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

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*
BNR	Belgian Nano Register
Cefic	European Chemical Industry Council
CPNP	Cosmetics Products Notification Portal
DPR	Danish Product Registry
EC	European Commission
ECHA	European Chemicals Agency
EEA	European Economic Area
EFTA	European Free Trade Association
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
PET	Polyethylene Terephthalate
R&D	Research and Development

SCCS	Scientific Committee on Consumer Safety
ToR	Terms of Reference of this study
tpa	Tonnes per annum
UIC	*Union des Industries Chimiques*
VAT	Value Added Tax
XAN	The XAN number is the name approved by a specific country (X) for a cosmetics product

Executive Summary

This report is one of several outcomes of a study on regulatory oversight of 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 the two schemes;*
- *Findings from a key stakeholder meeting, run as part of the project;*
- *Analysis of publically available information about the two schemes (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;*
- *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.*

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 3,941 notifications from 933 notifiers.

Interestingly, 50-60% of the notified substances at nanoscale will not require registrations under the REACH regulation because manufactured or imported in quantities lower than the REACH information requirements threshold. However, over 60% of the substances registered under the FNS have bulk form equivalents that have a full REACH registration dossier.

It is also interesting, that around 80% of the substances registered under the FNS were already on the market before 1981. It is not possible to establish whether any of their nanoforms were commercialised before that date, however, when referring to the most common nanomaterials and to a large share of pigments and dyes notified to the FNS, industry confirmed that their nanoforms had been on the market for many years.

The administrative burden is predominantly a result of substance characterisation activities, but a good deal of resources are spent on familiarisation with and understanding of the legislation, as well as interpretation of the nanomaterial definition and the terminology. This diverts resources from research and innovation activities, and is particularly significant for SMEs. 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.

Companies affected by the scheme report 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 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 remain conflicted about the scheme. To them, it is on the one hand a first step towards better regulation of an under-regulated area, but on the other hampered by insufficient transparency and the absence of some nanomaterials of particular concern, namely nanosilver and carbon nanotubes.

The nanotechnology sector could benefit from the notification scheme in terms of insurability of nanomaterial production risk: the new information over the supply chains of nanomaterials could enable the calculation of insurance risk premiums.

Currently the authorities are planning to use the gathered information for an epidemiological study on workers exposed to seven nanomaterials. The marginal added value of the information might reside on the ability to enable a better monitoring of exposure pattern changes.

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

.

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
- Rask 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, which preliminary findings are presented in the second draft of the building blocks report) and the findings of the public consultation (launched in early May and closing the 5 August 2014) will support the option assessment. A first draft of the Option Assessment report has been drafted detailing the methodology that will be followed for the exercise.

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 by representatives of:

  - DG Enterprise and Industry;
  - DG Environment;
  - DG Research and Innovation;
  - DG for Health and Consumers;
  - DG Joint Research Centre; and
  - French competent authorities on the FNS.

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

- **Task 1.3**: overview and comparative analysis of past, present and proposed NM transparency measures, in order to put the current regulatory situation concerning NMs in context and to evaluate the advantages and disadvantages of the respective transparency measures;

- **Task 1.4:** in-depth analysis of the FNS, aiming to gather relevant information on the experience from these NMs registries. This subtask has been organised in five interrelated parts:

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

1.2 Evaluation Methodology

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

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

A stakeholder meeting (**Task 1.4a**) has being organised on 10 March 2014 in Paris in conjunction with the session of French working group on nanomaterials 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 being analysed and compared to the ECHA

[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

registered substances database[2], the European chemical Substances Information System - ESIS[3]) and to the Classification and Labelling Inventory.[4] For this exercise, valuable support has been provided by Cefic and NIA and their members.

In parallel to the analysis of the available information, an online survey[5] 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.

In order to model the impact of the availability of the information gathered to the authorities, consumers and workers on long term health and environmental benefits (**Task 1.4d**), an analysis of the past and current debate in France over the notification system has been carried out. This in order to estimate any changes in the public perception of nanomaterials, resulting in behavioural changes in dealing with nanomaterials of both workers (e.g. increased awareness over health and safety issues of nanomaterials) and consumers (e.g. aversion to products containing nanomaterials). This part of the 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**) and to provide some recommendations for EU policy directions.

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 administrative burden posed on companies and of the impacts on competitiveness and innovation of the FNS;
- Section 5 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 6 highlights the critical issues to be considered in extrapolating the findings on the FNS to the EU level and provides some recommendations for EU policy directions.

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

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.[6]

The following sub-sections provide an overview of the initiatives in Belgium, Denmark, Germany, Norway as well as the CPNP, while the FNS and 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.[7] The study reported that nanomaterials are present on the Belgian market in a large variety of products within many economic sectors and along the entire supply chain. The authors concluded that imposing notification requirements and obligations to allow the traceability of the nanomaterials along their lifecycle would result in significant costs for industry stakeholders. The analysis revealed that, in many sectors, it is very difficult to obtain accurate information on nanomaterials in products due to unavailability of data communication issues along the supply chain. This is particularly true for importers.

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

[6] 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.

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

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

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

Based on these findings, the Belgian FPS developed a draft decree[8] 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 has been reached in February 2014[9] 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) Cosmetic products which have been notified in accordance with the provisions of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products;
2) Biocides and treated articles falling within the scope of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocides and biocides which have been registered or authorised in accordance with the Royal Decree of 22 May 2003 concerning the placing on the market and use of biocides;
3) Medicines falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency;
4) Medicines for human use and veterinary medicines falling within the scope of the Royal Decree of 14 December 2006 on medicinal products for human and veterinary use;
5) The foodstuffs and materials and objects intended to come into contact with foodstuffs referred to in Article 1, 1° and 2°, b) of the Law of 24 January 1977 on the protection of consumer health in regard to foodstuffs and other products;

[8] For details, see *Royal Decree on the market placement of substances manufactured at 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

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

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

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* (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 uncertainty):
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 agglomerates, the average agglomerate size, these sizes being given	

Table 2-1: Information requirement of the Belgian Notification Register		
No.	**Information requirements**	**Comment**
	relative to a standard deviation when available	- 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* (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 of the exposure of consumers and the environment to nanomaterials as well as the types of nanomaterials to which they were exposed.[10] Based on a screening process of products imported and manufactured in Denmark, the product categories `paint and varnish´, `coatings´, `other building materials´ (e.g. bricks, cement/concrete), `sports´, `cleaning´, `textiles´ as well as `electric and electronic products´ were identified as those product types which are most likely to contain nanomaterials. A `miscellaneous´[11] category was added for products which do not fall into the aforementioned categories. Carbon black, titanium dioxide, pigments, silica and metals/metal compounds were identified as the most utilised nanomaterials within the different product categories.

[10] 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.

[11] 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 in case of introducing a nano-product database[12], where reporting requirements would be limited to products covered by the Danish Chemicals Act and exclude products already covered by other regulations.[13] At the time when the impact assessment was conducted, 949 companies had been registered as manufacturers or importers of products in the aforementioned categories on the basis of the related trade codes. More than 75% of these companies had less than 50 employees (full-time equivalents) and almost 60% had less than 20 employees (full-time equivalents). As a result of the evaluation, the following conclusions were made:

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

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

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)	Implement ation (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							

[12] 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.

[13] cosmetics, foodstuff, foodstuff contact materials, 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 minimize the work related to reporting obligations; and
- Reduced competitiveness due to increased financial costs related to reporting.

The second impact assessment was published in 2013 and was related to possible ways of reducing the administrative burden identified by the previous study, and which would arise due to obligatory reporting to the nano-product register.[14] 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 with regard to products containing the carbon black and/or non-catalytically active titanium dioxide***	Carbon black and titanium dioxide are NMs that have been long known and used in large amounts as regular chemicals for a wide range of applications. Therefore, they are subject to registration under the REACH regulation. ***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 the health and

[14] 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**
		environmental impacts is higher.
3	***Exemption from reporting with regard to certain product groups,*** i.e. only chemical mixtures containing NMs and no other products (i.e. articles, cf. REACH)	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***[15] (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) as also used in the first impact assessment. The administrative burden of the product categories `Electronics and electronic products´ and `Miscellaneous´ are not included in the estimates of the total administrative burden.

[15] 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 to the first year of implementation.

Taking the results of both impact assessments into account, a draft order[16] for a nano-product register was elaborated, covering mixtures and articles that contain nanomaterials and indicating the reporting requirements for producers and importers. The Danish Environmental Protection Agency launched a public consultation[17] 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.[18]

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

[16] 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

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

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

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

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

> *A natural, incidental, or manufactured material that contains particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm (nanometres).*

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

A. Registrant's identity
    1. CBR No
    2. Registrant's name (entity name)
    3. Address
    4. Registrant's contact person(s)/email(s)
    5. Type of entity

6. Size of the entity

B. Product information

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

C. Information on the nanomaterial

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

D. Chemical information on the nanomaterial

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

Annex 2 lists information that notifiers could 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 up the rules for the protection of confidential information. The notifier can indicate whether specific information should be treated as confidential (trade secret), e.g. data on production methods, chemical information, substance identification, composition or purity. In this case, an appropriate justification must be delivered. . It must be noted that information may be disclosed in accordance with applicable Danish legislation. Access to the register is restricted to employees of the Danish Environmental Protection Agency and the Danish Working Environment Authority; however, data can be obtained upon request and to the extent necessary, for example, by other authorities.

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

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

2.4 Germany

Following a review of the legal feasibility of a mandatory nano-product registry in 2010, the German Federal Environment Agency (UBA) published a "Concept for a European Register of Products Containing Nanomaterials" (ENPR).[19] The proposed register aims at establishing regulatory oversight to set priorities in monitoring and enforcement, in enhancing transparency, in estimating exposure for humans and the environment, and in ensuring traceability.

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

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

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

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

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. Besides, a comparison between the ENPR and other already existing EU NM transparency measures was made. The IA identified obstacles related to the scope, appearing to be unclear for 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 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 IA assessment on the implementation of an ENPR generated a set of results, in which the most affected product categories would be coatings, inks, rubber products, paper products, cosmetics and health care. In addition, the extent of notification between the various economic sectors appeared to differ significantly. However, an ENPR would cost the notifiers significantly less than an independent nanoregister, which would cause a duplication of obligations. For substances registered under REACH 90-95% savings are expected, 80% in the area of cosmetics (related to Cosmetics Regulation), 95% for food (related to Novel Food Regulation) and 40% for cleaning and disinfection (related to Biocidal Products Regulation). The different costs structures between supply chain actors however, would lead to proportional higher implementation costs for manufacturers, and higher recurring costs for distributors. The EPNR would be beneficial for the fact that it would less distort the European markets than different parallel registers would do at national level. 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[20]) posted a notice[21] 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

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

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

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[22] or article 3 of the EU´s CLP Regulation if 100 kg or more of the product are imported or manufactured per year. Changes must be updated in the Register annually. In addition, microbiological and biocidal products must always be reported to the Norwegian Product Register regardless of quantity. 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 specification for substances and mixtures.

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

According to the Norwegian authorities,[23] the yearly update will cover quantities of the chemical products rather than the constituents of the products. This means that, on a yearly basis, newly-registered products will generally be subject to the nanomaterial evaluation in the form. The notification of possible nano-constituents of the already registered products will take longer and be notified over time. A possible speed-up of the registry of nanomaterials in the latter group of products may occur as a result of change from paper to digital notifications in the near future.

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

2.6 The Cosmetic Products Notification Portal

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

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

- the presence of substances in the form of nanomaterials;

[22] 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

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

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

Article 16 enlarges the information requirements to:

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

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

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

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

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

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

In order to implement the Cosmetics Regulation, DG SANCO has created and maintains the Cosmetics Products Notification Portal. As detailed on the website:[24] "*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*".

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

The Commission is currently working on a new definition of nanomaterials for cosmetics:[25] 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 first instance, the notifier has to identify the product, providing indication of the product category. The choice of a category at level 1 determines the categories available at level 2; the choice of a category at level 2 will determine the categories available at level 3. There are 4 level-one defined categories:

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

Table 2-5 provides the list of different cosmetic product categories per level.

Table 2-5: 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

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

Table 2-5: 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 2-5: 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 provided the product category, notifiers have to specify the foreseen cosmetic product name of the cosmetic product that will contain the nanomaterial notified.

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

A full characterisation of the nanomaterial has to be provided. Table 2-6 presents the list of physicochemical parameters required.

Table 2-6: 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 2-6: 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, Fiber, 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

2.7 Comparison of the Nanomaterials Transparency Measures

In this section the different transparency measures investigated (Belgium, Denmark, Germany, Norway, France and Cosmetics Regulation) are compared with each other, in particular in regard to the nanomaterial definition, the object of the notification (i.e. nanomaterials as substance as such, nanomaterials contained in mixtures and/or nanomaterials included in articles), the information requirements and the applicable deadlines, in order to highlight differences between the different measures. Table 2-7 (at the following page) gives an overview on the investigated systems in regard to the different aspects mentioned. Details on the different measures are available in the corresponding chapters.

The analysed measures to increase transparency on nanomaterials – already in force or planned – when defining nanomaterials, refer to the recommended definition of the European Commission. Notably, the Danish register differs from the other transparency measures because encompassing also natural and incidentally manufactured nanomaterials, where the CPNP focuses on insoluble or biopersistent nanomaterials.

With regard to the object of the notification, the transparency measures reviewed differ substantially among each other, while information requirements are similar and include the notifier's identity, physicochemical parameters on the nanomaterials and quantities, with the CPNP requiring available toxicological data and foreseeable exposure conditions.

The French system as well as the proposed Danish and Belgian systems are registers specifically set up and intended for nanomaterials, where the CPNP and the Norwegian registry set the focus on chemicals in general, integrating the nanomaterial issue in a wider frame.

Table 2-7: Comparison of the different investigated Transparency Measures on nanomaterials				
Transparency Measure	**NM definition**	**Object of notification**	**Data requirement**	**Deadlines**
Cosmetics Regulation	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.	All **cosmetic products** with special data requirements for cosmetic products containing NMs	NM identity, particle size, physicochemical properties, toxicological profile, NM quantity in product, NM safety data related to cosmetic product category, reasonably foreseeable exposure conditions	Notification to the CPNP once before placing cosmetic product on the European market; updates whenever necessary
French declaration system	Similar to EC definition recommendation, but only manufactured NMs are covered in the definition	**NMs 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** (NM substances only, `substance-based´ scheme)	Identity of notifier, of NM substance (characterisation) and professional user, information on notification, quantities, uses	FNS was launched in January 2013, first submission deadline was end of June 2013; annual updates required
Belgian declaration system (proposed)	Similar to EC definition recommendation, but only manufactured NMs are covered in the definition	**NM substances as such**, **preparations containing NMs**, **articles** and **complex objects containing NMs which can be released** (`product based´ scheme with everything having to be notified).	Identity of notifier, of professional users and the NM substance, quantities, uses	Annual updates foreseen; NM substances planned to be registered for the first time by January 2015; for preparations, articles and complex objects planned deadline is one year later
Danish declaration system (proposed)	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 1-100 nm.	**Mixtures and articles sold to consumers containing or releasing NM** or **nanoproducts releasing classified substances** (`product-based´ scheme, no NM substance as such has to be notified)	Identity of notifier, product and NM information contained in the product, identity of NM (voluntary: REACH descriptors, NM quantity in product, physico-chemical properties)	Annual updates foreseen

Table 2-7: Comparison of the different investigated Transparency Measures on nanomaterials				
Transparency Measure	**NM definition**	**Object of notification**	**Data requirement**	**Deadlines**
Norwegian declaration system	NM are **manufactured** substances with one or more dimensions at nanoscale (1-100nm) or an internal or surface structure at the nanoscale, **manufactured to have specific composition to utilize specific properties**.	All chemical **substances** and **mixtures**	Trade name of substance/mixture, classification, responsible company, quantities, manufacturer, company name on label, list of customers/Norwegian distributors, branches of industry where product is used, product type, constituents of the chemical products, physical data, other relevant data, confidentiality	Annual updates
German proposal for a European register	Follows EC definition recommendation	NM substances, mixtures and articles containing NMs, intended to be released under normal or reasonably foreseeable conditions of use, through the entire supply chain	No data available	Proposal, no deadline

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, "*Grenelles de l'environnement"*) that led to the commitment[26] to anticipate any risks deriving from the exposure to nanomaterials. The commitment was supported by Anses[27], 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 public, the consumers and the workers. The specific objectives were set in the *Grenelle II* Act, approved in July 2010, namely:

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

On this basis, Articles L.523-1 and L.523-2 of the Environment Code ("*Code de l'Environnement"*) established the notification duty and, in order to make it executive, two subsequent decrees[28] defined the scope, the information to be notified and the terms for the notifications. More precisely, the 2012-232 decree defines:

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

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;
- The quantities manufactured, imported or distributed in the year preceding the notification;

[26] *Engagement n. 159.*

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

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

- The uses of the nanomaterial;
- The identities of the professional users to whom the notifier has provided the nanomaterial.

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

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

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

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

On the 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 linked to it" is defined as:

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

By and large, the definition of nanomaterial adopted by the French legislation coincides with the EC recommended definition 2011/696/EU[29], 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 material intended to release such a substance under normal or reasonably foreseeable conditions of use.

[29] Commission Recommendation of 18 October 2011 on the definition of nanomaterial.

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 declaration, which needs to be passed on with all transfers of ownership to professional users and distributors so that they can make their declaration referring to their suppliers' declaration. All notifications need to be updated annually and non-confidential information will be disclosed six months after the deadline for the declaration. Non-compliance with the regulatory provisions may lead to a fine and daily penalties. It must be noted that the French notification scheme allows registrants to file a single declaration for different products containing the same substance at 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 declaration with specific provisions. Chemical names of the substances at nanoscale and their uses have been presented in the French public report, along with a first analysis of the number of notifications by economic sector and some aggregated quantities. Notifiers were required to use the system of descriptors developed by ECHA for the purpose of the REACH Regulation, namely to indicate:

- The sector of use category (SU): describes in which sector of the economy the substance is used;
- The chemical product category (PC): describes in which types of chemical products (= substances as such or in mixtures) the substance is finally contained when it is supplied to end-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.[30]

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 (2013b), 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;
- Users.

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

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

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	
Clients/Professional users identity per NACE code	For each NACE code activity, the notifiers have to enter manually or provide a list (in csv format) of the clients/professional users they provide the nanomaterial to, and their NACE code activities. If they have more than 30 clients for one NACE code activity, the notifiers can just indicate the number of clients/professional users with the provision to	
NACE code of the clients/professional users		

Table 3-1: Information to be notified		
Information	**Options**	**Examples/Notes**
	keep the list for possible inspections by the authorities.	
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 public organisms that choose the simplified notification)*	Carbon (diamond, fullerene, graphene...), Noble metal (ex: Platinum for catalysts), Silica (silica colloidal , silicene...), Non-magnetic oxides (TiO2, 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	-
Commercial name*	Commercial name if available	
	No commercial name	-
IUPAC name		
REACH registration number[+]	REACH registration number	-
	No REACH registration number	-

Table 3-1: Information to be notified		
Information	**Options**	**Examples/Notes**
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
	Agglomeration state determination method used	-
	Test guideline	-
	Attach file relative to the determination of the aggregation and agglomeration state	

Table 3-1: Information to be notified		
Information	**Options**	**Examples/Notes**
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 charge. Provide a justification for the non-availability: Pending results, Technic non available, Other specify justification.
	Specify the pH conditions	

Table 3-1: Information to be notified		
Information	**Options**	**Examples/Notes**
	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 on the basis of the analysis made by the Anses.

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

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

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

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

In terms of the number of nanomaterials notified, at November 2013 Anses was not in the position to provide an in-depth analysis of the database. As a matter of fact, only 59% of the notifications (1,632) reported a CAS number, while in the remaining 41% the nanomaterials were identified by a chemical name only. A more in-depth analysis is currently being prepared by the French authorities. In first instance, Anses estimated that between 243 and 422 different substances have been notified as nanomaterials on the French market. It has to be noted that for each different CAS number (around 243) and different chemical name (around 179), there might be several distinct nanomaterials varying on the basis of physicochemical parameters.

Within the FNS, quantities are treated as confidential. However, Anses provided the tonnage band for each different CAS number and chemical name notified, plus the aggregated tonnage for the most common substances.

Between June 2012 and June 2013, in France 282,014 tonnes of nanomaterials have been manufactured and 222,090 tonnes imported, for an aggregated amount of 504,104 tonnes. With all the limitations mentioned above, in first analysis it can be concluded that around 50-60% of the substances manufactured and/or imported that have been notified would not be triggered by the REACH Regulation (because manufactured/imported in less than 1 tonne per year).[31]

Table 3-3 reproduces for convenience Table 10 of the French public report (2013) reporting the most common nanomaterials on the French market (manufactured and/or imported in more than 100 tonnes).

Table 3-3: Nanomaterials manufactured and/or imported in more than 100 tonnes	
Chemical name	**Tonnes**
Carbon Black	274,837.135
Silicon dioxide / amorphous silica	155,071.912
Calcium carbonate	34,501.525
Titanium dioxide	14,321.436
Aluminium oxide	2,193.565
Copolymer of vinylidene chloride (declared name)	1,568.000
Magnetic Iron oxide yellow*	538.473
Silicic acid, aluminium and sodium salt*	492.000
Zinc oxide	287.695
Magnetic Iron oxide yellow*	242.188
2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[n-(2,4-dimethylphenyl)-3-oxobutyramide]	208.979
Diiron trioxide	173.641
Silicic acid, aluminium, magnesium and sodium salt*	150.975
Pyrrolo(3,4-c)pyrrole-1,4-dione, 2,5-dihydro-3,6-diphenyl- (declared name)	150.584

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

Table 3-3: Nanomaterials manufactured and/or imported in more than 100 tonnes	
Chemical name	**Tonnes**
2-[(2-methoxy-4-nitrophenyl)azo]-n-(2-methoxyphenyl)-3-oxobutyramide	141.232
2-propenoic acid, 2-methyl-methyl ester, polymer with 1,3-butadiene, butyl 2-propenoate and ethenylbenzene (declared name)	138.100
Pyrrolo[3,4-c]pyrrole-1,4-dione, 3,6-bis([1,1'-biphenyl]-4-yl)-2,5-dihydro- (declared name)	138.000
Aluminium hydroxide	136.500
4,4'-diamino[1,1'-bianthracene]-9,9',10,10'-tetraone	134.740
Cerium dioxide	107.796
Source: reproduced from Anses (2013), Table 10. * *These entries are reported twice: clarifications will be asked to Anses.*	

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

Table 3-4: Most common uses indicated in the notifications (> 2% of the notifications)	
Sector of use category, Chemical product category and Process category	**Percentage**
Formulation [mixing] of mixtures and/or re-packaging (excluding alloys)	19.6 %
Other	10.6 %
Coatings and paints, thinners, paint removers	8.1 %
Cosmetics, personal care products	6.1 %
Mixing or blending in batch processes for formulation of mixtures and articles (multistage and/or significant contact)	4.7 %
General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	4.4 %
Transfer of substance or preparation into small containers (dedicated filling line, including weighing)	3.9 %
Fuels	3.0 %
Scientific research and development	2.7 %
Manufacture of food products	2.6 %
Manufacture of fine chemicals	2.5 %
Manufacture of plastics products, including compounding and conversion	2.1 %
Source: French public report (2013), Table 6.	

3.3.2 Analysis of the substances listed in the French public report

Further analysing the 399 entries listed in the French public report,[32] the project team 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[33]). **However, this is not the definitive number of substances at nanoscale notified to the FNS and should be intended just as an indication.** As a matter of fact,

[32] 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.

[33] 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.

during the ongoing 2014 notification process, the French authorities already received almost double (over 7,000) the number of notifications received in 2013, many of which coming from the plant protection products and biocides sector, as also confirmed by industry.[34] 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[35], the ECHA registered substances database[36] 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 3-5 reports the number and percentage of the different substances identified per notified quantities (tonnage band).

Table 3-5: Number and percentage of substances 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 %**	

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

[34] Personal communication.
[35] http://esis.jrc.ec.europa.eu/clp/ghs/search.php
[36] http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Table 3-6: Results of the cross-analysis between 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 not sufficient to carry out the research	12

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[37]; 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.

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). Two substances might be covered by the exemption granted by the REACH Regulation to naturally occurring substances:

- Vitreous silica (also known as “fused silica”, EC number: 262-373-8, CAS number: 60676-86-0, number 82 in Table A3-1) is not covered by the Registration dossier for amorphous silica and it has not been registered because considered to fulfil the condition of the exemption granted to minerals which occur in nature, if not chemically modified (Article 2(7)(b));[38] and

- Palladium (EC number: 231-115-6, CAS number: 7440-05-3, number 78 in Table A3-1), that is a mineral which occurs in nature and thus exempted according to Article 2(7)(b).

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

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

Table 3-7: 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**

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

From the above 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.

The analysis focuses then on the uses and applications that have been notified to the FNS. Table 3-8 presents the number of substances per notified sectors of use.

Table 3-8: Number of substances per notified sectors of use (SU)			
Code	**Main user groups**		**NMs**
SU 3	Industrial uses: Uses of substances as such or in preparations* at industrial sites		0
SU 21	Consumer uses: Private households (= general public = consumers)		0
SU 22	Professional uses: Public domain (administration, education, entertainment, services, craftsmen)		0
Code	**Supplementary descriptor: Sectors of end-use**	**NACE codes**	**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

Table 3-8: Number of substances per notified sectors of use (SU)			
SU9	Manufacture of fine chemicals	C 20.2-20.6	27
SU 10	Formulation [mixing] of preparations and/or re-packaging (excluding alloys)	C 20.3-20.5	132
SU11	Manufacture of rubber products	C 22.1	24
SU12	Manufacture of plastics products, including compounding and conversion	C 22.2	70
SU13	Manufacture of other non-metallic mineral products, e.g. plasters, cement	C 23	10
SU14	Manufacture of basic metals, including alloys	C 24	2
SU15	Manufacture of fabricated metal products, except machinery and equipment	C 25	7
SU16	Manufacture of computer, electronic and optical products, electrical equipment	C 26-27	6
SU17	General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment	C 28-30,33	21
SU18	Manufacture of furniture	C 31	3
SU19	Building and construction work	F	28
SU20	Health services	Q 86	7
SU23	Electricity, steam, gas water supply and sewage treatment	C 35-37	2
SU24	Scientific research and development	C72	32
SU0	Other		147
Not reported			1

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.

Table 3-9: 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	2

Table 3-9: Chemical Product Category (PC)		
Code	**Category for describing market sectors (at supply level) regarding all uses (workers and consumers)**	**NMs**
	care products	
PC24	Lubricants, greases, release products	0
PC25	Metal working fluids	0
PC26	Paper and board dye, finishing and impregnation products: including bleaches and other processing aids	1
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

Table 3-9 presents the Chemical Product Category notified per number of substances: unsurprisingly, 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 3-10: 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 3-11: 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
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

Tables 3-10 and 3-11 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”.

4 Cost Analysis for Public Authorities and Industry

4.1 Stakeholder Meeting – Paris 10 March 2014

4.1.1 Participants

On 10 March 2014, a stakeholder meeting was held in Paris and hosted by MEDDE in its premises. Table 4-1 provides details and participants to the meeting.

Table 4-1: 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 Faivre	Ministère de l'agriculture, de l'agroalimentaire et de la forêt
Philippe Gaucher	Ministère de l'enseignement supérieur et de la recherche
Franck l'Hoir	Ministère de la Défense
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 Levy	Mouvement des Entreprises de France - Union des Industries Chimique
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)

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.

4.1.2 Definition of nanomaterial and object of the notification

The project team was asked 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.

It was noted that the ISO definition[39] 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.

4.1.3 Information and communication within the supply chain

It was 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

[39] 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

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.

It was 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.

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.40 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.

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.

It was noted that tracking tonnages for every raw material and product, 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 where the nanomaterials is not released under normal or reasonably foreseeable conditions of use and thus escaping notification obligations.

[40] 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

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 manufactured and imported nanomaterials are not true/definitive as there are a lot of incomplete/partial notifications. But the public will take that information as definitive. It was indicated that the uncertainty factor for quantities sometimes stretch to a factor of 10-100.

4.1.4 Direct cost of the notification system

It was 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. The cost for this could amount to millions of euros.

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 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.

4.1.5 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).

4.1.6 FNS vs. REACH modification

The project team then inquired as to the added value of FNS over a potential modification of REACH Annexes. 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 within the supply chain. This kind of participation is lacking within the FNS. In REACH, one is concerned about the downstream users. 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.

4.1.7 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 in France, NMs do not seem to have a better reputation now than previously. 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 company survey undertaken over the course of 3 months.

4.1.8 Confidentiality issues

It was suggested 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. It was also stated that this could be a disincentive for some companies as they would be reluctant to make such information available to their competitors.

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.

4.1.9 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.

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

4.1.10 Other critical issues with regard to FNS

Summarising the results of the stakeholder meeting:

- 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.

4.2 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.

4.2.1 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 chain 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 had to notify over 250 nanomaterials, 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 declaration 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 4-2 (next page) presents the direct cost estimates of the administrative burden of the two notification schemes by cost type. The direct costs due to the FNS and the CPNP have been estimated in over €300,000 for 2013, with over €260,000 for the characterisation of the substances in nanoforms to be notified.

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. An example is the definition of professional users and, in particular, the determination of the last professional users down the supply chains that are covered by the Regulations.

Table 4-2: Administrative burden of the notification schemes on a large enterprise – direct cost estimates* (for all substances notified, with the exception of the substance characterisation costs that are per substance)		
Cost type	**FNS**	**CPNP**
Understanding the legal requirements	≈ €7,500	≈ €650
Gathering of information to be submitted	≈ €3,750	≈ €940
Substance analysis characterisation cost	≈ €10,000 per substance	€10,250
Submission of the information	≈ €7,000	≈ €2,800
Responding to clients' enquiries	≈ €7,000	≈ €3,000
IT alignment and/or adapting product/account databases	≈ €2,800 - €3,750	≈ €560
Tot. without substance analysis costs	≈ 28,000	≈ €7,400
Tot. with substance analysis costs	Over €280,000	≈ €18,000
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 eight hours and a work week has five work days. The resulting numbers of hours have been multiplied by the EU average hourly labour costs. The average hourly labour costs have been estimated by Eurostat to be €23.4 in the EU27 (in 2012). The average masks significant differences between EU Member States (from €3.7 to €39). The impact of such differences will be analysed in the sensitivity analysis in the Option Assessment report. Source: http://epp.eurostat.ec.europa.eu/cache/ITY_PUBLIC/3-10042013-AP/EN/3-10042013-AP-EN.PDF*		

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.

4.2.2 Case Study 2 – SME in the pigments and dyes sector

This section elaborates a case study review of the experience of a small-medium size manufacturer in notifying its products to the French Notification System. The SME 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.

Primary role of the SME is as manufacturer of pigments and dyes; the company enacts also as importer and distributor. One fifth of the company's turnover is directly related with the manufacturing and commercialisation of nanomaterials. 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, at national level (France), European level 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.

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.

Although in terms of direct costs the characterisation of the substances remain the most burdensome, the time required to deal with the clients and needed to respond to their enquiries took a big toll as well (around 2 weeks).

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.

4.2.3 Case Study 3 – Distributor

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 euros, although the turnover share directly relating to nanomaterials accounts for less than 250,000 euros. 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 had to notify information for 10 nanomaterials. 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.

The notifier indicated that the most burdensome information requirements of the FNS relate to quantities, uses and identity of clients. The company also reported to have encountered difficulties with respect to the FNS´s terminology, particularly in understanding and interpret the nanomaterial definition.

Being a distributor, the highest regulatory burden is posed by the CLP Regulation (40%), followed by the REACH Regulation (30%). The FNS burden broadly equal the ones posed by the Regulation (EC) No 528/2012 on biocidal products and the Regulation (EC) No 1935/2004 (Food Contact Material) on a distributor.

The company reported that the FNS had a very strong negative influence on their research and development activities as well as on the general public perception of nanomaterials. It was noted that many of the companies´ clients want to stop using products subject to notification under the FNS in the next years, although no risks have been proven to arise from these products. The notifier also indicated that the company's ability to develop and market new products containing nanomaterials was negatively influenced, while no impacts on intra- and extra-EU competitiveness as well as on Intellectual Property rights and confidentiality aspects were noticed.

The differences in the definitions of nanomaterials used in different pieces of legislation and the different requirements in the notification systems implemented and proposed might pose problems with the company suppliers outside France.

4.3 Cost Analysis – Public Authorities

The costs entailed by the French public authorities for the implementation of the legislation and the database management have been previously assessed in BiPRO and Oko-Institut e.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 4-3 reports the costs related to the acquisition of the hardware and software plus yearly license and maintenance of the database.

Table 4-3: 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 4-4 reports these costs in terms of full-time equivalent[41] employees.

Table 4-4: Administrative costs – confirmation/update of old data						
Personnel	Intensity (fte)	Tasks	Duration (yr)	Number of weeks per year	Type of Costs	
					Impl.	Annual
1 desk officer	0,75	Organizing stakeholder meetings, drafting FAQs, answering inquiries	1		x	x
2 officers	1,50	Working within ANSES (French Agency for Food, Environmental and Occupational Health & Safety); assisting with the French RPN in answering basic questions, website support	1 (at least one officer dedicated for 2 years)		x	x

Assuming a 35-hours work week, 46 work weeks per year and an average hourly gross wage of €30 for a public officer, the additional costs are around €110,000 per year.[42]

With regard to the Cosmetic Products Notification Portal, Table 4-5 reports the cost figures provided by DG SANCO.

Table 4-5: CPNP management costs	
Maintenance and development	€200,000
Hosting	€52,000
Application support	€150,000
Total	**€402,000 per annum**

4.4 Cost Analysis – Industry

4.4.1 Overview

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). The questionnaire template is attached in Annex II.

[41] 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.

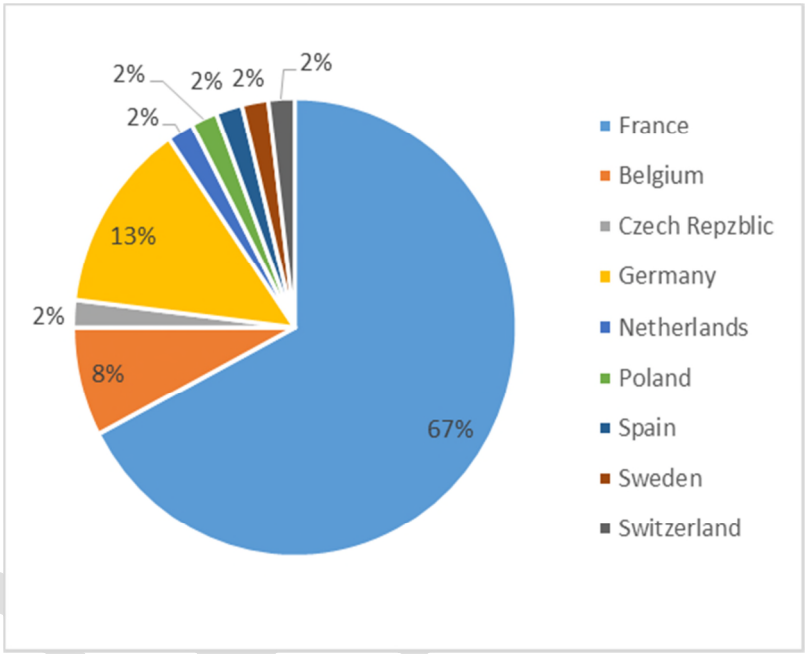
[42] (€30 x 35 hours x 46 work weeks) x 2.25 fte ≈ €110,000.

4.4.2 Origin of companies

French companies accounted for the majority of responses (67%), followed by companies from Germany (13%), Belgium (8%) and other countries as listed in table 4-6.

Table 4-6: Overview of responding companies by geography

Country	No.
France	35
Germany	7
Belgium	4
Czech Republic	1
Netherlands	1
Poland	1
Spain	1
Sweden	1
Switzerland	1
Total	**52**



4.4.3 Company size

With respect to company size, 65% of the respondents were large companies (65%), followed by medium (21%), small (10%) and micro sized companies (4%).

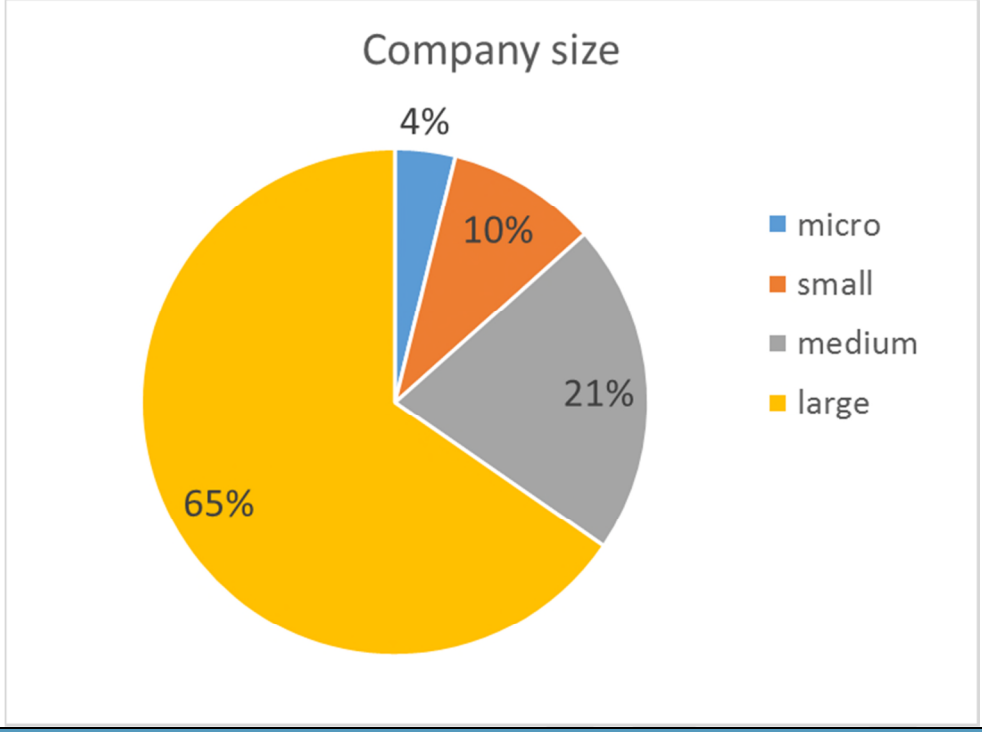


Figure 4-1: Overview on company size distribution of companies who provided replies

4.4.4 Primary business sector

Companies were asked to indicate their primary business sector (45 replies), and if applicable their secondary business sector (15 replies).

Table 4-7: Overview on the primary business sector of the companies	
NACE primary business sector	**No.**
C20 - Manufacture of chemicals and chemical products	**6**
C20.3.0 - Manufacture of paints, varnishes and similar coatings, printing ink and mastics	**6**
C20.4.2 - Manufacture of perfumes and toilet preparations	**6**
C20.1.2 - Manufacture of dyes and pigments	4
C20.1.3 - Manufacture of other inorganic basic chemicals	4
G46.7.5 - Wholesale of chemical products	4
C20.5.9 - Manufacture of other chemical products n.e.c.	3
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
C - Manufacturing	1
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	45

4.4.5 Supply chain characterisation

Most companies indicated to be manufacturers and/or distributors and/or importers (26 replies) when asked for their role in the supply chain (multiple ticks and indication of primary role possible[43]).

Table 4-8: 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**
Public research organisation	0	**0**

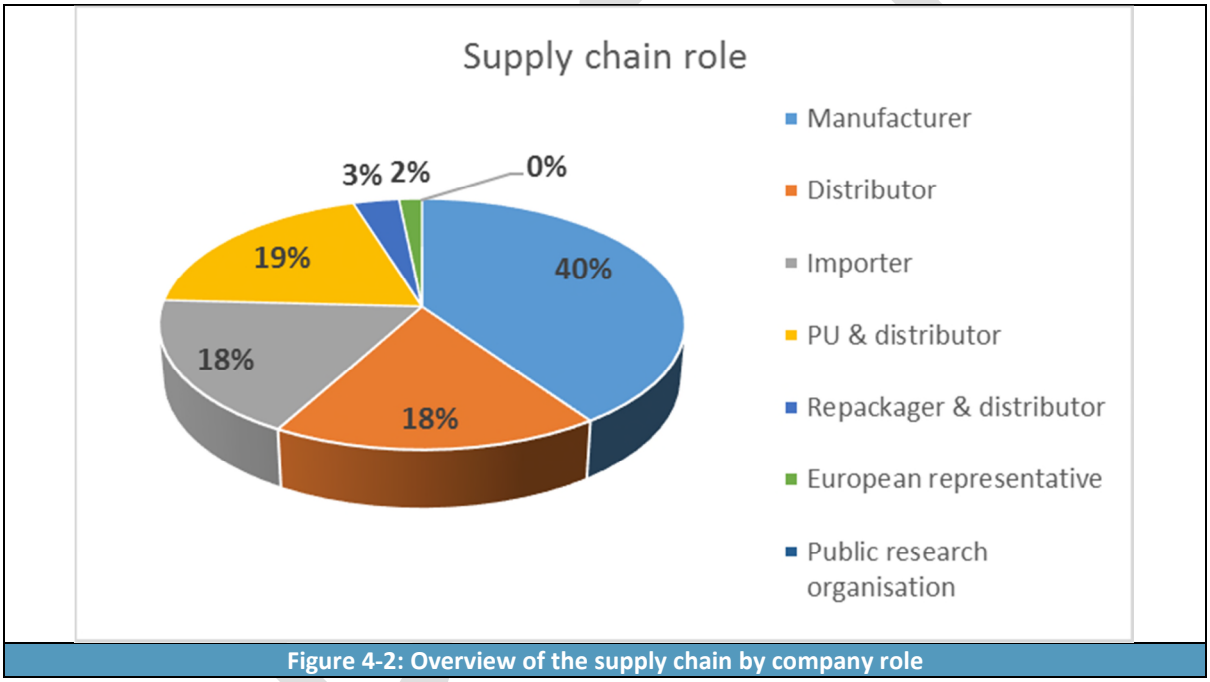


Figure 4-2: Overview of the supply chain by company role

Number of notifications

The number of notifications to the FNS for 2013 and 2014 (2014 based on estimations by the companies) were calculated (average and median) for each supply chain role, taking into account company sizes (table 4-9).

[43] 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.

Table 4-9: Number of notifications to the FNS in the year 2013 and 2014 by supply chain position and company size (no. of companies with a specific size with respect to supply chain position, years indicated with average and median value of notifications; median in brackets)					
Supply chain position	**No.**	**Micro**	**Small**	**Medium**	**Large**
Manufacturer	25	-	2 companies 2013: 11 (8) 2014: 11 (8)	6 companies 2013: 2 (1) 2014: 1 (1)	16 companies 2013: 832 (8) 2014: 815 (4)
Distributor	11	1 company 2013: 2 (2) 2014: 2 (2)	2 companies 2013: 3 (2) 2014: 2 (2)	3 companies 2013: 5 (6) 2014: 3 (3)	5 companies 2013: 24 (10) 2014: 27 (13)
Importer	11	-	1 company 2013: 3 (3) 2014: 3 (3)	1 company 2013: 2 (2) 2014: 2 (2)	9 companies 2013: 9 (7) 2014: 6 (3)
PU & distributor	12	-	1 company 2013: 13 (13) 2014: 13 (13)	3 companies 2013: 10 (6) 2014: 8 (3)	8 companies 2013: 10 (3) 2014: 1 (0)
Repackager & distributor	2	-	-	1 company 2013: 6 (6) 2014: 3 (3)	1 company 2013: 22 (22) 2014: 24 (24)
European representative	1	-	-	1 company 2013: 6 (6) 2014: 3 (3)	-
Public research organisation	0	-	-	-	-

Figures 4-3 and 4-4 provide some more background information about the characteristics of the respondents to the survey.

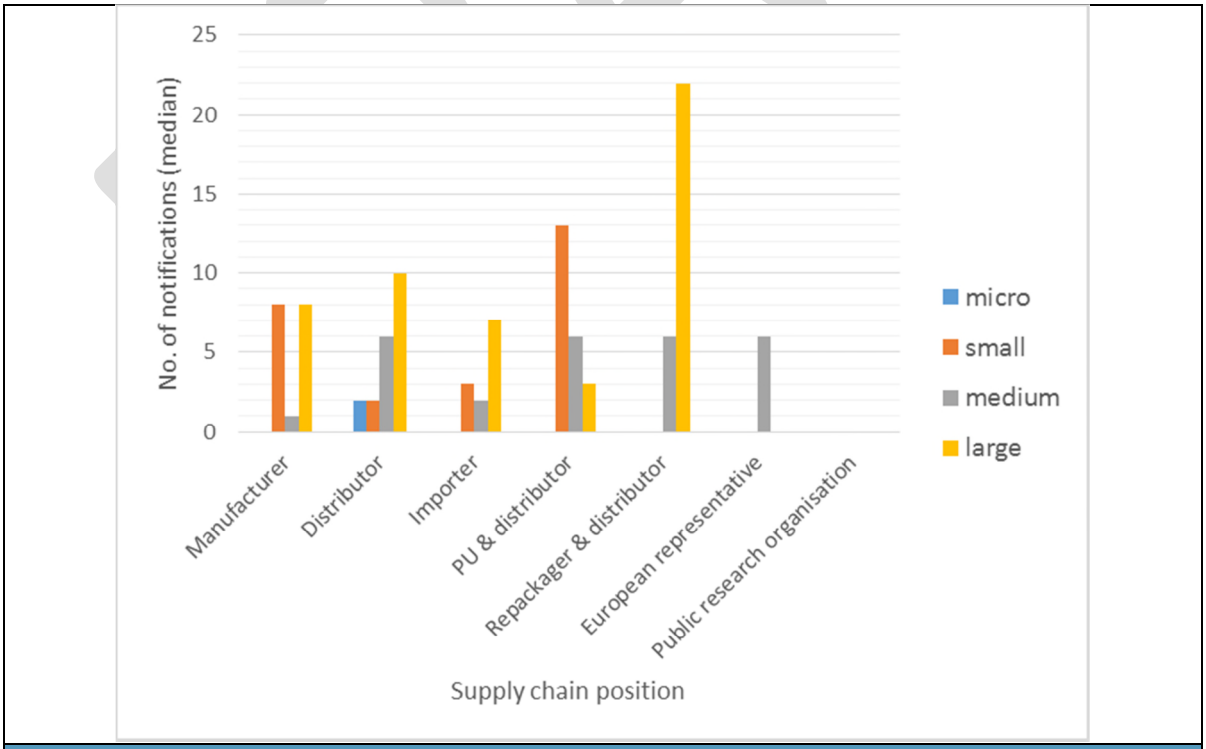


Figure 4-3: Overview on relation between supply chain positions and the number of notifications of companies with respect to company size

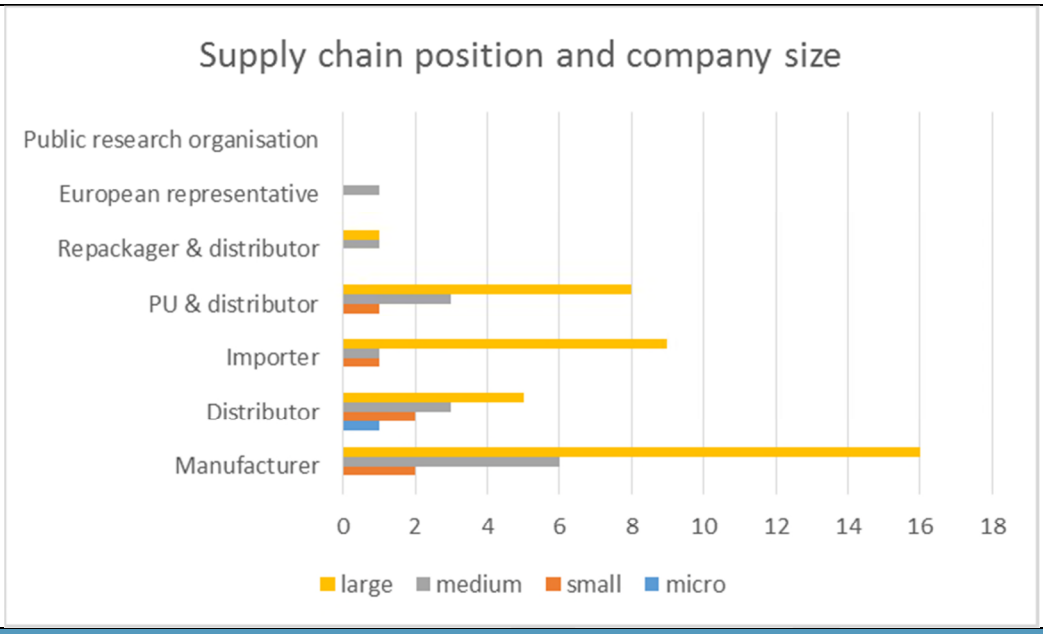


Figure 4-4: Overview of relationship between supply chain position and number of companies with respect to company size

Burden for supply chain actors based on data generation

The companies were asked to indicate how they generated and/or gathered data for notification purposes (Table 4-10).

Table 4-10: Overview on the different categories related to data generation and the number of replies[44]

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
We generated (internally or outsourced) **all the information** required by the regulation **for the purpose of the notification**	11
We generated **part of the information** required for the purpose of the notification, since some information were already available	19
We referred to the **declaration number(s)** of the supplier(s) for the "substance identity" part	29
Total	**64**

Many companies had the possibility of referencing the substance declaration number passed to them by their suppliers (nearly 50%), with another 30% of companies noting that some data were already available and so not all of the information had to be generated. Around 18% of the companies indicated that all data had to be generated for the purpose of notification. Only 6% of the companies stated that all the data were already available. To conclude, for most companies the regulatory burden with regard to data generation was limited since some of the data were already available or reference to the declaration number was possible (ca. 80%).

[44] Note: multiple ticks were possible.

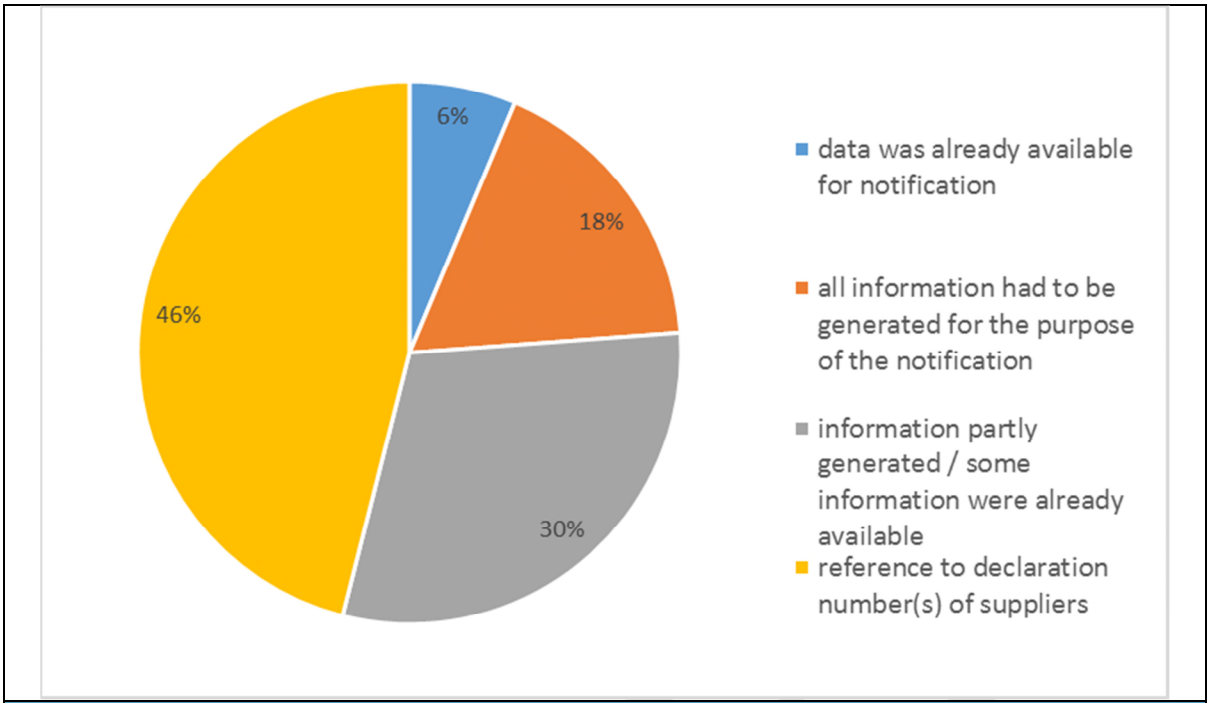


Figure 4-5: How companies generated the substance data relevant for notification

Distributors (70%), professional users and distributors (53%) and importers (60%) were the actors benefiting the most from the possibility to refer to the notification number of their providers. One third of the manufacturers that replied to the survey had to generate all the data (32%) or at least some of the data (32%) themselves.

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. 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 4-11).

Table 4-11: 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**

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

Regulatory burden in comparison with other pieces of legislation

When asked to compare the burden posed by the FNS with other pieces of legislation, the notification system ranked second just after the REACH Regulation and, surprisingly, before the CLP Regulation (Table 4-12). 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.

Table 4-12: Overview on the regulatory burden share (in %) related to different 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

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 was 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.

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 4-13 provides an overview on the results of the analysis.

Table 4-13: 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**

Difficulties with respect to interpretation of terminology

Companies were asked to indicate if they encountered any difficulty in interpreting the terminology and on which part of the legislation. Results are summarised in table 4-14.

Table 4-14: Overview on burden due to difficulties with respect to interpretation of terminology and related replies by companies[45]	
Definition of nanomaterial used	40 (38%)
Scope (who has to notify, what needs to be notified, exemptions etc.)	40 (38%)
Calculation of **volumes** related to volume thresholds	15 (14%)
Other (please specify in the next question)	11 (10%)

Concerning the nanomaterial definition, it was stated that the existence of different definitions (EC recommendation, definition according to Cosmetics Regulation, FNS definition, etc.) would lead to confusion and difficulties with communication across the supply chain. There is also a lack of certainty with regard to what is meant with "bound/unbound state" as used in the definition for mixtures containing substances at nanoscale and with "release under foreseeable conditions".

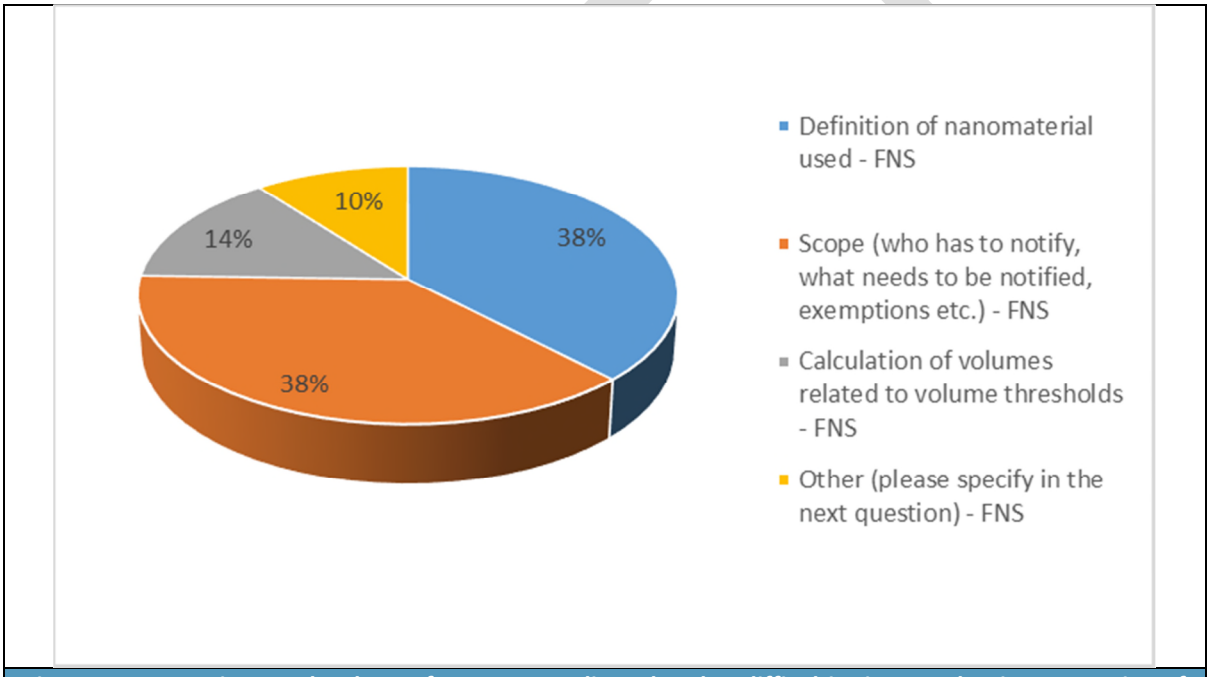


Figure 4-7: Overview on the share of company replies related to difficulties in regard to interpretation of terminology

The lack of standardised analytical methods was mentioned in many comments to this question.

4.4.6 Additional comments provided

Companies had the possibility to provide additional comments.

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.

[45] Multiple ticks were possible.

Some companies referred to have encountered problems in obtaining the relevant information from the suppliers. 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.

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 not certainty over their nanoscale status.

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

4.5 Direct Costs

The enterprises were asked to indicate their annual turnover and the nano-products related turnover[46], in order to estimate the burden of the costs 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.

Companies were asked to estimate the burden for different cost type in terms of time and resources for both the FND 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. Different cost types defined in the survey were:

- 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).

The companies where asked to indicate their annual turnover range (< 250 k, 250 k - < 2 m, 2m – < 10m, 10m – 50m, >50m, in Euros) in total as well as the nano-products related turnover. Most of the respondents (65%) declared an annual turnover higher than 50 million Euros, with another 25% of companies with an annual turnover between 10 and 50 million Euros.

The turnover declared and related to the commercialisation of nanomaterials and mixtures and articles containing nanomaterials is, in general, much lower. It was indicated by nearly 50% of the companies that the nano-products related share lies beneath €250,000. The calculated values are presented in table 4-15.

[46] Where for nano-products it was specified to refer to nanomaterials, mixtures and articles containing nanomaterials.

Table 4-15: Overview on the annual turnover of companies and the nano-related share		
Range in Euro	Turnover (%)	Nanotechnology share (%)
< 250 k	2	46
250 k ≤ 2 m	0	4
2m ≤ 10m	8	18
10m - 50m	25	14
> 50m	65	18

Companies reported substance characterisation costs ranging between €3,000 and €10,000 per substance. The amount of resources spent in understanding the legal requirements, in gathering the information to be submitted, in responding to clients' enquiries and in the actual submission of the information was proportionate to the number of notifications and could exceed €20,000 per large companies. 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.

4.6 Competitiveness and Innovation Impacts

In addition to what has been reported on competitiveness and innovation impacts during the stakeholder meeting, Table 4-16 presents the findings of the online survey.

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 4-16: 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

Table 4-16: Number of companies per opinion over impacts magnitude						
Impact category	**Very negative**	**Negative**	**No change**	**Positive**	**Very positive**	**Not applicable**
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

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

5.1 Introduction

The ToR requires:

- To present "*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

- "*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:

- Reviewed the information presented in the French public report and on the r-nano.fr website;
- Researched the French media in order to assess how journalists and bloggers are using the data made publicly available via the website and what is the public perception of nanomaterials and European media on news about nanomaterials use in cosmetic products;
- Compared the FNS and the CPNP to the RAPEX system;
- Held a face-to-face interview with the French public authorities (10 March 2014, Paris); and
- Had a subsequent phone interview organised by the Commission with the French public authorities (23 May 2014).

5.2 Information in the French Public Report

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

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

Between January and June 2013, the online application registered 28,459 visits with 13,907 unique visits and 54,782 viewed pages, with most of the visitors (around 60%) located in France.[47] The average duration of the visits to the webpage is of around 3 minutes, possibly meaning that the online application users have proceeded progressively to fill in the notification dossier.

[47] Determined on the basis of the IP address of the computer used to visit the webpage.

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

5.3 Nanotechnology and Nanomaterials in the French Press

5.3.1 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.

5.3.2 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?'*[48] discussed the development of nanomaterials and the possible associated risks. This article summarised some of the main concerns regarding nanomaterials (e.g. possible damage to DNA in certain conditions) but highlighted that in reality there are many unknowns and more research is needed to know the actual risks involved. In addition, in April 2010, a brief article was published in the free daily newspaper 20 Minutes, entitled *'Nanotechnologies: what are the risks?'*[49]. 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*

[48] La Croix (2009): **Faut-il avoir peur des nanotechnologies**, available from http://www.la-croix.com/Ethique/Sciences-Ethique/Sciences/Faut-il-avoir-peur-des-nanotechnologies-_NG_-2009-12-14-570302

[49] 20 Minutes (2010): **Nanotechnologies: quels sont les risques?,** available from http://www.20minutes.fr/sciences/397658-nanotechnologies-risques

food'[50] 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*'[51]. 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[52] is not identified as a nanomaterial as the European body in charge of food additives considers that it is not intended for use as a nanomaterial. The article discusses concerns regarding the safety of human health following the consumption of nanomaterials, however concludes with the fact that the impact of nanoparticles on human health is complex and not fully resolved.

Environment

In addition, the impact of nanotechnology on the environment was considered in the French media prior to the introduction of the nano-registry in January 2013. For example, an extensive article in the Le Monde newspaper in October 2009 entitled *'Nanotechnologies: the environmental point of view'*[53] 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[54] 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

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

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

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

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

[54] **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.

of their use are often exaggerated and untested, and would not be achieved for many years. Ultimately, like other articles in the French media at this time, this article highlights that the impacts of nanotechnology on health and the environment are relatively unknown and there is a general lack of knowledge on the range of nanomaterials available.

Other

Political Developments

As well as considering the possible risks and uncertainties associated with nanomaterials and nanotechnology, the mainstream French press has also reported relevant political developments. An article in La Libération from March 2010, entitled *'Nanotechogie: l'Afsset recommande le principe de precaution'*[55] reported on a study by Afsset[56] 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 La Libération in January 2010 ('*Nanotechnologies, the debate taken over by fear*'[57]) suggested that the public consultation was a 'farce' with few of the public attending. The article also claimed that some 'anti-nano' parties claimed that the public consultation was merely a way to legitimise decisions and avoid a backlash in the future should nanotechnology turn out to be harmful. Additionally, in February 2010, La Libération published an article ('*Nanotechnologies: the debate cut short*'[58]) 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?*'[59] 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

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

[56] Afsset: Agence française de sécurité sanitaire de l'environnement et du travail (French Agency for Environmental and Occupational Health)

[57] La Libération (2010): **Nanotechnologies, le débat confisqué par la peur,** available from http://www.Libération.fr/sciences/2010/01/27/nanotechnologies-le-debat-confisque-par-la-peur_606519

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

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

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%.

5.3.3 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'*[60]*)* 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*[61]' which detailed the economic importance of nanomaterials to France but also raised concerns over its safety for workers in many fields. In particular, this article suggests there is insufficient epidemiological data and also claims there are similarities between nanomaterials and asbestos. Additionally, in May 2013 an article in Le Monde (*'The toxicity of nanomaterials confirmed by an American study'*[62]) 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.

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

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

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

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*[63]*)* 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.

More specifically, an article published on the website 'L'Usine Nouvelle' entitled *'Why France cannot break into the race for nanotechnology*[64]*'* 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[65]. Furthermore, in February

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

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

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

2014, an article in Les Echos *('Nanotechnologies applied to medicine: France is in pole position'*[66]*)* highlights that France is at the forefront of the development of nanotechnology for the medical field with major laboratories already active in this area and a significant level of academic research already undertaken. This position was also mirrored by an article in La Libération which was published in February 2014 *('Nanomedicine: a market which could reach $129 billion by 2016'*[67]). 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 Chatenay-Malabray and 30 companies already active in this field. However, like the overall development of nanotechnology in France, this article suggests a lack of investment is a weakness to further development.

5.4 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'[68] 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 use of nanomaterials in toothpaste[69]. 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'[70] (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.

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

67 La Libération (2013): **Nanomédicine: un marché qui atteindrait 129 milliards de dollars en 2016,** available from http://www.Libération.fr/economie/2014/02/13/nanomedecine-un-marche-qui-atteindrait-129-milliards-de-dollars-en-2016_979997

68 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

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

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

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[71]. 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[72]. 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'.[73]

5.5 The FNS, the CPNP and the RAPEX system

RAPEX (Rapid Alert System for Non-Food Dangerous Products) is an EU system which allows the rapid exchange of information between Member States and the European Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers. The system does not apply to food, pharmaceutical and medical devices, which are covered by other mechanisms[74] 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.[75] 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.[76]

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

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

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

[73] 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

[74] 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

[75] 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

[76] 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

2012 this figure had grown to 2,278.[77] 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;
- the FNS has the purpose to light up the supply chains of the nanomaterials, where it is often uncertain the presence of substances in nanoforms in consumer products.

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

5.6 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 4.1), a second session followed with a close discussion between the project team 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. 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 has not be launched yet but will focus on seven nanomaterials (which identity is confidential) 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. The information that will be passed to the researchers refers to the identities of the manufacturers, the physicochemical parameters of the nanomaterials investigated and their quantities.

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

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.

5.7 Availability of the Information Gathered to the Authorities, Consumers and Workers and potential impacts on Long Term Health and Environmental Benefits

5.7.1 Introduction

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.

5.7.2 Available information to the general public

With regard to the availability of the information to the general public, the first registered reactions were of disappointment.[78] 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 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 has been notified 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.

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.

5.7.3 Availability of the information to industry

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,

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

something that was not done before. Importantly, many downstream users became aware of being handling nanomaterials.

This new information have a potential use on the insurability of 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.[79] The notification system could provide key background information to enable such calculation.

5.7.4 Availability of the information to the public authorities

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 information on the quantities provides an easy accessible tool for prioritisation, as it does the information on the identity of manufacturers/importers and their downstream users, where this enable a precise estimate of the workers population exposed to the nanomaterials to be investigated. However, the information to enable such prioritisation was already available to public authorities, as the results of the first year of implementation of the FNS presented in the French public report seem to be consistent with the information that was presented in e.g. the Commission Staff Working Paper on the types and uses of nanomaterials (EC, 2012)[80].

In terms of human health hazard and exposure assessment, a marginal added value of the information gathered 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.

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[79] 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

[80] Available at: http://ec.europa.eu/nanotechnology/pdf/second_regulatory_review_on_nanomaterials_-_staff_working_paper_accompanying_com(2012)_572.pdf

6 Critical Elements and Recommendations

6.1 Introduction

This section presents the main findings of the assessment of the first year of implementation of the French Notification System, highlights some elements critical for a successful extrapolation of the results to the EU level and provides some recommendations for EU policy directions.

6.2 Main Findings of the Assessment

The Interministerial decree No. 2012-232 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 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 3,941 notifications from 933 notifiers, although around 13.5% (532) of the notifications were only in draft version. Of the 933 notifiers, over 70% (670) were based in France, while the remaining 30% were based in other European countries of the European Free Trade Association (EFTA). At June 2014, the authorities have received over 7,000 notifications, meaning an increasing awareness of the notification obligations by different industry sectors.

In terms of the number of nanomaterials notified, Anses 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 project team identified around 258 different 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. It was estimated that around 50-60% of the **substances at the nanoscale** manufactured and/or imported that have been notified would not be triggered by the REACH Regulation (because manufactured/imported in less than 1 tonne per year). Nevertheless, around 80% of the **substances** that were notified to the FNS were already on the market before 1981 and over 60% of the substances (their bulk form) have a full REACH Registration dossier. It is not possible to establish if their nanoform(s) was/were commercialised before that date; however, when referring to the most common nanomaterials and to a large share of pigments and dyes notified to the FNS, industry confirmed that their nanoforms have been on the market since many years.

In terms of quantities, sectors of use and applications for the most common nanomaterials on the French market (manufactured and/or imported in more than 100 tonnes), the findings broadly confirm the publicly available information, e.g. the overview of nanomaterials, their markets, uses and benefits presented in the Commission Staff Working Paper (EC, 2012).

With regard to the direct costs for the public authorities, implementation costs of the FNS sum to around €250,000. The operational costs amount to around €140,000 per annum (€30,000 of maintenance costs for the IT tool plus around €110,000 of administrative costs). Operational costs for the CPNP amount to around €400,000 per annum.

With regard to the administrative burden posed by the FNS on the companies with notification obligations, the most significant cost relates to the characterisation of the substances at nanoscale (between €3,000 and €10,000 per substance). A good deal of resources was spent to familiarise with and understand the legislation, interpreting the nanomaterial definition and the terminology used, often diverting resources from research and innovation activities. This burden is particularly significant for SMEs. However, the amount of time spent in dealing with the notification obligations is expected to decrease significantly as companies get familiar with the legislation and have the information readily available from past years.

The main criticisms however focus on the mistrustful perception of the scheme by clients and providers of the companies with notification obligations, with a negative impact on competitiveness and innovation: it has been reported by different companies that many commercial partners asked for "no nano" products because they did not want to deal with an additional regulatory burden.

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

With regard to the latter, the French authorities reported that some of the information gathered through the FNS for seven nanomaterials will be passed to researchers and used within an epidemiological study focusing on workers. When comparing the information gathered through the FNS to the information available through other legislative mechanisms (especially the REACH Regulation), a marginal added value of the information 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.

The Notification System could have a role in enabling insurability of nano-related risks for companies.

Consumer and environmental organisations, although welcoming the initiative as a first step in what they see as a under-regulated area, were disappointed by the degree of transparency of the device: 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 and do not focus on the nanomaterials of most concern

but actually provides a catalogue of ultrafine dusts (notably pigments and dyes) that do not rise concerns over their common applications.

The virtual absences from the notification scheme of nanomaterials such as nanosilver and carbon nanotubes, 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.

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.

6.3 Critical Elements for the Extrapolation of the Results to the EU Level

On the basis of the number of notifications received in 2013 (around 3,900) and 2014 (over 7,000) and the number of different substances identified, a cautious estimate of 250 – 400 nanomaterials on the French (and European) market should be brought forward.

The analyses of the substances at the nanoscale and of the sectors of use that were notified give a good idea of sectors of the economy that would be more involved by a European measure and provide a good starting point to establish whether any Member State would be negatively or positively impacted by such a measure, on the basis of its main economic activities.

The results of the assessment of the costs for both public and private authorities are easily transferable to the European level.

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

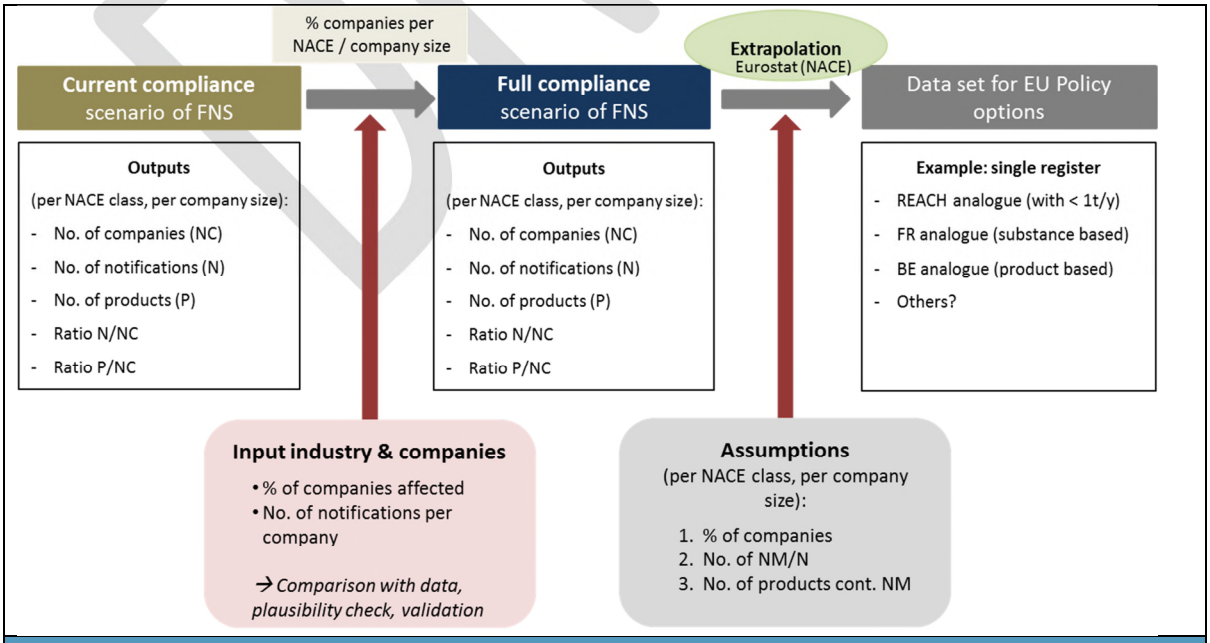

Figure 6-1: Extrapolation of the results from the analysis of the FNS to the EU level

The formula for the rate of compliance is,

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

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

The use of data extracted from the Eurostat Structural Business statistics database should ensure coherence and consistency to the exercise. Some of the data necessary for the estimate however have been classified as confidential: the project team will explore ways (in agreement with the Commission and the French public authorities) to make use of such data without disclosing any sensitive information.

6.4 Recommendations for EU Policy Directions

It is general opinion (shared by different stakeholders, from public authorities to consumer organisations and companies) that nanomaterials would be better covered by the REACH Regulation.

If a nanoregistry would have to be implemented, an EU level registry would be preferred to different national schemes, in order to avoid the creation of obstacles to trade and the disruption of the free movements of goods within Europe.

Such a scheme should ensure to balance the administrative burden posed on companies with notification obligations with the expected benefits of the system. More precisely, the registry should focus on those nanomaterials which origin most of the concerns and should exempt nanomaterials which have been commercialised within the European Union for decades.

Any new legislative (and non-legislative) initiative should use a clear and well-defined terminology (e.g. reasonably foreseeable conditions of release), preferably shared and agreed at global level, without leaving any space to interpretation.

Different notification deadlines should be established for the different actors within the supply chain, allowing downstream actors to receive any relevant information from the suppliers.

Notifications should be required not on a yearly base but only when any of the information to be notified changes.

Any publication of the data submitted by the companies should carefully avoid providing commercially sensitive information (such as tonnage range for substances with few notifications).

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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.

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

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

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

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

If you require further information about the study, please do not hesitate to contact the Project Manager, Marco Camboni, by e-mail (marco.camboni@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	tricalcium bis(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 molybdate sulfate 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	tricobalt tetraoxide	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 iron nanoparticles (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	triiron tetraoxide	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	diantimony pentoxide	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	-

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