IT tool developed to manage and facilitate the notifications (available at <https://www.r-nano.fr/>). Notifiers have to create an account in order to submit the information. Moreover, all the relevant legislation and the guidance documents for the submission can be found online.

### **3.1.1 Introduction**

The legal definition of “substance at nanoscale” is provided in Article R.523-12 of the Environment code:

*“Substance as defined in article 3 of EC Regulation no. 1907/2006, intentionally produced at nanometric scale, containing particles, in an unbound state or as an aggregate or as an*

*agglomerate and where, for a minimum proportion of 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, this minimum proportion may be reduced. This minimum proportion is specified in a joint order issued by the Ministers of Environment, Agriculture, Health, Labour and Industry. By derogation from this definition, fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as substances at nanoscale.*

*For the purposes of this definition, the terms “particle”, “agglomerate” and “aggregate” are defined as follows:*

- a) “Particle” means a minute piece of matter with defined physical boundaries,*
- b) “Aggregate” means a particle comprising of strongly bound or fused particles,*
- c) “Agglomerate” means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.”*

Currently, the minimum proportion of particles at nanoscale in the number size distribution is set at 50% (Article 1 of the Ministerial Order of 6 August 2012), in accordance to the EC recommended definition of nanomaterial. Moreover, “substance at nanoscale contained in a mixture without being linked to it” is defined as:

*“substance at nanoscale intentionally introduced in a mixture from which it is likely to be extracted or released under normal or reasonably foreseeable conditions of use.”*

By and large, the definition of nanomaterial adopted by the French legislation coincides with the EC recommended definition 2011/696/EU<sup>28</sup>, though the scope is restricted to intentionally manufactured nanomaterials only. Moreover, the French legislator deemed not necessary the additional provision in the EC recommended definition, where compliance may be determined on the basis of the specific surface area by volume.

**In the context of this report, the terms “substance at nanoscale”, “nanomaterial” and “manufactured nanomaterial” are used with the same meaning if not differently specified.**

The notification duty is on the manufacturers, importers and/or distributors to professional users of nanomaterials in quantities equal or in more than 100 grams per nanomaterial per annum. They have been defined as:

- “Manufacturer”: any party, in the course of its professional activities in France, that manufactures a substance at nanoscale, on its own or contained in a mixture without being bound to it, or a material intended to release such a substance under normal or reasonably foreseeable conditions of use, for its own use or in view of their transfer free of charge or upon payment.
- “Importer”: any party, in the course of its professional activities, introducing into France from another Member State of the European Union or from a non-EU State a substance at nanoscale, on its own or contained in a mixture without being bound to it, or a material

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<sup>28</sup> Commission Recommendation of 18 October 2011 on the definition of nanomaterial.

intended to release such a substance under normal or reasonably foreseeable conditions of use.

- “Distributor”: any party established in the territory, including retailers, providing storage and transfer services, free of charge or upon payment, intended for professional users, for a substance at nanoscale, on its own or contained in a mixture without being bound to it, or a material intended to release such a substance under normal or reasonably foreseeable conditions of use.

The dutyholders 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 declaration, which needs to be passed on with all transfers of ownership to professional users and distributors so that they can make their declaration referring to their suppliers’ declaration. All notifications need to be updated annually and non-confidential information will be disclosed six months after the deadline for the declaration. Non-compliance with the regulatory provisions may lead to a fine and daily penalties.

It must be noted that the French notification scheme allows registrants to file a single declaration for different products containing the same substance at nano scale. Moreover, public research organisations can make a single submission for a given class of substances on behalf of all their research units. When the production, import or distribution is in the context of research and development, activities are subject to declaration with specific provisions.

Chemical names of the substances at nanoscale and their uses have been presented in the French public report, along with a first analysis of the number of notifications by economic sector and some aggregated quantities. Notifiers were required to use the system of descriptors developed by ECHA for the purpose of the REACH Regulation, namely to indicate:

- The sector of use category (SU): describes in which sector of the economy the substance is used;
- The chemical product category (PC): describes in which types of chemical products (= substances as such or in mixtures) the substance is finally contained when it is supplied to end-users ;
- The process category (PROC): describes the application techniques or process types defined from the occupational perspective;
- The article category (AC): describes the type of article into which the substance has eventually been processed.<sup>29</sup>

It should be noted that a fifth indicator developed by ECHA, the environmental release category (ERC), describing the broad conditions of use from the environmental perspective, has not been used for the purpose of the notification scheme.

From an operational point of view, the annual notifications have to be submitted electronically, except when it comprises classified documents in accordance with Article R. 2311-2 of the Defence Code. Once the notifiers have registered to the website [www.r-nano.fr](http://www.r-nano.fr), a password to access the account is transmitted automatically by email. Based on Anses (2013b), the notification system is divided into six main parts:

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<sup>29</sup> ECHA (2010): Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system, Version: 2, European Chemicals Agency, March 2010.

- Identity of the notifier;
- Information on the notification;
- Identity of the substance (in the raw state, contained in a mixture or article);
- Quantities;
- Uses;
- Users.

Table 3-1 presents the information to be notified, the options provided by the online system and some notes and examples. Fields that are mandatory are flagged with an asterisk (\*) while fields that are flagged with a plus (+) indicate information that need to be notified if available at the time of declaration.

With regard to confidentiality, as already mentioned, all the information submitted is considered confidential with the exception of the chemical name and uses of the nanomaterial notified. However, the notifiers have the possibility to claim confidentiality also for these data, providing a justification. In the justification form, notifiers can specify the interests that might be compromised by the disclosure of the information (if industrial or commercial secret or the intellectual property of research results), if the information is part of the general knowledge of the industry and if it is the object of an on-going patent application. Moreover, the notifier is asked to provide more details on the reasons for the confidentiality claim, demonstrating that the disclosure of the information would cause damage and describing the measures adopted to ensure confidentiality.

Table 3-1: Information to be notified		
Information	Options	Examples/Notes
<b>Identity of the notifier</b>		
<b>Company name*</b>		
<b>Address* and Post Code*</b>		
<b>Town/City*</b>		
<b>EU VAT or National Directory of plants (RNE) number*</b>		
<b>Country*</b>		If different from France, notifiers have to specify whether: <ul style="list-style-type: none"> <li>• European organisation;</li> <li>• European representative.</li> </ul>
<b>Role in the supply chain*</b>	<ul style="list-style-type: none"> <li>• Manufacturer;</li> <li>• Distributor;</li> <li>• Importer;</li> <li>• Professional user and distributor;</li> <li>• Repackager and distributor;</li> <li>• European representative.</li> </ul>	
<b>Public research organisation*</b>	Yes/No	Public research organisations can provide simplified notifications
<b>Company registration certificate*</b>	To be attached	
<b>Business sector*</b>	NACE code list	10.41 Manufacture of oils and fats
<b>Plants/sites interested*</b>	Name, address, post code, city and country	
<b>Identity of the Notification administrator*</b>	Name, surname, email	
<b>Information on the notification</b>		
<b>Notification number</b>		Assigned automatically

Table 3-1: Information to be notified		
Information	Options	Examples/Notes
<b>Year of the notification*</b>		
<b>Role in the supply chain with regard to the notified NM*</b>	<ul style="list-style-type: none"> <li>• Manufacturer;</li> <li>• Distributor;</li> <li>• Importer;</li> <li>• Professional user and distributor;</li> <li>• Repackager and distributor;</li> <li>• Other.</li> </ul>	Each company can submit as many notifications as nanomaterials of interest
<b>NACE code (down to four digits) of the activities of interest</b>	NACE code list	10.41 Manufacture of oils and fats
<b>Plants/sites of interest*</b>	Name as previously specified	
<b>Clients/Professional users identity per NACE code</b>	For each NACE code activity, the notifiers have to enter manually or provide a list (in csv format) of the clients/professional users they provide the nanomaterial to, and their NACE code activities. If they have more than 30 clients for one NACE code activity, the notifiers can just indicate the number of clients/professional users with the provision to keep the list for possible inspections by the authorities.	
<b>NACE code of the clients/professional users</b>		
<b>Research and Development</b>	<ul style="list-style-type: none"> <li>• Scientific research;</li> <li>• R&amp;D on products and processes;</li> <li>• no R&amp;D.</li> </ul>	Public research organisations can provide simplified notifications
<b>R&amp;D only?</b>	Yes/No	
<b>NACE code for the R&amp;D activities</b>	NACE code list	
<b>R&amp;D NM put on the market?</b>	Yes/No	
<b>National Defence interest?</b>	The authorities may grant derogations when necessary to safeguard the interests of national defence: whenever a notifier deems this provision might apply, it has to fill in a form and send it by paper to the Ministry of Defence, which will have to decide on the application.	
<b>Substance identity</b>		
The notifiers have the option to import this part of the notification by entering the notification number from which they wish to import the data. The notifier who imports the data can view just the chemical name of the substance and can then insert new information on this part (i.e. modification of the surface coating).		
If any information about the substance identity is not available, the notifiers have the possibility to flag it and to select a reason between: <ul style="list-style-type: none"> <li>• Waiting for the results;</li> <li>• Substance/mixture/article imported: information not available;</li> <li>• The distributor did not pass the information.</li> </ul>		
<b>State of the substance*</b>	<ul style="list-style-type: none"> <li>• The substance is pure;</li> <li>• The substance is contained in a mixture without being bound to it;</li> <li>• The substance is contained in a material intended to release the substance under normal or reasonably foreseeable conditions of use</li> </ul>	Multiple choices are possible.
<b>Chemical name*</b>		Titan dioxide
<b>Chemical formula*</b>		TiO <sub>2</sub>

Table 3-1: Information to be notified		
Information	Options	Examples/Notes
<b>Is the NM contained in a mixture with a mass concentration equal to or higher than the applicable minimum threshold for the purposes of classification?</b>	Yes/No	
<b>Types of substance concerned</b> <i>(This is only for public organisms that choose the simplified notification)</i>	Carbon (diamond, fullerene, graphene...), Noble metal (ex: Platinum for catalysts), Silica (silica colloidal, silicene...), Non-magnetic oxides (TiO <sub>2</sub> , ZnO, CeO <sub>2</sub> ...), Carbides (SiC, BC...), Hydroxides and Silico-aluminate (boehmites, clay...), magnetic oxides (e.g. oxides of Fe, Cr...), Asbestos and amphibole, Diesel particles, Cd and alloys containing Cd, Transition metal and intermetallic alloys, Inorganic semiconductors (Quantum Dots) (without Cd, Be and non-nano scale toxic substances), Polymers, Lipids and liposomes, Fluorophores, describe if other category.	
<b>N°CAS*</b>	CAS number	13463-67-7
	CAS number not available	-
<b>EC reference*</b>	EC reference	236-675-5
	EC reference not available	-
<b>Commercial name*</b>	Commercial name if available	
	No commercial name	-
<b>IUPAC name</b>		
<b>REACH registration number*</b>	REACH registration number	-
	No REACH registration number	-
<b>Impurities<sup>+</sup></b>	Nature and quantity for each impurity with a mass concentration equal to or higher than 0.1%	
	Nature and quantity for each impurity with a mass concentration lower than 0,1% but mandatory according to other regulatory provisions	-
	Test guideline	
	Method used: X-Ray Fluorescence, ICP-OES, ICP-MS, Knowledge of the process, HPLC, GC, CE, NMR, FT-IR, other	Describe if other method and provide a justification if not available: pending results, method not available, other.
<b>Size of the particles*</b>	Mean particle size of the primary particles, associated with a standard delta	There might be one, two or three values, depending on the form. Examples: 1 Average diameter: 10 nm 1 Standard deviation: ± 5 nm 2 Average diameter: 320 nm 2 Standard deviation: ± 12 nm
	Determination method used: TEM (Transmission Electron Microscopy), MEB, AFM (Atomic Force Microscopy), other	Describe if other method. Attach file relative to the determination of the particle size.
	Test guideline	



Table 3-1: Information to be notified		
Information	Options	Examples/Notes
<b>Number size distribution for particles*</b>	Determination method used: DLS, Laser diffraction, Gravitational sedimentation, Differential centrifugal sedimentation, Raman (NTC), other	Describe if other method. Attach the number size distribution graph.
	Test guideline	
<b>Aggregation and agglomeration state*</b>	Mean size of aggregates with standard delta	The unit is nm. For example, for a monomodal distribution: Average diameter of 1: 1200 nm Standard deviation: ± 40 nm
	Aggregation state determination method used	-
	Is the substance sold in an agglomerated form?	Yes, No
	Mean agglomerate size, with standard delta	For example, for a bimodal distribution: Mean diameter 1: 3 000 nm Standard deviation 1: ± 500 nm Mean diameter 2: 12 000 nm Standard deviation 2: ± 1 000 nm
	Agglomeration state determination method used	-
	Test guideline	-
	Attach file relative to the determination of the aggregation and agglomeration state	
<b>Shape*</b>	Number of dimensions lower than 100 nm	1, 2, 3
	Qualitative description of the particle shape	Spherical, Pseudo spherical, Sticks, Star, Full fibre, Hollow fibre, Film, Capsule, Specify if other shape
	Specify if other shape	
	Determination method used: MET, MEB, AFM, other	Describe if other method. Attach file relative to the determination of the shape
	Test guideline	
<b>State of the mixture*</b>	State of the mixture containing the substance	Solid, Liquid, Gas, Powder
<b>Specific surface<sup>+</sup></b>	Mean specific surface, associated with a standard delta	Mean specific surface: 52 m <sup>2</sup> /g Standard deviation: : ± 10 m <sup>2</sup> /g
	Determination method used: BET using nitrogen, TEM/EM calculation, SAXS, other	Describe if other method and provide a justification if not available: pending results, method not available, other.
<b>Crystalline state<sup>+</sup></b>	These information are available	Yes, No
	Is the substance contained in a mixture?	Yes, No



Table 3-1: Information to be notified		
Information	Options	Examples/Notes
	Common name, if exists. Otherwise indicate the Bravais lattice: Cubic primitive, Cubic body-centred, Cubic face-centred, Tetragonal primitive, Tetragonal body-centred, Orthorhombic primitive, Orthorhombic body-centred, Orthorhombic faced-centred, Orthorhombic base-centred, Monoclinic primitive, Monoclinic base-centred, Triclinic primitive, Rhombohedral primitive, Hexagonal primitive	Justification for the non-availability: Pending results, Technic non available, Other specify justification. Attach the file relative to the crystalline state.
	Test guideline	
<b>Coating*</b>	Is there a coating?	Yes , No
	Nature of the coating: Organic, Inorganic, Other	Describe if other.
	Coating: Hydrophilic organic coating, Hydrophobic organic coating, Hydrophilic inorganic coating, Hydrophobic inorganic coating, Other	Provide a qualitative description if other.
<b>Surface charge<sup>+</sup></b>	Zeta potential value	Attach file relative to the determination of the surface charge. Provide a justification for the non-availability: Pending results, Technic non available, Other specify justification.
	Specify the pH conditions	
	Specify the medium in which the value has been measured	
	test guideline	
Quantities		
<b>Quantity*</b>	Quantity produced	The unit is kg.
	Quantity distributed	
	Quantity imported	
	Quantity distributed after use	
	Quantity distributed after repackaging	
	Other quantity	
Uses		
<b>Uses*</b>	Descriptor SU Descriptor PC Descriptor PROC Descriptor AC	
<b>The properties claimed</b>		
<b>Commercial name of the mixture<sup>+</sup></b>		
<b>Commercial name of the material<sup>+</sup></b>		

Table 3-1: Information to be notified		
Information	Options	Examples/Notes
<b>Users</b>		
<b>Clients (professional users)*</b>	Name, address, zip code, city, country, intercommunity VAT	

### 3.1.2 Analysis of the Data Presented in the French Public Report

This first analysis is based on the public data reported by French Authorities in November 2013 on the basis of the analysis made by the Anses.

The deadline for the first year was set to the 30<sup>th</sup> June. At the 1<sup>st</sup> July, the authorities have received 3,941 notifications from 933 notifiers, although around 13.5% (532) of the notifications were only in draft version. Of the 933 notifiers, over 70% (670) were based in France, while the remaining 30% were based in other European countries of the European Free Trade Association (EFTA).

For the purpose of the publication, 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. It has been reported that some notifiers have submitted information for substances not at nanoscale, but received this information only after the deadline. Unfortunately, the number of these erroneous notifications has not been reported.

Only around 3% of the notifications had some confidentiality claims (112 over 3,409). Around 50 were the simplified notifications submitted by public research organisations. Table 3-2 provides the number of notifications per type of information for which the confidentiality has been claimed.

Table 3-2: Number of notifications per type of information claimed confidential	
Confidentiality claim on:	Number of notifications
Chemical name	32
Uses	84
Properties for which the NM is used	34

In terms of the number of nanomaterials notified, at November 2013 Anses was 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. A more in-depth analysis is currently being prepared by the French authorities. In first instance, Anses 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 varying on the basis of physicochemical parameters.

Quantities are treated as confidential. However, Anses provided the tonnage band for each different CAS number and chemical name notified, plus the aggregated tonnage for the most common substances. Between June 2012 and June 2013, in France 282,014 tonnes of nanomaterials have been manufactured and 222,090 tonnes imported, for an aggregated amount of 504,104 tonnes. With all the limitations mentioned above, in first analysis it can be concluded that around 50-60% of the substances manufactured and/or imported that have been notified would not be triggered by the

REACH Regulation (because manufactured/imported in less than 1 tonne per year).<sup>30</sup> Table 3-3 reproduces for convenience Table 10 of the French public report (2013) reporting the most common nanomaterials on the French market (manufactured and/or imported in more than 100 tonnes).

Table 3-3: Nanomaterials manufactured and/or imported in more than 100 tonnes	
Chemical name	Tonnes
Carbon Black	274,837.135
Silicon dioxide / amorphous silica	155,071.912
Calcium carbonate	34,501.525
Titanium dioxide	14,321.436
Aluminium oxide	2,193.565
Copolymer of vinylidene chloride (declared name)	1,568.000
Magnetic Iron oxide yellow*	538.473
Silicic acid, aluminium and sodium salt*	492.000
Zinc oxide	287.695
Magnetic Iron oxide yellow*	242.188
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[n-(2,4-dimethylphenyl)-3-oxobutyramide]	208.979
Diiron trioxide	173.641
Silicic acid, aluminium, magnesium and sodium salt*	150.975
Pyrrolo(3,4-c)pyrrole-1,4-dione, 2,5-dihydro-3,6-diphenyl- (declared name)	150.584
2-[(2-methoxy-4-nitrophenyl)azo]-n-(2-methoxyphenyl)-3-oxobutyramide	141.232
2-propenoic acid, 2-methyl-methyl ester, polymer with 1,3-butadiene, butyl 2-propenoate and ethenylbenzene (declared name)	138.100
Pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis([1,1'-biphenyl]-4-yl)-2,5-dihydro- (declared name)	138
Aluminium hydroxide	136.500
4,4'-diamino[1,1'-bianthracene]-9,9',10,10'-tetraone	134.740
Cerium dioxide	107.796
<i>Source: reproduced from Anses (2013), Table 10.</i>	
<i>* These entries are reported twice: clarifications will be asked to Anses.</i>	

Table 3-4 presents the most common uses notified (use categories as defined by ECHA reported in more than 2% of the notifications), accounting for more than 70% of the notifications. For an exhaustive list, please consult the French public report (2013).

<sup>30</sup> Table 5 of French Public report (2013) suggests that 47.2% of the substances notified are manufactured/imported in less than 1 t per year. However, on the basis of the number of notifications received, this percentage is closer to 60%.

Table 3-4: Most common uses indicated in the notifications (> 2% of the notifications)	
Sector of use category, Chemical product category and Process category	Percentage
Formulation [mixing] of mixtures and/or re-packaging (excluding alloys)	19.6 %
Other	10.6 %
Coatings and paints, thinners, paint removers	8.1 %
Cosmetics, personal care products	6.1 %
Mixing or blending in batch processes for formulation of mixtures and articles (multistage and/or significant contact)	4.7 %
General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	4.4 %
Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	3.9 %
Fuels	3.0 %
Scientific research and development	2.7 %
Manufacture of food products	2.6 %
Manufacture of fine chemicals	2.5 %
Manufacture of plastics products, including compounding and conversion	2.1 %

Source: French public report (2013), Table 6.

On the basis of the data presented above, an estimate of the number of companies currently complying with the notification requirements has been tried for two sectors (“paints and coatings” and “rubber”) and compared with the full compliance scenario.

### 3.1.3 Analysis of the substances notified

The list of nanomaterials published in the French public report is being crosschecked against the ECHA registered substances database, in order to understand what types of nanomaterials have been notified and the additional insight that the FNS gives in comparison with other sources of information.

So far, 172 entries in the FNS list have been crosschecked against the ECHA database. Unfortunately, the French public report did not publish the CAS number of the substances: each name of the nanomaterials notified has been translated into English and the relevant identifiers (CAS number and EC numbers) have been found through searches in different chemical substances databases (i.e. ESIS).

Of these 172 entries, 6 report the same CAS number and EC number, reducing the number of distinct nanomaterials analysed to 169. Table 3-5 reports the number of nanomaterials analysed per notified quantities.

Table 3-5: Number and percentage of nanomaterials analysed per notified quantities		
Notified quantities	Number of NMs analysed	%
Not reported	7	4%
0.1 - 1 kg	8	5%
1-10 kg	12	7%
10-100 kg	27	16%
100 kg-1 t	61	36%
1-10 t	25	15%
10-100 t	11	7%
100-1000 t	10	6%
>1000 t	8	5%
<b>tot</b>	<b>169</b>	<b>100 %</b>

Over 68% of the nanomaterials analysed are below the 1 tonne REACH information requirements threshold. Around 55% of the substances notified to the FNS have a full registration dossier in the ECHA database. Around 45% could not be found among the list of the registered substances. Twenty-four nanomaterials (around 14%) have been identified as pigments (this number is likely higher). Seven are the polymers identified (not subject to Registration under REACH).

When looking into the nanomaterials notified in quantities between 0.1 and 1 kg (Table 3-6), it can be noted how 7 out of 8 of the bulk form of the substances were classified under the ESIS database as High Production Volume substances. All of them have been notified under REACH in very high quantities. The presence of Silver in this list comes to attention.

Additional crosschecking will be done against the Classification and Labelling Inventory and a compiled list of DNELs. Moreover, the sectors and uses notified will be compared with the sectors and uses of the substances registered under the REACH Regulation.

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Table 3-6: Nanomaterials notified in quantities between 0.1 and 1 kg					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
Nickel monoxide	215-215-7	1313-99-1	Full	10,000 - 100,000 tonnes per annum	Harmonised classification: Skin Sens. 1 H317 Carc. 1A H350i STOT RE 1 H372 Aquatic Chronic 4 H413
Dicopper oxide	215-270-7	1317-39-1	Full	1,000 - 10,000 tonnes per annum	Biocidal Acute Tox. 4 * H302 H302 Aquatic Acute 1 H400 Aquatic Chronic 1 H410 H410
Molybdenum	231-107-2	7439-98-7	Full	100,000 - 1,000,000 tonnes per annum	
Silicon	231-130-8	7440-21-3	Full	1,000,000+ tonnes per annum	
Silver	231-131-3	7440-22-4	Full	100,000 - 1,000,000 tonnes per annum	
Carbone	231-153-3	7440-44-0	Full	100,000 - 1,000,000 tonnes per annum	
Tricobalt tetraoxide	215-157-2	1308-06-1	Full	1,000 - 10,000 tonnes per annum	
Tungsten trioxide	215-231-4	1314-35-8	Full	10,000 - 100,000 tonnes per annum	

Table 3-7: Nanomaterials notified in quantities between 1 and 10 kg					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
Diiron nickel tetraoxide	235-335-3	12168-54-6	Not found		
Calcium bis[4-[[[1-[[[2-methylphenyl)amino]carbonyl]-2-oxopropyl]azo]-3-nitrobenzenesulphonate]	235-558-6	12286-66-7	Full	10 - 100 tonnes per annum	
[3-(2,3-epoxypropoxy)propyl]triethoxysilane	220-011-6	2602-34-8	Full	100 - 1,000 tonnes per annum	

Table 3-7: Nanomaterials notified in quantities between 1 and 10 kg					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
Lead chromate molybdate sulfate red	235-759-9	12656-85-8	Full	1,000 - 10,000 tonnes per annum	Pigment Carc. Cat. 2; R45 - Repr. Cat. 1; R61 - Repr. Cat. 3; R62 - R33 - N; R50-53 (May cause cancer)
Hydroxylapatite (Ca <sub>5</sub> (OH)(PO <sub>4</sub> ) <sub>3</sub> )	215-145-7	1306-06-5	Not found		
Graphite	231-955-3	7782-42-5	Full	100,000 - 1,000,000 tonnes per annum	
2,9-dichloro-5,12-dihydroquino[2,3-b]acridine-7,14-dione	221-424-4	3089-17-6	Full	10 - 100 tonnes per annum	
Sodium bis[4-hydroxy-3-[(2-hydroxy-1-naphthyl)azo]-N-(3-methoxypropyl)benzenesulphonamido (2-)]cobaltate(1-)	275-959-3	71735-61-0	Not found		
Styrene, oligomers	500-008-9	9003-53-6	Not found		
2-(3-oxobenzo[b]thien-2(3H)-ylidene)benzo[b]thiophene-3(2H)-one	208-336-1	522-75-8	Not found		
2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	228-768-4	6358-31-2	Full	1,000 - 10,000 tonnes per annum	
Calcium bis[4-[[1-[[[2-chlorophenyl)amino]carbonyl]-2-oxopropyl]azo]-3-nitrobenzenesulphonate]	276-057-2	71832-85-4	Full	10 - 100 tonnes per annum	

Table 3-8: Nanomaterials notified in quantities between 10 and 100 kg					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
Zirconium dioxide	215-227-2	1314-23-4	Full	10,000 - 100,000 tonnes per annum	
Triiron tetraoxide	215-277-5	1317-61-9	Full	100,000 - 1,000,000 tonnes per annum	

Table 3-8: Nanomaterials notified in quantities between 10 and 100 kg					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
Titanium dioxide	236-675-5	13463-67-7	Full	1,000,000 - 10,000,000 tonnes per annum	
1,4-bis(butylamino)anthraquinone	241-379-4	17354-14-2	Not found		
N,N'-[6,13-diacetamido-2,9-diethoxy-3,10-triphenodioxazinediyl]bis(benzamide)	241-734-3	17741-63-8	Not found		
Hydrogen [4-[4-(diethylamino)-5'-hydroxy-2',4'-disulphonatobenzhydrylidene]cyclohexa-2,5-dien-1-ylidene]diethylammonium, monosodium salt	243-654-4	20262-76-4	Not found		
Benzamide, 3,3'-[(2-Chloro-1,4-Phenylene)Bis[Imino(1-Acetyl-2-Oxo-2,1-Ethanediy)]-2,1-Diazenediy]]Bis[4-Methyl-	not found	not found			
Manganese, 3-hydroxy-4-[(1-sulfo-2-naphthalenyl)azo]-2-naphthalenecarboxylic acid complex	252-525-1	35355-77-2	Not found		
4-[4-(aminocarbonyl)phenyl]azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide	253-292-9	36968-27-1	Full	1 - 10 tonnes per annum	
Silicon carbide	206-991-8	409-21-2	Full	100,000+ tonnes per annum	
Not found	N.A.	474814-88-5	Not found		
Silica, vitreous	262-373-8	60676-86-0	Not found		
Chrome antimony titanium buff rutile	269-052-1	68186-90-3	Full	10,000 - 100,000 tonnes per annum	Pigment
Silicon dioxide	231-545-4	7631-86-9	Full	1,000,000+ tonnes per annum	
Cellulose	232-674-9	9004-34-6	Not found		
Amines, rosin, compds. with 9-(2-carboxyphenyl)-3,6-bis(diethylamino)xanthylium chloride and disodium hydrogen bis[4-[(4,5-dihydro-3-	308-114-5	97862-65-2			



Table 3-8: Nanomaterials notified in quantities between 10 and 100 kg					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
methyl-5-Oxo-1-phenyl-1H-pyrazol-4-yl)azo]-3-hydroxy-1-naphthalenesulfonato(3-)]chromate(3-)					
Hematite, chromium green black	272-713-7	68909-79-5	Full	1,000 - 10,000 tonnes per annum View	Pigment
4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-phenyl-3H-pyrazol-3-one]	222-530-3	3520-72-7	Full	100 - 1,000 tonnes per annum	Pigment
4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-(p-tolyl)-3H-pyrazol-3-one]	239-898-6	15793-73-4	Full	100 - 1,000 tonnes per annum	Pigment
2-[(4-chloro-2-nitrophenyl)azo]-N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-oxobutyramide	235-462-4	12236-62-3	Full	100 - 1,000 tonnes per annum Joint Submission	Pigment
N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxynaphthalene-2-carboxamide	235-464-5	12236-64-5	Full	10 - 100 tonnes per annum	Pigment
4-[(2,5-dichlorophenyl)azo]-N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-hydroxynaphthalene-2-carboxamide	230-258-1	6992-12-6	full	10 - 100 tonnes per annum	
Palladium	231-115-6	7440-05-3	Not found		
Chromium (III) oxide	215-160-9	1308-38-9	Full	10,000 - 100,000 tonnes per annum	
4-[(4-chloro-2-nitrophenyl)azo]-3-hydroxy-N-(2-methylphenyl)naphthalene-2-carboxamide	229-314-8	6471-50-7	Full	1 - 10 tonnes per annum	
Sodium bis[4-hydroxy-3-[(2-hydroxy-1-naphthyl)azo]-N-(3-methoxypropyl)benzene-1-sulphonamido(2-)]chromate(1-)	276-066-1	71839-80-0	Not found		
1-(methylamino)anthraquinone	201-417-2	82-38-2	Not found		

Table 3-9: Nanomaterials notified in quantities between 100 kg and 1 t					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
N-(5-Chloro-2-Methoxyphenyl)-2- [(2-Methoxy-4-Nitrophenyl)Azo]-3-Oxobutyramide	240-131-2	15993-42-7	Full	10 - 100 tonnes per annum	
Trisodium 5-Hydroxy-1-(4-Sulphophenyl) -4-(4-Sulphophenylazo)Pyrazole-3-Carboxylate	217-699-5	1934-21-0	Not found		
3,3'-[(9,10-Dihydro-9,10-Dioxo-1,4-Anthrylene)Diimino]Bis[N-Cyclohexyl-2,4,6-Trimethylbenzenesulphonamide]	245-728-1	23552-74-1	Not found		
1-(4-Methyl-2-Nitrophenylazo)-2-Naphthol	219-372-2	2425-85-6	Full	10 - 100 tonnes per annum	
Trisodium 1-(1-Naphthylazo)-2-Hydroxynaphthalene-4',6,8-Trisulphonate	220-036-2	2611-82-7	Not found		
1-[(2-Chloro-4-Nitrophenyl)Azo]-2-Naphthol	220-562-2	2814-77-9	Full	100 - 1,000 tonnes per annum	
Butyl 2-[[3-[[[(2,3-Dihydro-2-Oxo-1H-Benzimidazol-5-yl)Amino]Carbonyl]-2-Hydroxy-1-Naphthyl]Azo]Benzoate	250-800-0	31778-10-6	Full	10 - 100 tonnes per annum	
Dihydrogen (Ethyl)[4-[4-[Ethyl(3-Sulphonatobenzyl)]Amino]-2'-Sulphonatobenzhydrylidene]Cyclohexa- 2,5-Dien-1-Ylidene(3-Sulphonatobenzyl)Ammonium, Disodium Salt	223-339-8	3844-45-9	Not found		
4,11-Dichloro-5,12-Dihydroquino[2,3-B]Acridine-7,14-Dione	221-423-9	3089-16-5	Full	10 - 100 tonnes per annum	
Calcium Bis[4-[[3-[[2-Hydroxy-3-[[4-Methoxyphenyl)Amino]Carbonyl]- 1-Naphthyl]Azo]-4-Methylbenzoyl]Amino]Benzenesulphonate]	256-050-0	43035-18-3	Not found		
2,4-Dihydro-5-Methyl-2-Phenyl-4- (Phenylazo)-3H-Pyrazol-3-One	224-330-1	4314-14-1	Not found		

Table 3-9: Nanomaterials notified in quantities between 100 kg and 1 t					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
4,10-Dibromodibenzo[Def,Mno] Chrysene-6,12-Dione	224-481-3	4378-61-4	Full	10 - 100 tonnes per annum	
Bisbenzimidazo[2,1-B:2',1'-l]Benzo[Lmn][3,8]Phenanthroline- 8,17-Dione	224-597-4	4424-06-0	Not found		
3,3'-[(2-Methyl-1,3-Phenylene)Diimino]Bis[4,5,6,7-Tetrachloro -1H-Isoindol-1-One]	225-744-5	5045-40-9	Not found		
N,N'-(2,5-Dichloro-1,4-Phenylene)Bis[4- [[2-Chloro-5-(Trifluoromethyl)Phenyl]Azo]-3-Hydroxynaphthalene-2-Carboxamide]	257-776-0	52238-92-3	Full	10 - 100 tonnes per annum	
10,12-Dihydrobenz(De)Imidazo(4',5':5,6)Benzimidazo(1,2-A)Isoquinoline-8,11-Dione	408-170-1		Found but information confidential		
Diethyl 4,4'-[(3,3'-Dichloro[1,1'-Biphenyl] -4,4'-Diyl)Bis(Azo)]Bis[4,5-Dihydro-5-Oxo-1-Phenyl-1H-Pyrazole-3-Carboxylate]	228-788-3	6358-87-8	Full	10 - 100 tonnes per annum	
Barium Bis[2-[(2-Hydroxy-1-Naphthyl)Azo]Benzoate]	228-906-3	6372-81-2	Not found		
3-Hydroxy-4-[(2-Methyl-5-Nitrophenyl) Azo]-N-(O-Tolyl)Naphthalene-2-Carboxamide	229-681-4	6655-84-1	Not found		
4-[(2,4-Dichlorophenyl)Azo]-3-Hydroxy-N -(2-Methylphenyl)Naphthalene-2-Carboxamide	304-497-8	94276-08-1	Not found		
N-(5-Chloro-2,4-Dimethoxyphenyl)-4- [[5-[(Diethylamino)Sulphonyl]-2-Methoxyphenyl]Azo]-3-Hydroxynaphthalene-2-Carboxamide	229-107-2	6410-41-9	Full	10 - 100 tonnes per annum	
Calcium 3-Hydroxy-4-[(1- Sulphonato-2-Naphthyl)Azo]-2-Naphthoate	229-142-3	6417-83-0	Not found		
Not Found		114168-16-0	Not found		

Table 3-9: Nanomaterials notified in quantities between 100 kg and 1 t					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
[2,3'-Bis[[[(2-Hydroxyphenyl)Methylene] Amino]But-2-Enedinitrilato(2-)-N2,N3,O2,O3]Nickel	265-022-7	64696-98-6	Not found		
N-(2,3-Dihydro-2-Oxo-1H- Benzimidazol-5-Yl)-3-Oxo-2-[[2-(Trifluoromethyl)Phenyl]Azo]Butyramide	268-734-6	68134-22-5	Full	100 - 1,000 tonnes per annum	
Sodium Bis[3-[[1-(3-Chlorophenyl) -4,5-Dihydro-3-Methyl-5-Oxo-1H-Pyrazol-4-Yl]Azo]-4-Hydroxy-N-Methylbenzenesulphonamidato(2-)]Cobaltate(1)	275-863-1	71701-14-9	Not found		
Hydrogen Bis[2-[[4,5-Dihydro-3- Methyl-5-Oxo-1-Phenyl-1H-Pyrazol-4-Yl]Azo]Benzoato(2-)]Chromate(1-), Compound With 2-Ethylhexylamine (1:1)	275-864-7	71701-15-0	Not found		
Sodium Bis[3-[[1-(3-Chlorophenyl) -4,5-Dihydro-3-Methyl-5-Oxo-1H-Pyrazol-4-Yl]Azo]-4-Hydroxy-N-Methylbenzene-1-Sulphonamidato(2-)]Chromate(1-)	276-067-7	71839-81-1	Not found		
Xanthylium, 9-(2-Carboxyphenyl) -3,6-Bis(Diethylamino)-, 4-[[5-Chloro-2-Hydroxyphenyl]Azo]-4,5-Dihydro-3-Methyl-1-Phenyl-3H-Pyrazol-3-One 4,5-Dihydro-4-[[2-Hydroxy-5-Nitrophenyl]Azo]-3-Methyl-1-Phenyl-3H-Pyrazol-3-One 3-[[1-[[2-Ethylhexyl]A	276-160-2	71888-93-2	Not found		
Hydrogen [[[(2-Ethylhexyl)Amino] Sulphonyl]][(3-Methoxypropyl)Amino]Sulphonyl]-29H,31H-Phthalocyaninesulphonato(3-)-N29,N30,N31,N32]Cuprate(1-), Compound With N,N'-Di(O-Tolyl)Guanidine (1:1)	276-657-4	72428-99-0	Not found		

Table 3-9: Nanomaterials notified in quantities between 100 kg and 1 t					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
Hydrogen [1-[(2-Hydroxy-4- Nitrophenyl)Azo]-2-Naphtholato(2-)] [1-[(2-Hydroxy-5-Nitrophenyl)Azo]-2-Naphtholato(2-)]Chromate(1-), Compound With 3-[(2-Ethylhexyl)Oxy]Propylamine (1:1)	276-857-1	72812-34-1	Not found		
3-[(4-Chloro-2-Nitrophenyl)Azo]-2-Methylpyrazolo[5,1-B]Quinazolin-9(1H)-One	277-823-9	74336-59-7	Full	100 - 1,000 tonnes per annum	
Silicate(2-), Hexafluoro-, Disodium, Reaction Products With Lithium Magnesium Sodium Silicate	285-349-9	85085-18-3	Full	10 - 100 tonnes per annum	
Hydrogen Hydroxy[2-Hydroxy-3- [(2-Hydroxy-4-Nitrobenzylidene)Amino]-5-Nitrobenzenesulphonato(3-)] Chromate(1-), Compound With 3-[(2-Ethylhexyl)Oxy]Propylamine (1:1)	287-268-4	85455-34-1	Not found		
[1,3,8,16,18,24-Hexabromo-2,4,9,10,11,15,17,22,23,25- Decachloro-29H,31H-Phthalocyaninato(2-)-N29,N30,N31,N32]Copper	238-238-4	14302-13-7	Full	100 - 1,000 tonnes per annum	
2-[(2-Methoxy-4-Nitrophenyl)Azo] -N-(2-Methoxyphenyl)-3-Oxobutyramide	228-768-4	6358-31-2	Full	1,000 - 10,000 tonnes per annum	
29H,31H-Phthalocyaninato(2-)-N29,N30,N31,N32 Copper	205-685-1	147-14-8	Full	10,000 - 100,000 tonnes per annum	
3,3'-(1,4-Phenylenediimino)Bis[4,5,6,7-Tetrachloro-1H-Isindol-1-One]	226-999-5	5590-18-1	Not found		
3-Hydroxy-N-(O-Tolyl)-4-[(2,4,5-Trichlorophenyl)Azo]Naphthalene-2-Carboxamide	229-440-3	6535-46-2	Full	1,000 - 10,000 tonnes per annum	
4,4'-[(3,3'-Dichloro[1,1'-Biphenyl]- 4,4'-Diyl)Bis(Azo)]Bis[2,4-Dihydro-5-Methyl-2-(P-Tolyl)-3H-Pyrazol-3-One]	239-898-6	15793-73-4	Full	100 - 1,000 tonnes per annum	

Table 3-9: Nanomaterials notified in quantities between 100 kg and 1 t					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
5,12-Dihydroquino[2,3-B]Acridine-7, 14-Dione	213-879-2	1047-16-1	Full	1,000 - 10,000 tonnes per annum	
Octanoic Acid	204-677-5	124-07-2	Full	10,000 - 100,000 tonnes per annum	Food and feed area disinfectants
Citric Acid	201-069-1	77-92-9	Full	100,000 - 1,000,000 tonnes per annum	Private area and public health area disinfectants and other biocidal products
Acide Citrique Monohydrate	N.a.	5949-29-1	Not found		
2-Propenoic Acid, 2-Methyl-,Methyl Ester, Polymer With 1,3-Butadiene, Butyl 2-Propenoate And Ethyl 2-Propenoate	na	29896-54-6	Not found		Polymer exempted from Registration
Dimethyl 5-[[1-[[[(2,3-Dihydro-2-Oxo-1H-Benzimidazol-5-Yl)Amino]Carbonyl]-2-Oxopropyl]Azoterephthalate	249-955-7	29920-31-8	Full	10 - 100 tonnes per annum	
3,4,5,6-Tetrachloro-N-[2-(4,5,6,7 -Tetrachloro-3-Hydroxy-1-Oxo-1H-Inden-2-Yl)-8-Quinolyl]Phthalimide	248-610-8	27692-59-7	Not found		
2,9-Bis[4-(Phenylazo)Phenyl]Anthrax [2,1,9-Def:6,5,10-D'e'f']Diisoquinoline-1,3,8,10(2H,9H)-Tetrone	221-264-5	3049-71-6	Full	100 - 1,000 tonnes per annum	
Hydrogen 3,6-Bis(Diethylamino)-9- (2,4-Disulphonatophenyl)Xanthylum, Sodium Salt	222-529-8	3520-42-1	Not found		
1,1'-[(6-Phenyl-1,3,5-Triazine-2,4-Diyl)Diimino]Bisanthraquinone	223-912-2	4118-16-5	Not found		
2,9-Bis(3,5-Dimethylphenyl)Anthrax [2,1,9-Def:6,5,10-D'e'f']Diisoquinoline-1,3,8,10(2H,9H)-Tetrone	225-590-9	4948-15-6	Full	100 - 1,000 tonnes per annum	

Table 3-9: Nanomaterials notified in quantities between 100 kg and 1 t					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
Sodium Bis[2,4-Dihydro-4- [(2-Hydroxy-5-Nitrophenyl)Azo]-5-Methyl-2-Phenyl-3H-Pyrazol-3-Onato(2-)]Chromate(1-)	266-658-8	67352-37-8	Not found		
Trade Names: GRAPHTOL ORANGE 3RT PERMANENT ORANGE 2 RLD PERMANENT ORANGE 3 RTN	412-550-2		Full	10 - 100 tonnes per annum	Pigment
Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, molybdatetungstatephosphate	215-410-7	1325-87-7	Not found		
Barium bis[2-[(2-hydroxynaphthyl)azo]naphthalenesulphonate]	214-160-6	1103-38-4	full	1 - 10 tonnes per annum	
1,4-bis(mesitylamino)anthraquinone	204-155-7	116-75-6	full	1 - 10 tonnes per annum	
N-[4-(acetylamino) phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxynaphthalene-2-carboxamide	235-464-5	12236-64-5	Full	10 - 100 tonnes per annum	
Ferrate(4-), hexakis(cyano-C)-, methylated 4-[(4-aminophenyl)(4-imino-2,5-cyclohexadien-1-ylidene)methyl]benzenamine copper(2+) salts	235-468-7	12237-62-6	Full	100 - 1,000 tonnes per annum	
Copper chlorophthalocyanine	235-476-0	12239-87-1	Full	1,000 - 10,000 tonnes per annum	
Chromium iron oxide	235-790-8	12737-27-8	Full	10,000 - 100,000 tonnes per annum	

Table 3-10: Nanomaterials notified in quantities between 1 and 10 t					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
Benzenamine, 4-[(4-Aminophenyl)(4-Imino-2,5-Cyclohexadien-1-Ylidene)Methyl]-, N-Me Derivs., Molybdatetungstatephosphates;		1325-82-2			

Table 3-10: Nanomaterials notified in quantities between 1 and 10 t					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
1-[(2,4-Dinitrophenyl)Azo]-2-Naphthol	222-429-4	3468-63-1	Full	100 - 1,000 tonnes per annum	Pigment Orange 5
Calcium 4-[(5-Chloro-4-Methyl-2-Sulphonatophenyl)Azo]-3-Hydroxy-2-Naphthoate	230-303-5	7023-61-2	Full	1,000 - 10,000 tonnes per annum	Pigment Red 48:2
Triethoxyoctylsilane	220-941-2	2943-75-1	Full	1,000 - 10,000 tonnes per annum	
Calcium Chloride	233-140-8	10043-52-4	Full	100 - 1,000 tonnes per annum	
5,12-Dihydroquino[2,3-B]Acridine-7,14-Dione	213-879-2	1047-16-1	Full	1,000 - 10,000 tonnes per annum	
Calcium Bis[2-[(2-Hydroxynaphthyl)Azo]Naphthalenesulphonate]	214-161-1	1103-39-5	Not found		
N-(2,3-Dihydro-2-Oxo-1H-Benzimidazol-5-Yl)-3-Hydroxy-4-[[2-Methoxy-5-[(Phenylamino)Carbonyl]Phenyl]Azo]Naphthalene-2-Carboxamide	235-425-2	12225-06-8	Full	100 - 1,000 tonnes per annum	
N-(2,3-Dihydro-2-Oxo-1H-Benzimidazol-5-Yl)-3-Hydroxy-4-[[2-Methoxy-5-Methyl-4-[(Methylamino)Sulphonyl]Phenyl]Azo]Naphthalene-2-Carboxamide	257-515-0	51920-12-8	Full	10 - 100 tonnes per annum	
N-(4-Chloro-2,5-Dimethoxyphenyl)-2-[[2,5-Dimethoxy-4-[(Phenylamino)Sulphonyl]Phenyl]Azo]-3-Oxobutyramide	235-427-3	12225-18-2	Full	100 - 1,000 tonnes per annum	
Hydrogen [4-[4-(Diethylamino)-2',4'-Disulphonatobenzhydrylidene]Cyclohexa-2,5-Dien-1-Ylidene]Diethylammonium, Sodium Salt	204-934-1	129-17-9	Not found		
2-Propenoic Acid, Polymer With Butyl 2-Propenoate, Ethenylbenzene And 2-Propenamide		25586-24-7	Not found		Polymer exempted from Registration
Ammonium Iron(3+) Hexakis(Cyano-C)Ferrate(4-)	247-304-1	25869-00-5	Full	1,000 - 10,000 tonnes per annum	
4-[[4-(Aminocarbonyl)Phenyl]Azo]-3-Hydroxy-N-(2-Methoxyphenyl)Naphthalene-2-Carboxamide	253-292-9	36968-27-1	Full	1 - 10 tonnes per annum	Pigment red 266



Table 3-10: Nanomaterials notified in quantities between 1 and 10 t					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
2,2'-[(3,3'-Dichloro[1,1'-Biphenyl]-4,4'-Diyl)Bis(Azo)]Bis[N-(2-Methoxyphenyl)-3-Oxobutyramide]	224-867-1	4531-49-1	Full	100 - 1,000 tonnes per annum	Pigment yellow 17
Xanthylum, 9-(2-Carboxyphenyl)-3,6-Bis(Diethylamino)-, Molybdatesilicate	263-778-2	62973-79-9	Not found		
Bezoic Acid 2,3,4,5-Tetrachloro-6-Cyano-Methylester, Reaction Products With P-Phenylendiamine And Sodium Methoxide			Not found		
Diantimony Pentoxide	215-237-7	1314-60-9	Full	10 - 100 tonnes per annum	
2-[[1-[[[(2,3-Dihydro-2-Oxo-1H-Benzimidazol-5-Yl)Amino]Carbonyl]-2-Oxopropyl]Azo]Benzoic Acid	250-830-4	31837-42-0	Full	100 - 1,000 tonnes per annum	
4,4'-[(3,3'-Dichloro[1,1'-Biphenyl]-4,4'-Diyl)Bis(Azo)]Bis[2,4-Dihydro-5-Methyl-2-(P-Tolyl)-3H-Pyrazol-3-One]	239-898-6	15793-73-4	Full	100 - 1,000 tonnes per annum	
Dimethyl 2-[[1-[[[(2,3-Dihydro-2-Oxo-1H-Benzimidazol-5-Yl)Amino]Carbonyl]-2-Oxopropyl]Azo]Terephthalate	252-650-1	35636-63-6	full	10 - 100 tonnes per annum	
2,2'-(1,4-Phenylene)Bis[4-[(4-Methoxyphenyl)Methylene]Oxazol-5(4H)-One]	257-055-0	51202-86-9	n/a	n/a	
N-(2,3-Dihydro-2-Oxo-1H-Benzimidazol-5-Yl)-3-Hydroxy-4-[[5-Methoxy-2-Methyl-4-[(Methylamino)Sulphonyl]Phenyl]Azo]Naphthalene-2-Carboxamide	263-353-1	61951-98-2	n/a	n/a	
N-(4-Chloro-2,5-Dimethoxyphenyl)-3-Hydroxy-4-[[2-Methoxy-5-[(Phenylamino)Carbonyl]Phenyl]Azo]Naphthalene-2-Carboxamide	226-103-2	5280-68-2			
Cerium Oxide (CeO <sub>2</sub> ), Isostearic Acid-Modified		346608-13-7			

Table 3-11: Nanomaterials notified in quantities between 10 and 100 t					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
2-Chloro-5-[(2-Hydroxy-1-Naphthyl)Azo]Toluene-4-Sulphonic Acid	240-089-5	15958-19-7	not found		
Calcium 3-Hydroxy-4-[(4-Methyl-2-Sulphonatophenyl)Azo]-2-Naphthoate	226-109-5	5281-04-9	full	10,000 - 100,000 tonnes per annum	Pigment Red 57:1
N,N'-Phenylene-1,4-Bis[4-[(2,5-Dichlorophenyl)Azo]-3-Hydroxynaphthalene-2-Carboxamide]	223-460-6	3905-19-9	Full	100 - 1,000 tonnes per annum	
2,2'-Methylenebis(6-(2H-Benzotriazol-2-Yl)-4-(1,1,3,3-Tetramethylbutyl)Phenol)	403-800-1	103597-45-1	Not found		
2-[(4-Chloro-2-Nitrophenyl)Azo]-N-(2,3-Dihydro-2-Oxo-1H-Benzimidazol-5-Yl)-3-Oxobutyramide	235-462-4	12236-62-3	Full	100 - 1,000 tonnes per annum	Pigment Orange 36
Calcium 4-Chloro-2-(5-Hydroxy-3-Methyl-1-(3-Sulfonatophenyl)Pyrazol-4-Ylazo)-5-Methylbenzenesulfonate	403-530-4	129423-54-7	Full	10 - 100 tonnes per annum	Pigment Yellow
2-Propenoic Acid, Butyl Ester, Polymer With 1,1-Dichloroethene And 2-Propenenitrile		26300-99-2	Not found		Polymer exempted from Registration
Polychloro Copper Phthalocyanine	215-524-7	1328-53-6	Full	1,000 - 10,000 tonnes per annum	Pigment Green 7
Acide 5,5'-(1h-Isoindole-1,3(2h)-Diylidene)Dibarbiturique		72779-83-0			
Manganese, Complexe De L'acide [(Chloro-5 Methyl-4 Sulfo-2 Phenyl)Azo]-4 Hydroxy-3 Naphtalenecarboxylique-2					
N,N-Dimethylaniline	204-493-5	121-69-7	Not found		Carc. Cat. 3; R40 - T; R23/24/25 - N; R51-53

Table 3-12: Nanomaterials notified in quantities between 100 and 1000 t					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
Silice Amorphe De Synthèse/Silica, Amorphous, Fumed, Cryst-Free (Noms Stn)		112945-52-5	Not found		
Silicic Acid, Aluminum Magnesium Sodium Salt	234-919-5	12040-43-6	full	10,000 - 100,000 tonnes per annum	
Barium Titanium Trioxide	234-975-0	12047-27-7	Full	1,000 - 10,000 tonnes per annum	
Strontium Titanium Trioxide	235-044-1	12060-59-2	Full	10 - 100 tonnes per annum	
Tungsten Disulphide	235-243-3	12138-09-9	Not found		
Cerium Dioxide	215-150-4	1306-38-3	Full	1,000 - 10,000 tonnes per annum	
Diiron Trioxide	215-168-2	1309-37-1	full	100,000 - 1,000,000 tonnes per annum	Pigment
2,2'-[(3,3'-Dichloro[1,1'-Biphenyl]-4,4'-Diyl)Bis(Azo)]Bis[N-(2,4-Dimethylphenyl)-3-Oxobutyramide]	225-822-9	5102-83-0	full	1,000 - 10,000 tonnes per annum	Pigment Yellow 13
Iron Hydroxide Oxide Yellow	257-098-5	51274-00-1	Full	100,000 - 1,000,000 tonnes per annum	Pigment
Silicic Acid, Aluminum Sodium Salt	215-684-8	1344-00-9	Full	10,000 - 100,000 tonnes per annum	

Table 3-13: Nanomaterials notified in quantities over 1000 t					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
Carbon Black	215-609-9	1333-86-4	Full	1,000,000 - 10,000,000 tonnes per annum	Pigment
Boehmite (Al(OH)O)	215-284-3	1318-23-6	Full	10,000 - 100,000 tonnes per annum	
Silicic Acid	215-683-2	1343-98-2	Not found		Pigment
Calcium Oxide	215-138-9	1305-78-8	Full	1,000 - 10,000 tonnes per annum	
Calcium Carbonate	207-439-9	471-34-1	Full	1,000,000 - 10,000,000 tonnes per annum	

Table 3-13: Nanomaterials notified in quantities over 1000 t					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
2-Propenoic Acid, 2-Methyl-, Methyl Ester, Polymer With 1,1-Dichloroethene and 2-Methyl-2-Propenenitrile		32335-23-2			Polymer exempted from Registration
Silicic Acid, Magnesium Salt	215-681-1	1343-88-0	Full	1,000 - 10,000 tonnes per annum	
Aluminium Oxide	215-691-6	1344-28-1	Full	1,000 - 10,000 tonnes per annum	Pigment

Table 3-14: Nanomaterials notified with information on quantities not available or confidential					
Chemical name	EC number	CAS number	REACH Reg. type	ECHA quantities	Notes
Diiron Trioxide	215-168-2	1309-37-1	Full	100,000 - 1,000,000 tonnes per annum	Pigment
Manganese, 4-[(4-Chloro-5-Methyl-2-Sulfophenyl)Azo]-3-Hydroxy-2-Naphthalenecarboxylic Acid Complex	235-471-3	12238-31-2	Full	1 - 10 tonnes per annum	
2-[(P-Nitrophenyl)Azo]Acetoacetanilide	216-754-0	1657-16-5	Not found		
2-Propenoic Acid, Polymer With Butyl 2-Propenoate, Ethenylbenzene and 2-Methyl-2-Propenamide		35483-96-6?			Polymer exempted from Registration
Zinc Oxide	215-222-5	1314-13-2	Full	100,000 - 1,000,000 tonnes per annum	Wood preservative (N; R50-53)
2-Propenoic Acid, 2-Methyl-, Methyl Ester, Polymer With 2-Ethylhexyl 2-Propenoate		25265-15-0	Not found		Polymer exempted from Registration
2-Propenoic Acid, 2-Methyl-,Methyl Ester, Polymer With Butyl 2-Propenoate And Ethenylbenzene		27136-15-8	Not found		Polymer exempted from Registration

Not found		1325-82-2			
1-[(2,4-dinitrophenyl)azo]-2-naphthol	222-429-4	3468-63-1	Full	100 - 1,000 tonnes per annum	
calcium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate	230-303-5	7023-61-2	full	1,000 - 10,000 tonnes per annum	
triethoxyoctylsilane	220-941-2	2943-75-1	full	1,000 - 10,000 tonnes per annum	
calcium chloride	233-140-8	10043-52-4	full	100 - 1,000 tonnes per annum	
5,12-dihydroquino[2,3-b]acridine-7,14-dione	213-879-2	1047-16-1	full	1,000 - 10,000 tonnes per annum	
calcium bis[2-[(2-hydroxynaphthyl)azo]naphthalenesulphonate]	214-161-1	1103-39-5	Not found		
N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide	235-425-2	12225-06-8	Full	100 - 1,000 tonnes per annum	
N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-hydroxy-4-[[2-methoxy-5-methyl-4-[(methylamino)sulphonyl]phenyl]azo]naphthalene-2-carboxamide	257-515-0	51920-12-8	Full	10 - 100 tonnes per annum	
N-(4-chloro-2,5-dimethoxyphenyl)-2-[[2,5-dimethoxy-4-[(phenylamino)sulphonyl]phenyl]azo]-3-oxobutyramide	235-427-3	12225-18-2	Full	100 - 1,000 tonnes per annum	
hydrogen [4-[4-(diethylamino)-2',4'-disulphonatobenzhydrylidene]cyclohexa-2,5-dien-1-ylidene]diethylammonium, sodium salt	204-934-1	129-17-9	Not found		
Not found		25586-24-7	Not found		
ammonium iron(3+) hexakis(cyano-C)ferrate(4-)	247-304-1	25869-00-5	Full	1,000 - 10,000 tonnes per annum	
4-[[4-(aminocarbonyl)phenyl]azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide	253-292-9	36968-27-1	Full	1 - 10 tonnes per annum	
	224-867-1	4531-49-1	Full	100 - 1,000 tonnes per annum	

Xanthylum, 9-(2-carboxyphenyl)-3,6-bis(diethylamino)-, molybdatesilicate	263-778-2	62973-79-9	Not found		
Not found			Not found		
diantimony pentoxide	215-237-7	1314-60-9	Full	10 - 100 tonnes per annum	
2-[[1-[[[(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]benzoic acid	250-830-4	31837-42-0	Full	100 - 1,000 tonnes per annum	
4,4'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[2,4-dihydro-5-methyl-2-(p-tolyl)-3H-pyrazol-3-one]	239-898-6	15793-73-4	Full	100 - 1,000 tonnes per annum	
dimethyl 2-[[1-[[[(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]terephthalate	252-650-1	35636-63-6	full	10 - 100 tonnes per annum	
2,2'-(1,4-phenylene)bis[4-[(4-methoxyphenyl)methylene]oxazol-5(4H)-one]	257-055-0	51202-86-9	n/a	n/a	
N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-hydroxy-4-[[5-methoxy-2-methyl-4-(methylamino)sulphonyl]phenyl]azobenzophenone-2-carboxamide	263-353-1	61951-98-2	n/a	n/a	
N-(4-chloro-2,5-dimethoxyphenyl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide	226-103-2	5280-68-2			
Not found		346608-13-7			

### 3.1.4 Current Compliance and Full Compliance

The percentage of firms interested in the notification scheme will eventually be based only on the French firms having to notify compared to the total number of French firms in each NACE class, this is because including European firms outside of France which notify products in the French register will skew the results.

The formulas for estimating the number of French notifiers and number of total notifications for the full compliance scenario are shown in the following double nested summation functions.

$$FR\ Notifiers = \sum_i^P \cdot \sum_z^Q y_{i,z} F_{i,z} = (y_{1,1}F_{1,1} + y_{1,2}F_{1,2} \dots) + (y_{2,1}F_{2,1} + y_{2,2}F_{2,2} \dots) + \dots$$

Where the indices  $i$  = NACE class ( $P$  in total) and  $z$  = company size ( $Q=4$ ; micro, small, medium, large); and the symbols  $y$  = the fraction (of percentage) of *affected* firms per company size per NACE class according to the FR scheme;  $F$  = total number of Firms in France categorised as size  $z$  in NACE class  $i$ ;

Additionally, the total number of notifications can be estimated as follows:

$$FR\ Notifications = \sum_i^P \cdot \sum_z^Q y_{i,z} F_{i,z} N_{i,z} \\ = (y_{1,1}F_{1,1}N_{1,1} + y_{1,2}F_{1,2}N_{1,2} \dots) + (y_{2,1}F_{2,1}N_{2,1} + y_{2,2}F_{2,2}N_{2,2} \dots) + \dots$$

Where the indices and symbols are the same as in the equation before and  $N$  = number of notifications for company of size  $z$  in NACE class  $i$ .

The rate of compliance will be calculated in an analogue way, broken down according to sector and company size. This will help in identifying if certain sectors or sizes of companies are not complying or have not yet complied with the new regulation.

$$Rate\ of\ Compliance_{i,z} = \frac{N_{i,z})_{current\ compliance\ scenario}}{N_{i,z})_{full\ compliance\ scenario}}$$

Where the indices are the same as in the previous formulas.

In order to estimate and calculate the costs of full compliance in France, first the current compliance rate needs to be assessed. While awaiting further aggregated data from the French authorities, the estimate has been based on the data made publicly available, with Anses reporting 2,776 notifications for 828 notifiers. **An average of about 3.35 notifications per notifier can be deduced from these numbers.** By using this average, the current compliance rate can be estimated for different sectors. The French public report provides, together with the Danish study,<sup>31</sup> a basis for calculation.

<sup>31</sup> Danish Environmental Protection Agency, *Anvendelse af nanoprodukter på det danske marked - Vurdering af de administrative konsekvenser for virksomheder ved indberetning til en nanoproduktdatabase*, Miljøprojekt no. 1451, 2012.

### **Current compliance in the 'Paints and coatings' sector**

NACE-code C.20, manufacturer of chemicals and chemical products, contains likely the majority of NMs, since covering dyes and pigments, paints and coatings, personal care products, fillers, catalysts and additives.

From the French public report<sup>32</sup> one can deduce the share percentage of notifications dedicated to “coatings and paints, thinners and paint removers” (REACH usage code PC9a), which is 8.1%. Hence, the total number of notifications dedicated to that industry is about 225 (0.081 x 2,776). Combining this with the average of 3.35 notifications per declarant, an estimated 67 companies have declared nanomaterials to the FNR in the category coatings, paints, thinners and paint removers. Note, that a small number of these companies are European entities.

In order to calculate the current compliance rate in France, the total number of French companies active within a similar economic activity can be obtained via Eurostat. The NACE-code comparable to this category is “Manufacture of paints, varnishes and similar coatings, printing ink and mastics”, NACE-code C.20.3. The total number of French companies active in NACE-code C.20.3 is according to Eurostat<sup>33</sup> 270.

According to the Denmark study, about 100% of the companies with economic activities in paints and coatings, would declare to a nanomaterials registry (see also paragraph 2.3 on Denmark) since most pigments are classified as NM and many coatings have specific NM additives. In order to take this uncertainty into account and to make a conservative estimation, we assume that 90% of the total number of the companies will need to declare. The number of companies that would declare is thus equal to 243 (0.9 x 270).

A rough indication of the compliance rate for the paints, thinners and paints removers industry in France, can now be calculated with

$$\text{Rate of Compliance}_{i,z} = \frac{N_{i,z})_{\text{current compliance scenario}}}{N_{i,z})_{\text{full compliance scenario}}}$$

where  $N_{i,z})_{\text{current compliance scenario}}$  is equal to 67 and  $N_{i,z})_{\text{full compliance scenario}}$  is equal to 243 resulting in a rate of compliance of approximately 28%.

Uncertainties in this estimation include:

- Comparison of the NACE-code C.20.3 with the REACH usage code PC9a stated in the Anses report ;
- Unknown number of declarants that are from outside of France (the statistics specifying the number of companies in this NACE code are for France only);
- The average of 3.35 notifications per declarant which should be different for different areas of economic activity (i.e. NACE codes). One would actually expect more than 3.35 declarations per declarant in this sector due to the number of pigments and NM additives used in the manufacturing of paints and other coatings;

<sup>32</sup> The overview of share percentage of notifications per economic activity can be found on page 24, table 6.

<sup>33</sup> Year: 2011.



Therefore, the rate of compliance in the manufacture of paints and other coatings (NACE C.20.3) is approximately 28% and means approximately 175 companies (of a total of 270) from this NACE code have not complied.

### **Current compliance in the 'Rubber' sector**

A similar reasoning as in the previous paragraph can be performed for the manufacturing of rubber products. The most used NM found in this product category with NACE-code C.20.1.7 "Manufacture of synthetic rubber in primary forms" is carbon black which is used in vehicle tyres.

From the French public report it can be deduced that the share percentage of notifications dedicated to the manufacturing of rubber products is 1.9%. Hence, the total number of notifications dedicated to that industry is about 53 (0.019 x 2,776). Combining this with the average of 3.35 notifications per declarant, an estimated 15 companies have declared nanomaterials to the FNR in the sector manufacture of rubber.

In order to calculate the current compliance rate in France, the total number of French companies active within a similar economic activity can be obtained via the French website of statistics (Insee). NACE-code C.20.1.7 for the year 2011 delivers a total number of 13 companies. According to the Danish study, about 100% of the companies with economic activities in rubber would have to declare to the registry since carbon black and other additives are nanomaterials.

An indication of the compliance rate for the rubber manufacturing sector in France can now be calculated:

$$\text{Rate of Compliance}_{i,z} = \frac{N_{i,z})_{\text{current compliance scenario}}}{N_{i,z})_{\text{full compliance scenario}}}$$

In this case 100% of the manufacturers seem to have complied. Uncertainties in this estimation include:

- Comparison of the NACE-code C.20.1.7 with the 'manufacturing of rubber products' stated in the French public report (which is categorised according to SU REACH classification code);
- Unknown number of foreign notifiers (the statistics refer to French companies);
- The average of 3.35 notifications per notifier could be different for different areas of economic activity.

## **3.2 The Cosmetic Products Notification Portal**

The Cosmetics Regulation No 1223/2009 was the first piece of EU legislation to introduce a definition for nanomaterial. Art. 2(k) defines nanomaterial as "*an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm*". Art 2(3) provides the possibility for the Commission to adjust and adapt the definition to technical and scientific progress, in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

Article 13 establishes that for a cosmetic product containing nanomaterials, before it is placed on the market, there is a requirement to notify the following information to the Commission:

- the presence of substances in the form of nanomaterials;

- their identification including the chemical name (IUPAC), the Non-proprietary Names (INN) for pharmaceutical products, the CAS number, the EC number or ELINCS number, the XAN and the name in the glossary of common ingredients names;
- the reasonably foreseeable exposure conditions.

Article 16 enlarges the information requirements to:

- the specification of nanomaterial including size of particles, physical and chemical properties;
- an estimate of the quantity contained in cosmetic products intended to be placed on the market per year;
- the toxicological profile of the nanomaterial;
- the safety data of the nanomaterial relating to the category of cosmetic product, as used in such products; and
- the reasonably foreseeable exposure conditions.

Article 16(4) establishes that *“in the event that the Commission has concerns regarding the safety of a nanomaterial, the Commission shall, without delay, request the SCCS to give its opinion on the safety of such nanomaterial for use in the relevant categories of cosmetic products and on the reasonably foreseeable exposure conditions”*. The SCCS has six months to deliver its final opinion, and this opinion, as well as the starting consult of the Commission, should be made public.

Where the Commission, in the light of the opinion of the SCCS, believe there is a potential risk to the human health *“including when there is insufficient data”*, it may include the nanomaterial in the list of prohibited substances in Annex II or III.

By January 2014, the Commission should have published a catalogue of all nanomaterials used in cosmetic products placed on the market *“including those used as colorants, UV-filters and preservatives in a separate section, indicating the categories of cosmetic products and the reasonably foreseeable exposure conditions”* (Art.16(3)). The catalogue is currently being prepared by DG SANCO, however, the publication date is not known yet.

Every year, the Commission should submit a report to the Parliament and the Council, containing information about *“the new nanomaterials in new categories of cosmetic products, the number of notifications, the progress made in developing nano-specific assessment methods and safety assessment guides, and information on international co-operation programmes”*.

As a last provision, Article 19 prescribes that *“all ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word ‘nano’ in brackets”*.

In order to implement the Cosmetics Regulation, DG SANCO has created and maintains the Cosmetics Products Notification Portal. As detailed on the website:<sup>34</sup> *“the CPNP is making this information available electronically to the Competent Authorities (for the purposes of market surveillance, market analysis, evaluation and consumer information) and to the Poison Centres or similar bodies established by Member States (for the purposes of medical treatment). The CPNP is accessible to Competent Authorities, European Poison Centres, cosmetics products responsible persons and is already available for distributors of cosmetic products”*.

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<sup>34</sup> <http://ec.europa.eu/consumers/sectors/cosmetics/cnpn/>

The Commission is currently working on a new definition of nanomaterials for cosmetics:<sup>35</sup> the new definition is likely to introduce a different cut-off level from the EC recommended definition of nanomaterials in terms of number size distribution, a threshold for defining what is soluble and what is insoluble and some provisions about how to deal with aggregates.

The notification of cosmetic products containing nanomaterials is mandatory for those products containing nanomaterials that have not undergone a full risk assessment by the Scientific Committee on Consumer safety (SCCS). The notification of safety information allows the Commission to request a full risk assessment in case it has concerns related to the safety of the nanomaterials for human health. This means that if the product contains nanomaterials included in such form in Annexes III (list of restricted substances), IV (colorants), V (preservatives) or VI (UV filters) to Regulation (EC) No 1223/2009, it does not need to be notified under Article 16.

If a product is available in several shades, each shade containing a different nanomaterial should be notified under Article 16. If a product contains more than one nanomaterial, there should be one Article 16 notification per nanomaterial.

The information requirements for nanomaterials in cosmetic products are considerably higher than for the other notification schemes. In first instance, the notifier has to identify the product, providing indication of the product category. The choice of a category at level 1 determines the categories available at level 2; the choice of a category at level 2 will determine the categories available at level 3. There are 4 level-one defined categories:

- Skin products (with 10 level-two categories);
- Hair and scalp products (with 4 level-two categories);
- Nails and Cuticle products (with 4 level-two categories);
- Oral hygiene products (with 4 level-two categories).

Table 3-15 provides the list of different cosmetic product categories per level.

Table 3-15: Product category levels	
Level 1 Skin products	
Level 2	Level 3
Skin care Products	Face care products other than face mask
	Face mask
	Eye contour products
	Lip care products
	Hand care products
	Foot care products
	Body care products
	External intimate care products
	Chemical exfoliation products
	Mechanical exfoliation products
	Skin lightening products
Other skin care products	

<sup>35</sup> <http://chemicalwatch.com/14539/new-eu-nano-definition-for-cosmetics-scheduled-for-2014>

Table 3-15: Product category levels	
Skin Cleansing Products	Soap products
	Bath / shower products
	Make-up remover products
	External Intimate hygiene products
	Other skin cleansing products
Body Hair Removal Products	Chemical depilatories
	Physical epilation products
	Other body hair removal products
Bleach for Body hair products	Bleach for body hair
Correction of body odour and/or perspiration	Products with antiperspirant activity
	Products without antiperspirant activity
Shaving and pre- / after-shaving products	Shaving products
	Pre- / after-shaving products
	Other shaving and pre- / after- shaving products
Make-up products	Foundation
	Concealer
	Other face make-up products
	Mascara
	Eye shadow
	Eye pencil
	Eye liner
	Other eye make-up products
	Lip stick
	Lipstick sealer
	Other lip make-up products
	Body or face paint , including "carnival make-up"
	Other make-up products
Perfumes	Hydroalcoholic perfumes
	Non Hydroalcoholic perfumes
Sun and self-tanning products	Before and after sun products
	Sun protection products Self-tanning products
	Other sun and self-tanning products
Other skin products	Other skin products
Level 1 Hair and scalp products	
Level 2	Level 3
Hair and scalp care and cleansing products	Shampoo
	Hair conditioner
	Scalp and hair roots care products
	Antidandruff products
	Anti-hair loss products
	Other hair and scalp care and cleansing products
Hair colouring products	Oxidative hair colour products
	Non-oxidative hair colour products
	Hair bleaching and dye remover products
	Other hair colouring products
Hair styling products	Products for temporary hair styling

Table 3-15: Product category levels	
Other hair and scalp products	Permanent wave products
	Hair relaxer / straightener products
	Other hair styling products
	Hair sun protection products
	Other hair and scalp products
Level 1 Nails and Cuticle Products	
Level 2	Level 3
Nail varnish and remover products	Nail varnish / Nail make-up
	Nail varnish remover
	Nail varnish thinner
	Nail bleach
	Other nail varnish and remover products
Nail care/nail hardener products	Nail care products
	Nail hardener
	Other nail care / nail hardener products
Nail glue remover products	Nail glue remover
Other nail and cuticle products	Cuticle remover / softener
	Nail sculpting products
	Other nail and cuticle products
Level 1 Oral Hygiene products	
Level 2	Level 3
Tooth care products	Toothpaste
	Tooth cleansing powder / salt
	Other tooth care products
Mouth wash/breath spray	Mouth wash
	Breath spray
	Other mouth wash / breath spray products
Tooth whiteners	Tooth whiteners
Other oral Hygiene products	Other oral Hygiene products

Once provided the product category, notifiers have to specify the foreseen cosmetic product name of the cosmetic product that will contain the nanomaterial notified.

For the identification of the nanomaterial, the provision of the IUPAC name is compulsory and other descriptors (i.e. INCI, CAS number, EINECS and/or ELINCS (EC) number, INN number, XAN number) shall be provided if existent.

A full characterisation of the nanomaterial has to be provided. Table 3-16 presents the list of physicochemical parameters required.

Table 3-16: Physicochemical parameters required for the characterisation of the nanomaterials	
Particle size	
<b>Primary particle size</b>	Lowest cut off level (nm)
	Volume weighted median Min and Max (nm)
	Number weighted median Min and Max (nm)
<b>Secondary particle size</b>	Volume weighted median Min and Max (nm)
Morphology	
<b>Physical form</b>	Solid, Powder, Solution, Suspension, Dispersion, Other

<b>Crystalline shape</b>	Spherical, Hexagonal, Pyramidal, Rod, Plate, Wire, Whisker, Star-like, Needle-like, Fiber, Tube, Isometric, Crystalline, Irregular, Amorphous, Other
<b>Agglomeration/aggregation state</b>	Dispersed free particles, Agglomerate, Aggregate, Other
<b>Aspect ratio (of elongated particles)</b>	
<b>Surface characteristics</b>	
<b>Surface charge (zeta potential)</b>	mV Not measurable
<b>Surface modifications or functionalization</b>	Yes/No
<b>Coating</b>	
<b>Solubility (solubility/dissolution in relevant solvents)</b>	
<b>Aqueous media</b>	(mg/l)
<b>N-octanol</b>	(mg/l)
<b>Octanol/water partition coefficient</b>	
<b>Surface area</b>	
<b>BET specific surface area SSA</b>	m <sup>2</sup> /g
<b>Volume specific surface area VSSA</b>	m <sup>2</sup> /cm <sup>3</sup>
<b>Catalytic activity (in final formulation)</b>	
<b>Chemically reactive surface</b>	Yes/No
<b>Is there photocatalytic activity?</b>	Yes/No
<b>% to reference</b>	
<b>Core material doped?</b>	Yes/No
<b>Quantity</b>	
<b>Quantity (per year)</b>	(kg)
<b>Toxicological profile (following the SCCS Guidance on the safety assessment of nanomaterials in cosmetics)</b>	
<b>Summary of the toxicological studies</b>	
<b>Relevant toxicological studies</b>	<ol style="list-style-type: none"> <li>1- percutaneous absorption</li> <li>2- toxicokinetics</li> <li>3- acute toxicity</li> <li>4- irritation and corrosivity</li> <li>5- skin sensitisation</li> <li>6- mutagenicity/genotoxicity</li> <li>7- repeated dose toxicity</li> <li>8- carcinogenicity</li> <li>9- reproductive toxicity</li> <li>10- photo-induced toxicity</li> <li>11- Human data</li> </ol>
<b>Relevant scientific literature</b>	
<b>Safety data</b>	
<b>Safety data of the nanomaterial relating to the category of cosmetic product</b>	
<b>Exposure conditions (Reasonable Foreseeable Exposure Conditions of the Nanomaterial)</b>	
<b>Rinse off/ Leave on</b>	
<b>Exposure route</b>	Dermal/Oral/Inhalation
<b>Maximal concentration</b>	% w/w

### 3.2.1 Stakeholder meeting

A stakeholder meeting has been organised on 10 March 2014 in Paris, in conjunction with the session of the French Working Group on nanomaterials (a list of participants is provided in Table 3-17). The

meeting is hosted by the *Ministère de l'Écologie, du Développement durable et de l'Énergie* and has the purpose to gather valuable information for the assessment of the FNS and to foster participation to the ongoing consultation on the administrative burden that the notification system might pose on companies and to the public consultation planned between April and June 2014.

Table 3-17: Participants to the Groupe de Travail r-nano on 10 March 2014	
Name	Organisation
<b>Public authorities</b>	
Sophie Paultre	Ministère de l'Écologie, du Développement durable et de l'Énergie (MEDDE)
Olivier Pairault	Ministère de l'Écologie, du Développement durable et de l'Énergie (MEDDE)
Michaela Rusnac	Ministère des Affaires sociales et de la Santé
Myriam Perouel	Ministère des Affaires sociales et de la Santé
Jean-Daniel Lulewicz	Ministère de l'Economie et des Finances
Franck Faivre	Ministère de l'agriculture, de l'agroalimentaire et de la forêt
Philippe Gaucher	Ministère de l'enseignement supérieur et de la recherche
Franck l'Hoir	Ministère de la Défense
Aurélié Niaudet	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)
Olivier Merckel	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)
<b>European Commission</b>	
Michal Kubicki	DG Enterprise and Industry
<b>Non-Governmental Organisation</b>	
Danielle Lanquetuit	Association de Veille et d'Information Civique sur les Enjeux des Nanosciences et des Nanotechnologies - AVICENN
<b>Industry association</b>	
Sonia Benacquista	Union des Industries Chimique (UIC)
Patrick Levy	Mouvement des Entreprises de France - Union des Industries Chimique
Adeena Campas	Mouvement des Entreprises de France (MEDEF)
Clémence Liebert	Fédération des Industries des Peintures, Encres, Couleurs, Colles et adhésifs, préservation du bois (FIPEC)
Francis Brunet Manquat	Fédération des Industries des Peintures, Encres, Couleurs, Colles et adhésifs, préservation du bois (FIPEC)
Camille Helmer	Association Nationale des Industries Alimentaires (ANIA)
Pauline Raust	Association Nationale des Industries Alimentaires (ANIA)
Carole Sadaka	Association Nationale des Industries Alimentaires (ANIA)
<b>Companies</b>	
Caroline Petigny	BASF
Xavier Radisson	L'Oréal
Cristophe Zing	Cristal Global
<b>Project team</b>	
Marco Camboni	Risk & Policy Analysts ltd (RPA)
Vania Simittchieva	Risk & Policy Analysts ltd (RPA)
Yvonne Floredo	Beratungsgesellschaft für integrierte Problemlösungen (BiPRO)
Jan Vonderman	Beratungsgesellschaft für integrierte Problemlösungen (BiPRO)

The specific objectives of the meeting are:

- To present the EC study to the French stakeholders;
- To obtain information on the critical issues encountered during the development, implementation and first year operation of the notification scheme;

- To gather information on the first-hand experiences with the notification scheme of the companies and the industry associations attending the meeting, especially with regard to confidentiality and communication in the supply chain issues;
- To ask for the support of the industry associations in fostering the participation to the ongoing and planned consultation;
- To present our first assessment of the FNS and in particular:
  - the impacts of the notification system on the current public debate over nanomaterials and possible long term human health and environmental benefits;
  - the impact on competitiveness and innovation of the French companies;
- To request expert advice and reliable sources of information for the better estimation of the number of companies affected and the rate of compliance with the notification obligations;
- To discuss with the industry associations and companies attending the meeting, the possibility for further investigation through the development of case studies, in order to get a better understanding of the different nanotechnology supply chains.

Participants have the opportunity to share first-hand experiences and their views over a possible EU-wide nanomaterials notification scheme.

The meeting will have to separate sessions:

- The first session (from 2pm to 5pm) will be an open discussion structured around the main topics (as highlighted above) with all the members of the Working Group;
- The second session (from 5pm to 7pm) will be a discussion with the public authorities only (representatives of the different ministries involved and Anses) and will focus on the technical issues of managing a nanomaterials registry (e.g. confidentiality claims, possibility of importing data from other notification dossiers), the costs and the enforcement of the legislation.

The agenda for the full session is presented in Annex I.

### 3.2.2 Cost Analysis – Public Authorities

The costs entailed by the French public authorities for the implementation of the legislation and the database management have been previously assessed in BiPRO and Oeko-Institut e.V. (2013).

The main costs for the setting up and operation of the FNS have been indicated to relate to:

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

Table 3-18 reports the costs related to the acquisition of the hardware and software plus yearly license and maintenance of the database.

Table 3-18: Hardware/software costs – confirmation/update of old data			
Type	Costs (€)	Type of Costs	
		Implementation	Annual
Servers and other hardware	25,000	x	
Website/database development from an external firm	150,000	x	
Oracle database licenses	75,000	x	



Table 3-18: Hardware/software costs – confirmation/update of old data			
Type	Costs (€)	Type of Costs	
		Implementation	Annual
Corrective maintenance of the website/database	15,000		x
Oracle license support	15,000		x

The implementation costs were around €250,000; the operation costs around €30,000 per year. To the latter should be added the administrative costs related to the personnel working on the database. Table 3-19 reports these costs in terms of full-time equivalent<sup>36</sup> employees.

Table 3-19: Administrative costs – confirmation/update of old data						
Personnel	Intensity (fte)	Tasks	Duration (yr)	Number of weeks per year	Type of Costs	
					Impl.	Annual
1 desk officer	0,75	Organizing stakeholder meetings, drafting FAQs, answering inquiries	1		x	x
2 officers	1,50	Working within ANSES (French Agency for Food, Environmental and Occupational Health & Safety); assisting with the French RPN in answering basic questions, website support	1 (at least one officer dedicated for 2 years)		x	x

Assuming a 35-hours work week, 46 work weeks per year and an average hourly net wage of €20 for a public officer, the additional costs are around €72,000 per year.

A new survey has been submitted to the French authorities in order to confirm these values and update them if necessary.

With regard to the Cosmetic Products Notification Portal, Table 3-20 reports the cost figures provided by DG SANCO.

Table 3-20: CPNP management costs	
Maintenance and development	€200,000
Hosting	€52,000
Application support	€150,000
<b>tot</b>	<b>€402,000 per annum</b>

<sup>36</sup> Full-time equivalent (FTE) is obtained by comparing an employee's average number of hours worked to the average number of hours of a full-time worker. A full-time person is therefore counted as one FTE, while a part-time worker gets a score in proportion to the hours he or she works or studies. For example, a part-time worker employed for 20 hours a week where full-time work consists of 40 hours, is counted as 0.5 FTE.

### 3.2.3 Cost Analysis – Industry

An online survey has been launched on 27 February 2014 in order to assess the administrative burden that may be posed on the companies by the French Notification System and the Cosmetic Products Notification Portal. The questionnaire can be found in Annex II.

Moreover, the stakeholder meeting will provide the opportunity to gather first-hand experiences from the participants.

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## 4 Assessment of Long Term Human Health and Environmental Benefits

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### 4.1 Introduction

For the assessment of the long term human health and environmental benefits that might arise from the implementation of the FNS, a first investigation over the evidence for how the gathered information was used by authorities, consumers and workers has been carried out.

The <https://www.r-nano.fr/> notification webpage has been online since 1 January 2013. The French public report provides some statistics on the number of accesses to the online application from January to June 2013.

Answers received 477 questions (with more than 50% of the total made during the last two months of the period considered), of which 122 were redirected to the General Directorate for risk prevention (MEDDE) because relative to regulatory issues. The time needed to provide an answer goes from 5 days for technical issues with the online application to two weeks for scientific questions.

Between January and June 2013, the online application registered 28,459 visits with 13,907 unique visits and 54,782 viewed pages, with most of the visitors (around 60%) located in France.<sup>37</sup> The average duration of the visits to the webpage is of around 3 minutes, possibly meaning that the online application users have proceeded progressively to fill in the notification dossier.

A research on relevant news about the French notification scheme has been carried out in order to assess how journalists and bloggers are using the data made publicly available via the website and what is the public perception of nanomaterials.

### 4.2 Nanotechnology and Nanomaterials in the French Press

France has been a significant player in the development of nanotechnology, the use of nanomaterials and importantly, in the introduction of a registry for nanomaterial. Indeed, France was once the leading publisher of scientific papers on nanotechnology, although more recently has been overtaken by China in this field and is now approximately 5th in the world. That said, France remains a significant player in the research and development of nanotechnology and nanomaterials.

The important role played by France in the field of nanotechnology and nanomaterials is mirrored in the relatively high level of coverage this topic received prior to the introduction of the nano-registry in 2013, and following this date. The national media, including printed press and television has covered nanotechnology from a range of angles for a number of years. Additionally, nanotechnology has been discussed in online blogs and forums and websites dedicated to discussing nanotechnology and nanomaterials.

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<sup>37</sup> Determined on the basis of the IP address of the computer used to visit the webpage.

## 4.2.1 Nanotechnology and Nanomaterials in the French Press – pre 2013

### Health

Prior to the introduction of the registry for nanomaterials in France on 1<sup>st</sup> January 2013, articles in the mainstream French press (particularly newspapers) appear to have focused on the uncertainties surrounding nanomaterials and nanotechnology. Indeed, many articles discussed the uncertainty and possible risks associated with nanomaterials and their possible impact on human health and the environment. For example, in December 2009, an article in La Croix entitled '*Should we be afraid of nanotechnologies?*'<sup>38</sup> discussed the development of nanomaterials and the possible associated risks. This article summarised some of the main concerns regarding nanomaterials (e.g. possible damage to DNA in certain conditions) but highlighted that in reality there are many unknowns and more research is needed to know the actual risks involved. In addition, in April 2010, a brief article was published in the free daily newspaper 20 Minutes, entitled '*Nanotechnologies: what are the risks?*'<sup>39</sup>. The short article explained what nanomaterials are, where they can be found and, concerning the dangers to humans and the environment, highlighted that nothing has been proven '*with any great certainty*'.

### Nanomaterials in Food

As well as discussing concerns regarding the safety and toxicity of nanomaterials on humans and the environment, in general terms, more specific concerns have also featured in the French press. For example, the use of nanomaterials in food was discussed in two articles in the newspaper Le Monde in 2012. In February 2012, Le Monde published an article entitled '*Concerns of nanomaterials in food*'<sup>40</sup> in which AFOC (French Association of Working Consumers), expressed concerns over the potential risks of food products containing nanomaterials - pointing to a difference of many years between their placing on the market and the results of toxicological studies. Indeed, the article also emphasises that studies on the possible toxicity of nanomaterials are more complex due to the fact that the materials differ depending on the shape and the contact surface of the particles involved. That said, like other articles concerning nanomaterials and nanotechnology, this article highlighted the fact that the effects of nanomaterials on health and the environment remain poorly understood.

In December 2012, Le Monde published an article with a similar theme, entitled '*Nanoparticles: the ingredient that has been quietly invited to our table*'<sup>41</sup>. This article discussed some of the arguments surrounding whether nanomaterials were in fact used in food – in the EU, the use of nanomaterials in food is in its infancy compared with the USA where nanomaterials feature commonly in food products. This article reported that nanomaterials had been used for many years in food and packaging in the EU however there was some debate whether they could be classed as nanomaterials. For example,

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<sup>38</sup> La Croix (2009): **Faut-il avoir peur des nanotechnologies**, available from <http://www.la-croix.com/Ethique/Sciences-Ethique/Sciences/Faut-il-avoir-peur-des-nanotechnologies-NG-2009-12-14-570302>

<sup>39</sup> 20 Minutes (2010): **Nanotechnologies: quels sont les risques?**, available from <http://www.20minutes.fr/sciences/397658-nanotechnologies-risques>

<sup>40</sup> Le Monde (2012): **Inquiétudes autour des nanomatériaux dans les aliments**, available from [http://www.lemonde.fr/planete/article/2012/02/29/inquietudes-autour-des-nanomateriaux-dans-les-aliments\\_1649689\\_3244.html](http://www.lemonde.fr/planete/article/2012/02/29/inquietudes-autour-des-nanomateriaux-dans-les-aliments_1649689_3244.html)

<sup>41</sup> Le Monde (2012): **Nanoparticules: l'ingrédient qui s'est discrètement invité à notre table**, available from [http://www.lemonde.fr/planete/article/2012/12/31/nanoparticules-l-ingredient-qui-s-est-discretement-invite-a-notre-table\\_1810783\\_3244.html](http://www.lemonde.fr/planete/article/2012/12/31/nanoparticules-l-ingredient-qui-s-est-discretement-invite-a-notre-table_1810783_3244.html)

E551<sup>42</sup> is not identified as a nanomaterial as the European body in charge of food additives considers that it is not intended for use as a nanomaterial. The article discusses concerns regarding the safety of human health following the consumption of nanomaterials, however concludes with the fact that the impact of nanoparticles on human health is complex and not fully resolved.

### **Environment**

In addition, the impact of nanotechnology on the environment was considered in the French media prior to the introduction of the nano-registry in January 2013. For example, an extensive article in the Le Monde newspaper in October 2009 entitled '*Nanotechnologies: the environmental point of view*'<sup>43</sup> considered the development of nanotechnology from the 1980s, and the associated environmental concerns and possibilities. Importantly, this article emphasises the conflicting opinions concerning the impact of nanotechnology on the environment. Initially, it was suggested that nanotechnology could be good for the planet – offering the possibility for the more economic use of resources; however, other arguments emphasised the possible toxicity of nanomaterials and potential risks to the environment. Indeed, the article quotes the European Environmental Bureau stating '*nanotechnology was presented as offering technological solutions to a number of environmental problems such as climate change, pollution and access to drinking water*'. However, the article counters this by referencing a report by IPEN<sup>44</sup> which claims that such an 'angelic vision' of nanotechnology masks serious environmental concerns, as well as hidden costs that cannot be ignored. Furthermore, excerpts from the IPEN report highlight that the 'dark side' of nanomaterial production (e.g. increased demand for energy and water) is rarely recognised while the advantages of their use are often exaggerated and untested, and would not be achieved for many years. Ultimately, like other articles in the French media at this time, this article highlights that the impacts of nanotechnology on health and the environment are relatively unknown and there is a general lack of knowledge on the range of nanomaterials available.

### **Other**

#### *Political Developments*

As well as considering the possible risks and uncertainties associated with nanomaterials and nanotechnology, the mainstream French press has also reported relevant political developments. An article in La Libération from March 2010, entitled '*Nanotechologie: l'Afsset recommande le principe de précaution*'<sup>45</sup> reported on a study by Afsset<sup>46</sup> which highlighted the lack of knowledge on the long term effects of nanomaterials and consequently, the need for an acceleration of research in this area (only

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<sup>42</sup> Silicon dioxide is authorised by Regulation (EU) No 1130/2008 on food additives to be used as an additive to emulsifiers and colours in food without in *quantum satis*, i.e. in the amount which is needed. Regulation available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0178:0204:EN:PDF>

<sup>43</sup> Le Monde (2009): **Nanotechnologies: le point de vue environnemental**, available from [http://www.lemonde.fr/technologies/article/2009/10/15/nanotechnologies-le-point-de-vue-environnemental\\_1254555\\_651865.html](http://www.lemonde.fr/technologies/article/2009/10/15/nanotechnologies-le-point-de-vue-environnemental_1254555_651865.html)

<sup>44</sup> IPEN (International POPs Elimination Network) is a global network of more than 700 public interest non-governmental organisations working for the elimination of persistent organic pollutants.

<sup>45</sup> La Libération (2010): **Nanotechnologies: l'Afsset recommande le principe de précaution**, available from [http://www.Libération.fr/terre/2010/03/24/nanotechnologies-l-afsset-recommande-le-principe-de-precaution\\_617132](http://www.Libération.fr/terre/2010/03/24/nanotechnologies-l-afsset-recommande-le-principe-de-precaution_617132)

<sup>46</sup> Afsset: Agence française de sécurité sanitaire de l'environnement et du travail (French Agency for Environmental and Occupational Health)

2% of published studies on nanomaterials concerned their eventual risks with the rest dedicated to their development). Afsset also recommended at this time, the clear labelling and ensured traceability of nanomaterials.

The press also followed the public consultation launched in France concerning nanomaterials. Press articles noted that the consultation was poorly attended by the public and the website had few hits. Indeed, an article in La Libération in January 2010 (*'Nanotechnologies, the debate taken over by fear'*<sup>47</sup>) suggested that the public consultation was a 'farce' with few of the public attending. The article also claimed that some 'anti-nano' parties claimed that the public consultation was merely a way to legitimise decisions and avoid a backlash in the future should nanotechnology turn out to be harmful. Additionally, in February 2010, La Libération published an article (*'Nanotechnologies: the debate cut short'*<sup>48</sup>) which stated that public interest in the national consultation had been disappointing with low attendance at public meetings (a total of 3,000 people) and only 150,000 hits on the website in five months.

#### *Economic Importance of Nanomaterials*

The high profile of nanomaterials in France during the public consultation and during the preparation of the registry resulted in a range of issues being discussed in the media. The French nanomaterials/nanotechnology industry was also covered, including the economic importance and potential of the industry. For example, an article in Les Echos in March 2011, entitled *'Nanotechnology: what place for France?'*<sup>49</sup> highlighted the economic importance of nanotechnology to France, in spite of continuing concerns regarding the toxicity of nanomaterials. The article emphasised that the commercial stakes 'are enormous' and the market for nanotechnology had experienced significant growth – 400% between 2005 and 2009. Although the USA dominates the market with 53% followed by Asia (53%) and Europe with 15%, the industry was particularly important to France which devoted 0.8% of its public investment in R&D on nanotechnology, compared with 0.4% in the USA. This article also emphasized concern regarding private investment in industrial applications of nanotechnology. Indeed, less than 5% of nano-patents are French while the USA, Japan and Germany account for 75%.

### **4.2.2 Nanotechnology and Nanomaterials in the French Press – post 2013**

The introduction of the registry for nanomaterials in January 2013 in France has not significantly changed the reporting and content of articles concerning nanotechnology and nanomaterials in the French press. Indeed, articles concerning the safety of nanomaterials continue to appear.

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<sup>47</sup> La Libération (2010): **Nanotechnologies, le débat confisqué par la peur**, available from <http://www.Libération.fr/sciences/2010/01/27/nanotechnologies-le-debat-confisque-par-la-peur> 606519

<sup>48</sup> La Libération (2010): **Nanotechnologies : le débat tourne court**, available from <http://www.Libération.fr/sciences/2010/02/25/nanotechnologies-le-debat-tourne-court> 611996

<sup>49</sup> La Libération (2011): **Nanotechnologies : quelle place pour la France ?**, available from [http://www.lesechos.fr/28/03/2011/LesEchos/20899-43-ECH\\_nanotechnologies---quelle-place-pour-la-france--.htm](http://www.lesechos.fr/28/03/2011/LesEchos/20899-43-ECH_nanotechnologies---quelle-place-pour-la-france--.htm)

However, according to one article from the website 'Sciences et Avenir' from December 2013 (*'First report on the declaration of nanomaterials'*<sup>50</sup>) thanks to the mandatory reporting of nanomaterials in France, more is known of the use of nanomaterials in daily life.

### **Safety/Toxicity**

Following the introduction of the nano registry in France in 2013, articles concerning the safety of nanomaterials continued to appear. Indeed, in September 2013, an article was published in the Journal of the Environment entitled *'Nanomaterials, a professional risk'*<sup>51</sup> which detailed the economic importance of nanomaterials to France but also raised concerns over its safety for workers in many fields. In particular, this article suggests there is insufficient epidemiological data and also claims there are similarities between nanomaterials and asbestos. Additionally, in May 2013 an article in Le Monde (*'The toxicity of nanomaterials confirmed by an American study'*<sup>52</sup>) detailed that the toxicity of nanomaterials had in fact been confirmed by an American study.

Additionally, the website VeilleNanos ([veillenanos.fr](http://veillenanos.fr)) is a comprehensive source of information on nanomaterials and nanotechnology. This website is managed by the association AVICENN, a citizens association which aims to inform people, with impartial and independent information, on nanomaterials and nanotechnology. The association claims to not defend or attack nanomaterials and nanotechnology but simply defends the rights of citizens to be informed so that they are able to take part in discussions and decisions. The website publishes a significant level of information on the risks and issues concerning nanomaterials and in reference to the specific fields of application, e.g. food, environment, health, cosmetics and ethics. Importantly, VeilleNanos has been active since before the introduction of the nano registry in France in 2013 and continues to publish information.

### **Further Developments**

As well as articles concerning the possible safety of nanomaterials and nanotechnology, articles concerning the economic development of nanotechnology and also the use of nanotechnology in medicine have been published since 2013.

### **Economic Development**

In spite of concerns regarding the safety of nanotechnology and nanomaterials, articles on the economic importance also continue to be published. For example, an article was published in the Science supplement of Le Monde in April 2013 (*Nanotechnology, a pathway between promises and questions*<sup>53</sup>) which concerned the reasons for the slow economic development of nanotechnology. The article suggests that analysts are unanimous in their understanding that future industrial and

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<sup>50</sup> Sciences et Avenir (2013): **Premier bilan sur la déclaration des nanomatériaux**, available from <http://www.sciencesetavenir.fr/nature-environnement/20131202.OBS7844/premier-bilan-sur-la-declaration-des-nanomateriaux.html>

<sup>51</sup> Journal de l'Environnement (2013): **Les nanomatériaux, un risque professionnel**, available from <http://www.journaldelenvironnement.net/article/les-nanomateriaux-un-risque-professionnel,36421>

<sup>52</sup> Le Monde (2013): **La toxicité des nanomatériaux confirmée par une étude américaine**, available from [http://www.lemonde.fr/planete/article/2013/05/07/la-toxicite-des-nanomateriaux-confirnee-par-une-etude-americaine\\_3172367\\_3244.html](http://www.lemonde.fr/planete/article/2013/05/07/la-toxicite-des-nanomateriaux-confirnee-par-une-etude-americaine_3172367_3244.html)

<sup>53</sup> Le Monde (2013): **Les nanotechnologies, une filière entre promesses et interrogations**, available from [http://www.lemonde.fr/sciences/article/2013/04/10/les-nanotechnologies-une-filiere-entre-promesses-et-interrogations\\_3151370\\_1650684.html](http://www.lemonde.fr/sciences/article/2013/04/10/les-nanotechnologies-une-filiere-entre-promesses-et-interrogations_3151370_1650684.html)



societal revolutions will include nanotechnology and that countries who do not take part in this development will have great economic difficulty in the future. However, the article also suggests that from a global point of view, the predicted boom in nanotechnology was premature and the major economic impact from nanotechnology should not be expected until 2020.

Importantly, unlike other articles on nanotechnology, this article emphasises that *'from a societal point of view, the media hype surrounding this subject has created a reaction from citizens who have started to ask questions on the health impacts, environmental impacts and impacts on their private life'*. The article suggests that no one was prepared for these questions and consequently errors were made in the assessment, or in the communication on the use of certain substances which resulted in a slowdown in the development of these technologies. Additionally, the article emphasises that another reason for the delay in the industrialisation of nanotechnology is linked to a point that has been completely under-estimated, which is the time required for a scientific discovery or a particular property, to the realisation of a product. This process is not automatic and requires the development of technology to make an industrial process. In the field of technological research this is known as the 'Valley of Death' because the chance of failure at this stage of the process is large, development is difficult to predict and public funding for this stage of the development is scarce. It is in this stage that a large number of developments are abandoned, not for technical reasons but for economic ones.

More specifically, an article published on the website 'L'Usine Nouvelle' entitled *'Why France cannot break into the race for nanotechnology'*<sup>54</sup> explored the reasons why France is not challenging on the global scale in the nanotechnology field. Indeed, according to this article, in spite of France taking steps to build its nano strategy and infrastructure, investment is still too low to compete with countries like the USA. A lack of public and private investment is hindering the development of this field and to compete globally France requires better knowledge and an acceleration of the process from technology to industrial application.

### *Nanomaterials and Medicine*

In spite of the apparent slow development of nanotechnology in France, a number of articles appeared regarding the importance of nanomaterials in medicine. Indeed, France TV reported on the use of nanotechnology in the treatment of cancer in January 2014<sup>55</sup>. Furthermore, in February 2014, an article in Les Echos (*'Nanotechnologies applied to medicine: France is in pole position'*<sup>56</sup>) highlights that France is at the forefront of the development of nanotechnology for the medical field with major laboratories already active in this area and a significant level of academic research already undertaken. This position was also mirrored by an article in La Libération which was published in February 2014 (*'Nanomedicine: a market which could reach \$129 billion by 2016'*<sup>57</sup>). This article emphasises that

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<sup>54</sup> L'Usine Nouvelle (2013): Pourquoi la France n'arrive pas à percer dans la course aux nanotechnologies, available from <http://www.usinenouvelle.com/article/pourquoi-la-france-n-arrive-pas-a-percer-dans-la-course-aux-nanotechnologies.N218786>

<sup>55</sup> FranceTV (2014): VIDEO. La nanotechnologie, nouvelle arme contre le cancer, available from [http://www.francetvinfo.fr/sante/video-la-nanotechnologie-nouvelle-arme-contre-le-cancer\\_497716.html](http://www.francetvinfo.fr/sante/video-la-nanotechnologie-nouvelle-arme-contre-le-cancer_497716.html)

<sup>56</sup> Les Echos (2014): Nanotechnologies appliquées à la médecine : la France en pole position, available from <http://www.lesechos.fr/entreprises-secteurs/grande-consommation/actu/0203305056880-nanotechnologies-appliquees-a-la-medecine-la-france-en-pole-position-649388.php>

<sup>57</sup> La Libération (2013): Nanomédecine: un marché qui atteindrait 129 milliards de dollars en 2016, available from [http://www.Libération.fr/economie/2014/02/13/nanomedecine-un-marche-qui-atteindrait-129-milliards-de-dollars-en-2016\\_979997](http://www.Libération.fr/economie/2014/02/13/nanomedecine-un-marche-qui-atteindrait-129-milliards-de-dollars-en-2016_979997)



France has a number of important ‘assets’ in this field including the research facilities in Grenoble (Minatec) and the Galen Institute at Chatenay-Malabray and 30 companies already active in this field. However, like the overall development of nanotechnology in France, this article suggests a lack of investment is a weakness to further development.

### 4.3 Nanomaterials in Cosmetic Products in the Press

Reporting on the use of nanomaterials and nanotechnology in cosmetics is limited in the mainstream press in the EU, and to date has focused mainly on regulatory and political developments relating to the use of nanomaterials in cosmetics including measures such as labelling guidelines and REACH. For example, an article in the UK based Daily Telegraph from July 2013 reported on the ‘new labelling laws for beauty products’<sup>58</sup> and provided a brief summary of the new regulation and impacts on labelling. Importantly, this article did not appear in the main section of the newspaper nor in the science supplement but in the section relating to fashion. Additionally, in January 2014, an article appeared on the website of The Guardian ([www.theguardian.com](http://www.theguardian.com)) which discussed the use of nanomaterials in toothpaste<sup>59</sup>. It discussed specifically hydroxyapatite, silver and titanium dioxide explaining their functions in toothpaste and possible safety concerns. Interestingly, the website for the Guardian (UK) has a section entitled ‘Nanofutures’<sup>60</sup> (in association with Nanopinion) which is dedicated to articles and discussions concerning the uses of nanomaterials and nanotechnology, and developments in this field.

Reports and articles concerning nanotechnology and cosmetics specifically have, however, appeared more frequently in specialised media outlets such as publications and websites related to the cosmetics industry. The website Cosmetics Design Europe ([www.cosmeticsdesign-europe.com](http://www.cosmeticsdesign-europe.com)) has published many articles on nanotechnology and cosmetics including regulatory developments and developments in areas such as risk management and novel applications of nanomaterials. For example, in September 2013, an article concerning the more effective development of silver nanoparticles for cosmetics was published. Additionally, similar websites such as ‘Personal Care Magazine’ ([www.personalcaremagazine.com](http://www.personalcaremagazine.com)) and ‘Cosmetics and Toiletries – Science Applied’ ([www.cosmeticsandtoiletries.com](http://www.cosmeticsandtoiletries.com)) also report on developments in the uses of nanotechnology in cosmetics in terms of both regulatory and scientific developments. The industry association Cosmetics Europe ([www.cosmeticseurope.eu](http://www.cosmeticseurope.eu)) often reports on scientific developments in the field of nanotechnology and EU regulations.

Websites focusing on nanotechnology also report heavily on the use of nanotechnology and nanomaterials in cosmetics. The website of Nanopinion ([nanopinion.eu](http://nanopinion.eu)), an EC-funded project which monitors public opinion on innovations in nanotechnology has a section dedicated to cosmetics. It discusses innovative uses of nanotechnology in cosmetics and also highlights potential risks (see <http://nanopinion.eu/en/about-nano/cosmetics>). In a similar vein, the website Safe Cosmetics ([www.safecosmetics.org](http://www.safecosmetics.org)) has a section dedicated to the use of nanotechnology in cosmetics<sup>61</sup>. This web page discusses the uses of nanomaterials in cosmetics, highlighting particularly potential risks.

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<sup>58</sup> Young K. (2010): **New labelling laws for beauty products**, available from <http://fashion.telegraph.co.uk/beauty/news-features/TMG10171734/New-labelling-laws-for-beauty-products.html>

<sup>59</sup> Cave H. (2010): **The nanotechnology in your toothpaste**, available from <http://www.theguardian.com/what-is-nano/small-world/nanotechnology-in-your-toothpaste>

<sup>60</sup> Nanofutures can be found at <http://www.theguardian.com/what-is-nano>

<sup>61</sup> Nanotechnology - <http://www.safecosmetics.org/article.php?id=307>

For example, the page discusses the fact that preliminary scientific research has shown that many types of nanoparticles can be toxic to human tissue and cell cultures, resulting in increased oxidative stress, inflammatory cytokine production, DNA mutation and even cell death. They can penetrate cell walls, including organ tissues, and are known to be highly reactive. Additionally this page highlights possible risks to workers, suggesting possible similarities between asbestos and carbon nanotubes.

The French website 'VeilleNanos', which is a site dedicated to informing citizens of nanotechnology and nanomaterials, has a section dedicated to nanotechnology and cosmetics. This section of the website provides articles and links to regulatory information as well as articles and links to publications on the hazards and risks of nanomaterials. For example, in December 2013, VeilleNanos published a short article on the state of knowledge on the skin penetration of nanoparticles<sup>62</sup>. This issue was also discussed in an article published by VeilleNanos in October 2012 entitled 'Resumption of debate on the ability of nanoparticles to cross the skin barrier'.<sup>63</sup>

Of interest to this study will be recording the media reaction, if any, to the publication of the catalogue of nanomaterials contained in cosmetic products.

Media influence public perception and consumers' behaviour.

#### 4.4 The FNS, the CPNP and the RAPEX system

RAPEX (Rapid Alert System for Non-Food Dangerous Products) is an EU system which allows the rapid exchange of information between Member States and the European Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers. The system does not apply to food, pharmaceutical and medical devices, which are covered by other mechanisms<sup>64</sup> but is applicable to cosmetics. Since 2010, the system has also encompassed the rapid exchange of information on products posing a serious risk to the health and safety of professional users and on those posing a serious risk to other public interests protected via the relevant EU legislation.<sup>65</sup> Under the RAPEX system, national contact points contact the EC (DG SANCO) regarding the product, risks posed and measures taken to eliminate this risk. The EC then disseminates this information to other EU Member States who take appropriate action to check if the product is present on the market, and where necessary take steps to eliminate the risk.<sup>66</sup>

The RAPEX system was introduced in 2003 and has seen significant growth in the numbers of notifications disseminated since this date. Indeed, in 2003 there were 139 notifications whilst in 2012

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<sup>62</sup> VeilleNanos (2013): **Quel état des connaissances sur la pénétration cutanée des nanoparticules?** available from <http://veillenanos.fr/wakka.php?wiki=201312PenetrationCutaneeNano>

<sup>63</sup> VeilleNanos (2012): **INTERNATIONAL : Relance de la polémique sur la capacité des nanoparticules à traverser la barrière cutanée,** available from <http://veillenanos.fr/wakka.php?wiki=NanoBarriereCutaneeOct2012>

<sup>64</sup> EC (nd): **RAPEX,** available from <http://ec.europa.eu/consumers/safety/rapex/alerts/main/index.cfm?event=main.listNotifications&CFID=5611861&CFTOKEN=40607236&jsessionid=089cf1575ba9819c705fb667757d3937b5e2>

<sup>65</sup> EC (2014): **Rapid Alert System for Non-Food Products Posing a Serious Risk,** available from [http://ec.europa.eu/consumers/safety/rapex/index\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/index_en.htm)

<sup>66</sup> EC (2013): **How Does it Work? RAPEX – Statistics and Reports,** available from [http://ec.europa.eu/consumers/safety/rapex/how\\_does\\_it\\_works\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/how_does_it_works_en.htm)

this figure had grown to 2,278.<sup>67</sup> In terms of product categories notified under the RAPEX system, clothing, textiles and fashion items were the most notified in 2012 (34%), followed by toys (19%), electrical appliances and equipment (11%), motor vehicles (8%) and cosmetics (4%).

The functioning and purposes of the CPNP, the FNS and the RAPEX system are different in nature:

- the CPNP can be seen as a precautionary instrument to enable the SCCS to carry out a pre-screening and/or further investigate on the properties of the nanomaterials if deemed necessary on the basis of the physicochemical parameters, the intended use, the route of exposure and the toxicological data available;
- the RAPEX system is a tool enabling a rapid action on the EU market once a hazard or risk posed by a product has been discovered;
- the FNS has the purpose to light up the supply chains of the nanomaterials, where it is often uncertain the presence of substances in nanoforms in consumer products.

On this basis, the three systems are not alternatives one to each other but they complement their action.

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<sup>67</sup> EC (2014): **RAPEX – Statistics and Reports**, available from [http://ec.europa.eu/consumers/safety/rapex/stats\\_reports\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/stats_reports_en.htm)

## 5 Initial Assessment of Competitiveness and Innovation Impacts

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The initial assessment of the competitiveness and innovation impacts of the Notification schemes will be based on the results of the online survey launched on 27 February 2014.

Veillenanos<sup>68</sup> reports some critics to the French Notification System by the *Union des Industries Chimiques* (UIC): the FNS is seen as a “financial and bureaucratic burden” posed on the companies. The main difficulties are related to:

- Problems in identifying what is included or excluded in the nanomaterials definition;
- The Characterisation of the nanomaterials;
- The complexity of the system, that is poorly adapted to the reality of the supply chain.

In particular, there is confusion with regard to the role of subcontractors and there are technical problems in importing data from suppliers located outside France. Chemical mixtures could be imported from an EU country that received a premix from an Asian company that received the nanomaterials from an American firm. Moreover, the existence of a single deadline for all the notifiers disregarding the position in the supply chain causes difficulties to the downstream actors.

Both UIC and AVICENN<sup>69</sup> will be attending the meeting on 10 March 2014: their positions will be collected and explored together with the opinions of the other participants.

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<sup>68</sup> <http://veillenanos.fr/wakka.php?wiki=DeclarationObligatoireNanoFrance>

<sup>69</sup> Publisher of Veillenanos.

## 6 Extrapolation of the Results of the French Scheme to the EU Level

The identification of the critical issues for the extrapolation of the results of the French Notification System to the EU level will be based on the analysis of the data collected through the online survey of the companies and of the aggregated data requested to the French authorities and DG SANCO on their respective registries.

One critical element is the estimate of the full compliance rate. Figure 6-1 illustrates the data requirements, steps and assumptions for the extrapolation of the results.

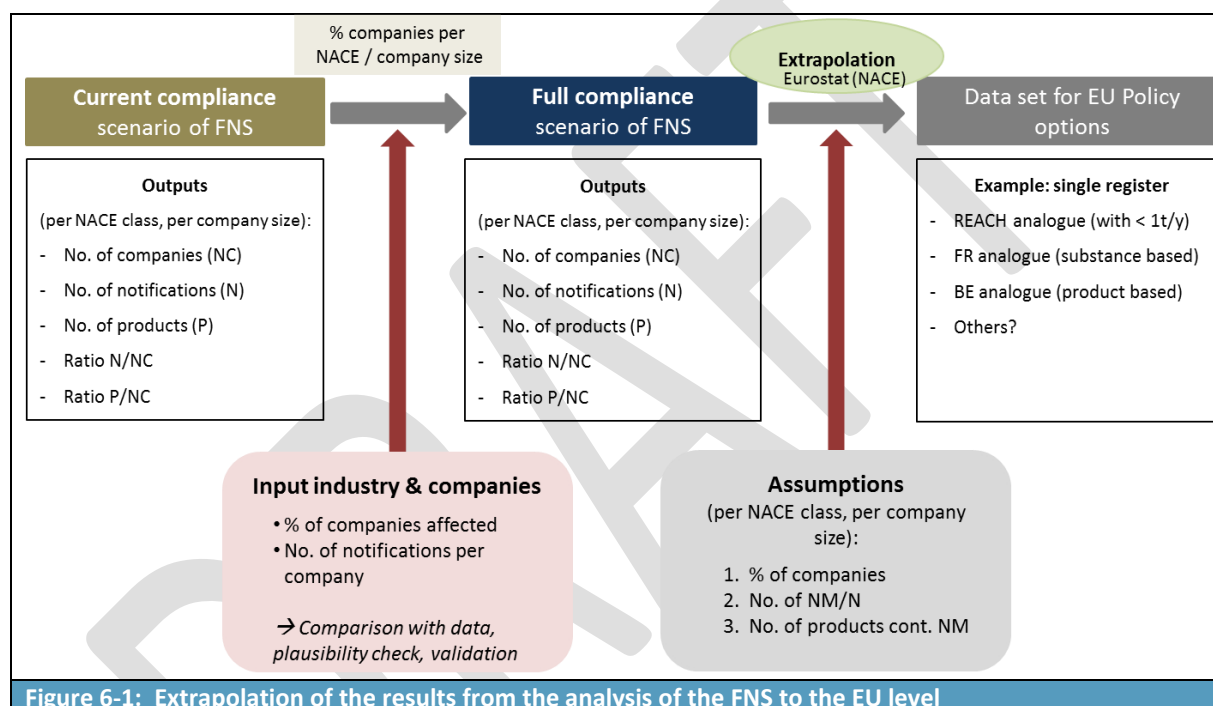


Figure 6-1: Extrapolation of the results from the analysis of the FNS to the EU level

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# Annex I Stakeholder Meeting Agenda

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## Study to Assess the Impact of Possible Legislation To Increase Transparency on Nanomaterials on the Market Stakeholder meeting

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Ministère de l'Ecologie, du Développement durable et de l'Energie  
Grande Arche de la Défense Paris  
18th Floor - Room 18N47

Within the European Union, France has become the first country to establish a mandatory reporting scheme for manufactured nanomaterials produced, imported or distributed in its territory. The Interministerial decree No. 2012-232 was published in February 2012 and entered into force in January 2013, allowing notifiers to submit their declarations until the 30<sup>th</sup> June 2013.

At the European level, when cosmetic products containing nanomaterials are put on the EU market, Article 16 of the Regulation (EC) No 1223/2009 requires the responsible persons to submit some information through the Cosmetic Product Notification Portal.

The European Commission (DG Enterprise and Industry) has now commissioned Risk & Policy Analysts Ltd. (RPA) and BiPRO GmbH to undertake a study to support the Commission on the preparation of an impact assessment to identify and develop the most adequate way to increase transparency and ensure regulatory oversight for nanomaterials.

Within this meeting, we would like to briefly present the study and its different tasks and gather relevant information on the experience of the companies in notifying information to the French Notification System (FNS) and, in particular, on the practical issues, the costs and the administrative burden that these obligations may put on the enterprises.

Time	Agenda
14:00	<b>Presentation of the study</b> (Marco Camboni, project manager) <ul style="list-style-type: none"><li>• Main objectives and work programme</li><li>• Objectives of the stakeholder meeting</li></ul>
14:30	<b>The French Notification System</b> <ul style="list-style-type: none"><li>• Presentation of the first results of the analysis (Marco Camboni)</li><li>• Open discussion: practical issues of the Notification System (all)<ul style="list-style-type: none"><li>• Interpretation of terminology (nanomaterials definition, quantities, etc.)</li><li>• Communication in the value chain</li><li>• Confidentiality and other critical issues</li></ul></li></ul>
15:30	<b>Value chain characterisation and assessment of competitiveness and innovation impacts</b> <ul style="list-style-type: none"><li>• Presentation of the first results of the analysis (Marco Camboni)</li><li>• Open discussion (all)</li></ul>
16:30	<b>Assessment of Long term human health and environmental benefits</b> <ul style="list-style-type: none"><li>• Presentation of the first results of the analysis (Marco Camboni)</li><li>• Open discussion (all)</li></ul>
17:00	End



# Annex II Questionnaire – Administrative burden of the Notification Schemes

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## Background to Study

Within the European Union, France has become the first country to establish a mandatory reporting scheme for manufactured nanomaterials produced, imported or distributed in its territory. The Interministerial decree No. 2012-232 was published in February 2012 and entered into force in January 2013, allowing notifiers to submit their declarations until the 30<sup>th</sup> June 2013.

At the European level, when cosmetic products containing nanomaterials are put on the EU market, Article 16 of the Regulation (EC) No 1223/2009 requires the responsible persons to submit some information through the Cosmetic Product Notification Portal.

The European Commission (DG Enterprise and Industry) has now commissioned Risk & Policy Analysts Ltd. (RPA) and BiPRO GmbH to undertake a study to support the Commission on the preparation of an impact assessment to identify and develop the most adequate way to increase transparency and ensure regulatory oversight for nanomaterials.

Within this project, we would like to gather relevant information on the experience of the companies in notifying information to the French Notification System (**FNS**) and the Cosmetic Products Notification Portal (**CPNP**) and, in particular, on the direct costs and the administrative burden that these obligations may put on the enterprises.

For this purpose, we have prepared the following questionnaire. In order for this survey not to constitute an additional burden for you, we have tried to keep it short: the 15 questions should take no more than 45 minutes to complete.

If you require further information about the study, please do not hesitate to contact the Project Manager, Marco Camboni, by e-mail ([marco.camboni@rpald.co.uk](mailto:marco.camboni@rpald.co.uk)) and/or telephone number (+44 1508 528465) or, alternatively, Craig Hawthorne, BiPRO project manager, by email ([craig.hawthorne@bipro.de](mailto:craig.hawthorne@bipro.de)) and/or telephone number (+49-89-18979050).

**We would be very grateful if you could provide your responses by 21<sup>st</sup> March 2014 at the latest. If you will need more time to provide your response, kindly let us know as soon as possible using the email address above.**

1. Please provide the following details:

Organisation (*compulsory):	
Location* (City and Country):	
Primary business sector ( <a href="#">NACE 4 digit code</a> ):	
Secondary business sector ( <a href="#">NACE 4 digit code</a> ):	
Contact name:	
Telephone number:	
E-mail address*:	

2. Please indicate your **role(s) in the supply chain (multiple ticks possible)**. In case of multiple ticks, please indicate which one is your primary role if possible.

	Role(s)	Primary role
Manufacturer		
Distributor		
Importer		
Professional user and distributor		
Repackager and distributor		
European representative		
Public research organisation		

3. Please indicate the **number of employees** in your organisation.

1-9 employees	
10-49 employees	
50-249 employees	
≥ 250 employees	

4. Please indicate the approximate **annual turnover** of your organisation and **the annual turnover which relates to nanotechnology** (nanomaterials, mixtures and/or articles containing nanomaterials).

	Annual turnover		Nano-related annual turnover
Less than €250k		Less than €250k	
Between €250k and €2m		Between €250k and €2m	
Between €2m and €10m		Between €2m and €10m	
Between €10m and €50m		Between €10m and €50m	
Over €50m		Over €50m	

5. Please indicate the **number of nano-related products** (where these include substances in nanoform as well as mixtures and articles containing nanomaterials) that you place on the **French, EU and global market**. (NMs: nanomaterials; Mixt.: mixtures; Art.: articles)

	French market			EU market			Global market		
	NMs	Mixt	Art	NMs	Mixt	Art	NMs	Mixt	Art
Less than 6									
Between 6 and 10									
Between 11 and 50									
Between 51 and 100									
Between 101 and 250									
Between 251 and 500									
Between 501 and 1,000									
Over 1,000									

6. Please indicate the **number of customers** and, if applicable, **number of suppliers** for all your nano-related products combined (where these include substances in nanoform as well as mixtures and articles containing nanomaterials).

	No. of customers	No. of suppliers
Less than 6		
Between 6 and 15		
Between 16 and 30		
Between 31 and 50		
Between 51 and 100		
Over 100		

7. Please indicate the **number of notifications** you submitted to the FNS in 2013 and 2014 (already submitted or planned to be submitted this year). If applicable, please indicate the number of notifications with information on nanomaterials you submitted to the CPNP.

Number of notifications	2013	2014
French Notification System		
Cosmetic Products Notification Portal		

8. Please indicate how your organisation **generated and/or gathered the information** to be notified to the FNS and, if applicable, to the CPNP.

	FNS	CPNP
We generated (internally or outsourced) all the information for the purpose of product development and of complying with other legislation, so it was already available for notification		
We generated (internally or outsourced) all the information required by the regulation for the purpose of the notification		
We generated part of the information required for the purpose of the notification, since some information were already available		
We referred to the declaration number(s) of the supplier(s) for the “substance identity” part		

9. Please indicate if actions to comply with other pieces of EU legislation (if any) helped in meeting **the information requirements** of the FNS and, if applicable, of the CPNP.

	FNS	CPNP
Regulation (EC) No 1907/2006 ( <b>REACH</b> ) (i.e. information from registration dossiers)		
Regulation (EC) No 1272/2008 ( <b>CLP</b> ) (i.e. information from safety data sheets)		
Regulation (EC) No 1223/2009 ( <b>Cosmetic Products</b> )		X
Regulation (EU) No 528/2012 ( <b>Biocidal Products</b> )		
Regulation (EC) No 258/1997 ( <b>Novel Food</b> )		
Regulation (EC) No 1935/2004 ( <b>Food Contact Material</b> )		
Regulation (EU) No 1169/2011 ( <b>Food information to consumers</b> )		
Council Directive 98/24/EC ( <b>Chemical Agents Directive</b> )		
Interministerial decree No. 2012-232 ( <b>French Notification System</b> )	X	
Other (please specify)		
<i>Please explain:</i>		

10. Please estimate the **annual total cost/burden for all notifications** incurred by your organisation to comply with the notification requirements for the FNS and, if applicable, the CPNP.

French Notification System			
Type of cost/burden	Unit	2013	2014
Understanding of the legal requirements	Total hours		
Gathering of information to be submitted	Total hours		
Substance analysis characterisation costs (only the part of information generated for the purpose of the notification)	Euros (€) and/or total hours		
Submission of the information	Total hours		
Responding to clients' enquiries	Total hours		
IT alignment and/or adapting product/account databases	Euros (€) and/or total hours		
Other: <i>&lt;please specify&gt;</i>	<i>&lt;please specify&gt;</i>		
Cosmetic Products Notification Portal			
Type of cost/burden	Unit	2013	2014
Understanding of the legal requirements	Total hours		
Gathering of information to be submitted	Total hours		
Substance analysis characterisation costs (only the part of information generated for the purpose of the notification)	Euros (€) and/or total hours		
Submission of the information	Total hours		
Responding to clients' enquiries	Total hours		
IT alignment and/or adapting product/account databases	Euros (€) and/or total hours		
Other: <i>&lt;please specify&gt;</i>	<i>&lt;please specify&gt;</i>		

11. Please indicate which part of the information to be submitted to the **French Notification System** has proven to be the most burdensome. Please rate each part on a scale between 1 and 5 (1: least burdensome; 5: most burdensome).

	1	2	3	4	5
Identity of the notifier					
Information on the notification (ex.: role in the supply chain)					
Identity of the substance (ex.: CAS number, primary particle size, shape)					
Quantities					
Uses					
Customers (professional users)					

12. Please indicate if your organisation had difficulties (and on what) with respect to the **interpretation of terminology** used in the regulations.

	FNS	CPNP
Definition of nanomaterial used		
Scope (who has to notify, what needs to be notified, exemptions etc.)		
Calculation of volumes related to volume thresholds		
Other (please specify)		
<i>Please explain:</i>		

13. Please indicate the **percentage of the different cost types** in the total cost of manufacturing/importing/distributing nanomaterials in your organisation.

	%
Production costs (raw materials, personnel, utilities, overheads, etc.)	
Transaction costs (marketing, labelling, distribution, etc.)	
Costs related to regulatory obligations	
<b>Total</b>	<b>100</b>

14. Please estimate the **regulatory burden share** of the following pieces of chemicals legislation.

	%
Regulation (EC) No 1907/2006 ( <b>REACH</b> )	
Regulation (EC) No 1272/2008 ( <b>CLP</b> )	
Regulation (EU) No 528/2012 ( <b>Biocidal Products</b> )	
Regulation (EC) No 258/1997 ( <b>Novel Food</b> )	
Regulation (EC) No 1935/2004 ( <b>Food Contact Material</b> )	
Regulation (EU) No 1169/2011 ( <b>Food information to consumers</b> )	
Council Directive 98/24/EC ( <b>Chemical Agents Directive</b> )	
Other (please specify)	
Interministerial decree No. 2012-232 ( <b>French Notification System</b> )	
Regulation (EC) No 1223/2009 ( <b>Cosmetic Products</b> ) – Notification to the CPNP	
<b>Total</b>	<b>100 %</b>

15. Please indicate the **magnitude of the impacts** that the FNS and, if applicable, the CPNP had on your nanomaterials business.

Impact category	Very negative	Negative	No change	Positive	Very positive	Not applicable
<b>French Notification System</b>						
Impact on your ability to develop and market new products containing nanomaterials in France						
Impact on intra-EU competitiveness (your ability to successfully compete with manufacturers from other EU member states on the EU market)						
Impact on extra-EU competitiveness (your ability to compete with manufacturers from outside EU on the global market).						
Impact on Research & Development						
Impact on Intellectual Property rights and confidentiality aspects						
Impact on public perception of nanomaterials						
Other <please specify>						
<i>Please explain:</i>						
<b>Cosmetic Products Notification Portal</b>						
Impact on your ability to develop and market new products containing nanomaterials in France						
Impact on intra-EU competitiveness (your ability to successfully compete with manufacturers from other EU member states on the EU market)						
Impact on extra-EU competitiveness (your ability to compete with manufacturers from outside EU on the global market).						
Impact on Research & Development						
Impact on Intellectual Property rights and confidentiality aspects						
Impact on public perception of nanomaterials						
Other <please specify>						
<i>Please explain:</i>						

Please use the following space for **any comments** you would like to add.

**Thank you very much for answering our questions.**

DRAFT

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