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

Evaluation Report

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List of Abbreviations

AC	Article Category
Anses	*Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail*
ANSM	*Agence Nationale de Sécurité du Médicament et des Produits de Santé*
AVICENN	*Association de veille et d'information civique sur les enjeux des nanosciences et des nanotechnologies*
BNS	Belgian Notification System
Cefic	European Chemical Industry Council
CCT	UK Environment Agency Chemical Compliance Team
CLI	Classification and Labelling Inventory
CPNP	Cosmetics Products Notification Portal
DPR	Danish Product Registry
Defra	UK Department for Environment, Food & Rural Affairs
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Economic Area
EFTA	European Free Trade Association
ERC	Environmental Release Category
EU	European Union
ESIS	European chemical Substances Information System
FNS	French Notification System
FPS	Belgian Federal Public Service on Health, Food Chain Safety and Environment
GMO	Genetically Modified Organisms
Ineris	*Institut National de l'Environnement Industriel et des Risques*
INRS	*Institut national de recherche et de sécurité pour la prévention des accidents du travail et des maladies professionnelles*
InVS	*Institut de Veille Sanitaire*

MEDDE	*Ministère de l'Écologie, du Développement durable et de l'Énergie*
NIA	Nanotechnologies Industries Association
nm	Nanometre
NM	Nanomaterial, as defined by the French authorities, unless otherwise stated
OECD	Organisation for Economic Co-operation and Development
PC	Chemical Product Category
PEG	Polyethylene Glycol
PET	Polyethylene Terephthalate
PROC	Process Category
R&D	Research and Development
SCCS	Scientific Committee on Consumer Safety
SU	Sector of Use
ToR	Terms of Reference of this study
tpa	Tonnes per annum
UIC	*Union des Industries Chimiques*
UK	United Kingdom
VAT	Value Added Tax
XAN	The XAN number is the name approved by a specific country (X) for a cosmetics product
WFD	Water Framework Directive

Executive Summary

This report is one of several outcomes of a study on transparency measures on nanomaterials within the EU. To date, two relevant register-like schemes – both concerning nanomaterials and operating within the EU – have been established: the French Notification System (FNS) and the Cosmetic Products Notification Portal (CPNP). Meanwhile, other transparency measures have been established or proposed by EU states.

Clearly, lessons can be learned from these measures, and as such this report aims to evaluate their pros and cons, successes and failures, and to ensure that this information is fully utilised in the future identification and development of any EU wide solution.

It contains:

- *A review of the legislation underpinning transparency measures in the European Union;*
- *Findings from a key stakeholder meeting, run as part of the project;*
- *Analysis of publically available information about the FNS (with support from Cefic, the NIA and their members) – including analysis of the substances for which notifications to the FNS were made and comparison of the list with the ECHA registered substances database and the Classification and Labelling Inventory;*
- *The results of an online survey, run as part of the project, of company views on the financial and administrative burdens associated with notification;*
- *Information from questionnaires sent to the French authorities and DG SANCO;*
- *Analysis of the debate in France concerning the notification system; and*
- *The feedback from stakeholders (industry, authorities and NGOs) on the preliminary results of the study as presented during the Validation Workshop held in Brussels on 30 June 2014.*

The measures differ significantly in terms of the materials subject to notification. The FNS, for example, asks for manufactured nanomaterials and manufactured nanomaterials contained in mixtures. But, in Belgium, the manufactured nanomaterials and the mixtures containing nanomaterials must be registered. Additionally, nanomaterials regulated by other legislation are exempt. This perhaps reveals a diversity of ideas regarding both which materials are important and how the recorded data might be used. They also differ in their legislative environment, with some established specifically for nanomaterials and others, such as the CPNP and the Norwegian registry, merely including nanomaterials within the context of chemicals more generally.

But in other regards the measures are similar. In general, the information requirements are similar, including for example the notifier's identity, the physicochemical parameters of the nanomaterials and quantities.

As the first mandatory reporting scheme to be established, the FNS is of particular interest. The general aim of the legislators was to improve the information available to consumers, workers and the wider public. As of 1 July 2013, the authorities had received 3,409 notifications from 933 notifiers.

In 2013, the total administrative burden for the companies having to notify has been estimated at between ***€8 million and €15.5 million:*** *for the generation of information with regard to the characterisation of nanomaterials, the cost for industry stakeholders has been estimated at between* ***€5.5 million and €13 million;*** *the estimated total costs for the gathering and submitting of the*

information, for responding to clients' enquiries and for the adaptation of the product/account databases was ***around €2.6 million****. Assuming that, in a full compliance scenario, the number of notifications will be between 15,000 and 20,000 per year, the total recurring costs would range between* ***€750,000 and €1 million per year****. The administrative burden posed by the FNS is predominantly a result of substance characterisation activities, but a good deal of resources were spent on familiarisation with and understanding of the legislation, as well as interpretation of the nanomaterial definition and the terminology. It should be noted, however, that the amount of time spent in dealing with the notification obligations is expected to decrease significantly as companies become more familiar with the legislation and accumulate experience in this area. Moreover, during the validation workshop, trade unions and non-governmental organisations highlighted that the costs entailed by the FNS should not be considered as administrative burden, as companies should characterise their NMs to ensure that they are used safely and thus to comply with health and safety legislation.*

During the stakeholder meeting held in Paris in March 2014, consistently in the answers to the survey, during the interviews for the development of the case studies and during the validation workshop, industry stakeholders reported a high degree of mistrust of the scheme among their suppliers and customers, to the detriment of competitiveness and innovation. According to some, many commercial partners now ask for "no nano" products because they do not want to deal with the additional regulatory burdens. This might lead companies to question whether to invest money in the R&D of nanomaterials.

Moreover, the scope of the scheme is deemed to be too broad by industry as it is considered unnecessary to notify nanomaterials that many companies consider to have been 'safely commercialised for decades' and that have been thoroughly assessed in many applications. Industry describes the objective of the notification system as unclear and consider the added-value in comparison with the EU chemicals legislative framework as questionable.

Consumer and environmental organisations welcome the French initiative: to them, it is a first step towards better regulation of an under-regulated area. A French NGO noted however that the initiative is hampered by insufficient transparency, as the system does not allow identification of the consumer products containing nanomaterials and the information that was made public seems to confirm that many nanomaterials have been used in many applications for many years and do not focus on the nanomaterials of most concern but actually provides a catalogue of ultrafine dusts (notably pigments and dyes) that, in their opinion, do not rise concerns over their common applications.

The virtual absences from the public report of nanomaterials such as nanosilver and carbon nanotubes (under this name), which most of the concern around nanomaterials are based on, undermine the trust that consumer organisations have in the notification system as a useful device for enhancing the transparency on nanomaterials on the market. Nanosilver in particular might be contained in articles entering the French market and since articles containing nanomaterials (not intended to be released) are not within the scope of the FNS, the system is not able to adequately detect and monitor them.

The French authorities reported that some of the information gathered through the FNS for two "families" of nanomaterials (carbon nanotubes and titanium dioxide) will be passed to researchers and used within an epidemiological study focusing on workers. More generally, the French authorities can identify companies manufacturing or handling these nanomaterials and provide designated institutes and organisations the gathered data for risk assessment of specific nanomaterials, while collecting additional data on hazards and exposure. However, in the opinion of the consultants, the assessment of the exposure to some nanomaterials and the medical monitoring

of the workers could have been agreed anyway with the relevant companies, asking for their collaboration in providing the characterisation of the nanomaterials under investigation, their quantities and the identity of their downstream users. The setting up of a mandatory notification system does not seem fully justified, in the opinion of the consultants, by the planning of epidemiological studies, as these need anyway the collaboration of the companies involved. The notification system will indeed provide some data time series (with regard to workers' population exposure) that might be of value in the coming years for the study of any chronic effect of the nanomaterials. This value resides on the ability to enable a better monitoring of exposure pattern changes and to identify any potential disease directly related to the nanoform(s) of the substances or to focus on the potency of the nanoform(s) fraction of the substances to which the cohorts are exposed.

In terms of ability to deliver benefits to human health and the environment, the value of the full traceability achieved (or that will be achieved in the coming years) by the FNS on the professional users' market is, however, unclear. At the time of writing, November 2014, no accidents specifically linked to the use of nanomaterials have been found in the literature by the consultants (as detailed in the Building Blocks report, Section 2). Two accidents have been reported involving the use of nanomaterials, however the health effects observed seem more related to poor working environments and the lack of proper risk management measures and do not seem specific to the nanomaterials. Moreover, most of the concerns surrounding nanomaterials refer to potential chronic rather than acute effects and thus the rapid action that traceability allows might be of no use.

With regard to the environment and the quantification of any impact on the environmental media, it has to be noted that the French Notification System does not ask for Environmental Release Categories (ERC) descriptors, used for describing the broad conditions of use of the substances at the nanoscale from the environmental perspective and relevant for their subsequent service life in articles.

In terms of the level and quality of the information provided to the public, it is opinion of the consultants that the first public report lacks organisation and analysis: however, once the database is consolidated, the French authorities will be in a position to provide a good and in-depth overview on the nanomaterials manufactured, imported and distributed to professional users on the French market.

With regard to the information available to industry associations and workers' unions, the same limits found for the general public apply. The information made public provides a broad picture of the nanomaterials on the market but does not add much more to what it could be already known by an informed audience.

Nevertheless, companies with notification requirements and within the supply chains of nanomaterials did get new information thanks to the notification system: as this was designed to shed light on the supply chains, companies had to keep track of the quantities of nanomaterials handled, something that was not done before. Importantly, many downstream users became aware of their handling nanomaterials. This might led to some of them questioning the suitability of their risk management measures in dealing with nanomaterials.

The information generated by some manufacturers and importers on their nanomaterials might have some value with regard to the insurability of the nanomaterial production risk: currently nanotechnology liability risks reside outside conventional insurance practice given the impossibility to calculate insurance risk premiums, due to the knowledge gaps on the frequency and severity of the insurance losses. The information generated for notification purposes could provide key background information to enable such calculation: some physicochemical parameters (e.g. shape) have been

used in risk assessment and management for developing control banding tools that insurers might use as the basis for calculation of risk premiums.

Any conclusive assessment of the marginal value of the FNS in comparison with the current chemicals legislative framework will depend on the extent of the amendments of the REACH annexes, currently under consideration. The proposed amendment of the REACH annexes is aimed at collecting more information concerning nanomaterials, allowing for a better identification and characterisation of nanomaterials. At the time, on the basis of the consultants' analysis, over 60% of the substances notified to the FNS have REACH registration dossiers although these do not contain specific information on the nanoforms of the substances. By 2018, over 90% of the substances notified might have REACH registration dossiers. Notably, information on polymers at the nanoscale are captured by the FNS while polymers are outside of the scope of the REACH Regulation.

This assessment is based on the results of the first year of implementation of the notification system and its limits reside on the partial availability of the information and on the fact that it captures the picture of a device not running at "full regime" yet. Public authorities, as well as all the other stakeholders, will have the opportunity to learn from the experience of this pioneer exercise and to enhance the device where necessary.

1 Introduction

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:

- Task 1: Lessons learned from other schemes;
- Task 2: Background information for building blocks of policy options;
- Task 3: Organise and carry out public consultations;
- Task 4: Support for the option assessment; and
- Task 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). The results of task 1, together with the background information for building blocks of policy options (task 2, the findings of which are presented in the building blocks report) and the findings of the public consultation (launched in early May and closed on 5 August 2014) will support the option assessment. Moreover, the validation Workshop was held in Brussels on 30 June 2014, aiming to discuss with different stakeholders the preliminary findings of the study. The main points of discussion are presented in the Workshop report. When the discussion focused on some of the aspects of this report, this has been highlighted in the appropriate Sections.

1.1 Task Objectives

In order to gather relevant information on the experience from the FNS, 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 of 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, aiming to gather relevant information on the experience from this NMs registry. This subtask has been organised in five interrelated parts:

  - **Task 1.4a**: an industry stakeholders meeting has been organised in France (10 March 2014) 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 also served to maximise the response of participating companies to the targeted online survey;
  - **Task 1.4b:** qualitative and quantitative analysis of the FNS, aiming to identify critical aspects of the scheme, 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 scheme;
  - **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 has been 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**) has being organised on 10 March 2014 in Paris in conjunction with the session of French working group on nanomaterials' notification and it was hosted by the French *Ministère de l'Écologie, du Développement durable et de l'Énergie* (MEDDE).

The analysis of the FNS (**Task 1.4b**) is based on the public report[1] published by the French authorities on November 2013. Moreover, the list of substances notified to the FNS published in the French public report (Table 7 and 8, pages 27-80 and 81-108) has been analysed and compared with the

[1] French public report (2013): Éléments issus des declarations 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

ECHA registered substances database[2], the European chemical Substances Information System (ESIS[3]) and the Classification and Labelling Inventory.[4] For this exercise, valuable support has been provided by Cefic, NIA and their members. This exercise has been carried out in order to determine the level of information available on the substances notified to the FNS and if any of the information refers specifically to the nanoforms of the substances, as opposed to the substances in general. The results of this analysis are also important to appreciate any additional value of an EU-wide nanoregistry on top of the current chemicals legislative framework (REACH, CLP and the forthcoming amendments to the REACH Regulation). The comparison between the list of notified substances and the ECHA registered substances database is detailed in Section 3 of this report. The comparison with the CLI is detailed in the Building Blocks report. The conclusions of this analysis are presented in the Option Assessment report.

In parallel with the analysis of the available information, an online survey addressed to companies with relevant experience of the FNS and/or the CPNP was launched on 27 February 2014. The survey aimed 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 were sent to the French authorities and DG SANCO in order to gather information on the costs to set up and run the FNS and the CPNP for the public authorities.

An analysis of the past and current debate in France over the notification system has been carried out. This was done in order to model the potential impacts of the availability of the information, such as long term health and environmental benefits for consumers and workers stemming from changes in the public perception of nanomaterials and, ultimately, resulting in behavioural changes when dealing with nanomaterials of both workers (e.g. increased awareness over health and safety issues of nanomaterials) and consumers (e.g. aversion to products containing nanomaterials). (**Task 1.4d**). This analysis was also very important for the initial assessment of impacts on competitiveness and innovation (**Task 1.4e**). The assessment has being complemented with information gathered through the survey submitted to industry stakeholders.

The results and findings of the tasks described above have 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**).

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 functioning of the FNS and of the information available;
- Section 4 provides the assessment of the costs of setting up and maintain the FNS and the CPNP for the public authorities; it provides also some estimate for the implementation and running of the UK initiative;
- Section 5 presents the assessment of the administrative burden posed by the FNS on the companies having to notify to the FNS;

[2] http://echa.europa.eu/information-on-chemicals/registered-substances
[3] http://esis.jrc.ec.europa.eu/
[4] http://echa.europa.eu/web/guest/information-on-chemicals/cl-inventory

- Section 6 presents evidence for how the gathered information was used by authorities, consumers and workers and on what could be the potential impact on long term human health and environmental benefits; and
- Section 7 summarises the results of the analysis and draws some conclusions.

2 Overview of the Nanomaterials Transparency Measures

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.[5]

The following sub-sections provide an overview of the initiatives in Belgium, Denmark, Germany, Norway and the United Kingdom, and of the EU-wide Cosmetic Product Notification Portal. A summary presenting the main features of and differences between the transparency measures is provided at the end of this Section. The French Notification System is analysed in Section 3.

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.[6] 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 and communication issues along the supply chain. This is particularly true for importers.

[5] 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.

[6] BiPRO and Oko-Institute.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

The study also considered the risks, costs and benefits of inaction. It noted that some of the costs of inaction 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 market. However, other costs are better assessed from a political perspective (in terms of the level of transparency) or from a risk communication perspective, 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. It also mentions several other costs of inaction, such as the costs due to the implementation of multiple national and sectorial databases and difficulties in enforcement, health and safety surveillance, and dealing with false claims.

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

Based on these findings, the Belgian FPS developed a draft decree[7] 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. A political agreement was reached in February 2014[8] within the Belgian Council of Ministers.

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) 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;
2) 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;
3) 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;
4) The foodstuffs and materials and objects intended to come into contact with foodstuffs referred to in Article 1(1) and 1(2)(b) of the Law of 24 January 1977 on the protection of consumer health in regard to foodstuffs and other products;

[7] For details, see*Royal Decree on the market placement of substances manufacturedat the nanoscale*, SPF Santé publique, Sécurité de la Chaine 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

[8] http://www.laurette-onkelinx.be/production/content.php?ArticleId=100&PressReleaseId=515

5) 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;
6) Medicines and medicated animal feed falling within the scope of the Law of 21 June 1983 on medicated animal feed;
7) 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;
8) Pigments, defined as substances which are insoluble in typical suspension media, used for their optical properties in a mixture or article.

Although referring to the EC recommended definition on nanomaterial, the scope of the Belgian registry covers only manufactured 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 2-1.

Table 2-1: Information requirement of the Belgian Notification Register

No.	Information requirements	Comment
Section 1: Identification of the notifier		
1	Name of the person/company placing the substance on the market	-
2	*Banque Carrefour des Entreprises / Kruispuntbank van Ondernemingen* (KBO/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	-
Section 2: Identification of the substance		
1	Chemical identification of the substance(s), i.e. chemical name, chemical formula, CAS no., and, where applicable, the EC no (EINECS or ELINCS)	- 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
2	Average and median particle size, relative to a standard deviation	
3	Particle size distribution curve (by number)	
4	Average aggregate size and, if the substance is sold in the form of	

Table 2-1: Information requirement of the Belgian Notification Register		
No.	**Information requirements**	**Comment**
	agglomerates, the average agglomerate size, these sizes being given relative to a standard deviation when available	uncertainty): - method used to determine these variables, - explanation as to why this method is applicable to the substance concerned - description of the experimental conditions
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	-
Section 3: Quantity of the nanomaterial placed on the market during the reporting period		
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
Section 4: Uses of the nanomaterial (and, if applicable, of the mixture containing nanomaterial(s))		
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
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	*Banque Carrefour des Entreprises* (KBO/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 over the appropriate date of entry into force of the obligations regarding articles has been postponed.

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 to which consumers and the environment were exposed to nanomaterials, as well as the types of nanomaterials to which they were exposed.[9] Based on a screening process of products imported and manufactured in Denmark, the product categories “paint, varnish and 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”[10] category was added for products that 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.

[9] 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.

[10] Included in the category `miscellaneous´: catalysts, lubricants, fuel additives, polymer nano-composites such as thermoplastic products, tires and other rubber products

The impact assessment evaluated the administrative burden for Danish manufacturers and importers represented by the introduction of a nano-product database[11], where reporting requirements would be limited to products covered by the Danish Chemicals Act and exclude products already covered by other regulations.[12] 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 fewer than 50 employees (full-time equivalents) and almost 60% had fewer 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;
- Limited knowledge and issues associated with obtaining 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 as having 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.

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							

[11] 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.

[12] Foodstuff, foodstuff contact materials, feed additives, pesticides, medicine and medical equipment which are covered by other legislation.

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 minimise 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.[13] Table 2-3 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	***Moderate or substantial reduction of the amount of technical information to be reported for each nano-product*** 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 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.	***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.*** 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 the use of NMs in a subsequent environmental or health assessment.
2	***Exemption from reporting for products containing carbon black and/or non-catalytically active titanium dioxide***	Carbon black and titanium dioxide are NMs that have been long known. Additionally, they are used in large amounts as regular chemicals for a wide range of applications, meaning they are subject to registration under the REACH regulation. ***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%.*** 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

[13] 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**
		the health and environmental impacts is higher.
3	***Exemption from reporting for certain product groups,*** i.e. only chemical mixtures containing NMs and no other products such as articles containing nanomaterials	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. ***It is estimated that the total administrative burden in these product categories will be reduced by up to 90%.*** 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.
4	***Use of the information about mixtures already registered in the existing Danish Product Registry***[14] (DPR), so that only additional information about the nanomaterial in the mixtures has to be reported to the nano- product database	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 does not cover all nano-products. Therefore, importers of consumer products, i.e. ***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.*** Therefore, it is estimated that the administrative burden of these product categories will not be reduced considerably. On the other hand***, 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%*** when additional information about the NM in the mixtures still has to be reported to the nano-product database.

Table 2-4 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). The administrative burden of the product categories `Electronics and electronic products´ and `Miscellaneous´ are not included in the estimates of the total administrative burden.

[14] 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 2-4: 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							
Miscellan-eous	No data	No data	0	20-30	60-80	No data	No data	No data
Total hours of administrative burden for companies with nano-products			10.000 (100%)	8.000 (80%)	4.000 (40%)	7.500 (75%)	5.900 (59%)	9.200 (92%)
Total hours of administrative burden for companies without nano-products			11.000 (100%)	11.000 (100%)	11.000 (100%)	11.000 (100%)	3.700 (34%)	11.000 (100%)
Total administrative costs (hours)			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 with the first year of implementation.

Taking the results of both impact assessments into account, a draft order[15] for a nano-product register was written, 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[16] related to the draft order on 4th 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 5th November 2013 by submitting the draft order proposal.[17]

As stipulated in the 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.

[15] 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

[16] Information on the public consultation available at: http://hoeringsportalen.dk/Hearing/Details/16910

[17] 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

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.
k) Articles on which the nanomaterial is used as ink directly on the article or on the labels on the article, 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 voluntary 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 the rules for the protection of confidential information. The notifier can indicate whether specific information should be treated as confidential (trade secret), e.g. information on chemical information, substance identification, composition or purity. In this case, an appropriate justification must be delivered. The following information shall normally be regarded as confidential without this being specified separately by the notifier: 1) Details of the full composition of a mixture, 2) The precise use, function or application of a substance or mixture, including information about its precise use as an intermediate, 3) The precise tonnage of the substance or mixture manufactured or placed on the market and 4) Links between a manufacturer or importer and his distributors or downstream users. Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, the information referred to above may be disclosed. 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 in accordance with the Danish Public Administration Act rules on disclosure, 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 18thJune 2014 (art. 16) and the first reporting is due no later than 30thAugust 2015 for the period from 20th June 2014 to 20thJune 2015. The Danish Environmental Protection Agency will publish an annual report on the previous reporting year. The report will not contain confidential information. Reporting for producers and importers is obligatory on an annual basis and should be carried out digitally via the portal at http://virk.dk. Support for companies which have to notify will be provided in the form of a guidance document as well as in form of a help desk 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" (ENPR).[18] The proposed register revolves around the precautionary principle and is based on the possibility of negative effects on human health and the environment that could be the consequence of widespread use and subsequent exposure to nanomaterials of various origins. It 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.

[18] UBA (2012): *Concept for a European Register of Products Containing Nanomaterials*, German Federal Environment Agency.

A key criterion of the Concept is that regulatory overlaps and administrative efforts should be minimised. To this end, it suggests that an umbrella regulation sets out general provisions and that the register should be established at European, rather than national, level. Subject to notification are substances and mixtures that are themselves, 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; the product and trade name; and the name and address of the registrant. For confidentiality reasons, the proposed register would contain both a publicly accessible and a secured part.

In particular, for the characterisation of the nanomaterials, notifiers should submit the following data:

- Information on particle size and distribution
- Shape (length, width, form, etc.)
- Crystallinity
- Chemical composition
- Specific surface area (if applicable)
- Chemical composition of the surface region, if modified.

The concept paper served as a basis for a subsequent study assessing the impacts of a European register of products containing nanomaterials.[19]

The scope of this impact assessment (IA) concerned substances, mixtures and articles containing NMs, intended to be released under normal or reasonably foreseeable conditions of use, through the entire supply chain. An estimation of costs for notifiers and competent authorities related to the ENPR-concept was made, and benefits for public authorities, companies and consumers were assessed. Furthermore, a comparison between the ENPR and existing EU NM transparency measures was made. The IA identified as a potential obstacle the scope being unclear for some companies. Uncertainties occurred regarding the nano-definition and the obligations to notify, especially further down the supply chain and in articles. Many companies seemed to have no knowledge of the possible content of NMs in their products. Also it appeared to be unclear what information was already available via other legislations, such as REACH. Additionally, there seemed to be insufficient information present on NMs and their areas of application. Altogether, these obstacles resulted in the fact that companies found it difficult to estimate costs and reliable figures for a European nanoregister.

In order to estimate the total number of notifications, the authors carried out research to gain a preliminary estimation and to determine the number of companies per sector (based on NACE)[20],

[19] Öko-Institut and BiPRO (2014): Assessment of Impacts of a European Register of Products Containing Nanomaterials, Report prepared for the Federal Environment Agency (UBA). Available at: https://www.umweltbundesamt.de/publikationen/assessment-ofimpacts-of-a-european-register-of

[20] European Commission (2008). Statistical classification of economic activities in the European Community. NACE Rev.2.

and expert interviews (individual companies, industry representatives) were held to gain the following information:

- Verification of uses of nanomaterials in different application areas;
- Verification of whether notification obligations arise for nanoproducts selected;
- Complementing existing information;
- Estimation of number of notifications per sector;
- Estimation of number of companies concerned per sector;
- Reliable estimates of the time required to retrieve and submit information per company.

A quantitative estimate of the number of companies according to size in each sector (obtained from Eurostat for the relevant NACE categories), an estimate of the percentage of those companies having to notify a product and an estimate of the number of notifications was made.

All the identified nanoproducts were grouped in the following sectors:

1. Substances (C20.12 - Manufacture of dyes and pigments, C20.13 - Manufacture of other inorganic basic chemicals, C20.14 - Manufacture of other organic basic chemicals, and C20.4 - Manufacture of basic precious and other non-ferrous metals)
2. Cosmetics (C20.4.2 - Manufacture of perfumes and toilet preparations)
3. Health Care (C21.2 - Manufacture of pharmaceutical preparations)
4. Food & Feed (C10.8 - Manufacture of other food products and C11.0.7 - Manufacture of soft drinks; production of mineral waters and other bottled waters)
5. Coatings & Inks (C20.3 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics)
6. Cleaning & Disinfection (C20.2 - Manufacture of pesticides and other agrochemical products, and C20.4.1 - Manufacture of soap and detergents, cleaning and polishing mixtures)
7. Rubber Products (C22.1.1 - Manufacture of rubber tyres and tubes; retreading and rebuilding of rubber tyres, and C22.1.9 - Manufacture of other rubber products)
8. Building & Construction (C20.5.2 - Manufacture of glues, C23.2 - Manufacture of refractory products, C23.3 - Manufacture of clay building materials, C23.5 - Manufacture of cement, lime and plaster, and C23.6 - Manufacture of articles of concrete, cement and plaster)
9. Textiles (C13 - Manufacture of textiles, C14 - Manufacture of wearing apparel, and C15.1 - Tanning and dressing of leather; manufacture of luggage, handbags, saddlery and harness; dressing and dyeing of fur)
10. Paper Products (C17 - Manufacture of paper and paper products)
11. Complex Objects & Other Products (e.g. C25 - Manufacture of fabricated metal products, except machinery and equipment, C26 - Manufacture of computer, electronic and optical equipment, C27 - Manufacture of electrical equipment, C28 - Manufacture of machinery and equipment n.e.c., C29 - Manufacture of motor vehicles, trailers and semi-trailers, etc.).

Tables 2-5 and 2-6 provide an overview of the number of companies in each sector (obtained from Eurostat for the relevant NACE categories), an estimated range of the fraction of companies in each sector likely to notify a product, and an estimated range of the number of companies per sector likely to notify a product, and an estimate of the number of notifications.

Table 2-1: Overview of the estimated number of companies in total for each sector, and the number affected (having to notify a product)					
Sectors	Companies				
	total	Proportion affected		Absolute number affected	
		min	max	min	Max
Total	766,660	5%	8%	37,500	58,000
1. Substances	3,180	20%	40%	700	1,300
2. Cosmetics	4,400	60%	80%	2,600	3,500
3. Health Care	3,800	50%	80%	1,900	3,000
4. Food & Feed	9,170	5%	10%	500	900
5. Coatings & Inks	4,400	90%	95%	4,000	4,200
6. Cleaning & Disinfection	4,350	30%	60%	1,300	2,600
7. Rubber Products	8,500	75%	90%	6,300	7,800
8. Building & Construction	2,600	20%	40%	500	1,100
9. Textiles	127,330	5%	10%	6,000	13,000
10. Paper Products	18,500	60%	80%	11,000	15,000
11. Complex Objects & Other Products	580,430	0.5%	1%	3,000	6,000

5-8% (or 37,500-58,000) of the 766,660 enterprises whose main activity was in one of the aforementioned economic sectors may be affected by the implementation of an ENPR. This general picture is distorted by businesses that were assigned to the sector "complex objects and other products" and which make up the majority of all companies analysed (roughly 75%, 580,430 enterprises). However, they account for only about 6-10% (or 3,000-6,000) of all companies affected. A more detailed analysis reveals that following sectors could be particularly affected due to a high number of notifications within the sector: "coatings & inks" (90-95% of all companies in this sector), "rubber products" (75-90%), "paper products"(60-80%), "cosmetics" (60-80%) and "health care" (50-80%).

The implementation of the ENPR could lead to as many as 4.1 million notifications, the large share of which can be attributed to coatings & inks (roughly 60%), "paper products" (around 25%), "rubber" and "textile products" as well as "complex objects and other products" (around 3.5% each). Each company affected needs to submit between 16 and 57 notifications. Whereas the administrative burden for companies affected accounts for 5 to 20 notifications on average, businesses within the sectors health care, paper products and complex objects and other products could be obliged to notify as many as 75 products per company, and entities in the sector coatings & inks could be particularly affected, with up to 610 notifications per company. The high number of notifications is due to the registry requirement that each new mixture, where mixtures with the same components but different concentrations of each are considered different mixtures, shall be notified.

Table 2-2: Overview of the estimated number of notifications in total for each sector, and the number per company affected (having to notify a product)										
Sectors	Notifications									
	Total		Total per company affected		Substances		Mixtures		Articles	
	min	max	min	max	min	max	min	max	min	max
Total	2,400,000	4,100,000	16	57	7,000	10,500	1,574,800	2,641,500	838,200	1,480,500
1. Substances	7,000	11,000	5	16	7,000	11,000	--	--	--	--
2. Cosmetics	23,000	35,000	7	13	--	--	23,000	35,000	--	--
3. Health Care	70,000	145,000	23	75	--	--	70,000	145,000	100	200
4. Food & Feed	2,000	15,000	2	32	--	--	2,000	15,000	--	--
5. Coatings & Inks	1,500,000	2,400,000	350	610	--	--	1,500,000	2,400,000	--	--
6. Cleaning & Disinfection	11,000	26,000	4	20	--	--	11,000	26,000	--	--
7. Rubber Products	85,000	170,000	11	27	--	--	--	--	85,000	170,000
8. Building & Construction	2,800	5,300	3	12	--	--	1,300	3,300	1,500	2,000
9. Textiles	20,000	185,000	2	31	--	--	--	--	20,000	185,000
10. Paper Products	650,000	950,000	43	86	--	--	--	--	650,000	950,000
11. Complex Objects & Other Products	100,000	150,000	16	59	--	--	--	--	100,000	150,000

Most strikingly, it appears that after pigments and paints, the largest share of notifications may be attributed to the use of filling materials. Fillers are commonly used materials to reduce the consumption of expensive binder material and to improve the physical properties of the resulting material. Filling materials include, amongst others, calcium carbonate (paper and plastics), SAS (paints, coatings, adhesives and sealants, plastics and rubber) and carbon black (rubber and to a minor extent in plastics and paints). Although some fillers may need to be considered "incidentally formed nanomaterials," a large share of products containing these kinds of materials could nonetheless fall under the notification scheme of the register (provided relevant concentration thresholds were exceeded).

The costs for industry were analysed in two scenarios:

- Scenario 1 specifies the impacts resulting from the implementation of an ENPR, if no information gained in other legislative frameworks is used. As a consequence, implementation of the ENPR would involve duplication of efforts.
- Scenario 2 describes the impacts resulting from the implementation of an ENPR if parts of the information can be retrieved from other legislative frameworks (REACH, the Cosmetic Regulation, Novel Food Regulation, Food Contact Material and the Biocidal Products Regulation). As a consequence, implementation of the ENPR would involve no duplication of efforts.

For both scenarios two sub-scenarios affecting the recurring costs were investigated:

- Sub-scenario a: The product notification must be updated only when the formulation has changed (only information that has changed must be updated);
- Sub-scenario b: The product notification must be updated yearly.

For each (sub)-scenario analysed, direct costs incurred to industry were estimated on a sector-by-sector basis and separated into implementation and recurring costs.

For both scenarios the comparison of costs on a 5 year basis shows the following results:

- Some sectors could be particularly affected, such as Coatings & Inks with 6.26 -10.20 million hours (e.g. approximately 44-50% of the costs, in case the product notification has to be updated when the formulation change and that all costs are attributed to the ENPR [scenario 1a]), Paper Products with approximately 3.01-4.48 million hours, and Textiles with approximately 0.91 - 1.93 million hours.
- On an h/company basis over five years, this corresponds to approximately 790-1220 h/firm, 140-150 h/firm, and 130-150 h/ firm for the sectors Coatings & Inks, Paper Products, and Textiles respectively.
- For sectors with low numbers of notifications per company, the ratio of implementation costs to recurring costs is high (often an order of magnitude larger compared to sectors with a high number of notifications per company). An example is cosmetics. This means most of the costs are incurred for the task of modifying company procedures and systems, personnel training, and the first administrative entering of the data.
- For sectors with a high number of notifications or companies, the ratio of implementation costs to recurring costs is low since potentially hundreds of products have to be updated (and checked). An example is coatings & inks.
- In total, implementation costs are approximately 4-5 times as large as recurring costs.
- Distribution of costs for substances, mixtures, articles: For scenario 1a and 2a respectively, substances account for less than 1% of all costs, mixtures for 42-53%, and articles for

approximately 47-57%. This changes only slightly for sub-scenario b. In general, substance costs are an order of magnitude lower than both costs related to mixtures and articles. This is to be expected since substances are at the beginning of the production chain, and one substance is used in multiple different products (which all have to be notified) in which a multiplier effect occurs as the substance moves along the production chain.

A comparison of the costs of scenario 1 and 2 (irrespective of the sub-scenarios (a) or (b) reveals that:

- Avoiding duplicate notification (scenario 2) does not lead to a significantly reduced administrative burden when considering all companies affected (total costs may be reduced by 5.5%). This is explained by the fact that the sectors concerned by implementing scenario 2 (Substances, Cosmetics, Food & Feed, and Cleaning & Disinfection) add little to the overall costs (around 7%) in scenario 1.
- Significant savings are expected in the sectors with regulations requiring information on nanoproducts congruent with the ENPR (scenario 2):
    - Substance manufacturers (REACH) ~ 90-95% savings,
    - Cosmetics (Cosmetics Regulation) ~ 80% savings,
    - Food (Novel Food Regulation) ~ 95% savings,
    - Cleaning & Disinfection (BPR) ~ 40% savings.
- All other sectors are not affected by the parameters under scenario 2 since they are not already notified according to an existing regulatory scheme.

The costs for a public authority implementing the ENPR are assessed based on the experience from public authorities responsible for running similar registries. The cost elements analysed comprise hardware/software costs and administrative costs.

For the ENPR the hardware/software costs are estimated to be approximately €500,000 assuming a stand-alone system without an interface with other EU regulations collecting information on nanomaterials (e.g. REACH, Cosmetics Regulation). The transfer, modification, and integration of data from the existing and planned registries in the ENPR database would incur additional costs.

The estimated administrative costs include functions such as providing guidance based on relevant regulations, establishing FAQs to help streamline the process, working with stakeholders to improve the notification procedure (including type of information required in the notification). Since all Member States (28 in total) are involved in an ENPR, the number of desk officers is estimated to be at least 8 for the first year of implementation to carry out the administrative requirements associated with the register, including the yearly publication of any reports containing aggregate data for decision makers and the public. A similar number of support staff is also anticipated in the first year of implementation. Costs associated with the scientific assessment involved in determining if the correct particle analysis method for classifying substances as nanomaterials is used could lead to additional administrative costs. The costs incurred for public authorities in the implementation phase can depend heavily on the effectiveness of implementation which includes providing clear definitions and guidance on the scope of the registry.

Uncertainties occurred regarding the nano-definition and the obligations to notify, especially further down the supply chain and in articles. Many companies seemed to have no knowledge of the possible content of NMs in their products. Also, it appeared to be unclear which information was already available via other legislations, such as REACH. Additionally, there seemed to be insufficient

information present on NMs and their areas of application. Altogether, these obstacles resulted in the fact that companies found it difficult to estimate costs and reliable figures of a European nanoregister.

The ENPR would generate increasing knowledge for the public authorities on the possible exposure of humans and the environment to NMs, thereby being able to support them in the selection of possible risk measures. Companies would benefit from the ENPR by gaining more knowledge about the use of NMs throughout the product chain. Consumers would have the choice between products containing NMs and without NMs. In addition, increased transparency could retain trust in NM technologies.

2.5 Norway

On 9 January 2013, the Norwegian Climate and Pollution Agency (presently the Norwegian Environment Agency[21]) posted a notice[22] 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. According to the notice, the 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[23] or article 3 of the EU´s CLP Regulation if 100 kg or more of the product is 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. Only intentionally added nanomaterials, in substances or mixtures subject to registration, need to be registered in the Norwegian Product Register of Chemicals, and the criteria for reporting nanomaterials follows the EC Recommendation 2011/696/EU.

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 specifications 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,[24] 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-

[21] http://www.miljodirektoratet.no/english/

[22] http://www.miljodirektoratet.no/no/Nyheter/Nyheter/Old-klif/2013/Januar_2013/Innrapportering_av_arsmengder_for_2012_til_produktregisteret/

[23] Forskrift om klassifisering, merking mv. av farlige kjemikalier, FOR-2002-07-16-1139. Available at: http://lovdata.no/dokument/SF/forskrift/2002-07-16-1139

[24] Based on personal communication with Norwegian authorities, February 2014.

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.

2.6 United Kingdom

In 2012–2013, the UK Environment Agency's Chemical Compliance Team, working on behalf of Defra, continued their research on the producers and users of nanomaterials in the UK and the types of nanomaterials in use and on the UK market. This work built on a pilot study conducted in 2011-2012 that involved selecting and contacting target organisations directly and that produced encouraging results in terms of response rates. The aim was to test the phone survey methodology for further research. The pilot campaign was reviewed in July 2012 and internal and external partners (Defra, the Health and Safety Executive and the Nanotechnology Knowledge Transfer Network) agreed that the key factor for the encouraging results was the wording of the call script, especially with regard to the use of the gathered data. The pilot study was then extended into 2012-2013 to include additional organisations, with the primary focus being on the UK industry.

Altogether, through desk-based research and direct telephone contact, the Chemical Compliance Team identified over 260 organisations as potentially producing or using nanomaterials[25]. Around a quarter of these (66 organisations) confirmed that they were currently involved in the production, use or distribution of nanomaterials in the UK in sectors such as healthcare, energy, electronics, chemicals manufacture and R&D. These sectors also provided for the most common applications of those nanomaterials, in addition to coatings and pharmaceuticals. It should be noted that a few organisations were only indirectly involved in the production or use of nanomaterials, through, for example, characterising them, using them to test measuring equipment or providing nanomaterial production facilities to customers. With regard to types of nanomaterials[26], the most commonly identified were metallic (silver, copper, gold), inorganic (titanium dioxide and aluminium oxide) and carbon-based (carbon nanotubes, graphene). Other nanomaterials identified were photovoltaic inks and PEGylated fatty acids[27].

During 2013-2014, the Chemical Compliance Team updated its database of nanotechnology contacts and, importantly, expanded its focus to include universities, as well as industry contacts not listed in nanotechnology membership groups or directories.

The Environment Agency Chemical Compliance Team is part of the National Trading and Regulatory Service and is responsible for enforcement activities, information sharing and information

[25] Environment Agency (2013): Chemical Compliance Team Annual Report 2012-2013, Environment Agency, Bristol.

[26] The focus was on manufactured nanomaterials that measure 1-100 nm and that are free or have the potential to become airborne.

[27] PEGylated (polyethylene glycol) fatty acids are mainly used in cosmetic formulations as surfactants (emulsifying or solubilising agents) or as non-ionic surfactants in oral, topical and parental drug delivery systems. Source: http://www.cir-safety.org/sites/default/files/pegoil122012final_faa-final%20for%20posting.pdf

management with regard to chemicals legislation[28]. Among its responsibilities are the development of proposals for environment risk management of substances under the REACH Regulation and the identification and understanding of the uses and sources of WFD substances into the water environment. Expertise of the CCT members is thus centred on product flow research and supply chain analysis.

The call script followed for the phone interviews emphasises the importance of identifying the correct persons in the organisations with whom to talk. Once a first contact has been established, the interviewer has to clarify the purpose of the call: given the current uncertainties over hazards and risks of nanomaterials, this is to build a database of companies producing or using nanomaterials for risk mitigation purposes and to reassure concerned stakeholders about the public authorities' ability to act in the event of a problem. The interviewer has then to highlight that, although it is the intention of the authorities to keep the information confidential, following a request under the Freedom of information provisions, some information might have to be released.

Table 2-7 presents the types of information pursued through the interviews.

Table 2-7: Information pursued through the CCT survey
Contact details
- Name, job title, location, contact number, email address -Company registration number (if applicable)
Information on nanomaterials
- Nanomaterials produced/used/interested in - Applications of the nanomaterials - Product sectors
Information on the supply chain
- Providers of the nanomaterials - Downstream users of the nanomaterials

The full time work of one officer for around three to four months was required to build the database. In contrast, the maintenance and yearly update of the database requires just one officer for about one month of full time work.

2.7 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:

[28] National transpositions of the REACH Regulation (EC) 1907/2006, the Persistent Organic Pollutants Regulation (EC) 850/2004, the Disposal of Polychlorinated Biphenyls and Other Dangerous Substances EU Council Directive 96/59/EC, the Fluorinated Greenhouse Gases Regulations, the Controls on Ozone-Depleting Substances Regulations and the Water Framework Directive 2000/60/EC.

- 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 was expected to 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[29] 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:[30] "*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*".

[29] August 2014.

[30] http://ec.europa.eu/consumers/sectors/cosmetics/cpnp/

The Commission is currently working on a new definition of nanomaterials for cosmetics:[31] 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 Article16 notification per nanomaterial.

The information requirements for nanomaterials in cosmetic products are considerably higher than for the other notification schemes. In the first instance, the notifier has to identify the product, providing some 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 determines 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 2-8 provides the list of different cosmetic product categories per level.

Table 2-8: 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

[31] http://chemicalwatch.com/14539/new-eu-nano-definition-for-cosmetics-scheduled-for-2014

Table 2-8: 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

Table 2-8: Product category levels	
Hair styling products	Products for temporary hair styling
	Permanent wave products
	Hair relaxer / straightener products
	Other hair styling products
Other hair and scalp 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 the product category has been provided, 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 2-9 presents the list of physicochemical parameters required.

Table 2-9: Physicochemical parameters required for the characterisation of the nanomaterials	
Particle size	
Primary particle size	Lowest cut off level (nm)
	Volume weighted median Min and Max (nm)
	Number weighted median Min and Max (nm)
Secondary particle size	Volume weighted median Min and Max (nm)

Table 2-9: Physicochemical parameters required for the characterisation of the nanomaterials	
Morphology	
Physical form	Solid, Powder, Solution, Suspension, Dispersion, Other
Crystalline shape	Spherical, Hexagonal, Pyramidal, Rod, Plate, Wire, Whisker, Star-like, Needle-like, Fibre, Tube, Isometric, Crystalline, Irregular, Amorphous, Other
Agglomeration/aggregation state	Dispersed free particles, Agglomerate, Aggregate, Other
Aspect ratio (of elongated particles)	
Surface characteristics	
Surface charge (zeta potential)	mV Not measurable
Surface modifications or functionalization	Yes/No
Coating	
Solubility (solubility/dissolution in relevant solvents)	
Aqueous media	(mg/l)
N-octanol	(mg/l)
Octanol/water partition coefficient	
Surface area	
BET specific surface area SSA	m^2/g
Volume specific surface area VSSA	m^2/cm^3
Catalytic activity (in final formulation)	
Chemically reactive surface	Yes/No
Is there photocatalytic activity?	Yes/No
% to reference	
Core material doped?	Yes/No
Quantity	
Quantity (per year)	(kg)
Toxicological profile (following the SCCS Guidance on the safety assessment of nanomaterials in cosmetics)	
Summary of the toxicological studies	
Relevant toxicological studies	1- percutaneous absorption 2- toxicokinetics 3- acute toxicity 4- irritation and corrosivity 5- skin sensitisation 6- mutagenicity/genotoxicity 7- repeated dose toxicity 8- carcinogenicity 9- reproductive toxicity 10- photo-induced toxicity 11- Human data
Relevant scientific literature	
Safety data	
Safety data of the nanomaterial relating to the category of cosmetic product	
Exposure conditions (Reasonable Foreseeable Exposure Conditions of the Nanomaterial	
Rinse off/ Leave on	
Exposure route	Dermal/Oral/Inhalation
Maximal concentration	% w/w

2.8 Comparison of the Nanomaterials Transparency Measures

This section presents a comparison of the different transparency measures investigated. The following key features are highlighted:

- Definition of nanomaterial;
- Object of the notification;
- Exemptions; and
- Information requirements.

Overall, the Belgian, Danish, French, the cosmetics sector schemes and the German proposal are of the same type and can be described as conventional registers, which is to say they are based on the idea of (companies and other organisations) being required to submit formal notifications to the relevant regulatory agency.

In the main, those notifications concern NMs, the exceptions being the Danish scheme, which requires companies to submit notifications about articles containing NMs, and the Belgium scheme, which will eventually require companies to submit notifications about articles containing NMs, as well as NMs in mixtures or as such – although the requirement concerning articles has not yet come into force. Additionally, those notifications are primarily limited by geography, specifically Member State boundaries, the exception being the CPNP, which limits notifications primarily by sector of use – although the other schemes contain some exemptions by sector.

The Norwegian and UK schemes are fundamentally different, both from the conventional registers and from each other. The Norwegian scheme is not so much a register in itself as a change to a register already in existence. As such, the scope, exemptions and information requirements reflect those of the preceding scheme – a chemical products register.

The UK scheme is effectively a company register, albeit a voluntary one that places the burden of contact between regulatory agency and company on the former. That is to say, the regulatory agency seeks out companies operating in the NM sector and reaches out to them by phone – there is no obligation on the company to take part.

There are some key differences between the conventional registers (the Belgian, Danish, French, German and cosmetics sector schemes) in terms of what exactly is registered and how. These differences relate roughly to the following topics:

- Mixtures: for NMs in mixtures, the Belgium scheme records the mixture once, rather than separating out each NM and recording each in isolation;
- Intended use: the Belgian scheme is limited to NMs for professional use. The Danish scheme to mixtures and articles for consumer use.

Beyond this, the key differences relate to exemptions and information requirements.

Exemptions can be categorised by sector of use or behaviour of the nanomaterial. Sectors of use representing the basis of exemptions include the pigments, foods and pharmaceuticals. It is notable, that there is no overlap between the CPNP and the Danish schemes because the former concerns only cosmetic products, while the latter exempts them entirely. The last category is exemptions relating to the use of the behaviour of the NM, which comprises just one exemption: the Danish and German schemes exempt articles that contain NMs but do not release them over the course of their lifetimes.

Information requirements relate to:

- The organisation making the notification;
- The physicochemical characteristics of the NM triggering the notification;
- The uses of the NM;
- The business context; and
- The toxicological and hazard characteristics of the NM.

In general, the Belgian, French and cosmetics sector schemes focus on the physicochemical characteristics of the NM triggering the notification. The Danish scheme asks for this information, but since the requirements in this area are voluntary it remains to be seen whether companies will provide it and to what extent. The UK scheme focuses on the business context, but only relatively lightly. Meanwhile, the CPNP stands out as the only scheme to require toxicological and hazard information.

Considering the schemes in the round, there are some requirements for unique identifiers, such as REACH registration numbers (Belgian and French schemes) and product category codes (Danish scheme). This would suggest the possibility of some kind of retroactive homogenisation of data across the schemes if it were not for their relatively limited use mentioned and the substantive differences in the basis for schemes – typified by some recording articles while others record NMs.

Table 2-10: Measures to increase transparency on the nanomaterials on the market							
Key parameters	**Belgian Notification System**	**Cosmetic Products Notification Portal**	**Danish Product Register**	**French Notification System**	**German proposal for a European Register**	**Norwegian Register**	**UK pro-active survey**
Definition	EC Recommended definition, but only intentionally manufactured nanomaterials in the scope of the measure	NM means an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1-100 nm.	EC Recommended definition, but only intentionally manufactured nanomaterials in the scope of the measure	EC Recommended definition, but only intentionally manufactured nanomaterials in the scope of the measure		EC Recommendation 2011/696/EU	EC Recommended definition, but only intentionally manufactured nanomaterials in the scope of the measure
Object of the notification	NMs as such or in mixtures or in articles for professional use, in quantities equal to or more than 100 grams per annum [+]The date for the entering into force of the requirements for NMs in articles has not been decided yet. In the case of a NM in a mixture, the mixture, rather than the NM, is subject to notification	NMs in cosmetics	Mixtures and articles for sale to consumers that contain NMs and may release those NMs	NMs as such or unbound in mixtures for professional use, in quantities equal to or more than 100 grams per annum NMs in articles that are intended to release the NMs	Substances and mixtures containing NMs Articles that release (intentionally or otherwise) NMs	NMs intentionally added to substances and mixtures classified with respect to health, environmental or fire and explosion hazards under section 6 of the Norwegian Chemical Labelling Regulations or article 3 of the CLP Regulation, if 100 kg or more is imported or manufactured per year	Companies using NMs, including manufacture, import and distribution.
Exemptions			NMs bound in a matrix	NMs bound in a matrix			
			Cosmetics				
	Biocides		Pesticides				
	Medicines (human and veterinary)		Medicines and medical devices				

Table 2-10: Measures to increase transparency on the nanomaterials on the market							
Key parameters	**Belgian Notification System**	**Cosmetic Products Notification Portal**	**Danish Product Register**	**French Notification System**	**German proposal for a European Register**	**Norwegian Register**	**UK pro-active survey**
Exemptions	Foods		Foods				
	Animal feeds (including medicated animal feeds)		Animal feeds				
	Processing aids for organically produced agricultural ingredients						
	Pigments		Articles with NM inks used directly Textiles with NM inks or dyes Paints, wood preservatives, glues and fillers containing NM pigments				
			Rubber articles with carbon black or NM silicon dioxide				
			Mixtures and articles produced or imported by individuals for their own, non-commercial use				
			Waste				
Information requirements	Identity of notifier		Identity of notifier	Identity of notifier	Identity of notifier		Contact details for relevant person at the organisation
			Type and size of entity	Supply chain role			
	Sector of activity			Sector of activity			Product sectors

Table 2-10: Measures to increase transparency on the nanomaterials on the market							
Key parameters	**Belgian Notification System**	**Cosmetic Products Notification Portal**	**Danish Product Register**	**French Notification System**	**German proposal for a European Register**	**Norwegian Register**	**UK pro-active survey**
Information requirements	Chemical identity of the substance (chemical name, chemical formula, CAS no., EC no.)	Identity of NM, including: chemical name (IUPAC); the non-proprietary name (INN), if a pharmaceutical product; CAS number; EC or ELINCS number or number, XAN and the name in the glossary of common ingredients names.	Chemical identity of the substance (chemical name, chemical formula, CAS no., EC no.)	Identity of NM, including: chemical name, formula, CAS number, EC or ELINCS number	Chemical composition	Chemical composition	NMs produced, used or interested in
	Mean and median particle size	Particle size	Particle size*	Mean particle size	Particle size and distribution		
	Particle size distribution curve (by number)	Range of physical and chemical properties (see table 2-7)	Numerical size distribution*	Number size distribution (graph)			
	Average aggregate size and, if the substance is sold in the form of agglomerates, average agglomerate size, relative to a standard deviation (when available)		Aggregation and agglomeration*	Aggregation and agglomeration			
	Qualitative description of particle shape		Form*	Shape	Particle shape (length, width, form)		
	Qualitative description of particle coatings (if applicable)						
	Impurities (if applicable)			Impurities			

Table 2-10: Measures to increase transparency on the nanomaterials on the market							
Key parameters	**Belgian Notification System**	**Cosmetic Products Notification Portal**	**Danish Product Register**	**French Notification System**	**German proposal for a European Register**	**Norwegian Register**	**UK pro-active survey**
Information requirements	Crystallographic phases		Crystalline state*	Crystalline state	Crystallinity		
	Average specific surface area		Specific surface area*	Specific surface area	Specific surface area, if applicable		
	Zeta potential		Surface charge*	Surface charge			
	Mass concentration (if in a mixture)		Nano content in product (mass and %)*		Concentration of NM in the product		
	Physical state (e.g., solid)			State of the mixture			
			Surface chemistry*	Coating	Chemical composition of the surface region, if modified		
	REACH registration number (if registered)		Is the NM registered under REACH? (Yes/no)	REACH registration number (if registered)			
			REACH category codes (product, process, environmental release, article)*				
	Quantity placed on market	Quantity contained in cosmetic products intended to be placed on the market	Production volume	Quantity	Quantity manufactured or imported	Quantity of the chemical product	
	Uses		Description of application	Uses	Use (including functionality) of the NM		Applications of the NMs

Table 2-10: Measures to increase transparency on the nanomaterials on the market							
Key parameters	**Belgian Notification System**	**Cosmetic Products Notification Portal**	**Danish Product Register**	**French Notification System**	**German proposal for a European Register**	**Norwegian Register**	**UK pro-active survey**
Information requirements	Trade name	Product category (see table 2-6)	Product name	Commercial name	Product and trade name		
			Professional application? (Yes/no)				
			Name of nanomaterial				
			Manner of inclusion in the product				
	Claimed properties for which the notified substance is used*			Properties for which the notified substance is used*			
	Identity of users			Identity of users			Downstream users and providers of the NMs
		Foreseeable exposure conditions					
		Toxicological profile of the NM					
		Safety data					
**Voluntary information*							

3 Analysis of the French Notification System

3.1 Introduction

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, "*Grenelle de l'environnement"*) that led to the commitment[32] to anticipate any risks deriving from the exposure to nanomaterials. The commitment was supported by Anses[33], 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 30th April 2013 (for the first year of implementation, an additional period of two months was granted postponing the deadline to the 30th June 2013).

The general aim was to improve the information available to the authorities, 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;
- To gather 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[34] defined the scope, the information to be notified and the terms for the notifications. More precisely, the 2012-232 decree defines:

- The duty-holders;
- 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.

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

- The Notifier identity;
- The identity of the nanomaterial;

[32] *Engagement n. 159.*

[33] Anses ("*Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail*") was born by the merge between Afssa and Afsset.

[34] *The "décret n. 2012-232 du 17 février 2012"* and "*l'arrêté du 6 août 2012*."

- 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 a specific decree: Ineris, InVS, INRS, ANSM and other organisations in charge of toxicological vigilance).

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, is considered confidential, as well as the information about the quantities, the commercial name of the nanomaterial or mixture and the identity of the notifier and its customers.

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, upon justification, 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 data contained in the notifications should enable the traceability of the nanomaterials in the supply chains, from the manufacturers/importers to the professional users. 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 1st 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.

3.2 Scope, Duty-holders and Information Requirements

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 bound 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[35], 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 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

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

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

The duty-holders are required to submit a variety of information, including substance identity (e.g. chemical name, formula, CAS, mean particle size, number size distribution for particles with an indication of the determination method used) quantity, use information and the identity of their professional customers. In turn, they receive a unique number for each notification, which needs to be passed on with all transfers of ownership[36] to professional users and distributors so that they can make their notification referring to their suppliers' notification. All notifications need to be submitted annually and non-confidential information will be disclosed at the latest six months after the deadline for the notification. 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 notification for different products containing the same substance at nanoscale. 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 notification 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-uses ;
- 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.[37]

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, a password to access the account is transmitted automatically by email. Based on Anses (2013), the notification system is divided into six main parts:

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

[36] Not necessarily at the same time.

[37] ECHA (2010): Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system, Version: 2, European Chemicals Agency, March 2010.

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 notification. 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
Identity of the notifier		
Company name*		
Address* and Post Code*		
Town/City*		
EU VAT or National Directory of plants (RNE) number*		
Country*		If different from France, notifiers have to specify whether: • European organisation; • European representative.
Role in the supply chain*	• Manufacturer; • Distributor; • Importer; • Professional user and distributor; • Repackager and distributor; • European representative.	
Public research organisation*	Yes/No	Public research organisations can provide simplified notifications
Company registration certificate*	To be attached	
Business sector*	NACE code list	10.41 Manufacture of oils and fats
Plants/sites interested*	Name, address, post code, city and country	
Identity of the Notification administrator*	Name, surname, email	
Information on the notification		
Notification number		Assigned automatically
Year of the notification*		
Role in the supply chain with regard to the notified NM*	• Manufacturer; • Distributor; • Importer; • Professional user and distributor; • Repackager and distributor; • Other.	Each company can submit as many notifications as nanomaterials of interest
NACE code (down to four digits) of the activities of interest	NACE code list	10.41 Manufacture of oils and fats
Plants/sites of interest*	Name as previously specified	

Table 3-1: Information to be notified		
Information	**Options**	**Examples/Notes**
Clients/Professional users identity	The notifiers have to enter manually or provide a list (in csv format) of the clients/professional users they provide the nanomaterial to. If they have more than 30 clients for one NACE code activity, the notifiers can just indicate the NACE code and the number of clients/professional users with the provision to keep the list for possible requests by the authorities.	
NACE code of the clients/professional users		
Research and Development	• Scientific research; • R&D on products and processes; • no R&D.	Public research organisations can provide simplified notifications
R&D only?	Yes/No	
NACE code for the R&D activities	NACE code list	
R&D NM put on the market?	Yes/No	
National Defence interest?	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.	
Substance identity		
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: • Waiting for the results; • Substance/mixture/article imported: information not available; • The distributor did not pass the information.		
State of the substance*	• The substance is pure; • The substance is contained in a mixture without being bound to it; • The substance is contained in a material intended to release the substance under normal or reasonably foreseeable conditions of use	Multiple choices are possible.
Chemical name*		Titan dioxide
Chemical formula*		TiO_2
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?	Yes/No	
Types of substance concerned *(This is only for research public organisms that choose the simplified notification)*	Carbon (diamond, fullerene, graphene...), Noble metal (ex: Platinum for catalysts), Silica (silica colloidal , silicene...), Non-magnetic oxides (TiO_2, ZnO, CeO2...), 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.	
N°CAS*	CAS number	13463-67-7
	CAS number not available	-
EC reference*	EC reference	236-675-5
	EC reference not available	-

Table 3-1: Information to be notified		
Information	**Options**	**Examples/Notes**
Commercial name*	Commercial name if available	
	No commercial name	-
IUPAC name		
REACH registration number+	REACH registration number	-
	No REACH registration number	-
Impurities+	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.
Size of the particles*	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	
Number size distribution for particles*	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	
Aggregation and agglomeration state*	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

Table 3-1: Information to be notified		
Information	**Options**	**Examples/Notes**
	Agglomeration state determination method used	-
	Test guideline	-
	Attach file relative to the determination of the aggregation and agglomeration state	
Shape*	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	
State of the mixture*	State of the mixture containing the substance	Solid, Liquid, Gas, Powder
Specific surface+	Mean specific surface, associated with a standard delta	Mean specific surface: 52 m^2/g Standard deviation: : ± 10 m^2/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.
Crystalline state+	These information are available	Yes, No
	Is the substance contained in a mixture?	Yes, No
	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	
Coating*	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.
Surface charge+	Zeta potential value	Attach file relative to the determination of the surface

Table 3-1: Information to be notified		
Information	**Options**	**Examples/Notes**
		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		
Quantity*	Quantity produced	The unit is kg.
	Quantity distributed	
	Quantity imported	
	Quantity distributed after use	
	Quantity distributed after repackaging	
	Other quantity	
Uses		
Uses*	Descriptor SU Descriptor PC Descriptor PROC Descriptor AC	
The properties claimed		
Commercial name of the mixture[+]		
Commercial name of the material[+]		
Users		
Clients (professional users)*	Name, address, zip code, city, country, intercommunity VAT	

3.3 Analysis of the Information Presented in the French Public Report

3.3.1 Overview

This analysis is based on the public data reported by French Authorities in November 2013 and on some aggregated data provided by the French authorities for the purposes of this study.

The deadline for the first year was set to the 30th June. At the 1st July, the authorities have received 3,409 notifications from 933 notifiers. Of the 933 notifiers, over 70% (670) were based in France, while the remaining 30% were based in other European countries members of the European Economic Area and Switzerland.

For the purpose of the publication of the results of the first year of the FNS, of the 3,409 notifications finalised and validated, only 80% (2,776) were selected and analysed, excluding those notifications reported as erroneous by notifiers, those concerning actors outside the French territory and those covered by confidentiality rules. It has been reported that some notifiers have submitted information for substances not at nanoscale, but received this information only after the deadline. However, such error concerns only few notifications.

Around 1.5% (50 over 3,409) were simplified notifications submitted by public research organisations.

Only around 3% of the notifications had some confidentiality claims (112 over 3,409). 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 the French authorities were not in the position to provide an in-depth analysis of the database. As a matter of fact, only 59% of the notifications (1,632) reported a CAS number, while in the remaining 41% the nanomaterials were identified by a chemical name only. In first instance, the French authorities estimated that between 243 and 422 different substances have been notified as nanomaterials on the French market. It has to be noted that for each different CAS number (around 243) and different chemical name (around 179), there might be several distinct nanomaterials varying on the basis of physicochemical parameters.

Within the FNS, information on quantities of nanomaterial(s) per notifier are treated as confidential. However, the report provides 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. Around 50% of the substances notified are manufactured and/or imported in France in less than 1 tonne per year.

Notably, 50% of the number of notifications received in 2013 refers to four substances only: silicon dioxide (over 30%), titanium dioxide (over 8%), carbon black (over 6%) and cerium dioxide (over 5%).

In 2013, the top ten companies in terms of number of notifications provided around 20% of the notifications analysed. Companies submitted an average of four notifications (the median value is 2).

Table 3-3 provides an analysis of the number of notifications per notifier, while Figure 3-1 presents a histogram highlighting that over 60% of the notifiers submitted 2 or less notifications, with only 10% of notifiers submitting more than 8 notifications.

Table 3-3: Overview on the number of notifications per notifier	
No. of notifiers based in France	670
No. of notifications	2,776
Average no. of notifications per notifier	4
Median	2
Standard deviation / 2. Quartile / 3. Quartile	8 / 1 / 4
Min / Max	1 / 107

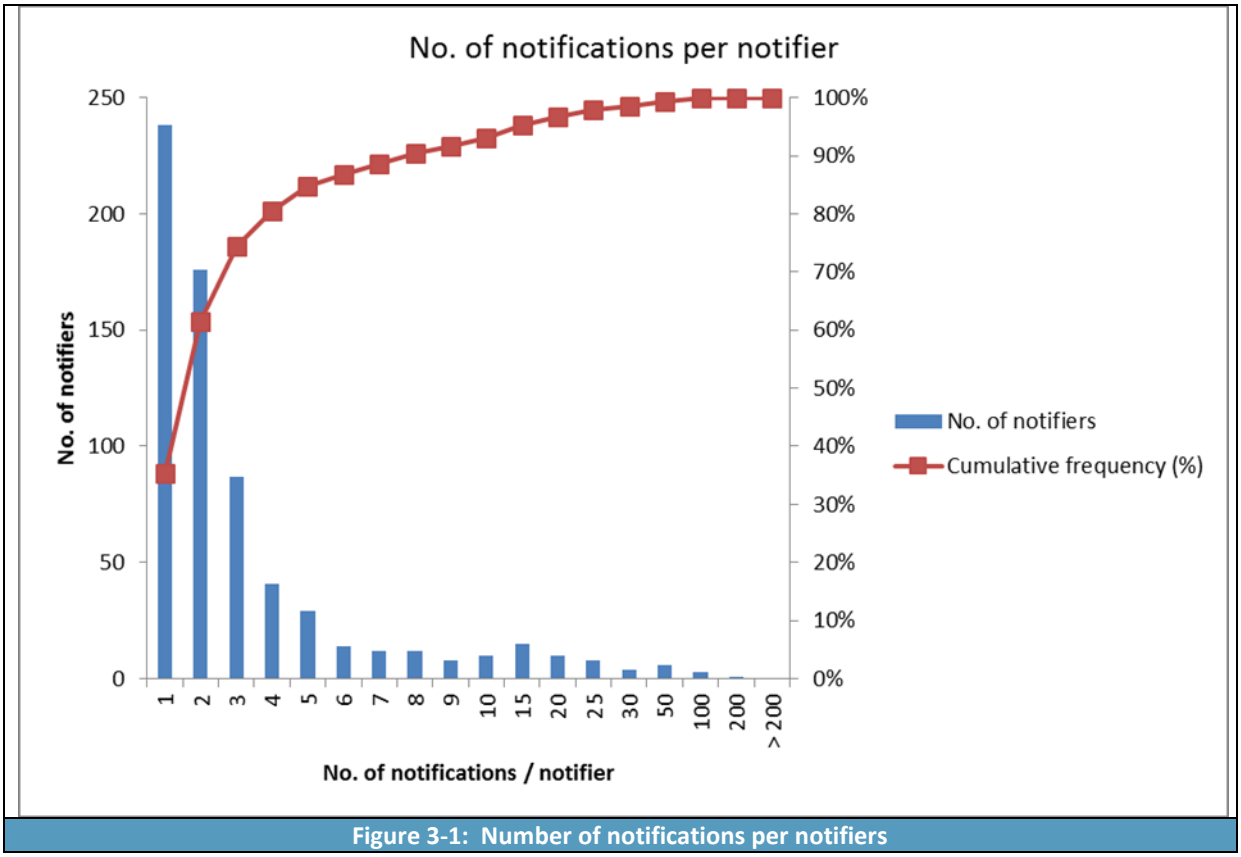

Figure 3-1: Number of notifications per notifiers

With regard to the number of notifiers per role played in the supply chains of nanomaterials, some preliminary data were published in the French public report (Figure 3-2)

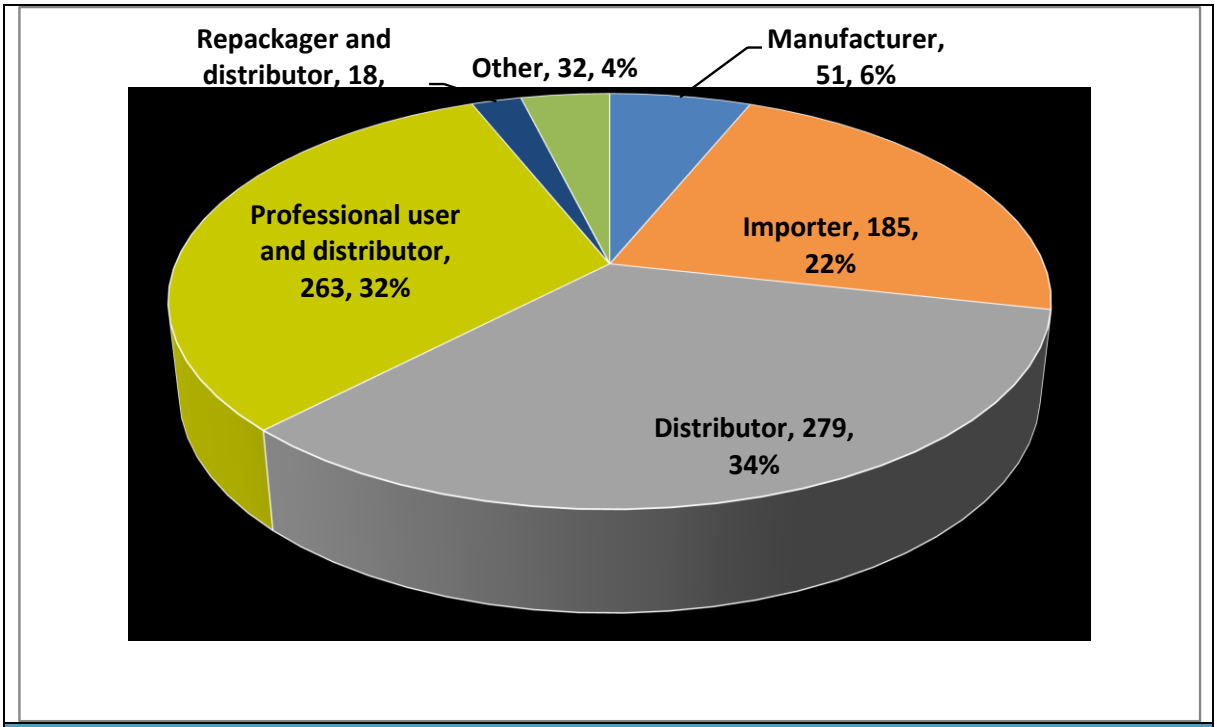

Figure 3-2: Distribution of the notifiers across the supply chain. Source: French public report (2013)

Table 3-4 presents the average number of notifications per role in the supply chain. No information has been reported on the 32 entities that indicated "other" as role in the supply chain. It must be noted that the notifiers could indicate multiple roles for each notification.

Table 3-4: Average number of notification per role in the supply chain

Role	No. of notifications	Average No. of notifications
Manufacturer	149	3
Importer	923	5
Distributor	1,121	4
Professional user and distributor	982	4
Repackager and distributor	35	2
Other	n/a	n/a

On the number of notifications that reported the state of the substance, around 1% indicated that the nanomaterial is contained in a mixture from which it is intended to be released; over 60% reported that the nanomaterial is contained in a mixture without being bound to it; over 30% of the notifications referred to nanomaterials not contained in a mixture).[38] In around 50% of the notifications reporting that the nanomaterial is contained in a mixture, the physical state of the mixture indicated is liquid, in around 30% solid and in around 20% is powder.

On the number of notifications that reported on the agglomeration state of the nanomaterials (around 65% of the notifications analysed), around 50% indicated that the nanomaterial is sold in agglomerated form, while the remaining 45% is not in agglomerated form.

Around 65% of the notifications analysed indicated whether the nanomaterials are coated and, if coated, the nature of the coating: around 15% of these notifications reported that the nanomaterials are coated and over 85% indicated that the nanomaterials have no coating.

Further analysis of the nanomaterials notified, of their quantities and their uses is provided in Section 6.2.

[38] Multiple choices were possible.

4 Cost Analysis - Public Authorities

4.1 Setting Up and Maintenance of a Notification System

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 Oko-Institute.V. (2013) and confirmed and validated by the French authorities for the purposes of this study.

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 4-1 reports the costs related to the acquisition of the hardware and software plus yearly license and maintenance of the database.

Table 4-1: 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	
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 4-2 reports these costs in terms of full-time equivalent[39] employees.

Table 4-2: Administrative costs – confirmation/update of old data

Personnel	Intensity (fte)	Tasks	Duration (yr)	Type of Costs	
				Impl.	Annual
1 desk officer	0,65	Organising stakeholder meetings, drafting FAQs, answering inquiries, communicating on and promoting the FNS, etc.	1	x	x
2 officers	1,50	Working within ANSES; assisting with the French RPN in answering basic questions, website support, managing the IT tool development and maintenance, preparing the annual report, extracting the data for authorised organisations	1 (at least one officer dedicated for 2 years)	x	x

[39] 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.

Assuming a 35-hours work week, 46 work weeks per year and an average hourly gross wage of €35 for a public officer, the additional costs are around €120,000 per year.[40]

DG SANCO provided some estimates with regard to the Cosmetic Products Notification Portal. These are presented in Table 4-3.

Table 4-3: CPNP management costs	
Maintenance and development	€200,000
Hosting	€52,000
Application support	€150,000
Total	**€402,000 per annum**

On the basis of the cost figures provided by the authorities, it can be noted that yearly costs for the CPNP are around two-three times higher than the costs for the FNS.

With regard to the UK initiative of surveying, on a voluntary basis, manufacturers, importers and professional users of nanomaterials, as reported in Section 2.6, the full time work of one officer for around three to four months was required to build the database. In contrast, the maintenance and yearly update of the database requires one officer for about one month of full time work. Thus, one-off costs for the setting up of the measure were around €16,000[41], with recurring costs of around €5,000[42].

The results of this analysis will be used for the assessment of the costs of the possible implementation of an EU-wide nanomaterials transparency measure in the Option Assessment report.

[40] (€35 x 35 hours x 46 work weeks) x 2.15 fte ≈ €120,000.
[41] (€35 x 37.5 hours x 12 work weeks) ≈ €16,000
[42] (€35 x 37.5 hours x 4 work weeks) ≈ €5,000

5 Cost Analysis - Companies

5.1 Introduction

This Section presents the analysis of the administrative burden posed by the French Notification System on companies. The analysis draws on the information provided by companies and industry associations during the stakeholders meeting held in Paris on 10 March 2014 (Section 5.2) and, primarily, on the results of the survey on the administrative burden of the notification systems conducted between February – June 2014 (Section 5.3).

Following the Validation Workshop held in Brussels on 30 June 2014 and the discussions with different stakeholders on the preliminary results of this assessment, some important remarks and distinctions have been added to the analysis.

Section 5.4 presents the estimate of the total costs for the notifiers in 2013.

Moreover, three case studies (Section 5.5) have been developed in order to better describe the administrative burden on different types of actors, namely:

- A large enterprise with multiple roles in the supply chain;
- A small-medium enterprise in the pigments and dyes sector; and
- A distributor of chemical products.

5.2 Stakeholder Meeting – Paris 10 March 2014

On 10 March 2014, a stakeholder meeting was held in Paris and hosted by MEDDE in its premises. The main objective of this meeting was to gather information directly from those companies that had already experience of the French Notification System. Therefore, **the remaining of Section 5.2 reports the views and the critical issues identified by the industry stakeholders present at the meeting**. The account of this meeting should be read together with the Workshop report, which relates the discussions between public authorities, industry, trade unions and non-governmental organisations on the analysis of the FNS and of the other transparency measures.

Section 5.2.1 presents the participants and provides an introduction to the objective of the meeting. The following subsections presents the main issues identified during the discussion.

5.2.1 Participants

Table 5-1 provides details and participants to the meeting.

The project team presented the study and the information required by the Commission, highlighting the different steps for the evidence gathering, such the launching of a public consultation before summer 2014. The meeting was also the perfect occasion to foster participation to the first phase consultation, consisting in an online survey targeted to industry stakeholders with relevant experience in notifying nanomaterials to the FNS and the CPNP and aiming to collect evidence on the administrative burden of the schemes on companies.

The presentation was then followed by an open discussion on the critical issues of companies when dealing with the FNS legislative requirements.

Table 5-1: Date, location and participants	
Date: 10 March 2014	**Start time:** 2:00 pm
Location: Ministère de l'Écologie, du Développement durable et de l'Énergie – Grande Arche de La Défense, Paroi Nord, 18th floor, room 18N47	
Public authorities	
Olivier Pairault (OP)	Ministère de l'Écologie, du Développement durable et de l'Énergie (MEDDE)
Sophie Paultre (SP)	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 l'Hoir	Ministère de la Défense
Aurélie 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)
European Commission	
Michal Kubicki	DG Enterprise and Industry
Non-Governmental Organisation	
Danielle Lanquetuit	Association de Veille et d'Information Civique sur les Enjeux des Nanosciences et des Nanotechnologies - AVICENN
Industry association	
Sonia Benacquista	Union des Industries Chimique (UIC)
Patrick Lévy	Mouvement des Entreprises de France - Union des Industries Chimiques
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)
Companies	
Caroline Petigny	BASF
Xavier Radisson	L'Oréal
Cristophe Zing	Cristal Global
Project team	
Marco Camboni	Risk & Policy Analysts ltd (RPA)
Vania Simittchieva	Risk & Policy Analysts ltd (RPA)
Jan Vorderman	Beratungsgesellschaft für integrierte Problemlösungen (BiPRO)

5.2.2 Definition of nanomaterial and object of the notification

The project team was asked by industry stakeholders to relay the difficulty in understanding the existing (EC-recommended) definition of NM. The fact that there exists no international standard covering all NMs was stressed. It was stated that the current definition is not suitable, i.e. the intentional production aspect as well as the number-particle distribution threshold are difficult to assess.

It was stated that every new regulation brings a new definition and that there must be agreed-upon, uniform and standard terms on which regulations should be based. The current definition is seen as too broad (i.e. not specific enough). It was also stated that the requirements of the different registries differ in terms of what needs to be notified. For example, the Belgian registry requires notifications per nanomaterial and per mixture. There is high concern on per use types of registries (vs. per substance registries) as they are seen as more burdensome, especially for downstream users. The case of pigments, dyes and paints has been highlighted and it was remarked the focus should be only on the "very innovative" nanomaterials.

The lack of uniformity and the fact that the definition is not a scientifically-defined term and/or based on the ISO dictionary has resulted in some substances being notified and others not due to the different interpretations on a case-by-case basis.

One of the industry representatives noted that the ISO definition[43] is preferred because it is better suited to industry. It was also noted that the ISO definition should be the horizontal definition and there should be vertical definitions for different regulations differentiated in terms of the characteristics of concerns.

Overall, the need for a clear text which leaves no room for interpretation/discussion was expressed.

5.2.3 Information and communication within the supply chain

Industry stakeholders stated that a particular difficulty within the chemical industry has been the communication of information within the value chain, i.e. suppliers provide different degrees of information and customers challenge the need and/or reason for the notification. Even within the same company (and even within large companies with information management systems implemented) it is very difficult to find all the information requested and sometimes the same substance at the nanoforms is considered a NM by a department/site but not a NM by another department/site of the same company. The tracking system inside the companies needed to be changed. Moreover, very often the suppliers do not provide the complete information but only partial data.

It was stated that often it is unclear who the end/professional user is: it is unclear where the supply chain stops for regulatory purposes. The public authorities underscored that a relatively narrow interpretation of the supply chain was proposed for the first year, taking into account the lack of experience of most of the users.

Some industry stakeholders also indicated that companies often provide internally-generated information due to communication fatigue on part of suppliers that do not supply the information or the notification number.

[43] Nanomaterial: material with any external dimension in the nanoscale (2.1) or having internal structure or surface structure in the nanoscale. Note 1 to entry: This generic term is inclusive of nano-object and nanostructured material. [SOURCE: ISO/TS 80004-1:2010, definition 2.4] Nanoscale: size range from approximately 1 nm to 100 nm. Note 1 to entry: Properties that are not extrapolations from a larger size will typically, but not exclusively, be exhibited in this size range. For such properties the size limits are considered approximate. Note 2 to entry: The lower limit in this definition (approximately 1 nm) is introduced to avoid single and small groups of atoms from being designated as nano-objects or elements of nanostructures, which might be implied by the absence of a lower limit. [SOURCE: ISO/TS 27687:2008, definition 2.1]. Available at: https://www.iso.org/obp/ui/#home

It was indicated that suppliers often have confidentiality issues with providing the information and that receiving the necessary information is a time-consuming process. What happened is that manufacturers give at once the entire list of notifications. Consequently, downstream users have to go through the entire list to identify what substances are in what products and thus what notification numbers are needed. One common deadline (as it exists currently) is seen as an inconvenience because the large number of people involved in the process makes it difficult to notify on time. As such, it was suggested that there be separate deadlines with sufficient time between them, e.g. the manufacturer of the raw material could be required to declare at a different (earlier) date. This would ensure that the information is gathered and there is time to process it. Moreover, distributors are likely to have to process/manage a huge amount of information related to the notifications. The interval time between each step of the supply chain for notification purposes should exceed one month. It should be noted that both in 2013 and 2014[44], the deadline for the notifications has been postponed, in order to take these issues into account.

The question was raised as to what will be done with all the data and information collected. The objective/purpose of such a notification system is unclear to industry. AVICENN stated that if the objective was to stop the manufacturing and commercialisation of a product when something goes wrong, it is a problem that public cannot access the registry. It was stated that, although the improvement of the traceability of substances improves the health risk management, there is the need to work simultaneously on communication and transparency of such a register. When you want to make the information readable for the public, you need to improve the tool. In the opinion of the industry stakeholders present at the meeting, the FNS is now far from being an appropriate tool and far from being proportionate.[45]

Industry stakeholders noted that tracking tonnages of the substances at the nanoscale and of those substances at the nanoscale contained in mixtures and not bound to them, as required by the FNS, is very difficult and time-consuming. Without information on exposure routes, there is no sense in tracking tonnage. AVICENN stated that it is important to keep track on numbers as, for example, it is then possible to monitor how much nanosilver is going into the water resources. However, the case of nanosilver highlights the fact that the notification system might be not suitable to catch this phenomenon as silver was notified in very low quantities and for research and development purposes, while nanosilver might be entering in France in imported articles that are not designed to release the NM under normal or reasonably foreseeable conditions of use and thus escaping notification obligations.

It was stated that the difficulties in communication and gathering information also stem from the different definitions of NM being used.

Another issue is the communication of the information gathered to the public: for example, the tonnage bands and the total tonnage for some manufactured and imported nanomaterials[46] are not true/definitive as there are a lot of incomplete/partial notifications. But the public will take that

[44] Exceptionally for 2014 and to consider the problem of distributors of substances with nanoparticle state, including those at the end of the distribution chain, receiving a report number from a provider only later, deadline for reporting 2014 has been postponed by the French authorities only for distributors to professional users, 31 May 2014. This provision does not apply to producers of substances with nanoparticle state. *Source: www.r-nano.fr*

[45] The consultants have been asked by the French authorities to note that the industry stakeholders present at the meeting took actively part in its development and agreed on every development made and that every decision has been taken by consensus with industry and NGOs on this project.

[46] Especially for substances above a certain threshold.

information as definitive. It was indicated that the uncertainty factor for quantities sometimes stretch to a factor of 10-100.

It should be noted that during the second year of the implementation of the system, the French authorities received three times the number of notifications and far less questions on the functioning of the system than during the first year of implementation, showing the existence of a learning curve.

5.2.4 Direct costs of the notification system

The participants were asked by the consultants to provide an estimate on the actual costs of the notification process.

One industry representative noted that companies are not used to keeping track of NMs internally and/or didn't know that their materials contained NMs. The new requirements have made it necessary to change the tracking system for raw materials and resulted in an increased workload. He added that the cost for this could amount to millions of euros. However, no information was provided to substantiate such estimate.

It was also noted that resources have been spent for the interpretation of terms (e.g. importer, distributor, etc.). Some of these were introduced by REACH but some others are new. Moreover, not all the sectors/industries (i.e. food industry) are familiar with the REACH terminology. Multinational companies spend a lot of resources on internal meetings and discussions just to clarify terms and to ensure the same understanding across the different departments/sites.

In general, the resources and time dedicated to complying with FNS for the first year were emphasized (e.g. in terms of number of hours and workers). A chemical industry estimate is that it takes up to 2 days of work per substance. This includes supply chain communication to explain the decree to suppliers. However, it was noted that the presence of experts within the company makes the process less time-consuming (e.g. it did not start at zero). A large chemical company indicated that it had notified 130 nanomaterials, contained in 280 different mixtures and 440 different products. It also noted that the time necessary to complete the notifications at a partial stage is still uncertain and difficult to estimate.

Another chemical industry company noted that, although no exact figures are available, the notification exercise involves several departments and requires more than 2 days of work.

A food industry estimate is that, for large companies, the notification exercise requires about 1,500 hours of work (roughly consistent with two work days per substance).

The frequency of notification is also seen as burdensome. It was suggested that updates to the notifications should be made only when something has changed.

In terms of the cost to characterize NMs, a chemical industry estimate is that it is between €3,000 and €10,000 per substance for the mandatory fields.

It should be noted that these estimates refer to the first year of implementation: it is expected that, once the companies have familiarised with the legislative requirements and the system, resources spent on the notification exercise will decrease. Moreover, nanomaterials' characterisation costs are incurred by companies only in the first year. Unless any characteristic of the nanomaterials is modified, notifiers can submit the same information in the following years. The analysis of the direct costs, based on the results of the survey, is provided in Section 5.3.6.

5.2.5 Compliance level

It is general opinion that an estimate of the compliance level is not possible at such early stage of implementation and full compliance cannot be expected.

With regard to the ability of SMEs to comply with the FNS, it was noted that the process is likely more complex for them and, as such, their ability to comply is compromised. Moreover, in order to understand if they are dealing with NMs, SMEs are more likely to send the materials to external labs and thus spending money irrespectively of the results of the tests (NMs or not).

5.2.6 FNS vs. REACH modification

The project team then asked the participants to the meeting whether they were aware of the ongoing discussion on the potential amendment of the REACH Annexes and inquired as to the added value of FNS over a potential modification of the REACH Annexes. Most of them agreed that this would depend upon the kind of amendments implemented. An industry representative responded that the most adequate regulatory framework for nanomaterials is REACH: within REACH, there is the obligation to ensure the safe use of the chemicals throughout the supply chain. He added that what is missing within the FNS is the obligation of remaining responsible for downstream users and thus being involved in the rest of the supply chain.

The consultants have been asked by the French authorities to clarify that the REACH Regulation and the FNS are not mutually exclusive and that, in their views, REACH will not solve all of the concerns raised by nanomaterials.

5.2.7 Public perception of the FNS

When the project team inquired whether there has been a change in public perception of NMs due to the FNS, it was noted that, so far, the system did not have any noticeable impact on the public perception of nanomaterials. It was stated that, according to a survey which explored the public's opinion of labelling NMs in products, people are not concerned with the issue. This was a worldwide, internal and confidential survey carried out by a global and recognised company over the course of 3 months.

5.2.8 Confidentiality issues

It was suggested by the industry stakeholders that the confidentiality aspect could be improved. Declaring the name of the company and its customers gives rise to concerns as to whether providing this information is safe. Such concerns are partly due to the existence of hackers and their ability to compromise IT systems.

Moreover, even to publish the tonnages in terms of tonnage bands might damage companies' businesses, as it would be possible to understand that there are niche/market opportunities.

It should be noted that companies however have the possibility to ask for keeping confidential also the chemical names and the quantities of the nanomaterials notified, providing a substantial justification for the request.

5.2.9 Impacts on competitiveness and innovation

The project team inquired as to the possible impacts of the FNS on the competitiveness of national, European and global markets.

It was noted that the resources for complying with the FNS have been diverted from research and, as such, there is likely to be less innovation. It was noted that it is very important for industry to perceive that public authorities consider nanotechnologies crucial for the economic growth and not just a potential risks to the public health and the environment.

Moreover, an industry association reported that some clients asked for products without nanomaterials because they do not want to be subject to the notification obligations and spend time and resources for regulatory purposes. This results in industry not investing in R&D and innovative applications with NMs. Indeed other companies indicated that, although they did not lose clients due to the FNS by today, however it has made the discussion with them more complicated.

Industry stakeholders stated that the FNS does not make France look attractive in terms of a place for research and innovation and it is uncertain whether a right balance exists between risk and added value. There was a general consensus among industry representatives that the national strategy on nanotechnology is not clear and this causes uncertainty for industry. Lastly, it was indicated that the FNS is perceived by some as over-regulation.

5.2.10 Other critical issues with regard to FNS

In summary, the views on the FNS of the industry stakeholders present at the meeting were the following:

- A preference for using existing regulations was expressed;
- It was indicated that tonnage tracking is unnecessary. If an EU notification system is implemented, this should be avoided. Instead, there should be a direct link in order to avoid duplication of work;
- It was queried the need for the entire chain to notify;
- Overall, a maximum level of simplification is desired. Right now, there is a disproportion between the burden posed on industry by the regulation and the (unclear) benefits of the notification system.

5.3 Results of the Survey on the Administrative Burden of the Notification Systems

5.3.1 Introduction

The online survey on the administrative burden posed by the FNS and the CPNP was launched at the end of February 2014 in English and French. Its aim was to gather relevant information on the experiences of companies providing information to the French Notification System (FNS) and the Cosmetic Products Notification Portal (CPNP), in particular on the direct costs and the impacts on research and innovation. In total, 52 replies were received (status: 5 June 2014; 32 replies to the French questionnaire version, 20 replies to the English version). Moreover, the *Union des Industries*

Chimiques submitted a position document highlighting some key points on behalf of its members. These have been reported in Section 5.3.8.

The questionnaire template is attached in Annex II.

5.3.2 Country of origin

Over 60% of the answers were received from companies based in France. Seven enterprises with headquarters in Germany and four Belgian companies also participated in the survey. Other six replies have been received from companies based in Czech Republic, the Netherlands, Poland, Spain, Sweden and Switzerland.

Table 5-2: Number of respondents by country of origin		
Country	**Number of respondents**	**Share**
France	35	67%
Germany	7	13%
Belgium	4	8%
Czech Republic	1	2%
Netherlands	1	2%
Poland	1	2%
Spain	1	2%
Sweden	1	2%
Switzerland	1	2%
Total	**52**	**-**

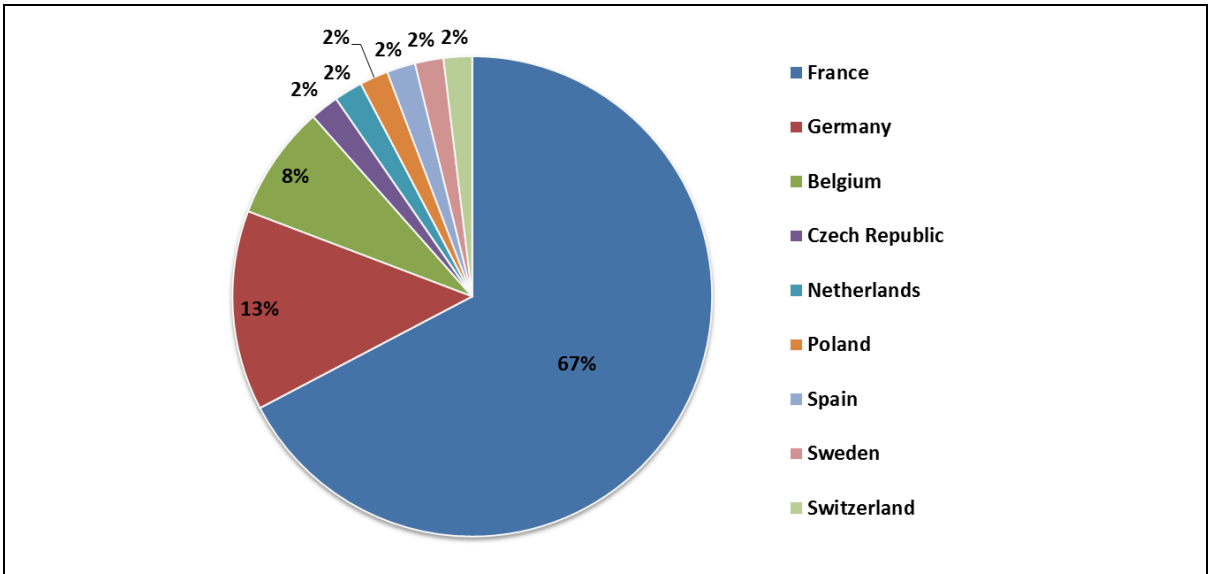

Figure 5-1: Respondents by country of origin

5.3.3 Company size

The participants to the survey were asked to provide number of employees and annual turnover in two separate questions, rather than asking for the company size, in order to facilitate the answers. The replies have been combined and the profile of the companies checked trough internet searches, in order to determine whether SMEs were actual autonomous enterprises or partner/linked

enterprises (with effect on their SME status[47]). No information has been asked with regard to annual balance sheet total to avoid overcomplicating the survey. The results are provided in Table 5-3 and presented in Figure 5-2.

Table 5-3: Respondents by company size		
Company size	**Number of respondents**	**Share**
Small enterprise	3	6%
Medium enterprise	9	17%
Large enterprise	40	77%
Total	52	-

Around 80% of the replies (40 respondents) have been received from large enterprises (companies with over 250 employees and annual turnover over €50 million). Seventeen percent of replies (9 respondents) classifies as medium enterprises (companies with fewer than 250 employees and turnover of less than €50 million). Only three replies (6%) came from small enterprises (companies with fewer than 50 employees and turnover of less than €10 million). No micro enterprises (companies with fewer than 10 employees and turnover of less than €2 million) participated in the survey.

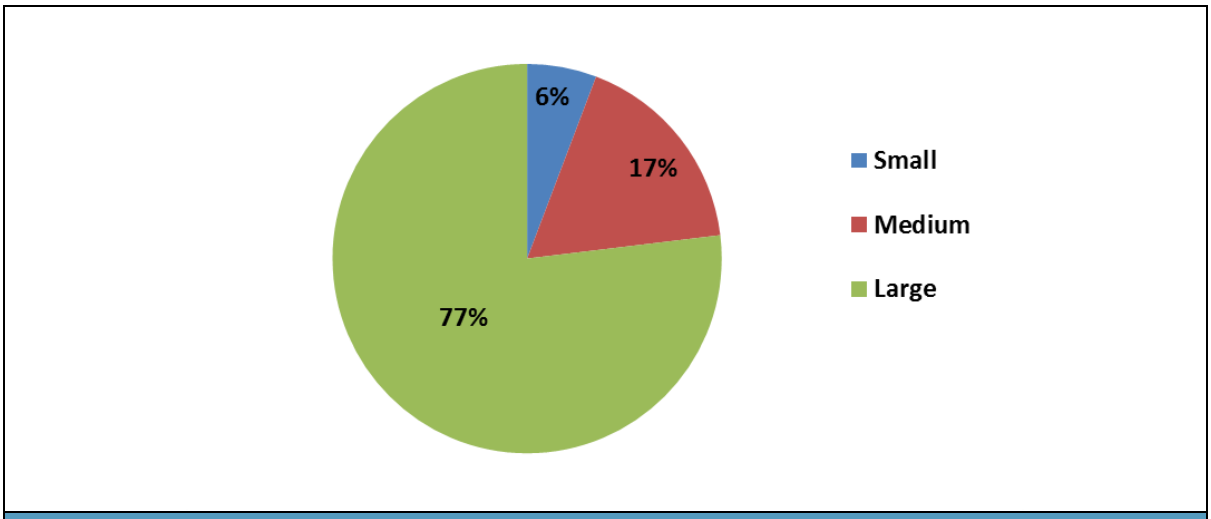

Figure 5-2: Share of respondents by company size

Companies were also asked to provide an estimate of the turnover (in terms of ranges) directly linked with the manufacturing, importing or commercialising of nanomaterials and mixtures or articles containing nanomaterials. Twenty-eight companies provided an estimate: these are presented in Table 5-4 along with overall annual turnovers. Estimates on the number of nanomaterials, mixtures and articles containing nanomaterials that are put on the market by each company are presented in the Building Blocks report (Section 3).

Forty companies provided an indication for the annual turnover, with most of them (65%) declaring an annual turnover over€50 million and another 25% declaring an annual turnover between €10 and €50 million. Three companies declared an annual turnover between €2 million and €10 million and one company an annual turnover of less than €250 thousand.

[47] For further information on the EU definition of SME, see: http://ec.europa.eu/enterprise/policies/sme/files/sme_definition/sme_user_guide_en.pdf

Table 5-4: Annual turnover of companies and the nanotechnology related share		
Range in Euro	Number of respondents (and %) per annual turnover	Number of respondents (and %) per nanotechnology-related turnover
< 250 k	1 (2.5%)	13 (46%)
250 k ≤ 2 m	0 (0%)	1 (4%)
2m ≤ 10m	3 (7.5%)	5 (18%)
10m - 50m	10 (0.25%)	4 (14%)
> 50m	26 (65%)	5 (18%)

It was indicated by nearly 50% of the companies that the nano-products related turnover lies beneath €250,000. Other 50% of the respondents that provided an estimate (14 over 28 companies) indicated a nanotechnology-related turnover higher than €2 million.

5.3.4 Primary business sector

Companies were asked to indicate their primary business sector (52 replies[48]), and if applicable their secondary business sector(s) (15 replies). Table 5-5 presents the primary business sector of the respondents. Seven companies provided only 2 digits for NACE code C20 "Manufacture of chemicals and chemical products": some of them might be active across the different groups and classes[49]. Four companies provided 3 digits for NACE code C20.4 "Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations", C20.5 "Manufacture of other chemical products" and G46.3 "Wholesale of food, beverages and tobacco".

Table 5-5: Overview on the primary business sector of the companies	
NACE primary business sector	No.
C20.4.2 - Manufacture of perfumes and toilet preparations	8
C20 - Manufacture of chemicals and chemical products	7
C20.3.0 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics	7
C20.1.2 - Manufacture of dyes and pigments	5
C20.1.3 - Manufacture of other inorganic basic chemicals	5
C20.5.9 - Manufacture of other chemical products n.e.c.	5
G46.7.5 - Wholesale of chemical products	4
C20.4 - Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations	2
G46.4.5 - Wholesale of perfume and cosmetics	2
C10.8.9 - Manufacture of other food products n.e.c.	1
C20.1.4 - Manufacture of other organic basic chemicals	1
C20.2.0 - Manufacture of pesticides and other agrochemical products	1
C20.4.1 - Manufacture of soap and detergents, cleaning and polishing preparations	1
C20.5 - Manufacture of other chemical products	1
G46.3 - Wholesale of food, beverages and tobacco	1
M72.1.9 - Other research and experimental development on natural sciences and engineering	1
Total	52

[48] 45 respondents provided NACE codes, six respondents provided national codes equivalent to NACE codes and one company did not indicate the primary role as their business cover several NACE codes. For the latter, a NACE code has been assigned on the basis of the highest revenue among the company business sectors.

[49] For the detailed structure of NACE code C20 Rev.2, see page 65 at: http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-RA-07-015/EN/KS-RA-07-015-EN.PDF

5.3.5 Supply chain characterisation

This subsection characterises the respondents in terms of the role(s) played in the supply chains of nanomaterials and provides some data on the number of notifications completed by the respondents. Further analysis of the supply chains of the respondents (number of nanomaterials and mixtures or articles containing nanomaterials put on the French, European and global markets, number of clients, number of providers) is provided in Section 3 of the Building Blocks report.

Role in the supply chains of nanomaterials

Thirty-two companies indicated to play multiple roles in the supply chains of nanomaterials, with just eight companies indicating to be only manufacturers, five indicating to be only importers, other five indicating to be professional users and distributors and two indicating to be only distributors. Table 5-4 presents the different roles as indicated by the respondents (multiple ticks and indication of primary role possible[50]).

Table 5-6: Overview on the supply chain position of the companies

Supply chain position	No. of companies	of which primary role
Manufacturer	26	**25**
Distributor	26	**11**
Importer	26	**11**
Professional user (PU) & distributor	15	**12**
Repackager& distributor	4	**2**
European representative	2	**1**

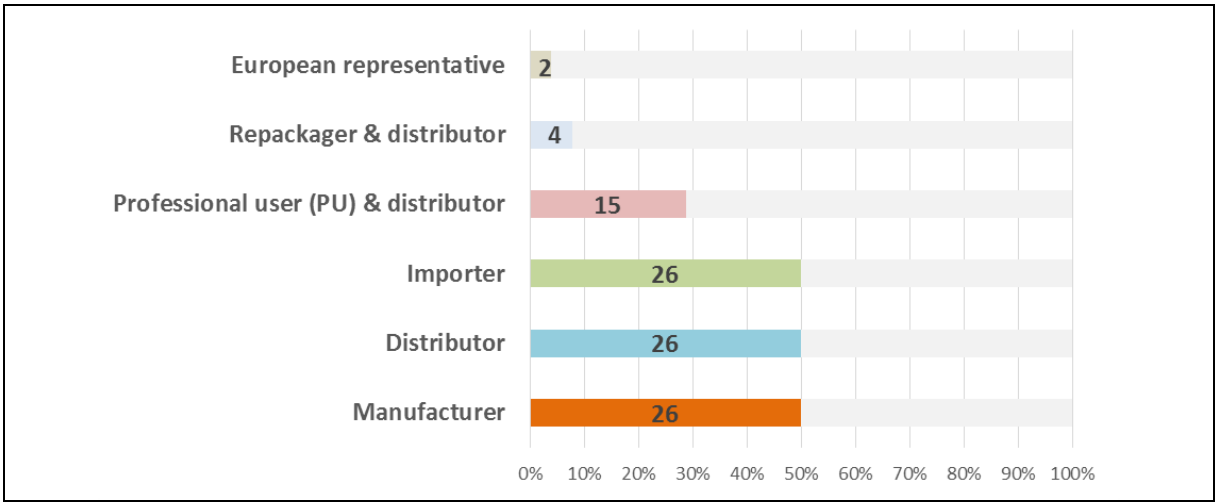

Figure 5-3: Overview of the supply chain by company role

Number of notifications

Companies were asked to provide the number of notifications completed in 2013 and completed or planned for 2014.

[50] For companies, who only selected one role, the selected role was considered as their primary role. For companies indicating more than one role, but without stating one of the roles as being their primary role, all selections were equally counted as primary role.

Overall, in 2013, 933 companies completed around 3,409 notifications: 52 companies (around 6% of the total number of notifiers) participated in the survey and indicated to have completed around 800 notifications (24% of the total number of notifications). It can be concluded that many of the big actors on the French market participated in the survey.

Only eight respondents notified nanomaterials to the CPNP: notably, a large cosmetics manufacturer completed over 50 notifications to the FNS and over 10,000 notifications to the CPNP. It should be noted however that companies have to notify all cosmetic products to the CPNP, disregarding whether they contain or not contain nanomaterials and, if a product is available in several shades, each shade containing a different nanomaterial should be notified under Article 16.

With regard to notifications in 2014, respondents generally provided or the same number of notifications or a higher number or the additional number of notifications: it can be concluded that 2013, being the first year of implementation of the system, has been a "learning" period for companies. This seems to be confirmed also by the fact that in 2014 the French authorities received three times the number of notifications than in 2013.

5.3.6 Industry cost analysis

Generation/gathering of information for notification purposes

The companies were asked to indicate whether they had to and how they generated and/or gathered data for notification purposes, in order to determine the amount of work necessary for each respondents and link it to their different characteristics (e.g. role in the supply chains, company size). Table 5-7 and Figure 5-4 present the results (multiple ticks were possible).

Table 5-7: Generation/gathering of information for notification purposes

	No.	%
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	4	8%
We generated (internally or outsourced) **all the information** required by the regulation **for the purpose of the notification**	11	21%
We generated **part of the information** required for the purpose of the notification, since some information were already available	19	37%
We referred to the **notification number(s)** of the supplier(s) for the "substance identity" part	29	56%

Over 50% of the respondents had the possibility to refer to the notification numbers for some of their nanomaterials. On the 29 respondents that indicated to refer to the notification number(s) of the supplier(s) for the "substance identity" part, 12 (around 23%) did not have to generate any "substance identity" information for any of their nanomaterials. Table 5-8 reports the business sectors indicated by the respondents that did not have to generate any data for the characterisation of nanomaterials.

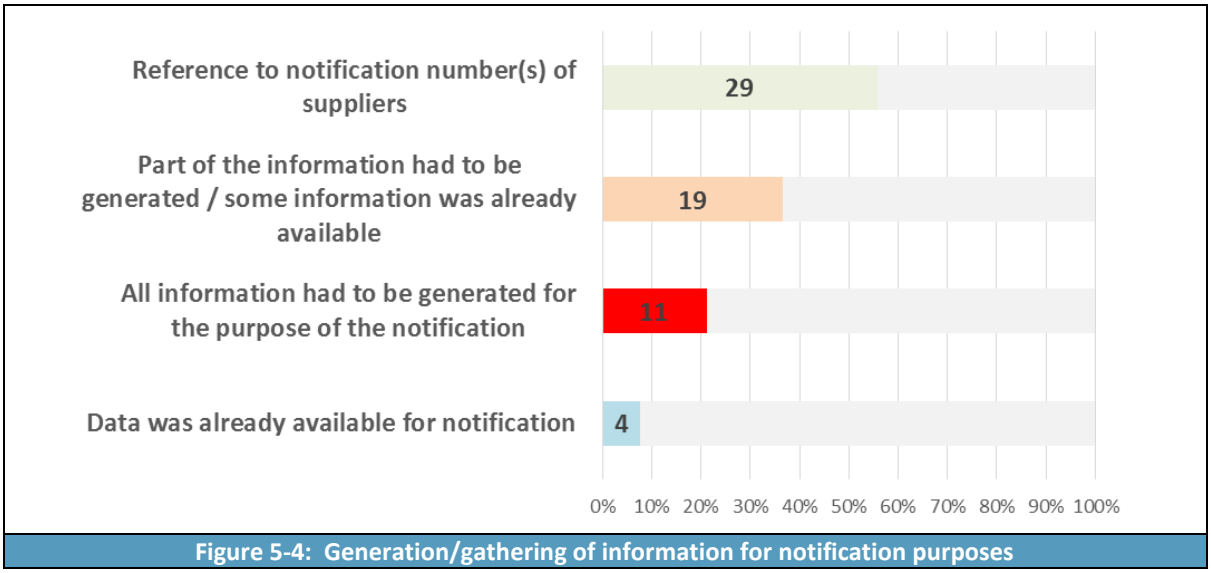

Figure 5-4: Generation/gathering of information for notification purposes

Table 5-8: Business sectors of the respondents that did not have to generate any "substance identity" information

NACE code	No.
G46.7.5 - Wholesale of chemical products	4
C20.3.0 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics	3
C20.5.9 - Manufacture of other chemical products n.e.c.	2
C20.4.1 - Manufacture of soap and detergents, cleaning and polishing preparations	1
C20.4.2 - Manufacture of perfumes and toilet preparations	1
M72.1.9 - Other research and experimental development on natural sciences and engineering	1

From their profiles, it can be concluded that distributors and formulators are the types of companies that benefit the most from the possibility to refer to the notification number of the suppliers of their nanomaterials.

Other 19 companies (around 37%) indicated to have partially benefit from the possibility to refer to the notification numbers of their suppliers but also had to generate part of the information for the notification purposes.

Notably, 11 companies (around 21% of the respondents) replied that they had to generate (internally or outsourcing) all the information required by the regulation for the purpose of the notification for some of their nanomaterials. Of these eleven, 7 indicated that they had to generate the information for all their nanomaterials. Table 5-9 reports their business sectors.

Table 5-9: Business sectors of the respondents that had to generate all the information for all their nanomaterials for information purposes

NACE code	No.
C20.1.3 - Manufacture of other inorganic basic chemicals	3
C20.1.2 - Manufacture of dyes and pigments	2
C20 - Manufacture of chemicals and chemical products (manufacture of catalysts and specialty chemicals)	1
20.5.9 - Manufacture of other chemical products n.e.c (manufacture of specialty chemical products for human health (cancer treatments))	1

Looking at the profiles of the companies that had to generate some of the information for all or part of their nanomaterials portfolio, manufacturers and importers of basic chemicals (and notably of dyes and pigments) are the actors more likely to entail the costs for the characterisation of the nanomaterials.

During the Validation Workshop held in Brussels on 30 June 2014, there was a lot of discussion on what are the actual administrative burdens posed by the French legislation and what instead are costs already incurred by companies for product development purposes. Further investigating on this aspect, and in particular on which of the nanomaterials' parameters required by the FNS might be already fully determined for product development purposes, one manufacturer of pigments and dyes noted the following:

- With regard to the size of the particles, the problem lies on the relevance of the measurement metric and technique: in most cases, the metric relevant for the application properties is volume or mass based, and existing particle size measurements will presumably be performed in the application medium or in the actual state of the product. In most cases, this is not linked to and will not lead to results on the number size distribution of primary particles;

- With regard to the particle number size distribution, this is measured only in exceptional cases, as it is not relevant for the application properties of the products;

- With regard to aggregation/agglomeration state, this is the most important factor determining the application behaviour of a given material and is based on the dispersion status in a given medium. The target normally is to reach an optimal dispersion in the respective application medium because this will lead to the best application behaviour as well;

- With regard to the shape, this will often be known from the R&D phase;

- With regard to coating, and referring only to organic pigments, these are generally used in complex mixtures and their composition and the presence of a coating will differ for every mixture/product/application.

During the Validation Workshop, representatives of NGOs and environmental groups made the case that the characterisation of NMs should not be considered as an administrative burden of the FNS and should be instead part of the normal operational activity of companies to ensure protection of human health and the environment. Industry representatives countered that there are many ways to characterise NMs, and those required by the schemes are not part of the normal activity for companies using NMs.

Four companies indicated that they had to generate all the information for the purpose of product development and of complying with other legislation, so it was already available for notification. Two of these companies are manufacturers of cosmetic products (and thus the characterisation of the nanomaterials had to be completed also for the notification to the CPNP); one company is specialised in the manufacturing of carbon black and one indicated to operate in the Manufacture of paints, varnishes and similar coatings, printing ink and mastics.

In conclusion, **for over 50%of the companies (mostly formulators and distributors), the regulatory burden linked to the generation of information on "substance identity "was limited, since some or all of the data were already available or companies could refer to the notification number of substances already declared (by their suppliers).Around 20% of the companies (mostly**

manufacturers/importers of basic chemicals and pigments and dyes) indicated that all data had to be generated for the purpose of notification.

Support by other pieces of legislation

When gathering information for notification purposes, some of the companies had the possibility to benefit from information generated to comply with other legislative acts (for example, the information on substance identity within a registration dossier and not specific to the nanoscale could have been used for notification purposes).

In particular the REACH and the CLP Regulations were indicated to be helpful in meeting the information requirements for the FNS: 24% of the companies declared the REACH Regulation as valuable, followed by the CLP Regulation (22%) (Table 5-10). However, some of the companies commented that none of the pieces of legislation listed helped in complying with the French decree and that the FNS entailed new administrative burdens: for example, one company commented that they had to ask by letter to over 500 suppliers whether their substances or mixtures where covered by the FNS and they had to file the incoming information into an adapted database.

Concerning the notification obligations to the CPNP, the REACH, CLP and Biocidal Products Regulations were attributed a minor supporting role (ca. 7% respectively).

Table 5-10: Information support by other legislative requirements

Legislation	No. of replies
Regulation (EC) No 1907/2006 (REACH) (i.e. information from registration dossiers)	13
Regulation (EC) No 1272/2008 (CLP) (i.e. information from safety data sheets)	12
Regulation (EC) No 1223/2009 (Cosmetic Products)	7
Regulation (EU) No 528/2012 (Biocidal Products)	2
Regulation (EC) No 1935/2004 (Food Contact Material)	2
Council Directive 98/24/EC (Chemical Agents Directive)	1
Regulation (EC) No 258/1997 (Novel Food)	0
Regulation (EU) No 1169/2011 (Food information to consumers)	0
Total	**55**

Regulatory burden in comparison with other pieces of legislation

Companies were asked to provide the burden share posed by the FNS in comparison with other pieces of legislation: the notification system ranked second just after the REACH Regulation and, surprisingly, before the CLP Regulation (Table 5-11). However, this could be due to the initial implementation stage of the FNS: perception of companies over the notification system might change once they get familiar with the legislation and the information to be notified is already available from previous years.

From another perspective, the FNS figured higher up than the Cosmetic Products Regulation, where the latter requires additional information. This might be due to the profiles of the respondents to the survey, where most of them had to notify more substances to the FNS than to the CPNP.

A general comment was that, more than the regulatory burden posed by a single legislative act, the problem is the total burden due to different and differing legislation. In case of additional legislative measures on nanomaterials, a European wide solution would be favoured instead of many different national notification systems with different notification requirements.

Table 5-11: Regulatory burden in comparison with other pieces of legislation	
	Average in %
Regulation (EC) No 1907/2006 (**REACH**)	32
Interministerial decree No. 2012-232 (**French Notification System**)	27
Regulation (EC) No 1272/2008 (**CLP**)	21
Regulation (EC) No 1223/2009 (**Cosmetic Products**)	10
Other (please specify)	9
Council Directive 98/24/EC (**Chemical Agents Directive**)	8
Regulation (EU) No 528/2012 (**Biocidal Products**)	6
Regulation (EC) No 1935/2004 (**Food Contact Material**)	5
Regulation (EU) No 1169/2011 (**Food information to consumers**)	2
Regulation (EC) No 258/1997 (**Novel Food**)	1

Most burdensome requirements of the FNS

Companies were asked to rate the most burdensome information requirements of the notification scheme on a range from 1 to 5 (1 least burdensome, 5 most burdensome).

Table 5-12 provides an overview on the results of the analysis.

Table 5-12: Rating of the FNS information requirements in terms of administrative burden (rating 1-5 with 1 least burdensome and 5 most burdensome, results presented in percent, %)					
Burden type	**1**	**2**	**3**	**4**	**5**
Identity of the notifier	**49%**	18%	14%	16%	2%
Information on the notification (ex.: role in the supply chain)	**29%**	22%	27%	12%	10%
Identity of the substance (ex.: CAS number, primary particle size, shape)	17%	10%	13%	6%	**54%**
Quantities	17%	17%	**29%**	21%	17%
Uses	**32%**	17%	17%	28%	6%
Customers (professional users)	20%	18%	11%	7%	**43%**

For over 50% of the companies, **the provision of the information regarding the substance(s) (and thus the characterisation of the nanomaterial(s)) is the most burdensome part of the notification exercise. The provision of information regarding quantities and identity of the customers also ranked high in terms of administrative burden posed by the system.**

Difficulties with respect to interpretation of terminology

Companies were asked to indicate if they found difficult the terminology used and on which part of the legislation. Results are summarised in Table 5-13. Around 80% of the companies had difficulties with the definition of nanomaterial and the scope of the legislation. With regard to the nanomaterial definition, it was stated that the existence of different definitions (EC recommended definition, definition according to the Cosmetics Regulation, ISO definition, etc.) lead to confusion and difficulties with communication across the supply chain. Respondents found also a lack of clarity on what is meant with "*bound/unbound state*" as used in the definition for mixtures containing

substances at nanoscale and with "*release under foreseeable conditions*". Another critical issue flagged by several companies was the lack of standardised analytical methods.

Table 5-13: Difficulties with respect to interpretation of terminology		
	No.	**Proportion**
Definition of nanomaterial used	40	77%
Scope (who has to notify, what needs to be notified, exemptions etc.)	40	77%
Calculation of **volumes** related to volume thresholds	15	29%
Other	11	21%

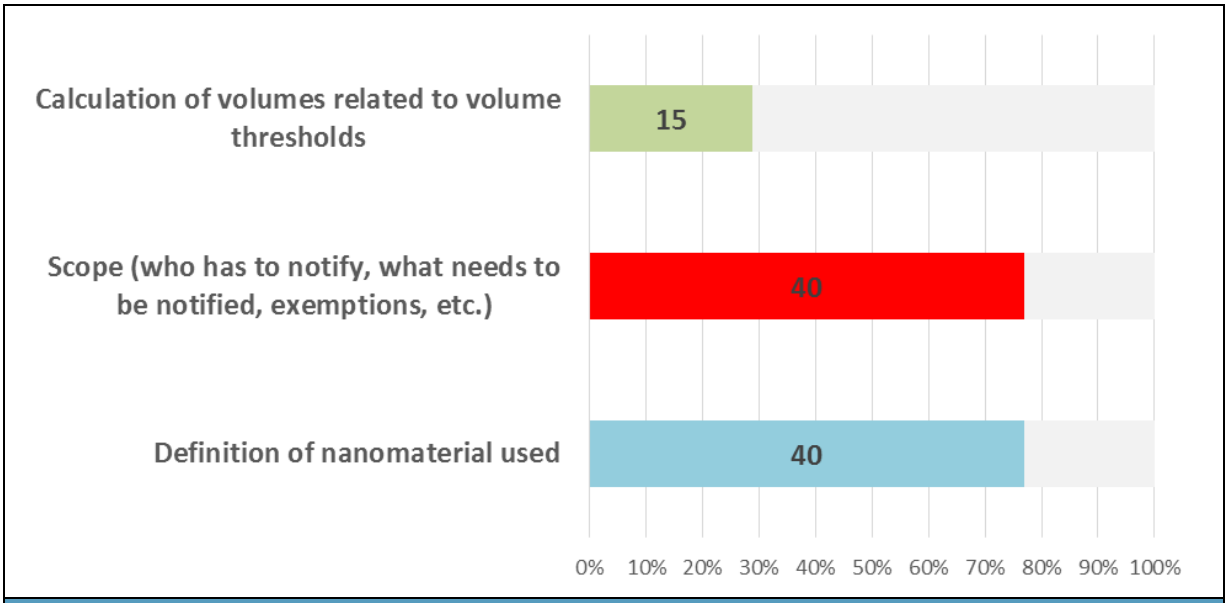

Figure 5-5: Respondents' difficulties with regard to interpretation of terminology

Direct Costs

In order to consider the different requirements for different actors in the supply chain, the cost factors were allocated according to two categories:

- Company size (SMEs and large enterprises); and
- Role of the notifier (manufacturer/importer vs. industrial user/distributor).

As noted above, manufacturers and importers are usually the actors that have to generate the information regarding the substance identity, while distributors and professional users can often just refer to the notification number of the nanomaterials already notified by their suppliers.

The enterprises were asked to indicate their annual turnovers and the nanotechnology-related turnovers (Table 5-4), in order to estimate the burden on different sized actors across the supply chain and to compare the magnitude of different cost types to the total costs for manufacturing, importing and distributing nanomaterials.

Moreover, companies were asked to estimate the burden for different cost type in terms of time and resources for both the FNS and the CPNP in 2013 and 2014. **It is expected to observe a decrease of the burden in 2014 compared to the first year of implementation, as companies will have familiarised with the legislation and the notification IT tool and will have generated most of**

the information for the first notification. In order to account for this expected decrease, costs have been differentiated between one-off costs and recurring costs.

Different cost types defined in the survey were:

1. Administrative costs:
   - Understanding of the legal requirements (Total hours); **(one-off cost)**
   - Gathering of information to be submitted (Total hours); **(recurring cost)**[51]
   - Submission of the information (Total hours); **(recurring cost)**
   - Responding to clients' enquiries (Total hours); **(recurring cost)**
2. Substance analysis characterisation costs (only the part of information generated for the purpose of the notification) (Euros (€) and/or total hours);**(one-off cost)**
3. IT alignment and/or adapting product/account databases (Euros (€) and/or total hours).**(one-off cost)**

It should be noted that even for the recurring costs, a certain learning curve (and thus a decrease in the costs) is expected: the information submission exercise should take less time once the responsible person has familiarised with the online system (r-nano.fr) and enquiries from the clients are expected to decrease in the long run.

1. Administrative costs

Understanding of the legal requirements

Forty-six companies provided estimates of the amount of time needed for understanding and familiarise with the legal requirements. These estimates range from 4 hours, indicated by two distributors that had to notify few nanomaterials, to over 300 hours estimated by some large enterprises that rank the highest in terms of number of notifications completed. In the high end is encompassed all the time necessary for meetings and communication between different departments dealing with nanomaterials, time necessary to ensure that a common understanding of the legislation is shared across the company. A high number of hours has been estimated also by a large enterprise active in the wholesale of food products: this might indicate that companies that are not familiar with the chemical legislative framework and the terminology used within REACH (that the French decree recalls) might need more time for understanding the legislation.

Remarkably, those enterprises that had to generate part or all the information for the notification purposes indicated more time for the understanding of the legislation. On the other side, companies that could refer to the notification numbers of their suppliers indicated time spans between 20 and 50 hours.

Companies were also asked to provide an estimate for 2014: some companies reported times from two to twenty times lower than in the first year; some others reported higher numbers of hours: this seems to be linked to the fact that many companies did not complete all the notifications for the first year. Nevertheless, it is expected that the time necessary for understanding and familiarise with the legislative requirements will drastically decrease in the next years: however, in order to capture this decrease and to obtain more solid estimates, the companies should be surveyed again in the coming years.

[51] Each year, companies will have to verify whether the information submitted in the previous year is still valid or new/updated information needs to be submitted.

Gathering of information to be submitted

Forty-four companies provided estimates of the amount of time needed for the gathering of the information to be submitted. Estimates range from a couple of hours necessary for one company to gather the required information for one single notification to over 500 hours for another companies gathering information for over 20 different notifications. When the total number of hours provided by each company is divided per the number of notifications completed, the range spans from half an hour to 65 hours per notification, with a median value of around 10 hours per notifications.

Submission of the information

Thirty-seven companies provided an estimate of the time necessary to submit the information through the online system: this ranges from half an hour to six hours per notification. The median value is of one hour per notification.

Responding to clients enquiries

Thirty-five companies provided estimates of the time required to reply to clients' enquiries with regard to the notification of the nanomaterials. The estimates range from one hour to six hours per notification, with a median value of two hours per notification.

2. *Substance analysis characterisation costs*

Among the companies that had to characterise the nanomaterials, four of them estimated costs ranging from €3,000 to €10,000 per substance. Although only four companies provided a clear and defined figure for the characterisation of the nanomaterials, it should be noted the two of them rank among the companies that notified the highest number of nanomaterials to the FNS and consistently reported an estimate of €10,000 per substance.

Other 5 companies provided a figure ranging between €3,000 and €5,000: these companies had to generate only part of the information for the purpose of the notification. These are formulators having to submit, for example, information on the agglomeration/aggregation state or information on the modification of the surface coating. Other nine companies provided estimates in terms of hours spent on the task: these range from 5 to 450 hours; however, no additional information has been provided for a better understanding of these time figures.

It should be noted that the European Commission has recently[52]made available online the study supporting the impact assessment of relevant regulatory options for nanomaterials in the framework of REACH[53]: it provides a cost range for a "characterisation" package ranging from €40,000 to €500,000. This range was provided by a laboratory with significance experience in characterising nanomaterials and involved in the projects of the OECD working groups. The explanation provided for such wide range was that "*it was difficult to provide generic costs per assay, as each nanoform they had experience with presented its own unique challenges when being characterised, and different methods were needed to obtain different parameters and measures to characterise size, shape, and a range of other properties that could be relevant to the toxicological properties of the material*". Moreover, the lower estimate refers to "*a technically straightforward analysis of simple particulates*" and the higher estimate to "*more complex characterisation of*

[52] May 2014.

[53] Matrix (2014): Request for Services in the Context of the FC ENTR/2008/006, lot 3: A Study to Support the Impact Assessment of Relevant Regulatory Options for Nanomaterials in the Framework of REACH, London, 31st March 2014.

nanoforms (e.g. nanoforms with unusual size and shape properties) that involve more complex analytical techniques".[54]

When comparing the range provided by the companies surveyed for the present study and the range provided by the laboratory surveyed in Matrix (2014), it should be noted that the FNS requires the mandatory submission of information only on a limited number of parameters, namely:

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

Information on any impurities, the crystalline state and the surface charge should be submitted if available at the time of notification.

The estimated range of €40,000 to €500,000 refers instead to the list of parameters needed for the full characterisation of the nanomaterials (as determined by the OECD Working Party on Manufactured Nanomaterials), and namely:

- Agglomeration/aggregation state;
- Water solubility/Dispersibility;
- Crystalline phase;
- Representative Electron Microscopy (TEM) picture(s);
- Particle size distribution – dry in relevant media;
- Specific surface area;
- Zeta potential (surface charge);
- Surface chemistry, where appropriate;
- Photocatalytic activity;
- Pour density;
- Porosity;
- Octanol-water partition coefficient;
- Redox potential;
- Radical formation potential; and
- Other relevant parameters.[55]

3. *IT alignment and/or adapting product/account databases*

Sixteen companies have provided estimates with regard to any IT alignment and/or adaptation of their product/account databases. Estimates range from a couple of hours, as indicated by companies completing few notifications, to 150 hours, as indicated by two large enterprises that completed a high number of notifications. The median value is of around 10 hours. One company indicated a cost of €50,000.

5.3.7 Perception on competitiveness and innovation impacts

In addition to what has been reported on competitiveness and innovation impacts during the stakeholder meeting, Table 5-14 presents the findings of the online survey with regard the

[54] Matrix (2014), page 38.
[55] Matrix (2014): Appendix 5 Data Capture ExerciseAverageCost per Assey, page157.

companies' perception on the potential competitiveness and innovation impacts of the FNS and the CPNP.

Enterprises were asked to indicate the magnitude of the impacts that the FNS and, if applicable, the CPNP had on their business, rating on a scale ranging from `very negative´, `negative´, `no change´, `positive´ and `very positive'. The results of the survey capture the overall perception of the companies about the potential impacts of the notification system over competitiveness and innovation.

Table 5-14: Number of companies per opinion over impacts magnitude						
Impact category	**Very negative**	**Negative**	**No change**	**Positive**	**Very positive**	**Not applicable**
French Notification System (respondents: 46)						
Impact on your ability to develop and market new products containing nanomaterials in France	12	18	8	1	-	-
Impact on intra-EU competitiveness (your ability to successfully compete with manufacturers from other EU member states on the EU market)	7	16	13	1	-	5
Impact on extra-EU competitiveness (your ability to compete with manufacturers from outside EU on the global market).	6	13	14	-	1	7
Impact on Research & Development	10	14	17	-	-	4
Impact on Intellectual Property rights and confidentiality aspects	3	12	22	1	-	6
Impact on public perception of nanomaterials	13	20	9	-	-	3
Cosmetic Products Notification Portal (respondents: 17)						
Impact on your ability to develop and market new products containing nanomaterials in France	4	7	1	-	-	5
Impact on intra-EU competitiveness (your ability to successfully compete with manufacturers from other EU member states on the EU market)	1	5	5	-	-	5
Impact on extra-EU competitiveness (your ability to compete with manufacturers from outside EU on the global market).	3	5	4	-	-	4
Impact on Research & Development	4	6	2	-	-	5
Impact on Intellectual Property rights and confidentiality aspects	1	4	5	-	-	6
Impact on public perception of nanomaterials	3	6	4	-	-	4

In conclusion, the majority of responding companies notifying to the FNS indicated that the FNS had very negative to negative impacts on their nanomaterial business with respect to different business areas. Impacts related to the ability to develop and market new products containing nanomaterials were perceived as very negative/negative (~77%), while some of the other respondents (~20%) felt that no change applied. In contrast, about 3% of the respondents felt that the FNS had a positive effect. Furthermore, around half of the companies indicated that their intra- (~55%) and extra-EU

competitiveness (~46%) would be affected in a negative/very negative way, while about one third stated to perceive no change at all. Also, the impacts on R&D activities were perceived negative to very negative by most companies (~53%) as well as changes in the public perception on nanomaterials (~73%). For the category 'Impact on Intellectual Property rights and confidentiality aspects,' half of the companies responded that no changes have been observed.

One large manufacturer of chemicals commented that, for the time being, the highest impact they observed was on the perception of the downstream actors in the value chains; no impact has been observed so far on the public. Another large manufacturer reported a very negative impact on the marketing of their products because, no matter if the products have no hazard classifications according to the CLP Regulation or the same products were used for many years, the "nano" stigma is sufficient to hinder sales. On their opinion however, the notification has no impact on public perception. Moreover, the same company reported that manufacturers of the same substances do not all end up with the same conclusion about the "nano" status of their substances, which leads to conflicting information on the market. Confirming what reported by other companies, other two large manufacturers commented that the notification system creates a lot of questions in other actors along the supply chains and even across the same companies. This has the effect to take away focus on the ordinary business and also scares some companies from doing business with their technology.

Reinforcing the comments above, a large chemical distributor reported that many of their customers have indicated the will to stop using the products subject to notification in the coming years, even if the risks are not proven.

A large distributor of food, beverage and tobacco commented that it is still too early to observe any impact but that depending on how the topic develops, a significant change in the public perception and on the intra-EU and extra-EU competitiveness might be observed.

Another large manufacturer of chemicals commented to be very concerned about the potential leaking or hacking of confidential information.

A large manufacturer of pigments and dyes commented that having to notify very common substances (carbon black, titanium dioxide, calcium carbonate and silicon dioxide) has a very negative impact on the public. In their opinion, the system should be limited to new nanomaterials.

One medium-sized distributor of cosmetic products commented that, given the present regulatory uncertainty, their policy is to limit as much as possible the commercialisation of products containing nanomaterials, although they believe that nanomaterials could deliver very desirable characteristics to the products they distribute.

Finally, one large manufacturer of pigments and dyes commented that they do not consider themselves as in the "nanomaterials business", as it just happen that some of the substances used for the formulation of dry inks for printing toners are at the nanoscale.

During the Validation Workshop, the representative of a company active in the pigments and dyes sector that had to notify a high number of nanomaterials, reported as an example for the effects of the FNS on a company's business that manufacturers of nanomaterials and downstream users of the same substances take different solutions on whether or not to notify and that clients turn to those suppliers who did not notify.

For the CPNP, similar results as for the FNS resulted from the company survey responses. Around half of the participating companies notifying to the CPNP indicated that introduction of the CPNP had negative to very negative impacts on their businesses.

5.3.8 Additional comments provided during the survey

Companies had the possibility to provide additional comments at the end of the online survey.

Many companies indicated that the different definitions of nanomaterials existing EU wide lead to confusion of different actors along the supply chain and to poor communication between actors, in particular with partners from outside France. This is particularly true for those companies having to notify nanomaterials to both the FNS and the CPNP, where the nanomaterials have different definitions.

The lack of standardised analytical methods has often been indicated to cause problems in defining what is "in" and what is "out" the scope of the legislation.

It was noted that many suppliers, considering the uncertainties over the definition of nanomaterial, might not carefully scrutiny their portfolios of products. It should be noted however, that among the notifiers a precautionary approach was followed, notifying substances where there was no certainty over their nanoscale status. Notably, some companies reported to have dedicated substantial resources to deal with the notification requirements also where the analyses over the "nano" status of their substances were negative.

Some companies referred to have faced problems in obtaining the relevant information from their suppliers, especially from those suppliers located outside France and/or Europe. One company noted that this would be a sufficient reason to draw back from nanomaterials in the near future.

It is general opinion that many suppliers located outside Europe might not be well informed on the legal developments in France/EU. For their downstream users located in Europe/France, it has been particularly difficult to gather the relevant information to be notified. It was suggested to introduce two different deadlines per year instead of one overall substance notification deadline dependant on the supply chain position of the notifiers.

Some companies reported to have perplexities with regard to the terminology used, especially when defining what nanomaterials are bound/not bound to a mixture and when determining the possibility of release of the nanomaterials in normal or foreseeable conditions.

On top of the specific contributions received from companies, the *Union des Industries Chimiques* (UIC) has submitted a position paper on the administrative burden posed by the FNS, summarising the difficulties faced by the companies (which have been reported above) and underlining the main issues:

- The broad scope of the scheme (the obligation to report substances marketed for decades without known health and environmental impacts[56]);
- The "*mistrustful perception of the scheme by economic partners and consequently, the negative impact on competitiveness and innovation*", that might lead to question business developments and location of R&D activities in France;
- The "*disruption of the free movements of goods within the EU*";
- The risk of releasing confidential information; and
- The questionable added-value of such a scheme.

[56] Exemples reported are: carbon black, calcium carbonate, titanium dioxide, amorphous silica.

5.4 Total Costs for the Notifiers

On the basis of the estimates provided by the companies for different one-off and recurring cost categories and on the analysis of the survey results (presented in Section 5.3.6), this Section presents the estimate, developed by the consultants, of the total costs for the companies that had to notify to the FNS in 2013 and the estimate of the recurring costs for the following years.

For the purposes of the calculation, the consultants assume that:

- The cost for generating all the information for the purposes of notification range between €3,000 to €10,000;
- The cost for generating only part of the information range between €3,000 to €5,000;
- For 70% of the notifications completed by manufacturers and importers, the information had to be generated completely for the purposes of the notification; for 20% only part of the information had to be generated, for the remaining 10%of the notifications completed by manufacturers and importers, the information was already available for product development purposes;
- 60% of the notifications completed by distributors and professional users refers to the notification numbers of the nanomaterials notified by their suppliers and no information had to be generated; for 40% of the notifications, companies had to generate part of the information for notification purposes.

Table 5-5 presents the estimate of the total cost for the notifiers to generate all or part of the information on the characterisation of the nanomaterials in 2013.

Table 5-5: Estimate of the total cost for the notifiers to generate information for notification purposes

	No. of notifications	Cost
Completed by manufacturers and importers		
All information generated for notification purposes	(70%) 750	≈€2,250,000 - €7,500,000
Part of the information generated for notification purposes	(20%) 214	≈€640,000 - €1,070,000
No information had to be generated	(10%) 108	-
Total	**1,072**[+]	**≈€2,890,000 - €8,570,000**
Completed by distributors and professional users		
Refer to the notification numbers of suppliers	(60%) 1,283	-
Part of the information generated for notification purposes	(40%) 855	≈€2,560,000 - €4,270,000
Total	**2,138**[+]	**≈€2,560,000 - €4,270,000**
Overall total	**3,210**	**≈€5,460,000 - €12,840,000**

Source: [+] French public report (2013), page 18.

The assumptions try to keep into account the fact that many notifiers play multiple roles within the supply chains of nanomaterials. For example, one company might have had to generate all the information for the nanomaterials manufactured but only part of the information for the nanomaterials imported.

For the generation of information with regard to the characterisation of nanomaterials, it has been estimated that the cost for industry stakeholders was between **€5.5 million and €13 million in 2013.** Using the low end (€40,000) of the estimate provided in Matrix (2014), the total cost would range between €30 million and €35 million.

Table 5-6 presents the estimate of the total cost for the notifiers to gather and submit the information, to respond to clients' enquiries and to adapt their product/account databases. For 2013, the total cost for these action was of **around €2.6 million**.

Table 5-6: Estimate of the total cost for the notifiers to gather and submit the information, to respond to clients' enquiries and to adapt their product/account databases			
Understanding of the legal requirements	**No. of notifiers**	**Hours (median)**	**Cost***
Manufacturers and importers	236[+]	30	≈€250,000
Distributors and professional users	560[+]	25	≈€490,000
Gathering of the information	**No. of notifications**	**Hours (median)**	**Cost***
Manufacturers and importers	1,072	10	≈€380,000
Distributors and professional users	2,138	10	≈€750,000
Submission of the information	**No. of notifications**	**Hours (median)**	**Cost***
All notifiers	3,210	1	≈€120,000
Responding to enquiries	**No. of notifications**	**Hours (median)**	**Cost***
All notifiers	3,210	2	≈€340,000
Adapting product/account databases	**No. of notifiers**	**Hours (median)**	**Cost***
All notifiers	796	10	≈€280,000
		Total	**≈€2,610,000**
Source: [+] French public report (2013), page 18. ** Assuming an average hourly gross wage of €35*			

In summary, in 2013 the total administrative burden for the companies having to notify has been estimated between **€8 million and €15.5 million.**

It should be noted that in 2014 the French authorities have received over 10,000 notifications. However, no more detailed information is currently[57] available to attempt any estimate with regard to how many notifications refer to new substances, how many come from manufacturers and importers, etc.

It is also important to note that during the Validation Workshop, non-governmental organisations expressed the opinion that the costs for the characterisation of the nanomaterials should not be considered as administrative burden of the FNS since companies should characterise the nanomaterials to comply with the CLP Regulation and the Health and Safety legislation.

In terms of the yearly recurring costs, assuming that the time necessary to the different actors for understanding the legal requirements and the time needed to respond to clients' enquiries about the notifications of nanomaterials would tend to zero with the passing of the years, the only costs to be considered relate to the gathering and submission of the information. Assuming that, after the first years, the time necessary to gather the information would be of around 1 hour per notification (updating of any changed item, verification of the validity of the information from the past years, gathering of new information referring to new nanomaterials commercialised) and the time necessary for the submission of the information would be of around 0.5 hour per notification, yearly recurring costs per notification would be of around €50. Assuming that in a full compliance scenario the number of notifications are between 15,000 and 20,000 per year, the total recurring cost would range between **€750,000 and €1 million per year**.

[57] August 2014.

5.5 Case Studies

Three case studies have been developed in order to better assess the administrative burden of the notification system on different types of actors across the supply chain.

5.5.1 Case Study 1 – Large Enterprise with Multiple Roles in the Supply Chain

This case study focuses on the experience of a large enterprise with multiple roles in the supply chains in notifying its products to the French Notification System and the Cosmetic Products Notification Portal. The case study has been developed on the basis of the responses provided to the survey on the administrative burden of the notification schemes and on a follow-up teleconference with the main contact person and the responsible persons from the different departments of the company directly involved with nanomaterials and nanomaterials related products.

The notifier is a multinational enterprise whose primary role in the Nanotechnology sector is as manufacturer of nanomaterials, but which acts in the different nanomaterials supply chains also as importer and distributor (mere distributor, professional user end distributor and repackager distributor). Due to the wide range of their nanomaterials and nanomaterials related products, the company was not in the position to quantify the number of employees and the turnover related to the Nanotechnology sector. Indeed, its portfolio of products covers different business sectors and the company places hundreds of nanomaterials, hundreds of mixtures containing nanomaterials and hundreds of articles containing nanomaterials on the French, European and global markets, having over one hundred suppliers and over one hundred customers for their nanomaterials related products.

In 2013, the first year of implementation of the French Notification System, the company completed over 250 notifications, while just one notification was submitted to the Cosmetic Products Notification Portal. The notifier was not able to estimate the number of notifications for submission to the FNS in 2014, due to the fact that more than half of the notifications were just partially completed and the notifier was still gathering the necessary information to complete the notifications of the previous year.

However, some of the information required by both the notification systems (the FNS and the CPNP) was readily available, and the company had to generate only part of the information. The notifier indicated that the Regulation (EC) No 1223/2009 on cosmetic products also helped in meeting the information requirements of the FNS. Moreover, in some cases the notifier had the opportunity to refer to the notification numbers of the suppliers for the “substance identity” part.

When estimating the annual direct costs incurred to comply with the notification requirements for the FNS, the notifier indicated that, across the company, around 40 work days were spent to familiarise with and understand the legal requirements. Slightly more than 20 work days were then spent in gathering the necessary information. Although the company had already in place an information management system, this had to be adapted and aligned in order to facilitate the exchange and gathering of the relevant information, with an estimated burden for this task of around 3 - 4 weeks. For the submission of the information, slightly more than one hour was spent for each notification, with the same amount of time spent in replying to clients’ enquiries (the company could not provide an estimate of the number of enquiries received). Quite a lot of time was spent in communicating with the suppliers of certain nanomaterials, but the notifier was not able to provide a precise estimate of the administrative burden. In terms of generating the information necessary for the characterisation of the nanomaterials, the notifier reported a figure of

around €10,000 per nanomaterial, estimate that is consistent with the other replies received during the survey.

When the notifier was asked to rate which part of the information to be submitted to the FNS had proven to be the most burdensome, the part related to the characterisation of the substance and the part related to the identity of the clients were indicated as the most resource consuming.

With regard to the single notification submitted to the CPNP, the notifier reported an estimate of three work days for familiarising and understanding the legal requirements, five work days spent in gathering the information to be submitted and around three weeks for the preparation of the notification dossier. Other six work days were then spent in responding to client's enquiries. Three days were instead necessary for the adaptation and alignment of the information management system. In terms of the direct costs of generating the information necessary for the characterisation of the nanomaterial, the same figure of €10,000 was reported, with additional €250 for summarising the available toxicological information required by the CPNP.

Table 5-7 presents the estimate of the administrative burden posed on the company by the two notification schemes. Of the 250 notifications and more that had to be completed for the FNS, over 100 referred to nanomaterials not contained in mixtures, while the remaining refer to nanomaterials contained in mixtures. For the purpose of the calculation, we assumed that the company had to generate the information for the nanomaterials not contained in mixtures.

Table 5-7: Administrative burden of the notification schemes on a large enterprise

Cost type	FNS	CPNP
Understanding the legal requirements	≈ €10,500	≈ €800
Gathering of information to be submitted	≈ €5,250	≈ €940
Substance analysis characterisation cost	≈ €10,000 per substance	€10,250
Submission of the information	≈ €9,000	≈ €3,950
Responding to clients' enquiries	≈ €9,000	≈ €3,000
IT alignment and/or adapting product/account databases	≈ €3,950 - €5,250	≈ €800
Tot. without substance analysis costs	≈ 48,000	≈ €9,500
Tot. with substance analysis costs	Over €1,000,000 (over 250 notifications)	≈ €20,000 (one notification)

Notes:
** These estimates are based on the number of work days reported by the notifier for each cost type item. It has been assumed that a work day has 7.5 hours and a work week has five work days. The hourly labour cost is assumed to be €35.*

The administrative burden posed by the FNS on a large enterprise with multiple roles across the supply chains of nanomaterials and with a high number of notifications have been estimated in over €1 million for 2013. However, most of the costs are due to the characterisation of the nanomaterials. The recurring costs should be lower than €50,000 per year. With regard to the single notification submitted to the CPNP, the costs have been estimated in around €20,000, with recurring costs lower than €5,000 per year.

The notifier reported to have encountered many difficulties with respect to the terminology used in both the French Interministerial decree and the Cosmetic Products Regulation, in particular with the definition of nanomaterials used, the scope, the calculation of the quantities to be notified and the lack of defined analytical methods to be used for the characterisation of the nanomaterials.

When asked about the impacts of the French Notification System on competitiveness and innovation, the notifier reported that, although they do not foresee any impact on intellectual property rights and confidentiality aspects, very negative impacts are expected on the ability to develop and market new products containing nanomaterials in France and on the research and development activities. Very negative impacts on the intra- and extra-EU competitiveness of the company, namely the ability to successfully compete with manufacturers from other EU Member States and from outside the EU on the European and global markets, are also expected. It is opinion of the notifier that the French Notification System has a negative impact on the public perception of nanomaterials, although currently the more significant impacts in terms of perception is observed within the supply chains, with distributors and downstream users asking for "no nanos" chemicals.

When asked about the impacts of the Cosmetic Products Notification Portal on competitiveness and innovation, the notifier reported that, although they do not foresee any impact on the research and development activities and on the public perception of nanomaterials, they do expect a negative impact on the intellectual property rights and confidentiality aspects and consequently on marketing new products containing nanomaterials in France. Moreover, although the notifier does not foresee any impact on the ability of the company to successfully compete with manufacturers from other EU Member States on the European market, they expect a very negative impact on the competitiveness of the company with other manufacturers from non-EU Member States on the global market.

5.5.2 Case Study 2 – Medium-sized enterprise in the pigments and dyes sector

This section elaborates a case study review of the experience of a medium-sized manufacturer of pigments and dyes in notifying their products to the French Notification System. This company did not have to notify to the Cosmetic Products Notification Portal. The case study has been developed on the basis of the responses provided to the survey on the administrative burden and on a follow-up email contact with the enterprise, in order to validate the information.

The company has head offices in Japan. The European branch acts as importer and distributor of the pigments and dyes manufactured in Japan. Around one fifth of the company's turnover is directly related with the manufacturing and commercialisation of substances at the nanoscale. The company produces, imports and distributes a relatively small set of products in the dyes and pigments sector, i.e. 1-50, but widely commercialising and distributing them on several markets, in France, in other European countries and on the global market. The company maintains relations with 6 to 15 suppliers, and has about 16 to 30 clients.

In the first year of the implementation of the FNS, the company had to notify 25 nanomaterials. In 2014, the company reiterated the notification for the same amount of substances at nanoscale.

The information to be notified was generated exclusively for the purposes of the notification. The characterisation of the nanomaterials was carried out in Japan; the European branch was not able to provide an estimate of the costs, indicating however that this was the most burdensome part of the notification.

In terms of the resources spent on the notification of the nanomaterials, the company estimated that around 2.5 days were spent for familiarising with and understanding the legal requirements. Almost 10 work days were additionally spent to gather the necessary information to be submitted.

Around two weeks was the time required to deal with the clients' enquiries.

Table 5-8 presents the estimate of the administrative burden posed on the company by the FNS.

In general, the notifier had difficulties with the terminology used within the legislative acts and in particular with the definition of nanomaterials. The scope of the notification was unclear.

When compared to other pieces of chemicals legislation, the regulatory burden of the FNS was estimated to correspond to around one fifth of the burden posed by the REACH Regulation and more or less equal to the one posed by the CLP Regulation.

It was indicated that the FNS had a general negative impact on the innovation and competitiveness of the company, due to the worries raised by the legislation on the clients at European and global level.

Table 5-8: Administrative burden of the FNS on a medium-sized enterprise in the pigments and dyes sector

Cost type	Time	Total costs (€)
Understanding the legal requirements	20 hrs	≈ 700
Gathering of information to be submitted	75 hrs	≈ 2,600
Substance analysis characterisation cost	n/a	
Submission of the information	10 hrs	≈ 350
Responding to clients' enquiries	100 hrs	≈ 3,500
IT alignment and/or adapting product/account databases	n/a	0
	Total	**≈ 7,150 (25 notifications)**

Notes:
** These estimates are based on the number of work days reported by the notifier for each cost type item. It has been assumed that a work day has 7.5 hours and a work week has five work days. The hourly labour cost is assumed to be €35.*

5.5.3 Case Study 3 – Large distributor of chemical products

This section sets out the case study review of the experience of a distributor of products containing nanomaterials in notifying information to the French Notification System. The case study has been developed on the basis of the responses provided to the survey on the administrative burden of the notification schemes and on a follow-up email contact to validate the information gathered.

The distributor enacts also as importer and repackager in different nanomaterials supply chains. The company has more than 250 employees and an annual turnover of more than €50 million. The company's business sector is the wholesale of chemical products, with 11 to 50 nanomaterial related products placed on the French market, coming from 6 to 15 suppliers and sold to more than 100 clients.

In 2013, the first year of implementation of the French Notification System, the company completed 10 notifications. No notifications were made to the Cosmetic Products Notification Portal (CPNP).

The company did not have to generate the information, as they solely had to refer to the notification numbers of the suppliers for the "substance identity" part.

In estimating the administrative burden posed by the FNS, the company indicated to have spent half a day for the understanding of the legal requirements and around one week in gathering the required information. The company did not have to incur any cost for the characterisation of the nanomaterials, as they just had to refer to the notification numbers of their suppliers. Two days were spent for the submission of the information and one day was required to reply to clients' enquiries.

Table 5-9 presents the estimate of the administrative burden posed by the FNS in 2013 and 2014 (between parentheses in the Table).

The administrative burden posed by the FNS on this distributor of chemical products is of around €2,000. Costs for 2014 were estimated of the same magnitude, where to a significant decrease in the time required in understanding the legal requirements there was a slight increase in the time needed to reply to clients' enquiries.

Table 5-9: Administrative burden of the FNS on a large distributor of chemical products in 2013 (and 2014)

Cost type	Time	Total costs (€)
Understanding the legal requirements	4hrs (1h)	≈€140 (€35)
Gathering of information to be submitted	37.5hrs (37.5h)	≈ €1,300 (€1,300)
Substance analysis characterisation cost	€0	
Submission of the information	15hrs (15h)	≈ 525 (€525)
Responding to clients' enquiries	7.5hrs (10h)	≈ 260 (€350)
IT alignment and/or adapting product/account databases	n/a	0
Total		**≈ €2,200 (€2,200) (10 notifications)**

Notes:
** These estimates are based on the number of work days reported by the notifier for each cost type item. It has been assumed that a work day has 7.5 hours and a work week has five work days. The hourly labour cost is assumed to be €35.*

The company indicated that the most burdensome part was for them to gather the information on quantities, uses and identity of clients. The company faced some problems with respect to the terminology, particularly with regard to the nanomaterial definition.

As distributor of chemical products, the highest regulatory burden was indicated to be posed by the CLP Regulation (40%), followed by the REACH Regulation (30%). The burden posed by the FNS was broadly estimated to be equal to the burden posed by the Regulation (EC) No 528/2012 on biocidal products or the one posed by the Regulation (EC) No 1935/2004 on Food Contact Materials.

It is opinion of the company that the FNS had a very strong negative influence on research and development activities as well as on the general public perception of nanomaterials. Some of their clients expressed the will to stop using products subject to notification in the next years, although no risks have been proven to arise from these products. This has a negative impact on the ability of the company to develop and market new products containing nanomaterials. However the company does not expect the FNS to have impacts on intra- and extra-EU competitiveness as well as on Intellectual Property rights and confidentiality aspects.

Some concerns were expressed on the existence of different definitions of nanomaterial and on diverging legal requirements. This might pose problems with the suppliers located outside France.

6 Use of the Information Gathered Through the FNS and its Potential Impact on Long Term Health and Environmental Benefits

6.1 Introduction

The Terms of Reference for the present study requires the consultants:

- To collect "*evidence for how gathered information was used by authorities, consumers and workers, as well as assessment of possible future use; this shall inter alia include an assessment of the number of uses of the public and confidential databases and a comparison of detail and user-friendliness of information with other existing information sources, such as the Commission Staff Working Paper on Nanomaterial Types and Uses and the databases mentioned in this Staff Working Paper*"; and

- To "*model the impact of the availability of the information gathered to the authorities, consumers and workers on long term health and environmental benefits*".

In order to meet these requirements, the project team assessed whether the general aim and the specific objectives of the French Notification System were met, namely whether:

- The level of information available to the authorities, the public, the consumers and the workers increased, in terms of having a deeper knowledge on nanomaterials, their identities, the quantities handled and the different uses and applications;
- The traceability of the nanomaterials on the market has been obtained: from the manufacturers or importers via the distributors to the final professional users;
- Information on hazard and exposure of nanomaterials was gathered with the view to evaluate the risks.

Key requisite for proceeding in this exercise is to determine what and how much information each different stakeholder group received from the notification system:

- The French authorities got all the information regarding the identities of the nanomaterials on the French market, their quantities, the different uses and applications. Although it does not seem that full compliance among all actors was achieved during the first year, it can be assumed that the French authorities will receive, as time goes by, a trustful picture of the nanomaterials on the market;

- Consumers received information through the publication by the French authorities of the report on the first year of implementation of the system on the chemical names of the nanomaterials, some information on their quantities (total quantity of nanomaterials on the market and quantities in form of tonnage bands for most of the nanomaterials), some information on their uses (through lists of descriptors) and some statistics on the notification process and the number of companies involved;

- Workers, being part of the public, received the same information that was received by consumers (the French public report). Moreover, some companies might have discovered to be handling nanomaterials; some of these companies might have passed the information to

their workers and maybe assessed the suitability of their implemented Risk Management Measures in dealing with nanomaterials. The physicochemical parameters of the nanomaterials are generated by some manufacturers and importers but not passed down the supply chains. Downstream actors have just the possibility to refer to the notification numbers of their suppliers.

Further analysis of the potential impacts of the availability of the information gathered to the authorities, consumers and workers on long term health and environmental benefits is provided in the following subsections, namely:

- Section 6.2 provides a comparison between the information presented in the French public report (French public report, 2013) and the information that was already available to the public through different sources;
- Section 6.3 presents the results of the research on how journalists and bloggers and more in general the French media are using the data made publicly available and whether there has been any change in the public perception of nanomaterials;
- Section 6.4 presents the results of the research carried out on European media on news about nanomaterials use in cosmetic products;
- Section 6.5 provides a comparison of the FNS and the CPNP to the RAPEX system;
- Section 6.6 details the interview with the French Authorities with regard to the planned uses of the information gathered;
- Section 6.7 summarises the findings of the assessment of any potential benefits of the FNS on the human health and the environment.

6.2 Information on Nanomaterials on the Market

6.2.1 Introduction

In order to assess whether the first specific objective of the French Notification System was met, namely if the system provides a *"deeper knowledge on nanomaterials, their identities, the quantities handled and the different uses and applications*", this Section presents a comparison between the information provided in the French public report (French public report, 2013) and the information that was already available to the public through different sources, namely:

- The ECHA database of registered substances;
- The Classification and Labelling Inventory (CLI); and
- The Commission Staff Working Paper on types and uses of nanomaterials (EC, 2012, Section 3 and Appendix 2).

The comparison considers also the information that have been gathered through the FNS but that have not been made public, in order to assess any benefit stemming from the use of that information by the public authorities.

Before proceeding with the analysis of the added value of the FNS, it is important to make some introductory remarks:

- As reminded throughout this report, the present analysis of the FNS is based on the results of the first year of implementation. This is particularly important considering that during the 2014 notification process, the French authorities have received three times (over 10,000) the number of notifications received in 2013. Moreover, the information published in the first

public report by the French authorities, in the opinion of the consultants, lack of analysis and clarity, especially on the substances notified and their uses. The consolidation of the database will allow a better analysis and organisation of the information to be published;

- The consultants acknowledge that currently very few REACH registration dossiers provide sufficient and adequate information on nanomaterials. However, the comparison with the ECHA database of registered substances is important in light of the ongoing discussion[58] on the amendments to the REACH annexes, that might increase the level of information provided via the dossiers and improve its quality;

- Throughout this report, the consultants followed the terminology used by the Commission in previous studies on nanomaterials, in particular the definition of nanomaterial as laid down in Commission Recommendation 2011/696/EU. As clarified by the Commission in EC (2012) "*however, in most cases the same substance exists in particle sizes below and above 100 nm, and it is sometimes unclear whether the collected information refers to one or the other, or both*". The following analysis is structured according to chemical substances which are nanomaterials or have forms which are nanomaterials. "*This follows in essence the REACH substance definition, without prejudice to whether the substance only exists as nanoform or whether the substance has different bulk and nanoforms*"[59];

- EC (2012) draws on a variety of information sources, primarily on SRI Consulting reports. These are in-depth business and process analysis research reports that are not public but can be purchased on the IHS website[60]. On some specific subjects, EC (2012) consulted other public sources like the sectorial reports of ObservatoryNano[61], the DaNa Knowledge Base Nanomaterials[62] and the ECHA website.[63]

6.2.2 Nanomaterials on the Market and Tonnages

Analysis of the substances listed in the French public report

Through the analysis of the 399 entries listed in the French public report,[64] the consultants identified around 258 different substances: over 100 entries revealed to be double entries and attributable to the same substances (e.g. carbon black listed as "carbon black" and "noir de carbon", different forms of silicon dioxide or titanium dioxide or various pigments listed with their chemical names as well as their Colour Index Generic Names[65]). **However, this is not the definitive number of substances at nanoscale notified to the FNS and should be intended just as an indication.** As mentioned above, during the 2014 notification process, the French authorities received almost three times (over

[58] August 2014.
[59] EC (2012), p. 43
[60] http://chemical.ihs.com/IHS/Public/Aboutus.html
[61] The website observatorynano.eu is not available anymore.
[62] http://www.nanopartikel.info/en/
[63] For more information about the information sources, please see Section 1 of Appendix 2 at page 43 of EC (2012).
[64] 237 entries listed in Table 7 (Quantities and uses of the notified substances at nanoscale identified by CAS numbers, at page 27) and the 162 entries listed in Table 8 (Quantities and uses of the notified substances at nanoscale identified by chemical names, at page 81); the methodology followed in listing the substances in tables 7 and 8 is explained at page 22 of the French public report.
[65] The Colour Index database is maintained by the Society of Dyers and Colourists and the American Association of Textile Chemists and Colourists and works as international reference for these colorants.

10,000) the number of notifications received in 2013. A list of the different substances identified and further analysed for statistical purposes and for the investigation of their notified uses and potential applications is provided in Annex III to this report (Table A3-1 and A3-2). Table A3-1 presents the chemical name, the EC numbers and CAS numbers of the substances as they were found on the ESIS database[66], the ECHA registered substances database[67] and through Internet searches.

Table A3-1 presents (when available) also the tonnage band assigned by the French authorities in accordance to the quantities notified to the FNS along with the tonnage band found on the ECHA registered substances database when the substances were found in the database. In case of double entries in Tables 7 and 8 of the French public report, the higher tonnage band has been reported. The higher tonnage band has been reported also in case of multiple REACH registration entries. Table 6-1 reports the number and percentage of the different substances at the nanoscale identified per notified quantities (tonnage band).

Table 6-1: Number and percentage of substances at the nanoscale per notified quantities

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

Around one fifth of the different substances identified on the French public report list did not have assigned any tonnage band.

Comparison with the Commission Staff Working Paper on the types and uses of nanomaterials

EC (2012) identifies the following as the main categories in terms of market volume:

- Inorganic non-metallic nanomaterials (e.g. synthetic amorphous silica, aluminium oxide, titanium dioxide);
- Carbon base nanomaterials (e.g. carbon black, carbon nanotubes);
- Metal nanoparticles (e.g. nanosilver); and
- Organic, macromolecular or polymeric particulate materials (e.g. dendrimers).

Appendix 2 to EC (2012) provides more information (tonnages, market value, uses and hazard classifications) on specific nanomaterials, namely:

A. Inorganic non-metallic nanomaterials:
    1. Synthetic amorphous silica and its various forms;

[66] http://esis.jrc.ec.europa.eu/clp/ghs/search.php
[67] http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

2. Substances similar to synthetic amorphous silica (salts of silicic acid, silica fume, fused silica and polymerised forms of biogenic silica);
3. Titanium dioxide;
4. Zinc oxide;
5. Aluminium oxide;
6. Aluminium hydroxides and aluminium oxo-hydroxides;
7. Iron oxides (diiron trioxide and triirontetraoxide;
8. Cerium dioxide;
9. Zirconium dioxide;
10. Other oxide nanomaterials;
11. Calcium Carbonate;
12. Other non-oxide inorganic non-metallic nanomaterials (aluminium nitride, silicon nitride, titanium nitride, titanium carbonitride, tungsten carbide, tungsten sulphide);

B. Metals and metal alloys:
13. Gold;
14. Silver;
15. Other metallic nanoparticles (platinum and palladium alloy);
16. Copper nanopowders;
17. Iron nanoparticles;
18. Titanium nanoparticles;
19. Nickel, cobalt, aluminium, zinc, manganese, molybdenum, tungsten, lanthanum, lithium, rhodium;

C. Carbon-based nanomaterials:
20. Fullerenes;
21. Carbon nanotubes and carbon nanofibres;
22. Carbon black;
23. Graphene flakes;

D. Nanopolymers and dendrimers:
24. Polymer nanoparticles (polyalcylbenzene-polydiene (e.g. PAB-PDM) nanoparticles);
25. Polymer nanotubes, nanowires and nanorods (e.g. polyaniline (PANI) nanotubes);
26. Polyglycidylmethacrylate (PGMA) fibres;
27. Nanocellulose;
28. Nano-structured polymer-films (polyalcylthiophene-films, polyethylene oxide (PS-PEO) films or as acrylic glass (poly(methyl methacrylate) (PMMA)) films), styrene-ethylene-butylene-styrene (SEBS) nanofilms;
29. Polyacrylonitrile nanostructures (PAN);

E. Dendrimers;

F. Quantum dots:
30. Cadmium selenide;
31. Cadmium sulphide;
32. Indium arsenide;
33. Indium phosphide;

G. Nanoclays:
34. Montmorillonite;
35. Bentonite;
36. Kaolinite;
37. Hectorite;
38. Halloysite;

H. Nanocomposites;

I. Other

39. Nitrogen and phosphorous compounds;
40. Manganese dioxide;
41. Divanadiumpentoxide;
42. Dicopper oxide;
43. Siloxanes and silicones.

EC (2012) presents the information "*by specific nanoforms, or, in certain cases by groups of substances (e.g. polymers) or even broader material categories (e.g. quantum dots). This is done because it would not be possible to strictly distinguish all relevant information according to substance or form. Therefore, this listing is a pragmatic way to present information in the most structured way possible but not a scientific categorisation. While aiming at a structured approach in describing the different nanomaterials addressing the relevant features, the level and detail of presented information varies significantly*".

Most of the nanomaterials mentioned in EC (2012) are present in the list of substances notified to the FNS. Although EC (2012), in the opinion of the consultants, provides a clearer overview on the types of nanomaterials on the market and their various applications, the notification system allows the authorities to have the full list of nanomaterials on the market, with information specific to each nanoform. The French public report (2013) only provides a rough list of substances, but the additional information (tonnage bands and applications) is specific to the nanoforms of the substances listed. From the public report is not possible to distinguish nanomaterials by shape, so no information can be linked to categories as quantum dots or nanoclays. However, the French authorities have information on shapes and applications for each nanoform and have the possibility to publish, in the future, more structured information also by these categories, without releasing confidential information.

In terms of quantities, the tonnages reported in the French public report broadly confirm that inorganic non-metallic nanomaterials and carbon based nanomaterials are the main categories, with carbon black and silicon dioxide making most of the market.

Table 6-2 presents the information on the global tonnage of the main nanomaterials on the market according to market data from SRI consulting as reported in EC (2012).

Table 6-2: Global tonnage of the main nanomaterials on the market (EC, 2012)

Nanomaterial	Global Tonnage
All nanomaterials	≈ 11.5 million tpa
Carbon black	≈9.6 million tpa
Synthetic amorphous silica	≈1.5 million tpa
Aluminium oxide	≈200,000 tpa
Barium titanate	≈15,000 tpa
Titanium dioxide	≈10,000 tpa
Cerium oxide	≈10,000 tpa
Zinc oxide	≈8,000 tpa
Carbon nanotubes and carbon nanofibres	Several hundreds to few thousands tonnes

Source: SRI consulting

Table 6-3 reports the nanomaterials manufactured and/or imported in France in 2012 above 1,000 tonnes. Although Table 10 in the French public report provides figures for nanomaterials above 100 tonnes per year, those figures might be erroneous due to partial notifications by companies or partial analysis of the notifications by the French authorities.

Table 6-3: Nanomaterials manufactured and/or imported in more than 1,000 tonnes in France in 2012	
Chemical name	**Tonnes**
Carbon Black	≈ 275,000 tpa
Silicon dioxide / amorphous silica	≈ 155,000 tpa
Calcium carbonate	≈ 34,500 tpa
Titanium dioxide	≈ 14,300 tpa
Aluminium oxide	≈ 2,200 tpa
Copolymer of vinylidene chloride (declared name)	≈ 1,600 tpa
Source: reproduced from French public report (2013), Table 10.	

Figure 6-1 provides the shares on the total tonnage of nanomaterials on the French market in 2012.

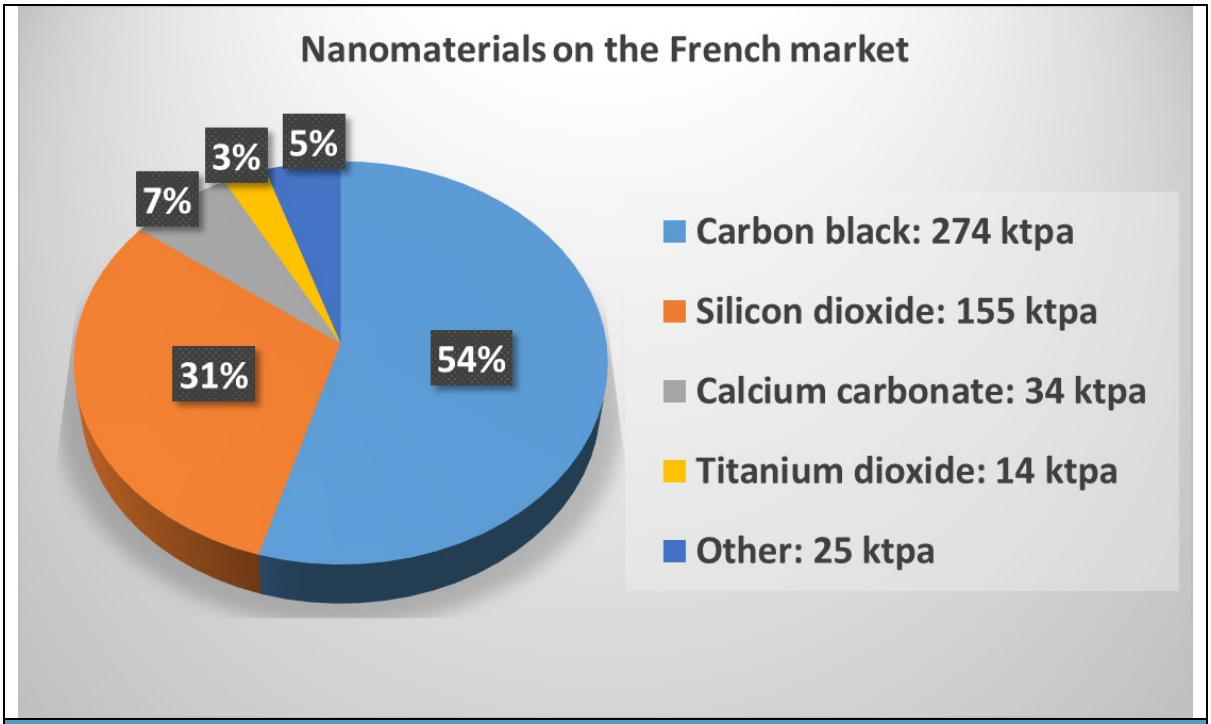

Figure 6-1: Shares on the total tonnage of nanomaterials on the French market in 2012

The market is dominated by four nanomaterials:

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

The remaining five percent of the nanomaterials' tonnage on the French market is made up of the other 254 substances, of which over 150 have been identified[68] as pigments and dyes.

Table 6-4 provides instead statistics from the Eurostat PRODCOM list for the five highest production volumes nanomaterials notified in France. The total figure (production plus import) for carbon black in France in 2012 roughly correspond to the quantity notified to the FNS. The figures for the other

[68] With the help and support of Cefic, NIA and their members.

substances are not easily comparable due to the fact that the nanoform (within 1 to 100 nanometres) is only one of the forms of the substances on the market.

It is interesting to notice that EC (2012) underestimated the quantity of titanium dioxide on the global market[69] since, only in France, the quantity manufactured and/or imported is higher than the figure quoted in the Commission report.

Table 6-4: Eurostat import and production volume in France and in the EU28 in 2012 (tonnes)						
Nanomaterials	**France**			**EU28**		
	Import	**Production**	**Total**	**Import**	**Production**	**Total**
Carbon black	160,000	107,000	**267,000**	591,000	1,624,000	**2,215,000**
Silicon dioxide	-	210,000	**-**	-	583,000	**-**
Aluminium oxide	735,000	463,000	**1,198,000**	713,000	5,691,000	**6,405,000**
Titanium dioxide	-	-	**-**	-	498,000	**-**
Calcium carbonate	189,000	150,000	**339,000**	1,736,000	4,890,000	**6,636,000**
PRODCOM codes: *20132130 - Carbon (carbon blacks and other forms of carbon, n.e.c.)* *20132475 - Silicon dioxide* *24421200 - Aluminium oxide (excluding artificial corundum)* *20121150 - Titanium oxides* *20134340 - Calcium carbonate*						

This brief comparison of the reported tonnages can just confirm how difficult is to estimate precisely the quantities of nanomaterials on the market. This is due to the fact that companies, although can have a knowledge of which substances produced/imported are at the nanoscale, do not know precisely what volume share will be within the values provided by the EC recommended definition of nanomaterials, at least for the widespread commodity nanomaterials and for pigments. With regard to the latter, EC (2012) notes that "*It is understood that inorganic pigments exist in grades that would have a fraction under the 100 nm cut-off that is widely used to discriminate between bulk and nanoforms. However, there is no consensus of what "particle" refers to in terms of the interpretation of the 100 nm cut-off. In addition, different methods for measuring particle size can yield vastly different values*".[70]

The tonnage data published in the French public report are not reliable yet. However, it is expected that following the consolidation of the system, the French authorities will have a clear picture on the tonnages of nanomaterials on the market. More precisely, they should have precise quantities for each nanomaterial by manufacturer/importer.

Comparison with the ECHA database of registered substances

In Table 6-1, when looking at the tonnage band shares over the total number of substances that did report quantities, over 40% of the substances identified are below the 1 tonne REACH information requirements threshold. It should be noted however that considering the EU-wide production/import of each substance such a percentage is likely to decrease. Actually, looking more in depth at the 88 substances notified in quantities between 0.1 kg and 1 tonne (entries between 53 and 140 in Table A3-1), 47 substances already have REACH Registration dossiers for their bulk forms. These dossiers do not contain information on nanoforms; this lack of information is expected to be addressed through the planned revision of the REACH Annexes. However, it is not clear what

[69] In Appendix 2 of EC (2012) at page 49, it is noted that the Commission received estimates which are higher but still in the same rough order of magnitude.

[70] EC (2012), p.72

information, if any, will be submitted by registrants on nanoforms manufactured/imported in quantities below one tonne. Of the 88 substances, 41 substances were not found in the ECHA database. Of these 41 substances:

- Thirty-four are pigments and dyes and thus likely to be manufactured/imported in the European Union in quantities above 1 tonne per year;
- Three substances (vitreous silica, palladium and hydroxylapatite) are naturally occurring minerals and thus outside the scope of the REACH Regulation according to Article 2(7)(b));
- Two substances (cellulose and Poly(methyl methacrylate) with buta-1,3 diene, butyl acrylate and ethyl acrylate) are polymers (outside the scope of the REACH Regulation according to Article 2(9)); and
- Two substances (styrene oligomers and diiron nickel tetraoxide) are object of research and development (styrene oligomers is investigated as polymeric organic matrix in biological applications for the treatment of cancer and diiron nickel tetraoxide is object of research in several applications for its magnetic and catalytic properties, e.g. in repulsive suspension for levitated railway systems, in solid oxide fuel cells, in high-density magnetic recording media, in lithium nickel iron oxide cathodes for lithium ion microbatteries[71]).

Table 6-5 presents the results of the cross-analysis between the list of notified substances and the ECHA registered substances database. Once again, it is important to note that this analysis refers to the chemical substances as defined by the REACH Regulation and that the information in the REACH registration dossiers of the substances that were found in the ECHA database are unspecific and do not refer to the nanoforms. Aim of the analysis is to identify the number of substances with forms at the nanoscale which bulk forms have been registered or will be registered by the 2018 deadline. It is expected that following the development of better guidelines for the registration of nanomaterials by ECHA and the future implementation of the amendments to the REACH Annexes, more and better information will be submitted on the nanoforms. However, it is currently not possible to determine the extent of the increase in the level of information and of its quality.

Table 6-5: Cross-analysis of the list of notified substances and the ECHA registered substances database	
Number of notified substances **found** on the ECHA registered substances database	**159**
Per tonnage band	**No.**
1 - 10 tonnes per annum	9
10 - 100 tonnes per annum	29
100+ tonnes per annum	1
100 – 1,000 tonnes per annum	46
1,000 – 10,000 tonnes per annum	33
10,000 – 100,000 tonnes per annum	17
100,000+ tonnes per annum	1
100,000 – 1,000,000 tonnes per annum	12
1,000,000+ tonnes per annum	2
1,000,000 – 10,000,000 tonnes per annum	5
100,000,000+ tonnes per annum	1
Tonnage data confidential	3
Number of notified substances that were **not found** on the ECHA registered substances database	**99**
Reason	**No.**
Polymer or polymer group (outside the scope of REACH)	16
Other (possible reason: tonnage lower than 100 tonnes per annum)	83
Total	**258**
Information on the substances not sufficient to carry out the analysis	12

[71] http://www.azonano.com/article.aspx?ArticleID=3377

Independently from the tonnages of **substances at nanoscale** that were notified to the FNS, around 62% of the **substances** have a full registration dossier in the ECHA database. The remaining 38% could not be found among the list of the registered substances: 16 substances have been identified as polymers and are thus outside the scope of the REACH Regulation[72]; for the other 83 substances, a possible reason is that they are currently manufactured/imported in quantities below 100 tonnes per annum and will be registered for the next Registration deadlines. Notably, none of the substances that were not found in the ECHA database have been notified to the FNS as manufactured/imported in more than 100 tonnes per year.

It is important to notice that the FNS provides, apart from a basic physicochemical characterisation and specific information[73] on the nanoforms of those substances that are within the scope of REACH but for which specific information is still lacking in the registration dossiers, information on the nanoforms of those substances outside the scope of the REACH Regulation, notably on nanoforms of polymers.

Table A3-3 presents the monomers that have been identified as part of the polymer substances notified to the FNS: 12 out of 13 have been found as registered in the ECHA database in high tonnages (over 1,000 tonnes per annum).

Three substances might be covered by the exemption granted by the REACH Regulation to naturally occurring substances:

- Vitreous silica (also known as "fused silica", EC number: 262-373-8, CAS number: 60676-86-0, number 82 in Table A3-1) is not covered by the Registration dossier for amorphous silica and it has not been registered because considered to fulfil the condition of the exemption granted to minerals which occur in nature, if not chemically modified (Article 2(7)(b));[74]
- Palladium (EC number: 231-115-6, CAS number: 7440-05-3, number 78 in Table A3-1), that is a mineral which occurs in nature and thus exempted according to Article 2(7)(b); and
- Hydroxylapatite (Ca5(OH)(PO4)3) (EC number: 215-145-7, CAS number: 1306-06-5, number 62 in Table A3-1) is a naturally occurring mineral (and thus outside the scope of the REACH Regulation according to Article 2(7)(b)) used in medicinal products (outside the scope of REACH according to Article 2(5)(a)) as main component of dental enamel and dentin.

Table 6-6 provides an analysis of the EC number of the substances notified to the FNS. It should be noted that the EC number is the same for the bulk form(s) and the nanoform(s) of the substances.

On the basis of this analysis, two hundred and eleven substances have an EC number starting with 2 or 3, meaning that they were commercially available in the European Union between 1971 and 1981 and thus considered phase-in substances under the REACH Regulation. Eleven substances have an EC number starting with 4, meaning that they became commercially available in the European Union after 1981. One substance (Styrene, oligomers, EC number: 500-008-9, CAS number: 9003-53-6) has an EC number starting with 5 and thus is a no longer polymer substance, namely a substance that was considered to be a polymer as defined by Directive 67/548/EEC but no longer considered to be a polymer after the definition of polymer was changed in the 7th amendment (92/32/EEC) to the Directive. Four substances had an EC number automatically assigned and starting with 6 because

[72] It should be noted that, although the French legislation refers to the definitions of the REACH Regulation, its requirements cover polymer substances.

[73] Quantities, uses and users.

[74] http://www.ima-reach-hub.eu/index.php?option=com_docman&task=doc_download&gid=138

identified only with a CAS number. One substance (Reaction mass of cerium dioxide and zirconium dioxide, EC number: 909-709-8) had an EC number automatically assigned and starting with 9 because it did not have a CAS number or any other numerical identifier.

Table 6-6: Number of substances per EC number		
EC Number	**Source**	**No.**
2xx-xxx-x	**EINECS** (**E**uropean **IN**ventory of **E**xisting **C**ommercial chemical **S**ubstances) List	205
3xx-xxx-x	**EINECS** (**E**uropean **IN**ventory of **E**xisting **C**ommercial chemical **S**ubstances) List	6
4xx-xxx-x	**ELINCS** (**E**uropean **LI**st of **N**otified **C**hemical **S**ubstances) List	11
5xx-xxx-x	**NLP** (**N**o-**L**onger **P**olymers) List	1
6xx-xxx-x	Automatically assigned to substances identified only with a CAS No.	4
7xx-xxx-x	Assigned manually to validated substances from inquiries by ECHA	0
8xx-xxx-x	Automatically assigned to substances identified only with a CAS No. (continuation of the 6xx-xxx-x series)	0
9xx-xxx-x	Automatically assigned to substances without a CAS No. or other numerical identifier	1
None/not found/not applicable		30
	Total	**258**

From the above it can be concluded that around 80% of the substances that were notified to the FNS were already on the market before 1981. It is, however, not possible, to establish if their nanoform(s) was/were commercialised before that date. Nevertheless, this analysis is relevant in consideration of the ongoing[75] discussion on the amendments of the REACH Annexes and the discrimination between phase in and non-phase in substances and, subsequently, in the definition of the added value of any national or EU-wide nanomaterials register.

Comparison with the Classification and Labelling Inventory

Although the French Notification System does not require information on physical, health and environmental hazards, a cross-analysis with the Classification and Labelling Inventory (CLI) has been carried out.

Each one of the substances notified to the FNS has been searched for in the CLI. The search has been performed by EC number when available. When an EC number was not available or the EC number was not found, the CAS number was entered in the search field. If also the search by CAS number gave no result, a significant part of the spelling of the chemical name of the substances was entered.

Table 6-7 presents the results of the analysis.

Table 6-7: Cross-analysis of the FNS with the CLI	
Substances searched in the CLI	258
Substances not found in the CLI	40
Substances found in the CLI	218
Substances with a harmonised classification	8
Substances found in the CLI but without classification	67
Substances with a classification (including substances with harmonised classification)	151
Substances with "nanomaterial" as one of the forms notified to the CLI	**23**

[75] August 2014.

Table A3-4 presents the list of substances notified to the FNS that have been found in the CLI with classifications referring to the nanoform(s). Of the twenty-three substances notified to the FNS and found in the CLI, ten were already listed in EC (2012)[76]. EC (2012) listed other four substances that, however, have not been notified to the FNS so far.

6.2.3 Applications and Uses of Nanomaterials on the Market

The analysis focuses then on the uses and applications that have been notified to the FNS. Table 7-8 presents the number of substances per notified sectors of use.

Although the most notified Sector of Use was SU0 "Other" that does not give much information, 132 substances notified SU10 "Formulation (mixing) of preparations and/or re-packaging (excluding alloys): most of them have been identified as pigments and dyes. The other main Sectors of Use are the manufacturing of plastic products (SU12) and Agriculture, forestry and fishery (SU1).

Notably, 32 substances are used for research and development purposes. On this aspect, both the French public report and EC (2012) do not provide additional information: the French public report only flags which substances are object of R&D (without any reference on which applications); EC (2012) focused on applications already on the market: "*applications at the stage of research and development are normally not specifically mentioned, although it cannot be excluded that some of the information relates to products at R&D stage*"[77].

Table 6-8: Number of substances per notified sectors of use (SU)

Code	Supplementary descriptor: Sectors of end-use	NACE codes[78]	NMs
SU1	Agriculture, forestry, fishery	A	60
SU2a	Mining, (without offshore industries)	B	3
SU2b	Offshore industries	B 6	1
SU4	Manufacture of food products	C 10,11	8
SU5	Manufacture of textiles, leather, fur	C 13-15	7
SU6a	Manufacture of wood and wood products	C 16	3
SU6b	Manufacture of pulp, paper and paper products	C 17	18
SU7	Printing and reproduction of recorded media	C 18	5
SU8	Manufacture of bulk, large scale chemicals (including petroleum products)	C 19.2+20.1	9
SU9	Manufacture of fine chemicals	C 20.2-20.6	27
SU10	Formulation [mixing] of preparations and/or re-packaging (excluding alloys)	C 20.3-20.5	132
SU11	Manufacture of rubber products	C 22.1	24
SU12	Manufacture of plastics products, including compounding and conversion	C 22.2	70
SU13	Manufacture of other non-metallic mineral products, e.g. plasters, cement	C 23	10
SU14	Manufacture of basic metals, including alloys	C 24	2
SU15	Manufacture of fabricated metal products, except machinery and equipment	C 25	7
SU16	Manufacture of computer, electronic and optical products, electrical equipment	C 26-27	6
SU17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	C 28-30,33	21
SU18	Manufacture of furniture	C 31	3

[76] EC (2012), Annex 3: Compiled public list of substances where information on nanomaterials was included in C&L notifications received by the end of June 2011, page 74-75.

[77] EC (2012), p. 44

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

Table 6-8: Number of substances per notified sectors of use (SU)			
SU19	Building and construction work	F	28
SU20	Health services	Q 86	7
SU23	Electricity, steam, gas water supply and sewage treatment	C 35-37	2
SU24	Scientific research and development	C72	32
SU0	Other		147
Not reported			1

The French public report lists sectors of use for each nanomaterial, along with chemical product and article categories (for some of them) (Table 6-9, 6-10 and 6-11). However, the information is not organised and lack of a "narrative": in the opinion of the consultants, the French public report (2013) does not provide a better picture on the uses and applications of nanomaterials to the public, nor gives additional information on which products contain nanomaterials. Conversely, the French Notification System does provide a more complete knowledge about uses and applications of nanomaterials to the authorities, and more importantly provides information on the process categories applied to the nanomaterials for their manufacturing, descriptors necessary to understand the routes of workers' exposure to nanomaterials.

Table 6-9 presents the Chemical Product Category notified per number of substances: PC9a "Coatings and paints, thinners, paint removers" and PC19 "Ink and toners" were the most notified product categories, followed by PC32 "Polymer preparations and compounds". All the six substances with PC9b "Fillers, putties, plasters, modelling clay" were notified to the FNS in quantities over 1,000 tonnes per annum.

Table 6-9: Chemical Product Category (PC)		
Code	**Category for describing market sectors (at supply level) regarding all uses (workers and consumers)**	**NMs**
PC1	Adhesives, sealants	4
PC2	Adsorbents	2
PC3	Air care products	3
PC4	Anti-Freeze and de-icing products	0
PC7	Base metals and alloys	0
PC8	Biocidal products (e.g. Disinfectants, pest control)	5
PC9a	Coatings and paints, thinners, paint removers	72
PC9b	Fillers, putties, plasters, modelling clay	6
PC9c	Finger paints	1
PC11	Explosives	0
PC12	Fertilizers	1
PC13	Fuels	3
PC14	Metal surface treatment products, including galvanic and electroplating products	5
PC15	Non-metal-surface treatment products	5
PC16	Heat transfer fluids	0
PC17	Hydraulic fluids	0
PC18	Ink and toners	22
PC19	Intermediate	4
PC20	Products such as ph-regulators, flocculants, precipitants, neutralization agents	2
PC21	Laboratory chemicals	4
PC23	Leather tanning, dye, finishing, impregnation and care products	2
PC24	Lubricants, greases, release products	0
PC25	Metal working fluids	0
PC26	Paper and board dye, finishing and impregnation products: including bleaches and other	1

Table 6-9: Chemical Product Category (PC)		
Code	**Category for describing market sectors (at supply level) regarding all uses (workers and consumers)**	**NMs**
	processing aids	
PC27	Plant protection products	1
PC28	Perfumes, fragrances	3
PC29	Pharmaceuticals	4
PC30	Photo-chemicals	2
PC31	Polishes and wax blends	1
PC32	Polymer preparations and compounds	12
PC33	Semiconductors	2
PC34	Textile dyes, finishing and impregnating products; including bleaches and other processing aids	0
PC35	Washing and cleaning products (including solvent based products)	2
PC36	Water softeners	0
PC37	Water treatment chemicals	1
PC38	Welding and soldering products (with flux coatings or flux cores.), flux products	0
PC39	Cosmetics, personal care products	9
PC40	Extraction agents	0
PC0	Other (use UCN codes: see last row)	6

Tables 6-10 and 6-11 present the Article Categories without and with intended release of substances. Only 36 substances were found to have an associated AC, with just one notifying an article category with intended release (silicon dioxide). AC2 "Machinery, mechanical appliances, electrical/electronic articles" was the article category most notified, followed by AC1 "Vehicles" and AC4 "Stone, plaster, cement, glass and ceramic articles".

Table 6-10: Article categories, no release intended (AC)		
Code	**Article categories (and non-exhaustive examples) for describing the type of article in which the substance is contained during service life and waste life**	
Code	**Categories of complex articles**	
AC1	Vehicles	10
AC2	Machinery, mechanical appliances, electrical/electronic articles	23
AC3	Electrical batteries and accumulators	1
Code	**Categories of material based articles**	
AC4	Stone, plaster, cement, glass and ceramic articles	9
AC5	Fabrics, textiles and apparel	0
AC6	Leather articles	1
AC7	Metal articles	5
AC8	Paper articles	2
AC10	Rubber articles	3
AC11	Wood articles	0
AC13	Plastic articles	6
	Other	0

Table 6-11: Use descriptor for articles with intended release of substances		
Code	**Descriptor based on an indicative list of examples**	
AC30	Other articles with intended release of substances, please specify	1
AC31	Scented clothes	0

Table 6-11: Use descriptor for articles with intended release of substances		
Code	**Descriptor based on an indicative list of examples**	
AC32	Scented eraser	0
AC34	Scented Toys	0
AC35	Scented paper articles	0
AC36	Scented CD	0
AC38	Packaging material for metal parts, releasing grease/corrosion inhibitors	0

6.3 Nanotechnology and Nanomaterials in the French Press

A brief research on how journalists and bloggers and more in general the French media are using the data made publicly available and whether there has been any change in the public perception of nanomaterials has been carried out and the results presented below.

6.3.1 Overview

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.

6.3.2 Nanotechnology and Nanomaterials in the French Press – pre 2013

Health

Prior to the introduction of the registry for nanomaterials in France on 1st 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?'*[79] 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

[79] La Croix (2009): **Faut-il avoir peur des nanotechnologies**, availablefromhttp://www.la-croix.com/Ethique/Sciences-Ethique/Sciences/Faut-il-avoir-peur-des-nanotechnologies- NG -2009-12-14-570302

published in the free daily newspaper 20 Minutes, entitled *'Nanotechnologies: what are the risks?'*[80]. 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*'[81] 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'*[82].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, E551[83] 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*

[80] 20 Minutes (2010): **Nanotechnologies: quels sont les risques?,**availablefromhttp://www.20minutes.fr/sciences/397658-nanotechnologies-risques

[81] Le Monde (2012): **Inquiétudes autour des nanomatériaux dans les aliments**, availablefromhttp://www.lemonde.fr/planete/article/2012/02/29/inquietudes-autour-des-nanomateriaux-dans-les-aliments_1649689_3244.html

[82] Le Monde (2012): **Nanoparticules: l'ingrédient qui s'est discrètement invité à notre table,** availablefromhttp://www.lemonde.fr/planete/article/2012/12/31/nanoparticules-l-ingredient-qui-s-est-discretement-invite-a-notre-table_1810783_3244.html

[83] 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. Regulationavailableat: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0178:0204:EN:PDF

view'[84] 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[85] 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 Libération from March 2010, entitled *'Nanotechnologie: l'Afsset recommande le principe de précaution'*[86] reported on a study by Afsset[87] 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 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 Libération in January 2010 ('*Nanotechnologies, the debate taken over by fear'*[88]) 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, Libération published an article ('*Nanotechnologies: the*

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84 Le Monde (2009): **Nanotechnologies: le point de vue environnemental**, availablefromhttp://www.lemonde.fr/technologies/article/2009/10/15/nanotechnologies-le-point-de-vue-environnemental_1254555_651865.html

85 **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.

86 La Libération (2010): **Nanotechnologies: l'Afsset recommande le principe de precaution,**availablefromhttp://www.Libération.fr/terre/2010/03/24/nanotechnologies-l-afsset-recommande-le-principe-de-precaution_617132

87 Afsset: Agence française de sécurité sanitaire de l'environnement et du travail (French Agency for Environmental and OccupationalHealth)

88 La Libération (2010): **Nanotechnologies, le débat confisqué par la peur,**availablefromhttp://www.Libération.fr/sciences/2010/01/27/nanotechnologies-le-debat-confisque-par-la-peur_606519

debate cut short'[89]) 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?'*[90] 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%.

6.3.3 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.

However, according to one article from the website 'Sciences et Avenir' from December 2013 *('First report on the declaration of nanomaterials'*[91]*)* 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*[92]' 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

[89] La Libération (2010): **Nanotechnologies : le débat tourne court,** availablefromhttp://www.Libération.fr/sciences/2010/02/25/nanotechnologies-le-debat-tourne-court_611996

[90] La Libération (2011): **Nanotechnologies : quelle place pour la France ?,** availablefromhttp://www.lesechos.fr/28/03/2011/LesEchos/20899-43-ECH_nanotechnologies---quelle-place-pour-la-france--.htm

[91] Sciences et Avenir (2013): **Premier bilan sur la déclaration des nanomatériaux,**availablefromhttp://www.sciencesetavenir.fr/nature-environnement/20131202.OBS7844/premier-bilan-sur-la-declaration-des-nanomateriaux.html

[92] Journal de l'Environnement (2013): **Les nanomatériaux, un risque professionel**, availablefromhttp://www.journaldelenvironnement.net/article/les-nanomateriaux-un-risque-professionnel,36421

article in Le Monde (*'The toxicity of nanomaterials confirmed by an American study'*[93]) detailed that the toxicity of nanomaterials had in fact been confirmed by an American study.

Additionally, the website VeilleNanos (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*[94]*)* 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 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.

[93] Le Monde (2013): **La toxicité des nanomateriaux confirmée par une étude americaine,** availablefromhttp://www.lemonde.fr/planete/article/2013/05/07/la-toxicite-des-nanomateriaux-confirmee-par-une-etude-americaine_3172367_3244.html

[94] Le Monde (2013): **Les nanotechnologies, une filière entre promesses et interrogations**, availablefromhttp://www.lemonde.fr/sciences/article/2013/04/10/les-nanotechnologies-une-filiere-entre-promesses-et-interrogations_3151370_1650684.html

More specifically, an article published on the website 'L'Usine Nouvelle' entitled *'Why France cannot break into the race for nanotechnology*[95]*'* 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[96]. Furthermore, in February 2014, an article in Les Echos *('Nanotechnologies applied to medicine: France is in pole position'*[97]*)* 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 Libération which was published in February 2014 *('Nanomedicine: a market which could reach $129 billion by 2016'*[98]). This article emphasises that France has a number of important 'assets' in this field including the research facilities in Grenoble (Minatec) and the Galen Institute at Châtenay-Malabry 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.

6.4 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'[99] 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) which discussed the

[95] L'Usine Nouvelle (2013): Pourquoi la France n'arrive pas à percer dans la course aux nanotechnologies, availablefromhttp://www.usinenouvelle.com/article/pourquoi-la-france-n-arrive-pas-a-percer-dans-la-course-aux-nanotechnologies.N218786

[96] FranceTV (2014): **VIDEO. La nantoechnologie, nouvelle arme contre le cancer,**availablefromhttp://www.francetvinfo.fr/sante/video-la-nanotechnologie-nouvelle-arme-contre-le-cancer_497716.html

[97] Les Echos (2014): **Nanotechnologies appliquées à la médecine : la France en pole position**, availablefromhttp://www.lesechos.fr/entreprises-secteurs/grande-consommation/actu/0203305056880-nanotechnologies-appliquees-a-la-medecine-la-france-en-pole-position-649388.php

[98] La Libération (2013): **Nanomédicine: un marché qui atteindrait 129 milliards de dollars en 2016,**availablefromhttp://www.Libération.fr/economie/2014/02/13/nanomedecine-un-marche-qui-atteindrait-129-milliards-de-dollars-en-2016_979997

[99] 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

use of nanomaterials in toothpaste[100]. 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'[101] (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) 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) and 'Cosmetics and Toiletries – Science Applied' (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) 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), 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) has a section dedicated to the use of nanotechnology in cosmetics[102]. This web page discusses the uses of nanomaterials in cosmetics, highlighting particularly potential risks. 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[103]. 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'.[104]

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[100] Cave H. (2010): **The nanotechnology in your toothpaste**, available from http://www.theguardian.com/what-is-nano/small-world/nanotechnology-in-your-toothpaste

[101] Nanofutures can be found at http://www.theguardian.com/what-is-nano

[102] Nanotechnology - http://www.safecosmetics.org/article.php?id=307

[103] VeilleNanos (2013): **Quel état des connaissances sur la pénétration cutanée des nanoparticules?**availablefromhttp://veillenanos.fr/wakka.php?wiki=201312PenetrationCutaneeNano

[104] 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

6.5 The Traceability in the FNS and a Comparison with the CPNP and the RAPEX System

The French Notification System provides the authorities (or will provide, once the full compliance has been achieved) with the ability to track nanomaterials from the manufacturers and importers to the professional users via the distributors (second specific objective of the system). The authorities have information on the quantities of the nanomaterials at each different step in the supply chains and can access information on the identity of the clients of each different actor. However, the FNS keeps track only of the nanomaterials, in themselves or contained in mixtures without being bound to them or where the possibility of release cannot be excluded, and in articles that are designed to release these NMs, for the professional users market. In addition, the FNS requires the commercial name of the substance, mixture or article, if available.

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[105] 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.[106] 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.[107]

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 this figure had grown to 2,278.[108] 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 risk posed by a product has been discovered;

[105] 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

[106] 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

[107] 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

[108] EC (2014): **RAPEX – Statistics and Reports**, available from http://ec.europa.eu/consumers/safety/rapex/stats_reports_en.htm

- 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 chemical products for professional users.

In terms of generating information, the three systems are not alternatives one to each other but they complement their action.

In terms of the ability to delivering benefits to the human health and the environment, the full traceability achieved (or that will be achieved in the coming years) by the FNS on the professional users' market is, however, unclear. At the time of writing[109], no accidents specifically linked to the use of nanomaterials have been found in the literature by the consultants (as detailed in the Building Blocks report, Section 2). Two accidents have been reported involving the use of nanomaterials, however the health effects observed seem more related to poor working environments and the lack of proper risk management measures and do not seem specific to the nanomaterials. Moreover, most of the concerns surrounding nanomaterials refer to potential chronic rather than acute effects and thus the rapid action that traceability allows might be of no use.

6.6 Interview with the French Authorities on the Uses of the Information Gathered

After the first session with public and industry stakeholders during the meeting held in Paris on 10 March 2014 (Section 5.2), a second session followed with a close discussion between the consultants and the French public authorities.

The focus was on the legislative act and on the potential uses of the information through the mandatory notification scheme.

The project team enquired about the exclusion of the Specific Surface Area criterion from the definition referred by the French legislative act as well as the reason of not including solubility among the physicochemical parameters to be notified. The French authorities explained that the legislative act was elaborated by the Parliament and went through different committees and processes, so it might have been changed from the original draft. It explained as well that every decisions taken on the development of the regulation and of the system was the result of a consensus between industry representatives, NGOs, ministries and health assessment agencies. The exclusions might derive from difficulties in testing for those parameters.

With regard to the potential uses of the information gathered, the French authorities mentioned the planning of an epidemiological study that would benefit of such information.

In a subsequent phone interview organised by the Commission on 23 May 2014, the uses of the information gathered through the FNS was further investigated and more details were provided on the epidemiological study. This will focus on two "families" of nanomaterials (carbon nanotubes and titanium dioxide) and on the assessment of their potential impacts on health and safety of the workers, namely on the occurrence of diseases that might be attributed to exposure to manufactured nanomaterials.[110] The information that will be passed to the researchers refers to the identities of the manufacturers, importers and distributors, the physicochemical parameters of the

[109] August 2014.

[110] http://www.invs.sante.fr/Dossiers-thematiques/Travail-et-sante/Epinano-Dispositif-de-surveillance-epidemiologique-des-travailleurs-potentiellement-exposes-aux-nanomateriaux

nanomaterials investigated and their quantities. More in general, the French authorities reported to be now in the position to provide designated institutes and organisations with the data gathered for risk assessment of specific nanomaterials and to collect additional data on hazards and exposure. The French authorities indicated that they expect the data on the manufacturing and use of nanomaterials to contribute to knowledge on the risks of these materials.

The French authorities are also working on a prioritisation strategy that will draw on the information gathered through the FNS; however, this process is just at its initial phase and no specific documents are currently available. A dedicated working group led by the Anses will focus on the future uses of the data by the Agency.

6.7 Remarks on the Availability of the Information Gathered to Different Stakeholders and Potential Impacts on Long Term Health and Environmental Benefits

In order to model any impact on long term health and environmental benefits of the notification system, the project team looked at the availability of the information and the use of this information made by three different stakeholder categories:

- Consumers, consumer organisations and non-Governmental environmental Organisations;
- Industry (companies, industry associations and workers' unions); and
- Public authorities and health and safety research institutes.

With regard to the availability of the information to the general public, the first registered reactions were of disappointment.[111] The notification system does not allow to identify the consumer products containing nanomaterials and the information that was made public seems to confirm that many nanomaterials have been used in many applications for many years, but do not focus on the nanomaterials of most concern but actually provides a catalogue of ultrafine dusts (notably pigments and dyes) that, in their opinion, do not rise concerns over their common applications.

The cases of silver and carbon nanotubes have been spell out:

- The virtual absence of nanosilver (it appears in the public report in very low quantities for research and development) might be due to the fact that it is imported in articles and it is not intended to be released under normal conditions of use and, thus, escape the notification requirements;
- Carbon nanotubes are not easily identifiable within the public report under this name.

These absences undermine the trust that consumer organisations have on the notification system as a useful device for enhancing the transparency on nanomaterials on the market, although they acknowledge that the first reporting year probably reflect only a partial picture of the market.

In terms of the level and quality of the information provided to the public, it is opinion of the consultants that the first public report lacks of organisation and analysis: however, once the database will be consolidated, the French authorities will be in the position to provide a good and in-depth overview on the nanomaterials manufactured, imported and distributed to professional users on the French market.

[111] http://veillenanos.fr/wakka.php?wiki=BilanDeclarationObligatoire20122013

With regard to industry associations and workers' unions, the same limits found for the general public apply. The information made public provides a broad picture of the nanomaterials on the market but do not add much more to what it could be already known by an informed audience.

Nevertheless, companies with notification requirements and within the supply chains of nanomaterials did get new information thanks to the notification system: as this was designed to light up the supply chains, companies had to keep track of the quantities of nanomaterials handled, something that was not done before. Importantly, many downstream users became aware of being handling nanomaterials. This might led to some of them questioning the suitability of their risk management measures in dealing with nanomaterials. In terms of the information required for the risk assessment that each employer should carry out in order to comply with the health and safety legislation[112], it should be noted that each company had to provide information on the quantities (necessary for the estimate of the exposure) but only some manufacturers and importers characterised the physicochemical parameters of the nanomaterials, with downstream actors able only to refer to the notification numbers of their suppliers without having access to that information. However, some downstream users might ask their suppliers for the information on the characterisation of the nanomaterials in order to carry out the required risk assessment. Whether the communication of the information through the supply chain is currently happening or will happen in the coming years should be object of further research. Moreover, the French Notification System requires only a basic characterisation of the nanomaterials (see Section 5.3.6): for some nanomaterials, further characterisation is required in order to investigate any toxicological and ecotoxicological effects.

The information generated by some manufacturers and importers on their nanomaterials might have some value with regard to the insurability of the nanomaterial production risk: currently nanotechnology liability risks reside outside conventional insurance practice given the impossibility to calculate insurance risk premiums, due to the knowledge gaps on the frequency and severity of the insurance losses.[113] The information generated for notification purposes could provide key background information to enable such calculation: some physicochemical parameters (e.g. shape) have been used in risk assessment and management for developing control banding tools that insurers might use as basis for the calculation of risk premiums.

When assessing the potential impact of the availability of the information to the regulators, it is crucial to identify any marginal benefit of the new information gathered through the notification system.

With regard to the first use of the data in an epidemiological study reported by the French authorities, the crucial question is whether the new detailed data about the identity of the manufacturers/importers and their downstream users, the physicochemical parameters and the quantities of the nanomaterials enable a better targeting of the investigation and enhance the quality of such research.

In terms of focusing the epidemiological study on some nanomaterials instead of others, the system provides an easy accessible tool to identify manufacturers/importers of determined nanomaterials and their downstream users, where this enable a precise estimate of the workers population exposed to the nanomaterials to be investigated. The French authorities clarified that, once the companies and the plants handling the nanomaterials have been identified through the information

[112] See for example, the Chemical Agents Directive 98/24/EC.

[113] Mullins, A. *et al* (2013): The insurability of nanomaterial production risk, Nature Nanotechnology, Vol. 8, page 222, published in April 2013. Available at: http://www.nature.com/nnano/journal/v8/n4/full/nnano.2013.53.html?WT.ec_id=NNANO-201304

in the FNS, these will be contacted in order to make an *in situ* investigation on the potential exposure at the work station. A second step will be to contact the workers potentially exposed to propose them a long term medical monitoring, updated on a regular basis. The French authorities underlined that the robust characterisation of the nanomaterials is an important point as it allows to do comparisons of the results observed. However, in the opinion of the consultants, the assessment of the exposure to some nanomaterials and the medical monitoring of the workers could have been agreed anyway with the relevant companies, asking for their collaboration in providing the characterisation of the nanomaterials under investigation, their quantities and the identity of their downstream users. The setting up of a mandatory notification system does not seem fully justified, in the opinion of the consultants, by the planning of epidemiological studies, as these need anyway the collaboration of the companies involved. The notification system will indeed provide some data time series (with regard to workers' population exposure) that might be of value in the coming years for the study of any chronic effect of the nanomaterials. This value resides on the ability to enable a better monitoring of exposure pattern changes and to identify any potential disease directly related to the nanoform(s) of the substances or to focus on the potency of the nanoform(s) fraction of the substances to which the cohorts are exposed.

With regard to the environment and the quantification of any impact on the environmental media, it has to be noted that the French Notification System does not ask for Environmental Release Categories (ERC) descriptors, used for describing the broad conditions of use of the substances at the nanoscale from the environmental perspective and relevant for their subsequent service life in articles.

As this assessment is based on the results of the first year of implementation of the notification system, the public authorities will have the opportunity to learn on the experience of this pioneer exercise and to enhance the device where necessary.

7 Conclusions

The Interministerial decree No. 2012-232 was published in February 2012 and entered into force in January 2013. The general aim was to improve the information available to the authorities, the public, the consumers and the workers. The specific objectives were:

- 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).

At 1 July 2013, the authorities have received 3,409 notifications from 933 notifiers. Of the 933 notifiers, over 70% (670) were based in France, while the remaining 30% were based in other European countries members of the European Economic Area and Switzerland. At June 2014, the authorities have received over 10,000 notifications, meaning an increasing awareness of the notification obligations by different industry sectors.

In terms of the number of nanomaterials notified, the French authorities estimated that between 243 and 422 different substances have been notified as nanomaterials on the French market. Analysing the list of substances notified and published in the French public report, the consultants identified around 258 different substances.

In 2013 the total administrative burden for the companies having to notify has been estimated to be between **€8 million and €15.5 million:** for the generation of information with regard to the characterisation of nanomaterials, the cost for industry stakeholders has been estimated to be between **€5.5 million and €13 million;** the estimated total costs for the gathering and submitting of the information, for responding to clients' enquiries and for the adaptation of the product/account databases was of **around €2.6 million**. Assuming that, in a full compliance scenario, the number of notifications will be between 15,000 and 20,000 per year, the total recurring costs would range between **€750,000 and €1 million per year**. During the validation workshop, trade unions and non-governmental organisations highlighted that the costs entailed by the FNS should not be considered as administrative burden, as companies should characterise their NMs to ensure that they are used safely and thus to comply with health and safety legislation.

During the stakeholder meeting held in Paris in March 2014, consistently in the answers to the survey, during the interviews for the development of the case studies and during the validation workshop, industry stakeholders reported a high degree of mistrust of the scheme among their suppliers and customers, to the detriment of competitiveness and innovation. This is perhaps their main criticism. According to some, many commercial partners now ask for "no nano" products because they do not want to deal with the additional regulatory burdens.

Moreover, the scope of the scheme is deemed to be too broad by industry as it is considered unnecessary to notify nanomaterials that many companies consider to have been 'safely commercialised for decades'. The objective of the notification system is described as unclear and the added-value in comparison with the EU chemicals legislative framework is seen as questionable.

Consumer and environmental organisations welcome the French initiative: to them, it is a first step towards better regulation of an under-regulated area. A French NGO noted however that the initiative is hampered by insufficient transparency, as the system does not allow to identify the consumer products containing nanomaterials and the information that was made public seems to confirm that many nanomaterials have been used in many applications for many years and do not focus on the nanomaterials of most concern but actually provides a catalogue of ultrafine dusts (notably pigments and dyes) that, in their opinion, do not rise concerns over their common applications.

The virtual absences from the public report of nanomaterials such as nanosilver and carbon nanotubes (under this name), which most of the concern around nanomaterials are based on, undermine the trust that consumer organisations have on the notification system as a useful device for enhancing the transparency on nanomaterials on the market.

The French authorities reported that some of the information gathered through the FNS for two "families" of nanomaterials will be passed to researchers and used within an epidemiological study focusing on workers. More generally, the French authorities consider to be now able to identify companies manufacturing or handling these nanomaterials and to provide to designated institutes and organizations the gathered data for risk assessment of specific nanomaterials and to collect additional data on hazards and exposure. However, in the opinion of the consultants, the assessment of the exposure to some nanomaterials and the medical monitoring of the workers could have been agreed anyway with the relevant companies, asking for their collaboration in providing the characterisation of the nanomaterials under investigation, their quantities and the identity of their downstream users. The setting up of a mandatory notification system does not seem fully justified, in the opinion of the consultants, by the planning of epidemiological studies, as these need anyway the collaboration of the companies involved. The notification system will indeed provide some data time series (with regard to workers' population exposure) that might be of value in the coming years for the study of any chronic effect of the nanomaterials. This value resides on the ability to enable a better monitoring of exposure pattern changes and to identify any potential disease directly related to the nanoform(s) of the substances or to focus on the potency of the nanoform(s) fraction of the substances to which the cohorts are exposed.

In terms of the ability to delivering benefits to the human health and the environment, the full traceability achieved (or that will be achieved in the coming years) by the FNS on the professional users' market is, however, unclear. At the time of writing[114], no accidents specifically linked to the use of nanomaterials have been found in the literature by the consultants (as detailed in the Building Blocks report, Section 2). Two accidents have been reported involving the use of nanomaterials, however the health effects observed seem more related to poor working environments and the lack of proper risk management measures and do not seem specific to the nanomaterials. Moreover, most of the concerns surrounding nanomaterials refer to potential chronic rather than acute effects and thus the rapid action that traceability allows might be of no use.

With regard to the environment and the quantification of any impact on the environmental media, it has to be noted that the French Notification System does not ask for Environmental Release Categories (ERC) descriptors, used for describing the broad conditions of use of the substances at the nanoscale from the environmental perspective and relevant for their subsequent service life in articles.

In terms of the level and quality of the information provided to the public, it is opinion of the consultants that the first public report lacks of organisation and analysis: however, once the

[114] August 2014.

database will be consolidated, the French authorities will be in the position to provide a good and in-depth overview on the nanomaterials manufactured, imported and distributed to professional users on the French market.

With regard to the information available to industry associations and workers' unions, the same limits found for the general public apply. The information made public provides a broad picture of the nanomaterials on the market but do not add much more to what it could be already known by an informed audience.

Nevertheless, companies with notification requirements and within the supply chains of nanomaterials did get new information thanks to the notification system: as this was designed to light up the supply chains, companies had to keep track of the quantities of nanomaterials handled, something that was not done before. Importantly, many downstream users became aware of being handling nanomaterials. This might led to some of them questioning the suitability of their risk management measures in dealing with nanomaterials.

The information generated by some manufacturers and importers on their nanomaterials might have some value with regard to the insurability of the nanomaterial production risk: currently nanotechnology liability risks reside outside conventional insurance practice given the impossibility to calculate insurance risk premiums, due to the knowledge gaps on the frequency and severity of the insurance losses. The information generated for notification purposes could provide key background information to enable such calculation: some physicochemical parameters (e.g. shape) have been used in risk assessment and management for developing control banding tools that insurers might use as basis for the calculation of risk premiums.

Any conclusive assessment of the marginal value of the FNS in comparison with the current chemicals legislative framework will depend on the extent of the amendments of the REACH annexes, currently under consideration. At the time, over 60% of the substances, for which nanoforms have been notified to the FNS, have REACH registration dossiers (although these do not contain specific information on the nanoforms of the substances; this lack of information in the registration dossier is expected to be addressed through the planned revision of the REACH Annexes). By 2018, as lower tonnage thresholds require REACH registration, over 90% of the substances notified might have REACH registration dossiers. Notably, information on polymers at the nanoscale are captured by the FNS, while polymers are outside of the scope of the REACH Regulation.

This assessment is based on the results of the first year of implementation of the notification system and its limits reside on the partial availability of the information and on the fact that captures the picture of a device not running at "full regime" yet. Public authorities, as well as all the other stakeholders, will have the opportunity to learn on the experience of this pioneer exercise and to enhance the device where necessary.

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Annex I: Stakeholder Meeting Agenda

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

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 30th 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	**Presentation of the study** (Marco Camboni, project manager) • Main objectives and work programme • Objectives of the stakeholder meeting

14:30	**The French Notification System**
	• Presentation of the first results of the analysis (Marco Camboni)
	• Open discussion: practical issues of the Notification System (all)
	  • Interpretation of terminology (nanomaterials definition, quantities, etc.)
	  • Communication in the value chain
	  • Confidentiality and other critical issues

15:30	**Value chain characterisation and assessment of competitiveness and innovation impacts** • Presentation of the first results of the analysis (Marco Camboni) • Open discussion (all)
16:30	**Assessment of Long term human health and environmental benefits** • Presentation of the first results of the analysis (Marco Camboni) • Open discussion (all)
17:00	**End**

Annex II: Questionnaire – Administrative burden of the Notification Schemes

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 30th June 2013.

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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@rpaltd.co.uk) and/or telephone number (+44 1508 528465) or, alternatively, Craig Hawthorne, BiPRO project manager, by email (craig.hawthorne@bipro.de) and/or telephone number (+49-89-18979050).

We would be very grateful if you could provide your responses by 21st 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 (NACE 4 digit code):	
Secondary business sector (NACE 4 digit code):	
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 (**REACH**) (i.e. information from registration dossiers)		
Regulation (EC) No 1272/2008 (**CLP**) (i.e. information from safety data sheets)		
Regulation (EC) No 1223/2009 (**Cosmetic Products**)		X
Regulation (EU) No 528/2012 (**Biocidal Products**)		
Regulation (EC) No 258/1997 (**Novel Food**)		
Regulation (EC) No 1935/2004 (**Food Contact Material**)		
Regulation (EU) No 1169/2011 (**Food information to consumers**)		
Council Directive 98/24/EC (**Chemical Agents Directive**)		
Interministerial decree No. 2012-232 (**French Notification System**)	X	
Other (please specify)		
Please explain:		

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: *<please specify>*	*<please specify>*		

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: *<please specify>*	*<please specify>*		

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)		
Please explain:		

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	
Total	**100**

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

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

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

Impact category	Very negative	Negative	No change	Positive	Very positive	Not applicable
French Notification System						
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>*						
Please explain:						
Cosmetic Products Notification Portal						
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>*						
Please explain:						

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

Thank you very much for answering our questions.

Annex III: List of the Different Substances Identified that were notified to the FNS

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
1	1,2-benzisothiazol-3(2H)-one 1,1-dioxide, sodium salt	201-321-0	81-07-2	Not reported	1 - 10 tpa	(SU0 Other) - Food additive: artificial (high intensity) sweetener
2	triacetin	203-051-9	102-76-1	Not reported	10,000 - 100,000 tpa	(SU0 Other) – Food additive
3	3-hydroxy-2-methyl-4-pyrone	204-271-8	118-71-8	Not reported	Not registered	(SU0 Other) – Food additive : flavour enhancer
4	glycerol tristearate	209-097-6	555-43-1	Not reported	100 - 1,000 tpa	(SU0 Other) – hardening agent in candles and soaps
5	zinc distearate	209-151-9	557-05-1	Not reported	100 - 1,000 tpa	(SU0 Other) – Many different applications
6	lead sulfochromate yellow	215-693-7	1344-37-2	Not reported	1,000 - 10,000 tpa	Pigment
7	zinc sulphide	215-715-5	1345-05-7	Not reported	Not registered	Pigment
8	Calcium octadecanoate	216-472-8	1592-23-0	Not reported	Not registered	(SU0 Other) – Food additive
9	[3-(2,3-epoxypropoxy)propyl]triethoxysilane	220-011-6	2602-34-8	Not reported	100 - 1,000 tpa	PC9a Coating and paints, thinners, paint removers
10	4-[[4-(aminocarbonyl)phenyl]azo]-N-(2-ethoxyphenyl)-3-hydroxynaphthalene-2-carboxamide	220-509-3	2786-76-7	Not reported	100 - 1,000 tpa	Pigment
11	triethoxyoctylsilane	220-941-2	2943-75-1	Not reported	1,000 - 10,000 tpa	Used in cosmetics
12	2,9-bis[4-(phenylazo)phenyl]anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone	221-264-5	3049-71-6	Not reported	100 - 1,000 tpa	Pigment
13	2,9-dichloro-5,12-dihydroquino[2,3-b]acridine-7,14-dione	221-424-4	3089-17-6	Not reported	10 - 100 tpa	Pigment
14	2-ethyl-3-hydroxy-4-pyrone	225-582-5	4940-11-8	Not reported	Not registered	(SU0 Other) – Food additive : flavour enhancer
15	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 reported	Not registered	Pigment
16	barium bis[2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonate]	225-935-3	5160-02-1	Not reported	1,000 - 10,000 tpa	Pigment
17	manganese, 4-[(5-chloro-4-methyl-2-sulfophenyl)azo]-3-hydroxy-2-naphthalenecarboxylic acid complex	226-102-7	5280-66-0	Not reported	1 - 10 tpa	Pigment
18	N,N'-(2-chloro-1,4-phenylene)bis[4-[(2,5-dichlorophenyl)azo]-3-hydroxynaphthalene-2-carboxamide]	226-106-9	5280-78-4	Not reported	100 - 1,000 tpa	Pigment
19	3,3'-[(2-chloro-5-methyl-p-phenylene)bis[imino(1-acetyl-2-oxoethylene)azo]]bis[4-chloro-N-(3-chloro-o-tolyl)benzamide]	226-970-7	5580-57-4	Not reported	100 - 1,000 tpa	Pigment
20	4-[(2,5-dichlorophenyl)azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide	229-104-6	6410-38-4	Not reported	Not registered	Pigment
21	12H-phthaloperin-12-one	230-049-5	6925-69-5	Not reported	100 - 1,000 tpa	Dye
22	silicon	231-130-8	7440-21-3	Not reported	1,000,000+ tpa	All descriptors confidential
23	tricalciumbis(orthophosphate)	231-840-8	7758-87-4	Not reported	1,000 - 10,000 tpa	Su0 Other – Food additive: anticaking agent SU20 Products such as ph-regulators, flocculants, pre-cipitants, neutralization agents

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
24	antimony nickel titanium oxide yellow	232-353-3	8007-18-9	Not reported	1,000 - 10,000 tpa	Pigment
25	calcium chloride	233-140-8	10043-52-4	Not reported	100 - 1,000 tpa	Wide range of applications
26	Xanthan gum	234-394-2	11138-66-2	Not reported	not registered	SU0 Other – Food additive
27	barium titanium trioxide	234-975-0	12047-27-7	Not reported	1,000 - 10,000 tpa	SU9 Manufacture of fine chemicals SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU24 Research and development
28	strontium titanium trioxide	235-044-1	12060-59-2	Not reported	10 - 100 tpa	SU9 Manufacture of fine chemicals SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU24 Research and development
29	tungsten disulphide	235-243-3	12138-09-9	Not reported	Not registered	SU0 Other – Wide range of applications SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys)
30	N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-hydroxy-4-[[2,5-dimethoxy-4-[(methylamino)sulphonyl]phenyl]azo]naphthalene-2-carboxamide	235-426-8	12225-08-0	Not reported	10 - 100 tpa	Pigment
31	Iron oxide black	235-442-5	12227-89-3	Not reported	Not registered	Pigment
32	Manganese, 4-[(4-chloro-5-methyl-2-sulfophenyl)azo]-3-hydroxy-2-naphthalenecarboxylic acid complex	235-471-3	12238-31-2	Not reported	1 - 10 tpa	Pigment
33	lead chromate molybdatesulfate red	235-759-9	12656-85-8	Not reported	1,000 - 10,000 tpa	Pigment
34	[1-[[(2-hydroxyphenyl)imino]methyl]-2-naphtholato(2-)-N,O,O']copper	239-763-1	15680-42-9	Not reported	Not registered	Pigment
35	N,N'-[6,13-diacetamido-2,9-diethoxy-3,10-triphenodioxazinediyl]bis(benzamide)	241-734-3	17741-63-8	Not reported	Not registered	Pigment
36	ammonium iron(3+) hexakis(cyano-C)ferrate(4-)	247-304-1	25869-00-5	Not reported	1,000 - 10,000 tpa	Pigment
37	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 reported	Not registered	Pigment
38	isooctadecanoic acid	250-178-0	30399-84-9	Not reported	10,000 - 100,000 tpa	pc0 Other pc3 Air care products pc13 Fuels pc14 Metal surface treatment products, including galvanic and electroplating products
39	5,5'-(1H-isoindole-1,3(2H)-diylidene)dibarbituric acid	253-256-2	36888-99-0	Not reported	1,000 - 10,000 tpa	Pigment
40	N,N'-(2,5-dichloro-1,4-phenylene)bis[4-[(2,5-dichlorophenyl)azo]-3-hydroxynaphthalene-2-carboxamide]	255-005-2	40618-31-3	Not reported	10 - 100 tpa	Pigment
41	hydrogen bis[2,4-dihydro-4-[(2-hydroxy-5-nitrophenyl)azo]-5-methyl-2-phenyl-3H-pyrazol-3-onato(2-)]chromate(1-)	257-789-1	52256-37-8	Not reported	Not registered	Dye
42	Paraffin waxes and Hydrocarbon waxes, microcryst.	264-038-1	63231-60-7	Not reported	100,000 -	SU0 Other – Wide range of applications

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
					1,000,000 tpa	
43	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 reported	Not registered	Dye
44	2-cyano-2-[2,3-dihydro-3-(tetrahydro-2,4,6-trioxo-5(2H)-pyrimidinylidene)-1H-isoindol-1-ylidene]-N-methylacetamide	278-388-8	76199-85-4	Not reported	100 - 1,000 tpa	Pigment
45	2,9-bis(p-methoxybenzyl)anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone	280-472-4	83524-75-8	Not reported	10 - 100 tpa	Pigment
46	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 reported	Not registered	Fragrance agent/dye
47	2,9-diphenylanthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone, dichloro derivative	301-290-4	93983-03-0	Not reported	Not registered	Pigment
48	Cobalt aluminate blue spinel	310-193-6	1345-16-0	Not reported	1,000 - 10,000 tpa	Pigment
49	cerium oxide isostearate	419-760-3	346608-13-7	Not reported	Tonnage Data Confidential	As fuel additive (desulphurisation purposes) in diesel particulate filters
50	C.I. Acid Violet 66	none/n.f./n.a.	12220-53-0	Not reported	Not registered	Pigment
51	Solvent Red 127	none/n.f./n.a.	61969-48-0	Not reported	Not registered	Pigment
52	3,10-dichloro-5,12-dihydroquino[2,3-b]acridine-7,14-dione	none/n.f./n.a.	3573-01-1	Not reported	Not registered	Pigment
53	tricobalttetraoxide	215-157-2	1308-06-1	0.1-1 kg	1,000 - 10,000 tpa	SU0 Other SU9 Manufacture of fine chemicals SU 24 Research and development
54	nickel monoxide	215-215-7	1313-99-1	0.1-1 kg	10,000 - 100,000 tpa	SU9 Manufacture of fine chemicals SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 24 Research and development
55	tungsten trioxide	215-231-4	1314-35-8	0.1-1 kg	10,000 - 100,000 tpa	SU9 Manufacture of fine chemicals SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 24 Research and development
56	Copper(I) oxide	215-270-7	1317-39-1	0.1-1 kg	1,000 - 10,000 tpa	SU9 Manufacture of fine chemicals SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 24 Research and development
57	molybdenum	231-107-2	7439-98-7	0.1-1 kg	100,000 - 1,000,000 tpa	SU 24 Research and development
58	Silver	231-131-3	7440-22-4	0.1-1 kg	100,000 - 1,000,000 tpa	SU 24 Research and development

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
59	Carbone	231-153-3	7440-44-0	0.1-1 kg	100 - 1,000 tpa	SU9 Manufacture of fine chemicals SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 24 Research and development
60	pentacalcium hydroxide tris(orthophosphate)	235-330-6	12167-74-7	0.1-1 kg	10,000 - 100,000 tpa	SU0 Other
61	2-(3-oxobenzo[b]thien-2(3H)-ylidene)benzo[b]thiophene-3(2H)-one	208-336-1	522-75-8	1-10 kg	Not registered	Dye
62	Hydroxylapatite (Ca5(OH)(PO4)3)	215-145-7	1306-06-5	1-10 kg	Not registered	SU 20 Health services
63	Zero-valent ironnanoparticles (nZVI)	231-096-4	7439-89-6	1-10 kg	100,000,000+ tpa	SU 24 Research and development – potential applications in environmental remediation
64	Graphite	231-955-3	7782-42-5	1-10 kg	100,000 - 1,000,000 tpa	PC21 Laboratory chemicals PC32 Polymer preparations and compounds PC9a Coatings and paints, thinners, paint removers
65	diiron nickel tetraoxide	235-335-3	12168-54-6	1-10 kg	Not registered	SU0 Other
66	calcium bis[4-[[1-[[(2-methylphenyl)amino]carbonyl]-2-oxopropyl]azo]-3-nitrobenzenesulphonate]	235-558-6	12286-66-7	1-10 kg	10 - 100 tpa	Pigment
67	sodium bis[4-hydroxy-3-[(2-hydroxy-1-naphthyl)azo]-N-(3-methoxypropyl)benzenesulphonamidato(2-)]cobaltate(1-)	275-959-3	71735-61-0	1-10 kg	Not registered	Dye
68	calcium bis[4-[[1-[[(2-chlorophenyl)amino]carbonyl]-2-oxopropyl]azo]-3-nitrobenzenesulphonate]	276-057-2	71832-85-4	1-10 kg	10 - 100 tpa	Pigment
69	Styrene, oligomers	500-008-9	9003-53-6	1-10 kg	Not registered	No-longer-polymer substance SU 24 Research and development – potential applications in coatings
70	1-(methylamino)anthraquinone	201-417-2	82-38-2	10-100 kg	Not registered	Dye
71	silicon carbide	206-991-8	409-21-2	10-100 kg	100,000+ tpa	AC4 Stone, plaster, cement, glass and ceramic articles
72	chromium (III) oxide	215-160-9	1308-38-9	10-100 kg	10,000 - 100,000 tpa	Pigment
73	zirconium dioxide	215-227-2	1314-23-4	10-100 kg	10,000 - 100,000 tpa	SU17 General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment
74	triirontetraoxide	215-277-5	1317-61-9	10-100 kg	100,000 - 1,000,000 tpa	Pigment SU24 Research and development
75	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	10-100 kg	100 - 1,000 tpa	Pigment
76	4-[(4-chloro-2-nitrophenyl)azo]-3-hydroxy-N-(2-methylphenyl)naphthalene-2-carboxamide	229-314-8	6471-50-7	10-100 kg	1 - 10 tpa	Pigment
77	4-[(2,5-dichlorophenyl)azo]-N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-hydroxynaphthalene-2-carboxamide	230-258-1	6992-11-6	10-100 kg	10 - 100 tpa	Pigment
78	palladium	231-115-6	7440-05-3	10-100 kg	Mineral which occurs in nature	AC2 Machinery, mechanical appliances, electrical/electronic articles

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
						PC14 Metal surface treatment products, including galvanic and electroplating products PC15 Non-metal-surface treatment products SU16 Manufacture of computer, electronic and optical products, electrical equipment
79	Cellulose	232-674-9	9004-34-6	10-100 kg	Natural organic polymer	AC8 Paper articles
80	hydrogen [4-[4-(diethylamino)-5'-hydroxy-2',4'-disulphonatobenzhydrylidene]cyclohexa-2,5-dien-1-ylidene]diethylammonium, monosodium salt	243-654-4	20262-76-4	10-100 kg	Not registered	Pigment
81	manganese, 3-hydroxy-4-[(1-sulfo-2-naphthalenyl)azo]-2-naphthalenecarboxylic acid complex	252-525-1	35355-77-2	10-100 kg	Not registered	Pigment
82	Silica, vitreous	262-373-8	60676-86-0	10-100 kg	Article 2(7)(b)	PC15 Non-metal-surface treatment products
83	chrome antimony titanium buff rutile	269-052-1	68186-90-3	10-100 kg	10,000 - 100,000 tpa	Pigment
84	Hematite, chromium green black	272-713-7	68909-79-5	10-100 kg	1,000 - 10,000 tpa	Pigment
85	sodium bis[4-hydroxy-3-[(2-hydroxy-1-naphthyl)azo]-N-(3-methoxypropyl)benzene-1-sulphonamidato(2-)]chromate(1-)	276-066-1	71839-80-0	10-100 kg	Not registered	Dye
86	Amines, rosin, compds. with 9-(2-carboxyphenyl)-3,6-bis(diethylamino)xanthylium chloride and disodium hydrogen bis[4-[(4,5-dihydro-3-methyl-5-oxo-1-phenyl-1H-pyrazol-4-yl)azo]-3-hydroxy-1-naphthalenesulfonato(3-)]chromate(3-)	308-114-5	97862-65-2	10-100 kg	Not registered	dye
87	Strontium 4-chloro-2-(2-(2-hydroxy-6-sulfo-1-naphthalenyl)diazenyl)benzoate	none/n.f./n.a.	474814-88-5	10-100 kg	Not registered	Pigment - Colorant for all polymers intended for use in contact with food
88	iron(3+); oxygen(2-); hydrate	none/n.f./n.a.	90452-21-4	10-100 kg	Not registered	Pigment
89	Pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis(3-chlorophenyl)-2,5-dihydro-	none/n.f./n.a.	84632-67-7	10-100 kg	Not registered	Pigment
90	octanoic acid	204-677-5	124-07-2	100 kg-1 t	10,000 - 100,000 tpa	SU0 Other
91	barium bis[2-[(2-hydroxynaphthyl)azo]naphthalenesulphonate]	214-160-6	1103-38-4	100 kg-1 t	1 - 10 tpa	Pigment
92	2-[(p-nitrophenyl)azo]acetoacetanilide	216-754-0	1657-16-5	100 kg-1 t	Not registered	Pigment
93	trisodium 5-hydroxy-1-(4-sulphophenyl)-4-(4-sulphophenylazo)pyrazole-3-carboxylate	217-699-5	1934-21-0	100 kg-1 t	Not registered	Dye (cosmetic products)
94	1-(4-methyl-2-nitrophenylazo)-2-naphthol	219-372-2	2425-85-6	100 kg-1 t	10 - 100 tpa	Pigment
95	trisodium 1-(1-naphthylazo)-2-hydroxynaphthalene-4',6,8-trisulphonate	220-036-2	2611-82-7	100 kg-1 t	1 - 10 tpa	Pigment
96	1-[(2-chloro-4-nitrophenyl)azo]-2-naphthol	220-562-2	2814-77-9	100 kg-1 t	100 - 1,000 tpa	Pigment
97	hydrogen 3,6-bis(diethylamino)-9-(2,4-disulphonatophenyl)xanthylium, sodium salt	222-529-8	3520-42-1	100 kg-1 t	Not registered	Pigment
98	dihydrogen (ethyl)[4-[4-[ethyl(3-sulphonatobenzyl)]amino]-2'-	223-339-8	3844-45-9	100 kg-1 t	Not registered	Pigment

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
	sulphonatobenzhydrylidene]cyclohexa-2,5-dien-1-ylidene](3-sulphonatobenzyl)ammonium, disodium salt					
99	1,1'-[(6-phenyl-1,3,5-triazine-2,4-diyl)diimino]bisanthraquinone	223-912-2	4118-16-5	100 kg-1 t	Not registered	Pigment
100	2,4-dihydro-5-methyl-2-phenyl-4-(phenylazo)-3H-pyrazol-3-one	224-330-1	4314-14-1	100 kg-1 t	Not registered	dye
101	4,10-dibromodibenzo[def,mno]chrysene-6,12-dione	224-481-3	4378-61-4	100 kg-1 t	10 - 100 tpa	Pigment
102	bisbenzimidazo[2,1-b:2',1'-i]benzo[lmn][3,8]phenanthroline-8,17-dione	224-597-4	4424-06-0	100 kg-1 t	Not registered	Pigment
103	2,9-bis(3,5-dimethylphenyl)anthra[2,1,9-def:6,5,10-d'e'f']diisoquinoline-1,3,8,10(2H,9H)-tetrone	225-590-9	4948-15-6	100 kg-1 t	100 - 1,000 tpa	Pigment
104	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	100 kg-1 t	10 - 100 tpa	Pigment
105	barium bis[2-[(2-hydroxy-1-naphthyl)azo]benzoate]	228-906-3	6372-81-2	100 kg-1 t	Not registered	Pigment
106	N-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulphonyl]-2-methoxyphenyl]azo]-3-hydroxynaphthalene-2-carboxamide	229-107-2	6410-41-9	100 kg-1 t	10 - 100 tpa	Pigment
107	calcium 3-hydroxy-4-[(1-sulphonato-2-naphthyl)azo]-2-naphthoate	229-142-3	6417-83-0	100 kg-1 t	Not registered	Pigment
108	3-hydroxy-4-[(2-methyl-5-nitrophenyl)azo]-N-(o-tolyl)naphthalene-2-carboxamide	229-681-4	6655-84-1	100 kg-1 t	Not registered	Pigment
109	N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxynaphthalene-2-carboxamide	235-464-5	12236-64-5	100 kg-1 t	10 - 100 tpa	Pigment
110	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	100 kg-1 t	100 - 1,000 tpa	Pigment
111	copper chlorophthalocyanine	235-476-0	12239-87-1	100 kg-1 t	1,000 - 10,000 tpa	Pigment
112	Chromium iron oxide	235-790-8	12737-27-8	100 kg-1 t	10,000 - 100,000 tpa	Pigment
113	[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	100 kg-1 t	100 - 1,000 tpa	Pigment
114	N-(5-chloro-2-methoxyphenyl)-2-[(2-methoxy-4-nitrophenyl)azo]-3-oxobutyramide	240-131-2	15993-42-7	100 kg-1 t	10 - 100 tpa	Pigment
115	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	100 kg-1 t	Not registered	dye
116	dimethyl 5-[[1-[[(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azoterephthalate	249-955-7	29920-31-8	100 kg-1 t	10 - 100 tpa	Pigment
117	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	100 kg-1 t	10 - 100 tpa	Pigment
118	dichloro-5,12-dihydroquino[2,3-b]acridine-7,14-dione	254-100-6	38720-66-0	100 kg-1 t	10 - 100 tpa	Pigment (As a colorant in all types of food-contact

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
						polymers)
119	calcium bis[4-[[3-[[2-hydroxy-3-[[(4-methoxyphenyl)amino]carbonyl]-1-naphthyl]azo]-4-methylbenzoyl]amino]benzenesulphonate]	256-050-0	43035-18-3	100 kg-1 t	Not registered	Pigment
120	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	100 kg-1 t	10 - 100 tpa	Pigment
121	Zirconium and yttrium oxides	264-885-7	64417-98-7	100 kg-1 t	100 - 1,000 tpa	SU0 Other - Electrolyte material for solid oxide fuel cells
122	[2,3'-bis[[(2-hydroxyphenyl)methylene]amino]but-2-enedinitrilato(2-)-N2,N3,O2,O3]nickel	265-022-7	64696-98-6	100 kg-1 t	Not registered	dye
123	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	100 kg-1 t	Not registered	Pigment
124	N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-oxo-2-[[2-(trifluoromethyl)phenyl]azo]butyramide	268-734-6	68134-22-5	100 kg-1 t	100 - 1,000 tpa	Pigment
125	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	100 kg-1 t	Not registered	Dye
126	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	100 kg-1 t	Not registered	Dye
127	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	100 kg-1 t	Not registered	Dye
128	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	100 kg-1 t	Not registered	Dye
129	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	100 kg-1 t	Not registered	Dye
130	3-[(4-chloro-2-nitrophenyl)azo]-2-methylpyrazolo[5,1-b]quinazolin-9(1H)-one	277-823-9	74336-59-7	100 kg-1 t	100 - 1,000 tpa	Pigment
131	Silicate(2-), hexafluoro-, disodium, reaction products with lithium magnesium sodium silicate	285-349-9	85085-18-3	100 kg-1 t	10 - 100 tpa	AC4 Stone, plaster, cement, glass and ceramic articles
132	4-[(2,4-dichlorophenyl)azo]-3-hydroxy-N-(2-methylphenyl)naphthalene-2-carboxamide	304-497-8	94276-08-1	100 kg-1 t	Not registered	Pigment
133	10,12-dihydrobenz(de)imidazo(4',5':5,6)benzimidazo(1,2-a)isoquinoline-8,11-dione	408-170-1	none/n.f./n.a.	100 kg-1 t	Tonnage Data Confidential	Pigment
134	A mixture of: N-(4-chlorophenyl)-4-(2,5-dichloro-4-	412-550-2	none/n.f./n.a.	100 kg-1 t	10 - 100 tpa	Pigment

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
	(dimethylsulfamoyl)phenylazo)-3-hydroxy-2-naphthalenecarboxamide; N-(4-chlorophenyl)-4-(2,5-dichloro-4-(methylsulfamoyl)phenylazo)-3-hydroxy-2-naphthalenecarboxamide;					
135	Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, molybdatetungstatephosphate	450-350-7	none/n.f./n.a.	100 kg-1 t	Tonnage Data Confidential	Pigment
136	Not found	none/n.f./n.a.	61725-81-3	100 kg-1 t	Not registered	Dye
137	Not found	none/n.f./n.a.	61901-92-6	100 kg-1 t	Not registered	dye
138	Not found	none/n.f./n.a.	61901-98-7	100 kg-1 t	Not registered	dye
139	Not found	none/n.f./n.a.	61116-27-6	100 kg-1 t	Not registered	dye
140	PMMA with buta-1,3 diene (EC:203-450-8, CAS: 106-99-0), butyl acrylate (EC: 205-480-7, CAS: 141-32-2) and ethyl acrylate	none/n.f./n.a.	none/n.f./n.a.	100 kg-1 t	Polymer	PC32 Polymer preparations and compounds
141	citric acid	201-069-1	77-92-9	1-10 t	100,000 - 1,000,000 tpa	SU0 Food additive
142	hydrogen [4-[4-(diethylamino)-2',4'-disulphonatobenzhydrylidene]cyclohexa-2,5-dien-1-ylidene]diethylammonium, sodium salt	204-934-1	129-17-9	1-10 t	Not registered	Pigment
143	5,12-dihydroquino[2,3-b]acridine-7,14-dione	213-879-2	1047-16-1	1-10 t	1,000 - 10,000 tpa	Pigment
144	calcium bis[2-[(2-hydroxynaphthyl)azo]naphthalenesulphonate]	214-161-1	1103-39-5	1-10 t	Not registered	Pigment
145	diantimonypentoxide	215-237-7	1314-60-9	1-10 t	10 - 100 tpa	Flame retardant in plastics
146	2-[(4-methyl-2-nitrophenyl)azo]-3-oxo-N-phenylbutyramide	219-730-8	2512-29-0	1-10 t	100 - 1,000 tpa	Pigment
147	1-[(2,4-dinitrophenyl)azo]-2-naphthol	222-429-4	3468-63-1	1-10 t	100 - 1,000 tpa	Pigment
148		224-867-1	4531-49-1	1-10 t	100 - 1,000 tpa	Pigment
149	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	1-10 t	100 - 1,000 tpa	Pigment
150	3,3'-[(2,5-dimethyl-p-phenylene)bis[imino(1-acetyl-2-oxoethylene)azo]]bis[4-chloro-N-(5-chloro-o-tolyl)benzamide]	226-107-4	5280-80-8	1-10 t	100 - 1,000 tpa	Pigment
151	N,N'-(3,3'-dimethyl[1,1'-biphenyl]-4,4'-diyl)bis[2-[(2,4-dichlorophenyl)azo]-3-oxobutyramide]	227-783-3	5979-28-2	1-10 t	Not registered	Pigment
152	8,18-dichloro-5,15-diethyl-5,15-dihydrodiindolo[3,2-b:3',2'-m]triphenodioxazine	228-767-9	6358-30-1	1-10 t	1,000 - 10,000 tpa	Pigment
153	2-[(4-chloro-2-nitrophenyl)azo]-N-(2-chlorophenyl)-3-oxobutyramide	229-355-1	6486-23-3	1-10 t	100 - 1,000 tpa	Pigment
154	calcium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate	230-303-5	7023-61-2	1-10 t	1,000 - 10,000 tpa	Pigment
155	barium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate	231-494-8	7585-41-3	1-10 t	100 - 1,000 tpa	Pigment
156	calcium hydrogenorthophosphate	231-826-1	7757-93-9	1-10 t	100,000 -	Food additive

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
					1,000,000 tpa	
157	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	1-10 t	100 - 1,000 tpa	Pigment
158	2-[(4-chloro-2-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	236-852-7	13515-40-7	1-10 t	100 - 1,000 tpa	Pigment
159	bismuth vanadium tetraoxide	237-898-0	14059-33-7	1-10 t	1,000 - 10,000 tpa	Pigment
160	8,9,10,11-tetrachloro-12H-phthaloperin-12-one	244-007-9	20749-68-2	1-10 t	100 - 1,000 tpa	dye
161	2-[[1-[[(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]benzoic acid	250-830-4	31837-42-0	1-10 t	100 - 1,000 tpa	Pigment
162	dimethyl 2-[[1-[[(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]terephthalate	252-650-1	35636-63-6	1-10 t	10 - 100 tpa	Pigment
163	4-[[4-(aminocarbonyl)phenyl]azo]-3-hydroxy-N-(2-methoxyphenyl)naphthalene-2-carboxamide	253-292-9	36968-27-1	1-10 t	1 - 10 tpa	Pigment
164	2,2'-(1,4-phenylene)bis[4-[(4-methoxyphenyl)methylene]oxazol-5(4H)-one]	257-055-0	51202-86-9	1-10 t	Not registered	dye
165	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	1-10 t	10 - 100 tpa	Pigment
166	N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-2-[(4-nitrophenyl)azo]-3-oxobutyramide	258-221-5	52846-56-7	1-10 t	10 - 100 tpa	Pigment
167	methyl 4-[[(2,5-dichlorophenyl)amino]carbonyl]-2-[[2-hydroxy-3-[[(2-methoxyphenyl)amino]carbonyl]-1-naphthyl]azo]benzoate	263-272-1	61847-48-1	1-10 t	100 - 1,000 tpa	Pigment
168	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	1-10 t	Not registered	Pigment
169	Xanthylium, 9-(2-carboxyphenyl)-3,6-bis(diethylamino)-, molybdatesilicate	263-778-2	62973-79-9	1-10 t	Not registered	Pigment
170	[octabromooctachloro-29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32]copper	266-133-3	66085-74-3	1-10 t	Not registered	Pigment
171	benzenamine, 4-[(4-aminophenyl)(4-imino-2,5-cyclohexadien-1-ylidene)methyl]-, N-Me derivatives, molybdatephosphates	268-006-8	67989-22-4	1-10 t	Not registered	Pigment
172	Managanese ferrite black spinel	269-056-3	68186-94-7	1-10 t	1,000 - 10,000 tpa	Pigment
173	N-(5-chloro-2-methylphenyl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide	269-389-4	68227-78-1	1-10 t	1 - 10 tpa	pigment
174	Fumes, silica	273-761-1	69012-64-2	1-10 t	100,000 -	Pigment

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
					1,000,000 tpa	
175	5-[(2,3-dihydro-6-methyl-2-oxo-1H-benzimidazol-5-yl)azo]barbituric acid	276-344-2	72102-84-2	1-10 t	Not registered	Pigment
176	2,2'-[ethylenebis(oxyphenyl-2,1-eneazo)]bis[N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-oxobutyramide	278-770-4	77804-81-0	1-10 t	100 - 1,000 tpa	Pigment
177	N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-2-[(2-methoxyphenyl)azo]-3-oxobutyramide	279-914-9	82199-12-0	1-10 t	100 - 1,000 tpa	Pigment
178	Nitric acid, copper(2+) salt, reaction products with ammonia, chromic acid (H2CrO4) diammonium salt and manganese(2+) dinitrate, kilned	309-501-1	100402-65-1	1-10 t	Not registered	Use as laboratory reagent
179	Benzoic acid,2,3,4,5-tetrachloro-6-cyano-, methyl ester, reaction products with p-phenylenediamine and sodium methoxide	600-736-8	106276-80-6	1-10 t	100 - 1,000 tpa	Pigment
180	C.I. PIGMENT RED 184	602-672-6	99402-80-9	1-10 t	Not registered	Pigment
181	4-[(4-Aminophenyl)(4-imino-2,5-cyclohexadien-1-ylidene)methyl]-benzenamine N-Me derivs. Molybdatetungstatephosphates	603-635-7	1325-82-2	1-10 t	Not registered	Pigment
182	Butanamide, 2,2-(3,3-dichloro1,1-biphenyl-4,4-diyl)bis(azo)bisN-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-oxo-	616-600-6	78245-94-0	1-10 t	Not registered	Pigment
183	Poly(acrylic acid) with butyl acrylate, styrene and methacrylamide	none/n.f./n.a.	35483-96-6?	1-10 t	Polymer	PC9a Coatings and paints, thinners, paint removers
184	Acrylic acid polymer with butyl acrylate and 2-ethylhexyl acrylate	none/n.f./n.a.	25586-24-7	1-10 t	Polymer	PC9a Coatings and paints, thinners, paint removers
185	Acrylonitrile with styrene	none/n.f./n.a.	9010-96-2	1-10 t	Polymer	SU0 Other
186	Poly(methil methacrylate, EC: 201-297-1, CAS: 80-62-6); PMMA	none/n.f./n.a.	9011-14-7	1-10 t	Polymer	SU12 Manufacture of plastics products, including compounding and conversion
187	Ethene, homopolymer, oxidized	none/n.f./n.a.	68441-17-8	1-10 t	Polymer	PC9a Coatings and paints, thinners, paint removers
188	Silane, dichlorodimethyl-, reaction products with silica	200-901-0	75-78-5	10-100 t	100,000 - 1,000,000 tpa	AC7 Metal articles PC 9a Coatings and paints, thinners, paint removers PC29 Pharmaceuticals PC39 Cosmetics, personal care products
189	6,15-dihydroanthrazine-5,9,14,18-tetrone	201-375-5	81-77-6	10-100 t	100 - 1,000 tpa	Pigment
190	1,4-bis(mesitylamino)anthraquinone	204-155-7	116-75-6	10-100 t	10 - 100 tpa	dye
191	C.I. SOLVENT BLACK 27	204-793-5	12237-22-8	10-100 t	Not registered	dye
192	sodium hydrogencarbonate	205-633-8	144-55-8	10-100 t	1,000,000 - 10,000,000 tpa	SU1 Agriculture, forestry, fishery
193	29H,31H-phthalocyaninato(2-)-N29,N30,N31,N32 copper	205-685-1	147-14-8	10-100 t	10,000 - 100,000 tpa	Pigment
194	5,12-dihydro-2,9-dimethylquino[2,3-b]acridine-7,14-dione	213-561-3	980-26-7	10-100 t	1,000 - 10,000 tpa	Pigment
195	polychloro copper phthalocyanine	215-524-7	1328-53-6	10-100 t	1,000 - 10,000 tpa	Pigment

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
196	Silicic acid, calcium salt	215-710-8	1344-95-2	10-100 t	1,000 - 10,000 tpa	PC 9a Coatings and paints, thinners, paint removers
197	N,N'-phenylene-1,4-bis[4-[(2,5-dichlorophenyl)azo]-3-hydroxynaphthalene-2-carboxamide]	223-460-6	3905-19-9	10-100 t	100 - 1,000 tpa	Pigment
198	calcium 3-hydroxy-4-[(4-methyl-2-sulphonatophenyl)azo]-2-naphthoate	226-109-5	5281-04-9	10-100 t	10,000 - 100,000 tpa	Pigment
199	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2-methylphenyl)-3-oxobutyramide]	226-789-3	5468-75-7	10-100 t	1,000 - 10,000 tpa	Pigment
200	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(4-chloro-2,5-dimethoxyphenyl)-3-oxobutyramide]	226-939-8	5567-15-7	10-100 t	1,000 - 10,000 tpa	Pigment
201	3,3'-(1,4-phenylenediimino)bis[4,5,6,7-tetrachloro-1H-isoindol-1-one]	226-999-5	5590-18-1	10-100 t	Not registered	Pigment
202	4-[(2,5-dichlorophenyl)azo]-3-hydroxy-N-phenylnaphthalene-2-carboxamide	227-930-1	6041-94-7	10-100 t	1,000 - 10,000 tpa	Pigment
203	3-hydroxy-N-(o-tolyl)-4-[(2,4,5-trichlorophenyl)azo]naphthalene-2-carboxamide	229-440-3	6535-46-2	10-100 t	1,000 - 10,000 tpa	Pigment
204	barium sulfate	231-784-4	7727-43-7	10-100 t	10,000 - 100,000 tpa	SU0 Other
205	N-(4-chloro-2,5-dimethoxyphenyl)-2-[[2,5-dimethoxy-4-[(phenylamino)sulphonyl]phenyl]azo]-3-oxobutyramide	235-427-3	12225-18-2	10-100 t	100 - 1,000 tpa	Pigment
206	2-[(4-chloro-2-nitrophenyl)azo]-N-(2,3-dihydro-2-oxo-1H-benzimidazol-5-yl)-3-oxobutyramide	235-462-4	12236-62-3	10-100 t	100 - 1,000 tpa	Pigment
207	strontium 4-[(5-chloro-4-methyl-2-sulphonatophenyl)azo]-3-hydroxy-2-naphthoate	239-879-2	15782-05-5	10-100 t	100 - 1,000 tpa	Pigment
208	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	10-100 t	100 - 1,000 tpa	Pigment
209	2-chloro-5-[(2-hydroxy-1-naphthyl)azo]toluene-4-sulphonic acid	240-089-5	15958-19-7	10-100 t	Not registered	Pigment
210	1,4-bis(butylamino)anthraquinone	241-379-4	17354-14-2	10-100 t	Not registered	dye
211	Silicic acid, lithium magnesium sodium salt	258-476-2	53320-86-8	10-100 t	1,000 - 10,000 tpa	PC 9a Coatings and paints, thinners, paint removers PC39 Cosmetics, personal care products
212	N,N'-(2-chloro-1,4-phenylene)bis[4-[(2-chloro-4-nitrophenyl)azo]-3-hydroxynaphthalene-2-carboxamide]	261-476-5	58872-62-1	10-100 t	Not registered	Pigment
213	calcium 4,5-dichloro-2-[[4,5-dihydro-3-methyl-5-oxo-1-(3-sulphonatophenyl)-1H-pyrazol-4-yl]azo]benzenesulphonate	265-634-4	65212-77-3	10-100 t	100 - 1,000 tpa	Pigment
214	Nickel, 5,5'-azobis-2,4,6(1H,3H,5H)-pyrimidinetrione complexes	270-944-8	68511-62-6	10-100 t	not registered	Pigment
215	tetramethyl 2,2'-[1,4-phenylenebis[imino(1-acetyl-2-oxoethane-1,2-diyl)azo]]bisterephthalate	271-176-6	68516-73-4	10-100 t	100 - 1,000 tpa	Pigment
216	diisopropyl 3,3'-[(2,5-dichloro-1,4-phenylene)bis[iminocarbonyl(2-hydroxy-3,1-naphthylene)azo]]bis[4-methylbenzoate]	275-639-3	71566-54-6	10-100 t	10 - 100 tpa	Pigment
217	N-[4-(aminocarbonyl)phenyl]-4-[[1-[[(2,3-dihydro-2-oxo-1H-	277-873-1	74441-05-7	10-100 t	100 - 1,000 tpa	Pigment

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
	benzimidazol-5-yl)amino]carbonyl]-2-oxopropyl]azo]benzamide					
218	Benzenamine,N,N-dimethyl-, oxidized, molybdatetungstatephosphates	309-916-8	101357-19-1	10-100 t	Not registered	Pigment
219	3,6-bis(4-chlorophenyl)-2,5-dihydropyrrolo[3,4-c]pyrrol-1,4-dione	401-540-3	84632-65-5	10-100 t	1 - 10 tpa	Pigment
220	calcium 4-chloro-2-(5-hydroxy-3-methyl-1-(3-sulfonatophenyl)pyrazol-4-ylazo)-5-methylbenzenesulfonate	403-530-4	129423-54-7	10-100 t	10 - 100 tpa	Pigment
221	2,2'-methylenebis(6-(2H-benzotriazol-2-yl)-4-(1,1,3,3-tetramethylbutyl)phenol)	403-800-1	103597-45-1	10-100 t	100+ tpa	AC13 Plastic articles
222	3,6-Bis(4-tert-butylphenyl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	416-250-2	84632-59-7	10-100 t	10 - 100 tpa	Pigment
223	C.I. SOLVENT BLUE 44	none/n.f./n.a.	61725-69-7	10-100 t	Not registered	dye
224	C.I. SOLVENT BLUE 45	none/n.f./n.a.	37229-23-5	10-100 t	Not registered	dye
225	C.I. SOLVENT ORANGE 41	none/n.f./n.a.	61901-91-5	10-100 t	Not registered	dye
226	3,6-Bis(2-methylphenyl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	none/n.f./n.a.	330815-96-8	10-100 t	Not registered	SU0 Other
227	Cerium Iron Oxide Isostearate	none/n.f./n.a.	753480-32-9	10-100 t	Not registered	Photocatalyst
228	PMMA with 2-ethylhexyl acrylate	none/n.f./n.a.	25265-15-0	10-100 t	Polymer	PC 9a Coatings and paints, thinners, paint removers
229	PMMA with butyl acrylate and styrene	none/n.f./n.a.	27136-15-8	10-100 t	Polymer	PC32 Polymer preparations and compounds SU24 Scientific research and development
230	PMMA with buta-1,3 diene (EC:203-450-8, CAS: 106-99-0) and styrene	none/n.f./n.a.	9060-79-1	10-100 t	Polymer	PC32 Polymer preparations and compounds SU24 Scientific research and development
231	Poly(butyl acrylate) with 1,1-dichloroethene and acrylonitrile	none/n.f./n.a.	26300-99-2	10-100 t	Polymer	SU12 Manufacture of plastics products, including compounding and conversion
232	PMMA with buta-1,3 diene, divinylbenzene (EC: 215-325-5, CAS: 1321-74-0), styrene	none/n.f./n.a.	59858-50-3	10-100 t	Polymer	PC32 Polymer preparations and compounds SU24 Scientific research and development
233	cerium dioxide	215-150-4	1306-38-3	100-1000 t	1,000 - 10,000 tpa	AC1 Vehicles AC2 Machinery, mechanical appliances, electrical/electronic articles PC9b Fillers, putties, plasters, modelling clay PC15 Non-metal-surface treatment products PC33 Semiconductors
234	diiron trioxide	215-168-2	1309-37-1	100-1000 t	100,000 - 1,000,000 tpa	PC 9a Coatings and paints, thinners, paint removers
235	zinc oxide	215-222-5	1314-13-2	100-1000 t	100,000 - 1,000,000 tpa	PC 9a Coatings and paints, thinners, paint removers PC39 Cosmetics, personal care products
236	silicic acid, aluminum sodium salt	215-684-8	1344-00-9	100-1000 t	10,000 - 100,000 tpa	AC10 Rubber articles AC13 Plastic articles
237	[1,1'-Bianthracene]- 9,9',10,10'-tetrone, 4,4'-diamino-	223-754-4	4051-63-2	100-1000 t	100 - 1,000 tpa	Pigment
238	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[N-(2,4-	225-822-9	5102-83-0	100-1000 t	1,000 - 10,000 tpa	Pigment

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
	dimethylphenyl)-3-oxobutyramide]					
239	2-[(2-methoxy-4-nitrophenyl)azo]-N-(2-methoxyphenyl)-3-oxobutyramide	228-768-4	6358-31-2	100-1000 t	1,000 - 10,000 tpa	Pigment
240	Silicic acid, aluminum magnesium sodium salt	234-919-5	12040-43-6	100-1000 t	10,000 - 100,000 tpa	PC1 Adhesives, sealants
241	aluminium hydroxide	244-492-7	21645-51-2	100-1000 t	1,000,000 - 10,000,000 tpa	Fire retardants
242	iron hydroxide oxide yellow	257-098-5	51274-00-1	100-1000 t	100,000 - 1,000,000 tpa	PC1 Adhesives, sealants PC 9a Coatings and paints, thinners, paint removers
243	3,6-diphenyl-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	402-400-4	54660-00-3	100-1000 t	10 - 100 tpa	PC 9a Coatings and paints, thinners, paint removers
244	Iron oxide isostearate	476-890-3	none/n.f./n.a.	100-1000 t	100 - 1,000 tpa	Fuel additive
245	Vinylidene chloride copolymer	none/n.f./n.a.	25038-72-6; 9011-06-7	100-1000 t	Polymer	SU7 Printing and reproduction of recorded media
246	Methacrylic acid polymer with 2-ethylhexyl acrylate	none/n.f./n.a.	25086-15-1	100-1000 t	Polymer	PC32 Polymer preparations and compounds SU12 Manufacture of plastics products, including compounding and conversion SU24 Scientific research and development
247	Poly(butyl acrylate) with 1,1-dichloroethene	none/n.f./n.a.	9011-09-0	100-1000 t	Polymer	SU12 Manufacture of plastics products, including compounding and conversion
248	calcium carbonate	207-439-9	471-34-1	>1000 t	1,000,000 - 10,000,000 tpa	AC1 Vehicles AC13 Plastic articles
249	calcium oxide	215-138-9	1305-78-8	>1000 t	10,000 - 100,000 tpa	SU9 Manufacture of fine chemicals
250	Boehmite (Al(OH)O)	215-284-3	1318-23-6	>1000 t	10,000 - 100,000 tpa	AC4 Stone, plaster, cement, glass and ceramic articles PC 9a Coatings and paints, thinners, paint removers
251	Carbon Black	215-609-9	1333-86-4	>1000 t	1,000,000 - 10,000,000 tpa	Wide range of applications
252	3,6-Bis(biphenyl-4-yl)-2,5-dihydropyrrolo[3,4-c]pyrrole-1,4-dione	413-920-6	88949-33-1	>1000 t	100 - 1,000 tpa	PC 9a Coatings and paints, thinners, paint removers
253	Reaction mass of cerium dioxide and zirconium dioxide	909-709-8	none/n.f./n.a.	>1000 t	1,000 - 10,000 tpa	AC1 Vehicles PC 9a Coatings and paints, thinners, paint removers
254	silicic acid, magnesium salt	215-681-1	1343-88-0	>1000 t	1,000 - 10,000 tpa	SU0 Other – Food additive SU1 Agriculture, forestry, fishery
255	aluminium oxide	215-691-6	1344-28-1	>1000 t	1,000 - 10,000 tpa	Wide range of applications
256	silicon dioxide; Silica, amorphous, fumed, crystalline-free; silica gel	231-545-4	7631-86-9; 7631-86-9; 112926-00-8; 112945-52-5 112926-00-8	>1000 t	1,000,000+ tpa	Wide range of applications
257	PMMA with 1,1-dichloroethylene and methylacrylonitrile	none/n.f./n.a.	32335-23-2	>1000 t	Polymer	SU12 Manufacture of plastics products, including

Table A3-1: List of different substances identified						
No.	**Chemical name**	**EC number**	**CAS number**	**Notified tonnage**	**REACH tonnage**	**Applications and uses**
						compounding and conversion
258	titanium dioxide; C.I. pigment white 6	236-675-5; 619-318-1	13463-67-7; 98084-96-9	>1000 t	1,000,000 - 10,000,000 tpa	Wide range of applications
None/n.f./n.a.: None/not found/not available						

Table A3-2: List of entries				
No.	**Name as published**	**Chemical name**	**Notified tonnage**	**Generic information**
1	EOLYS 176	-	Not reported	Mixture of isoparaffin solvent (alkaner, C11-15-iso-) and Ce-Fe oxide isostearate. The notification might refer to the latter (number 227 in Table A3-1)
2	ASCORBIC ACID	Ascorbic acid (EC numbers: 200-066-2; 425-980-0; CAS numbers: 50-81-7; 129499-78-1)	Not reported	Ascorbic acid is listed in Annex IV of the REACH Regulation (Exemptions from the obligation to register in accordance to Article 2(7)(a)). However, it might refer to L-Ascorbic acid 2-glucoside, registered in quantities between 1 to 10 tonnes per annum and for which there is another registration dossier with Tonnage data confidential. Ascorbic acid might be used as cosmetic ingredient and for cancer treatment. The notified sector of use is “other”.
3	NANOPARTICULE LIPIDIQUE	Lipidic nanoparticles	0.1-1 kg	Pharmaceutical targeted delivery systems. The descriptors notified characterise the entry as object of R&D (SU24) in pharmaceuticals (PC29) and used in small amounts at small scale laboratories (PROC15).
4	LIPOSOME A BASE DE FULLY HYDROGENATED SOY PHOSPHATIDYLCHOLINE (HSPC) / CHOLESTEROL /N-(CARBONYL-METHOXYPOLYETHYLENE GLYCOL 2000)-1,2-DISTEAROYL-SN-GLYCERO-3-PHOSPHOETHANOLAMINE SODIUM SALT (MPEG-DSPE)	Liposome carriers which are composed of N-(carbonyl-methoxypolyethylene glycol 2000)-1,2-distearoyl-sn-glycero-3-phosphoethanolamine sodium salt (MPEG-DSPE); fully hydrogenated soy phosphatidylcholine (HSPC), and cholesterol.	1-10 kg	Liposome carriers used for targeted drug delivery in cancer treatment, invisible to the body's immune system. The descriptors notified characterise the entry as used in Health services (SU20) and processed in small amounts at small scale laboratories (PROC15).
5	FURANONE	Furanone	100 kg-1 t	Furanone is a class of organic compounds. It might refer to different food flavouring agents or to new anti-bacteria systems used in dental resin composites.
6	ADDITIF FILTRE A PARTICULES	Fuel additive for diesel particulate filter	100 kg-1 t	Fuel additive for diesel particulate filter. It might refer to Cerium Iron oxide (Number 227 in Table A3-1).
7	POLYSTYRENE BASED PARTICLES COATED WITH ANTI-HUMAN CRP F(AB)2FRAGMENTS	Polystyrene based particles coated with anti-human CRP F(AB)2 fragments	100 kg-1 t	Polymer used in health services (SU20) and processed in small amounts at small scale laboratories (PROC15). Used in medical assays (investigative analytical procedures).
8	COPOLYMERES ET TERPOLYMERES ETHYLENE-DERIVES ACRYLIQUES	Copolymers and terpolymers of acrylic acid	1-10 t	Polymer group

Table A3-2: List of entries				
No.	**Name as published**	**Chemical name**	**Notified tonnage**	**Generic information**
9	CITRATES	Citrates	1-10 t	Food additives used as flavouring agents or preservatives.
10	Confidential chemical name	-	-	SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys)
11	Confidential chemical name	-	-	SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys)
12	Confidential chemical name	-	-	-

Table A3-3: Identified monomers of the polymer substances notified to the FNS				
No.	**Chemical name**	**EC number**	**CAS number**	**REACH tonnage**
1	1,1-dichloroethylene	200-864-0	75-35-4	10,000 - 100,000 tpa
2	acrylic acid	201-177-9	79-10-7	1,000,000 - 10,000,000 tpa
3	methacrylamide	201-202-3	79-39-0	1,000 - 10,000 tpa
4	methacrylic acid	201-204-4	79-41-4	100,000 - 1,000,000 tpa
5	methyl methacrylate	201-297-1	80-62-6	100,000 - 1,000,000 tpa
6	styrene	202-851-5	100-42-5	1,000,000 - 10,000,000 tpa
7	2-ethylhexyl acrylate	203-080-7	103-11-7	100,000 - 1,000,000 tpa
8	buta-1,3 diene	203-450-8	106-99-0	1,000,000 - 10,000,000 tpa
9	Acrylonitrile	203-466-5	107-13-1	1,000,000 - 10,000,000 tpa
10	methylacrylonitrile	204-817-5	126-98-7	1,000 - 10,000 tpa
11	ethyl acrylate	205-438-8	140-88-5	100,000 - 1,000,000 tpa
12	butyl acrylate	205-480-7	141-32-2	100,000 - 1,000,000 tpa
13	divinylbenzene	215-325-5	1321-74-0	-

Table A3-4: Nanomaterials found in the CLI							
Name of the substance	**EC number**	**CAS number**	**Harmonised Classification**	**Forms notified**	**Physical hazards**	**Health hazards**	**Environmental hazards**
Silicon	231-130-8	7440-21-3	No	Nanomaterial, Powder, Solid	H228: Flammable solid	H315: Causes skin irritation H319: Causes serious eye irritation H335: May cause respiratory irritation	-
Barium titanium trioxide	234-975-0	12047-27-7	No	Powder, Solid, Nanomaterial	-	H302: Harmful if swallowed, H332: Harmful if inhaled, H319: Causes serious eye irritation, H335: May cause respiratory irritation, H373: May cause damage to organs through prolonged or repeated exposure (lungs)	-

Table A3-4: Nanomaterials found in the CLI							
Name of the substance	EC number	CAS number	Harmonised Classification	Forms notified	Physical hazards	Health hazards	Environmental hazards
Strontium titanium trioxide	235-044-1	12060-59-2	No	Nanomaterial, Solid	-	H319: Causes serious eye irritation	-
Tungsten disulphide	235-243-3	12138-09-9	No	Liquid, Powder, Solid, Nanomaterial	-	H315: Causes skin irritation, H319: Causes serious eye irritation, H335: May cause respiratory irritation (lungs)	-
Tricobalttetraoxide	215-157-2	1308-06-1	No	Powder, Solid, Nanomaterial	-	H315: Causes skin irritation, H317: May cause an allergic skin reaction, H319: Causes serious eye irritation, H351: Suspected of causing cancer, H335: May cause respiratory irritation (respiratory tract), H334: may cause allergy or asthma symptoms or breathing difficulties if inhaled, H370: Causes damage to organs (liver), H371: may cause damage to organs (heart), H350: May cause cancer (inhalation), H351: Suspected of causing cancer (inhalation), H360: may damage fertility or the unborn child, H373: May cause damage to organs through prolonged or repeated exposure (lung)	H400: Very toxic to aquatic life, H410: Very toxic to aquatic life with long lasting effects, H411: Toxic to aquatic life with long lasting effects H412: Harmful to aquatic life with long lasting effects
Nickel monoxide	215-215-7	1313-99-1	Yes	Powder, Solid, Nanomaterial	-	H317: May cause an allergic skin reaction, H350: May cause cancer (inhalation), H372: causes damage to organs through prolonged or repeated exposure	H413: may cause long lasting harmful effects to aquatic life
Copper(I) oxide	215-270-7	1317-39-1	Yes	Liquid, Powder, Solid, Nanomaterial, Other: Crystals or Powder	-	H302: Harmful if swallowed, H319: Causes serious eye irritation, H332: Harmful if inhaled	H400: very toxic to aquatic life, H410: very toxic to aquatic life with long lasting effects, H411: toxic to aquatic life with long lasting effects
Molybdenum	231-107-2	7439-98-7	No	Powder, Solid, Nanomaterial	H225: Highly flammable liquid and vapour H228: Flammable solid, H250: Catches fire spontaneously if exposed to air H252: Self-heating in large quantities; may catch fire	H319: Causes serious eye irritation, H361: suspected of damaging fertility or the unborn child, H372: causes damage to organs through prolonged or repeated exposure, H315: Causes skin irritation, H335: May cause respiratory irritation	H413: may cause long lasting harmful effects to aquatic life

Table A3-4: Nanomaterials found in the CLI							
Name of the substance	EC number	CAS number	Harmonised Classification	Forms notified	Physical hazards	Health hazards	Environmental hazards
Silver	231-131-3	7440-22-4	No	Solid, Powder, Nanomaterial, Other: Massive (Solid) and Powder, Other: Coating, Other: Solid (Powder And Flakes), Other: Solid And Powder, Other: Metal Powder	-	H315: Causes skin irritation, H319: Causes serious eye irritation, H335: May cause respiratory irritation, H317: May cause an allergic skin reaction, H370: Causes damage to organs (inhalation), H372: causes damage to organs through prolonged or repeated exposure	H400: very toxic to aquatic life, H410: very toxic to aquatic life with long lasting effects
Zero-valent ironnanoparticles (nzvi)	231-096-4	7439-89-6	No	Powder, Solid, Nanomaterial, Other: Part of alloy	H228: Flammable solid, H250: Catches fire spontaneously if exposed to air, H251: Self-heating; may catch fire	H319: Causes serious eye irritation, H335: May cause respiratory irritation, H370 (gastrointestinal system), H372: causes damage to organs through prolonged or repeated exposure (lungs), H371: may cause damage to organs	H400: very toxic to aquatic life
Graphite	231-955-3	7782-42-5	No	Powder, Solid, Nanomaterial	H228: Flammable solid	H319: Causes serious eye irritation, H335: May cause respiratory irritation (lungs), H372: causes damage to organs through prolonged or repeated exposure (lungs), H373: May cause damage to organs through prolonged or repeated exposure	H412: harmful to aquatic life with long lasting effects
Silicon carbide	206-991-8	409-21-2	No	Gaseous, Powder, Solid, Nanomaterial, Other	-	H315: Causes skin irritation, H319: Causes serious eye irritation, H335: May cause respiratory irritation (lungs), H370 (respiratory apparatus), H372: causes damage to organs through prolonged or repeated exposure (lungs), H351: Suspected of causing cancer, H350: May cause cancer (inhalation)	-
Chromium (III) oxide	215-160-9	1308-38-9	No	Powder, Solid, Nanomaterial	-	H302: Harmful if swallowed, H311: Toxic in contact with skin, H312: Harmful in contact with skin, H314: Causes severe skin burns and eye damage, H315: Causes skin irritation, H317: May cause an allergic skin reaction,	H412: harmful to aquatic life with long lasting effects, H400: very toxic to aquatic life, H410: very toxic to aquatic life with long lasting effects, H411: toxic to aquatic life with long

Table A3-4: Nanomaterials found in the CLI							
Name of the substance	EC number	CAS number	Harmonised Classification	Forms notified	Physical hazards	Health hazards	Environmental hazards
						H318: Causes serious eye damage, H319: Causes serious eye irritation, H330: Fatal if inhaled, H331: Toxic if inhaled, H332: Harmful if inhaled, H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled, H335: May cause respiratory irritation, H340: May cause genetic defects, H350: May cause cancer, H360: May damage fertility or the unborn child, H361: suspected of damaging fertility or the unborn child, H371: may cause damage to organs, H372: causes damage to organs through prolonged or repeated exposure, H373: May cause damage to organs through prolonged or repeated exposure	lasting effects, H413: May cause long lasting harmful effects to aquatic life
Zirconium dioxide	215-227-2	1314-23-4	No	Powder, Solid, Nanomaterial	-	H315: Causes skin irritation, H317: May cause an allergic skin reaction, H319: Causes serious eye irritation, H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled, H335: may cause respiratory irritation, H336: may cause drowsiness or dizziness, H372: causes damage to organs through prolonged or repeated exposure, H373: May cause damage to organs through prolonged or repeated exposure (liver) (oral)	-
Triirontetraoxide	215-277-5	1317-61-9	No	Powder, Solid, Nanomaterial	H225: Highly flammable liquid and vapour, H251: Self-heating; may catch fire, H252: Self-heating in large quantities; may catch fire	H315: Causes skin irritation, H318: Causes serious eye damage, H319: Causes serious eye irritation, H335: May cause respiratory irritation, H372: Causes damage to organs through prolonged or repeated exposure, H373: May cause damage to organs through prolonged or repeated exposure	-
Palladium	231-115-6	7440-05-3	No	Powder, Solid, Nanomaterial	H224: Extremely flammable liquid and vapour	H315: Causes skin irritation, H319: Causes serious eye irritation, H335: May cause respiratory irritation (lungs),	H413: May cause long lasting harmful effects to aquatic life

Table A3-4: Nanomaterials found in the CLI							
Name of the substance	**EC number**	**CAS number**	**Harmonised Classification**	**Forms notified**	**Physical hazards**	**Health hazards**	**Environmental hazards**
					H228: Flammable solid, H251: Self-heating; may catch fire, H252: Self-heating in large quantities; may catch fire, H271: May cause fire or explosion; strong oxidizer, H280: Contains gas under pressure; may explode if heated	H361: Suspected of damaging fertility or the unborn child, H370: Causes damage to organs, H371: May cause damage to organs, H334: may cause allergy or asthma symptoms or breathing difficulties if inhaled, H317: May cause an allergic skin reaction	
Cerium dioxide	215-150-4	1306-38-3	No	Powder, Solid, Nanomaterial	-	H302: Harmful if swallowed, H315: Causes skin irritation, H319: Causes serious eye irritation, H330: Fatal if inhaled, H331: Toxic if inhaled, H335: May cause respiratory irritation (respiratory system), H373: May cause damage to organs through prolonged or repeated exposure (inhalation)	H413: May cause long lasting harmful effects to aquatic life
Diiron trioxide	215-168-2	1309-37-1	No	Powder, Solid, Nanomaterial	-	H302: Harmful if swallowed, H315: Causes skin irritation, H318: Causes serious eye damage, H319: Causes serious eye irritation, H332: Harmful if inhaled, H335: May cause respiratory irritation (organs, lungs, inhalation, respiratory system/tract, irritant of mucosa, mouth, pharynx, oesophagus and gastrointestinal tract), H336: May cause drowsiness or dizziness, H370: Causes damage to organs, H372: Causes damage to organs through prolonged or repeated exposure (lungs, inhalation, respiratory tract/organs/apparatus, route of exposure: oral, mouth, pharynx, oesophagus and gastrointestinal tract)	H411: Toxic to aquatic life with long lasting effects

Table A3-4: Nanomaterials found in the CLI							
Name of the substance	**EC number**	**CAS number**	**Harmonised Classification**	**Forms notified**	**Physical hazards**	**Health hazards**	**Environmental hazards**
Zinc oxide	215-222-5	1314-13-2	Yes	Liquid, Powder, Solid, Nanomaterial, Other: The substance is an ingredient of ceramic and acrylic mixture (insulating coating), Other: Paste, Other: In Paste-Like Preparations	-	H300: Fatal if swallowed, H302: Harmful if swallowed, H314: Causes severe skin burns and eye damage, H315: Causes skin irritation, H317: May cause an allergic skin reaction, H318: Causes serious eye damage, H319: Causes serious eye irritation, H330: Fatal if inhaled, H332: Harmful if inhaled, H335: May cause respiratory irritation (respiratory tract), H341, H350: May cause cancer, H360: May damage fertility or the unborn child (H360Df), H370: Causes damage to organs (lungs), H372: causes damage to organs through prolonged or repeated exposure, H373: May cause damage to organs through prolonged or repeated exposure (central nervous system, reproductive system; route of exposure: oral; digestive system, hematopoietic system, nervous system, renal system)	H400: Very toxic to aquatic life, H410: very toxic to aquatic life with long lasting effects, H413: may cause long lasting harmful effects to aquatic life
Carbon black	215-609-9	1333-86-4	No	Liquid, Nanomaterial, Powder, Solid, Other: Mixture	H228: Flammable solid H251: Self-heating; may catch fire, H252: Self-heating in large quantities; may catch fire,	H315: Causes skin irritation, H319: Causes serious eye irritation, H332: Harmful if inhaled, H335: May cause respiratory irritation (respiratory system, lungs, inhalation), H351 (inhalation), H370: Causes damage to organs, H372: Causes damage to organs through prolonged or repeated exposure (respiratory system, lungs), H373: May cause damage to organs through prolonged or repeated exposure (lungs, inhalation)	H410: Very toxic to aquatic life with long lasting effects, H413: may cause long lasting harmful effects to aquatic life

Table A3-4: Nanomaterials found in the CLI							
Name of the substance	**EC number**	**CAS number**	**Harmonised Classification**	**Forms notified**	**Physical hazards**	**Health hazards**	**Environmental hazards**
Aluminium oxide	215-691-6	1344-28-1	No	Powder, Solid, Nanomaterial, Other	H225: Highly flammable liquid and vapour	H315: Causes skin irritation, H317: May cause an allergic skin reaction, H319: Causes serious eye irritation, H332: Harmful if inhaled, H335: May cause respiratory irritation (eyes, skin, respiratory system/tract, upper respiratory system, lung), H341, H350: May cause cancer, H361: Suspected of damaging fertility or the unborn child, H370: Causes damage to organs, H372: Causes damage to organs through prolonged or repeated exposure (lungs, inhalation, internal organs), H373: May cause damage to organs through prolonged or repeated exposure (lungs)	H412: Harmful to aquatic life with long lasting effects, H413: may cause long lasting harmful effects to aquatic life
Silicon dioxide; Silica, amorphous, fumed, crystalline-free; silica gel	231-545-4	7631-86-9 7631-86-9 112926-00-8 112945-52-5 112926-00-8	No	Nanomaterial, Solid, Powder, Liquid	H225: Highly flammable liquid and vapour	H302: Harmful if swallowed, H304: May be fatal if swallowed and enters airways, H312: Harmful in contact with skin, H314: Causes severe skin burns and eye damage, H315: Causes skin irritation, H319: Causes serious eye irritation, H332: Harmful if inhaled, H335: May cause respiratory irritation (respiratory tract, inhalation), H340: May cause genetic defects (inhalation), H350: May cause cancer (inhalation), H370: Causes damage to organs (lungs), H371: May cause damage to organs (inhalation), H372: Causes damage to organs through prolonged or repeated exposure (lungs, inhalation, kidney), H373: May cause damage to organs through prolonged or repeated exposure (bones, teeth, respiratory organs, kidneys, lungs, inhalation)	H412: Harmful to aquatic life with long lasting effects

Table A3-4: Nanomaterials found in the CLI							
Name of the substance	**EC number**	**CAS number**	**Harmonised Classification**	**Forms notified**	**Physical hazards**	**Health hazards**	**Environmental hazards**
Titanium dioxide; C.I. pigment white 6	236-675-5 619-318-1	13463-67-7 98084-96-9	No	Liquid, Powder, Solid, Nanomaterial	-	H302: Harmful if swallowed, H312: Harmful in contact with skin, H315: Causes skin irritation, H318: Causes serious eye damage, H319: Causes serious eye irritation, H320: Causes eye irritation, H332: Harmful if inhaled, H335: May cause respiratory irritation (respiratory tract, lungs, inhalation), H336: May cause drowsiness or dizziness (respiratory, inhalation), H350: May cause cancer, H351: Suspected of causing cancer (inhalation), H371: May cause damage to organs (respiratory system), H372: Causes damage to organs through prolonged or repeated exposure (lungs, inhalation), H373: May cause damage to organs through prolonged or repeated exposure	H412: Harmful to aquatic life with long lasting effects, H413: may cause long lasting harmful effects to aquatic life

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